Development of the Self-efficacy for Medication Adherence for Buprenorphine (SEMA-B) Assessment

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DEVELOPMENT OF THE SELF-EFFICACY FOR MEDICATION ADHERENCE -
BUPRENORPHINE (SEMA-B) ASSESSMENT

By

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ABSTRACT
DEVELOPMENT OF THE SELF-EFFICACY FOR MEDICATION ADHERENCE
FOR BUPRENORPHINE ASSESSMENT

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Each year in the United States, over 4 million people aged 12 or older are treated
for substance use disorders, and a growing percentage of those being treated are suffering
from opiate addiction. Research suggests that many variables should be considered in a
biopsychosocial approach to treating substance use disorders, and especially when
treating opiate addiction. Two of the variables that show a strong correlation with
positive treatment outcomes are self-efficacy and medication adherence. Buprenorphine
is a relatively new medication that has shown significant efficacy is treatment of opiate
addiction. Successful treatment also requires appropriate adherence to taking
buprenorphine as prescribed. The impact of self-efficacy on medication adherence is
unknown, however. To date, there is no assessment designed to measure self-efficacy for
medication adherence to buprenorphine.

This study adapted the Self-Efficacy for Medication Adherence – Hypertension
scale into the Self-Efficacy for Medication Adherence – Buprenorphine (SEMA-B). A
panel of psychiatrists and past Buprenorphine patients reviewed the SEMA-B for face
validity. Subtle changes were made to the assessment after this review. Data to evaluate
the psychometric properties of the new assessment were then gathered from 121 patients
in an opiate recovery program. The results suggest that the SEMA-B has adequate
internal consistency and temporal stability, and that it is comprised of multiple
underlying factors related to specific aspects of maintain buprenorphine treatment for
opioid addiction.

DEDICATION

This document would not be possible without the love and support of God and my family. My parents, Gary and Lenore, supported me by instilling the value of education. My sisters, Rachel and Rebekah, support me by showing how to love others. My primary support on this earth is my wife Anne. I don't know how people stop themselves from falling in love with her. About two months before the defense of this document we welcomed into the world our daughter Elise. She is a gift of God. We look forward to providing her the same love and support others have provided us.

The dedication in my master's thesis included the following quotes. While they do not come from the greatest philosophers of our time, they still ring true in my life. "Sometime you win. Sometimes you lose. Sometimes it rains." Bull Durham

"Dream on, dream on, dream until your dreams come true." Aerosmith

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Dr. Melchert picked up the pieces of a project that was not his responsibility put in the time necessary to see it to completion. I started this process by taking one of his classes and now my formal education ends with his guidance. He has my eternal thanks. Dr. Edwards also served as a guiding light with this project. I greatly appreciate her sacrifices.

While Dr. Burkard, Dr. Knox, and Dr. Bardwell did not directly have a hand in this project they most certainly played a large role in supporting me throughout my education. It is a privilege to learn from those who are dedicated to the success of the students they serve. Thank you to all of you from the bottom of my heart.

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CHAPTER ONE

INTRODUCTION

Opioid Addiction

Drug abuse is a significant chronic illness in America. According the National Institute on Drug Abuse, in 2006 there were nearly 1.8 million admissions for treatment of alcohol and drug abuse to facilities that report to state administrative systems. Heroin and other opioid abuse accounted for the largest percentage of all admissions (18%). According to the 2008 National Survey on Drug Use and Health, the number of current (i.e., within the past-month) heroin users aged 12 or older in the United States increased from 153,000 in 2007 to 213,000 in 2008. There were 114,000 first-time users of heroin aged 12 or older in 2008. The rate of use of Vicodin in 12-graders reached 9.7% in 2008 and the rate of Oxycontin use reached 4.7% in the same year ("National Institute on Drug Addiction", 2011).

Opioids are drugs naturally derived from the opium poppy. Synthetic and semi-synthetic forms have also been developed. The entire class of natural and synthetic drugs in this category is now commonly referred to as opioids (Rassool, 2009). The most common opioids are opium, morphine, codeine, and heroin (Harris, 2005). They are effective to relieve pain (analgesia) and reduce anxiety. They can dull the senses, decrease respiratory drive, induce sleep, and are often addictive. When these drugs are available in prescription form, they are regulated by the Food and Drug Administration. Common prescription opioids are hydrocodone and oxycodone (Harris, 2005). Chronic

abuse of opioids can lead to a development of tolerance and severe withdrawal upon cessation of use (Rassool, 2009).

Treatment of Opioid Addiction in the United States

Historically, those struggling with opioid addiction have been treated with opioid maintenance medications (i.e., agonists such as methadone, levo-alpha-acetyl-methadol (LAAM), or antagonists such as naltrexone). Agonists bind to the receptor of a cell and trigger a response by that cell. Antagonists block the action of the agonist. While these medications have been helpful in treating opioid addiction, they have limitations related to requirements for daily use at a clinic, poor adherence rates due to lack of control of some withdrawal symptoms, among other concerns (Fiellin, Rosenheck, & Kosten, 2001; Rosen and Rosen, 1995; O'Connor et al., 1997; Ling, 1994; Jasinski, Johnson, & Kocher, 1985).

Buprenorphine Treatment for Opioid Addiction

Buprenorphine provides an alternative treatment to methadone for opioid addiction. Buprenorphine is a partial agonist that acts on the μ opioid receptor. It has both a less active analgesic effect but also less potential for the adverse effects (e.g., abuse, respiratory depression, and overdose) that are associated with methadone, a pure opiate agonist (Jasinski, Pevnick, & Griffith, 1978; Walsh, Preston, Stitzer, Cone & Bigelow, 1994; Bikel, Stitzer, Bigelow, Liebson, Jasinski, & Johnson, 1998). Research suggests that the unique properties of buprenorphine make it appropriate for both detoxification (Krook et al., 2003) and maintenance (Stoller, Bigelow, Walsh, & Strain, 2001) treatment for individuals addicted to opioids. It also allows for prescription in-office care, which is often preferred (Fudala & O'Brein, 2005; Fiellin et al., 2001). When compared to other

maintenance programs, buprenorphine appears to be as effective, and sometimes more effective, than other medications in achieving abstinence, maintaining sobriety, and retention in treatment (Mintzner et al., 2007; Amato et al., 2005). Fudala and O'Brien (2005) found buprenorphine important in the treatment of opioid addiction: "it may represent the most important advance in addiction medicine since the introduction of methadone substitution pharmacotherapy 40 years ago" (p. 634).

Self-Efficacy

Self-efficacy refers to one's belief that he/she can reach a goal (Bandura, 1982). Self-efficacy, an important variable in Social Learning Theory, has empirical support as a contributing factor in positive treatment outcomes for those struggling with alcohol and drug addiction (Allsop, Saunders, & Phillips, 2000; Goldbeck, Myatt, & Aitchison, 1997; Miller & Longabaugh, 2003; Rychtarik, Prue, Rapp, & King, 1992; Stephens, Wertz, & Roffman, 1995). When applied to populations struggling with addiction, it is the belief that an individual can sustain abstinence (Bandura, 1995). Empirical evidence consistently suggests that individuals' self-efficacy remains an important factor for sustaining abstinence and reducing the risk of relapse (Avants, Margolin, & McKee, 2000; Ciraulo, Piechniczek-Buczek, & Iscan, 2003; Haaga, Hall, & Haas, 2006; Moos, 2007; Walitzer & Dearing, 2006, McKellar, Ilgen, Moos, & Moos, 2008).

Bandura notes that the concept of self-efficacy is domain specific. For example, one can have high self-efficacy for giving a speech in front of a group but low self-efficacy for taking a math exam. Self-efficacy will have variable effects depending on the behavior in question (Baudura, 1997). Self-efficacy needs to be measured and researched for each individual domain of behavior.

Evidence for the applicability of social learning theory, and specifically self-efficacy, to addiction treatment adherence has been accumulating over the past 20 years (Bosworth & Voils, 2006). The theoretical model has been applied to exercise (Jeffery, French, Rothman, 1999; Marcus, Rakowski, & Rossi 1992), contraceptive use (Grimley, Riley, Bellis, & Prochaska, 1993), and smoking (Plummer, et al., 2001; Clark, Rakowski, Kviz, & Hogan, 1997). Self-efficacy has also been shown to predict medication adherence in individuals diagnosed with chronic diseases such as hypertension (Oleary, 1985; Ogedegebe, Mancuso, Allegrante, & Charlson, 2003).

Medication Adherence

Medication adherence significantly impacts the effectiveness of treatment (Balkrishnan, 2005; Osterberg & Blaschke, 2005; DiMatteo et al., 2002). The World Health Organization (2003) reported that the average rate of medication adherence across numerous illnesses was only 50%, which significantly limits the impact of medical interventions.

Average adherence rates remain higher among patients with acute conditions as compared to those with chronic conditions such as drug addiction (Osterberg & Blaschke, 2005). McCann, Clark, and Lu (2008) view self-efficacy as a "cornerstone of medication adherence" (p. 333). While many factors contribute to relapse from chronic illness, non-adherence to medications is seen as the single most influential determinant of relapse (Green, 1988).

Statement of the Problem

Adherence to medications for chronic conditions is very important in treatment effectiveness, and self-efficacy for maintaining medication adherence is viewed as an

important factor in the process. To date, however, only one study has addressed self-efficacy for adherence to a medication regimen for any medical or psychiatric condition. Ogedegbe, Mancuso, Allegrante and Charlson (2003) created the Medication Adherence Self-Efficacy Scale (MASE) to measure several aspects of self-efficacy for adhering to prescribed medications for treating hypertension. No research has been found that has examined self-efficacy for adhering to medications used in the treatment of opioid addiction. Therefore, the present study was undertaken to develop a measure of self-efficacy for medication adherence for the treatment of opioid addiction.

Buprenorphine is a promising medication for treating opioid addition. Burpenorphine is the sole opiate recovery medication dispensed in the clinic where the data for this dissertation study were collected. The clinic utilizes buprenorphine as it has become well accepted as the leading medication for maintenance and withdrawal treatment of opiate addiction (Orman & Keating, 2009; Fudala & O'Brien, 2005; Krook et al., 2003; Strain, Stitzer, Liebson, & Bigelow, 1996; Ling, 1994). In order to investigate the role of self-efficacy for maintain medication adherence in the treatment of opioid addiction, a reliable and valid assessment of self-efficacy for medication adherence for this treatment population is needed.

Purpose of the Study

The purpose of this study was to develop and evaluate the psychometric properties of the Self-Efficacy for Medication Adherence Scale - Buprenorphine (SEMA-B). The specific aims of study were to:

1. Adapt the Medication Adherence Self-Efficacy Scale (Ogedegbe, G., Mancuso, C., Allegrante, J., & Charlson, M. (2003) for use with patients receiving opioid

addiction treatment that incorporates the use of buprenorphine.

2. Examine the internal consistency of the resulting instrument (i.e., the SEMA-B).

3. Examine the temporal stability of the SEMA-B.

4. Examine the construct validity of the SEMA-B through exploratory factor analysis.

CHAPTER TWO

REVIEW OF LITERATURE

The purpose of this dissertation is to create a reliable and valid assessment to measure self-efficacy for medication adherence in populations taking buprenorphine, a pharmaceutical treatment for opiate addiction. The literature review starts with a summary of research related to opiate addiction. Next the review addresses the history of opiate addiction treatment, with special attention paid to buprenorphine. Highlighted in the literature review is the importance of two psychological variables (self-efficacy and medication adherence) in the treatment of drug and opioid addiction. Specific attention will be paid to the measurement of self-efficacy and medication adherence. The chapter concludes with a discussion of the importance of self-efficacy for medication adherence, a concept that is currently only measured in populations struggling with hypertension. That concept is measured by the Medication Adherence Self-Efficacy questionnaire (MASE) (Ogedegbe et al., 2003). The chapter concludes with a discussion of the rationale for developing a measure of self-efficacy for medication adherence in populations struggling with opiate addiction. This dissertation will adapt the existing MASE for use with populations taking buprenorphine for the treatment of opiate addiction.

Opioid Addiction

Drug abuse and addiction is a chronic medical condition and a significant problem in America today (Harris, 2005; Stine, Cioe, Friedmann, 2005; Lowinson, 2005; Sees, Delucchi, Masson, Clark, Robillard, Banys, & Hall, 2000; Marion, Joseph & Dole, 1997). According to the National Institute on Drug Abuse (NIDA), in 2009 over 23 million

people in the United States 12 years of age or older needed treatment for an illicit drug or alcohol abuse. This was 9.3% of people 12 or older in the United States. Of this group, 2.6 million (11.2%) received treatment at a specialized facility ("National Institute on Drug Addiction", 2011).

One of the categories of drugs used and misused is opioids. Opioids are naturally derived from opium, and extracted from the *Papaver somniferum* (Harris, 2005). These drugs have the ability to impact the central nervous system by controlling pain, causing euphoria, dulling the senses and causing respiratory depression (Simon, 2005). These drugs come in prescription form and often are used to relieve pain (Simon, 2005). Common examples are hydrocodone, oxycodone, diacetylmorphine (heroin), morphine, codeine, fentanyl, methadone and propoxyphene (Harris, 2005). Opioid drugs are defined and placed in categories based on their capacity to bind and activate various opioid receptor sites. Those that bind and fully activate a receptor are referred to as agonists at that receptor. Those that bind but do not activate are antagonists to that receptor (Knapp, Ciraulo, & Jaffe, 2005).

Historically, the term opioid refers only synthetic drugs of this type. Recently, the term opioid has been used the term opioid to refer the entire family (natural, semi-synthetic and fully synthetic) of drugs that bind to the opioid receptors in the central nervous system (Rassool, 2009). For ease of reading, the rest of this paper will utilize the term opioid to refer to the entire family of drugs.

Chemical Properties of Opioids and Subsequent Dangers of Use

Opioids can be taken orally, injected, or in powder form intravenously. When an opioid enters the brain, it is converted to morphine and binds to opioid receptors. These

receptors are located throughout the body. The opioid receptors are involved in automatic processes critical for life, such as breathing (respiration), blood pressure, and arousal (Simon, 2005). As a result, opioid overdoses frequently involve a suppression of respiration (Harris, 2005). Opioids effectively change the way a person experiences pain. They can also impact regions of the brain control pleasure, resulting in the initial euphoria or "high". With regular opioid use, tolerance develops and more of the drug is needed to achieve the same intensity of effect. Opioid users are at high risk for addiction (Simon, 2005). The pleasurable feelings and pain reducing benefits of the drugs, as well as the rapid development of tolerance, dependence and withdrawal, contribute to estimates that suggest about 23 percent of individuals who use heroin become dependent on it ("National Institute on Drug Addiction", 2011). If a dependent user reduces or stops use of the drug abruptly the individual will more than likely experience severe symptoms of withdrawal (Knapp et al., 2005). These symptoms can include restlessness, muscle and bone pain, insomnia, diarrhea, nausea, and vomiting (Rassool, 2009). This withdrawal process can trigger continued abuse and/or relapse. Major withdrawal symptoms peak between 24 and 72 hours after the last dose (depending on half-life) of the drug and typically subside after about 1 week (Harris, 2005).

While acute use of opiates themselves cause little physical harm, chronic users of opioids may develop damage to the liver and kidneys, collapsed veins, infection of the heart lining and valves, and other health concerns. Chronic use of heroin can lead to physical dependence, a state in which the body has adapted to the presence of the drug (Harris, 2005).

Opioid Use Trends

According to the NIDA, in 2008 there were nearly 1.8 million admissions for treatment of alcohol and drug abuse to facilities that report to state administrative systems. Heroin and other opioids accounted for the largest percentage (20%) ("National Institute on Drug Addiction", 2011). The Drug Abuse Warning Network (DAWN) collected data on drug abuse-related hospital emergency room visits in the second half of 2003. DAWN was an initiative of the Substance Abuse and Mental Health Services Administration (SAMHSA), U.S. Department of Health and Human Services. DAWN estimated that heroin was involved in 8% of all drug related visits emergency department and unspecified opioids, some of which might be heroin, were involved in 4% of all emergency department visits. The same source reported that heroin accounted for 10% of the specific drugs most commonly associated with drug misuse or abuse related emergency department visits. Opioids and other pain relievers accounted for 17% of those visits (http://www.nida.nih.gov/Infofacts/hospitalvisists.html)**.**

NIDA reported a "concerning" trend in the increase in past-month nonmedical use of prescription drugs among those aged 18 to 25, from 5.4% in 2002 to 6.4% in 2006. In 2006 the number of new initiates in the nonmedical use of prescription pain relievers was roughly even with that of marijuana use among people 12 or older, which represented a significant increase when compared to previous years ("National Institute on Drug Addiction", 2011l).

This trend was especially concerning in the high school population, and highlighted as an "area of concern" by NIDA. In 2008, 15.4% of 12th graders reported non-medical use of prescription drugs within the past year. Specifically, hydrocodone

continued to be abused at high levels According to the 2008 National Survey on Drug

Use and Health, the number of current (past-month) heroin users aged 12 or older in the

United States increased from 153,000 in 2007 to 213,000 in 2008. There were 114,000

first-time users of heroin aged 12 or older in 2008. The rate of use of Vicodin in 12-

graders reached 9.7% in 2008 and the rate of Oxycontin reached 4.7% in the same year

("National Institute on Drug Addiction", 2011l).

Treatment for Opioid Addiction

Research suggests that the most effective treatment for opioid addiction was

opioid maintenance therapy (Lowinson, et al, 2005; Sees et al., 2000). Opioid

maintenance therapy consists of the use of legal and medically managed medications to

replace illegal drugs. These medications block the painful withdrawals and cravings.

They also limit the euphoric "high" that motivates continued use (O'Connor & Fiellin,

2000).

The oldest maintenance medication treatment for opioid addiction is methadone.

Methadone is a full u-opioid anta-agonist. Methadone binds to the glutamtergic NMDA

(N-methyl—D-asparate) receptor, acting as a receptor agonist against glutamate.

Glutamate is the primary excitatory neurotransmitter in the central nervous system (CNS)

(Harris, 2005). Methadone was developed in Germany in the late 1930's. After World

War II the allied forces acquired all patents and research including the research on

methadone. Methadone was introduced in the United States in 1947 and approved by the

Council on Pharmacy and Chemistry of the American Medical Association (Lowinson et

al., 2005)**.** Dr. Vincent P. Dole, a metabolic scientist, and Dr. Marie E. Nyswander, a

psychiatrist specializing in treatment of heroin addiction developed methadone

maintenance at the Rockefeller University in 1964-65 (Lowinson et al., 2005). This started the modern era of medical and neurobiological research for the treatment of those struggling with opioid addiction (Harris, 2005). Methadone maintenance programs are now strictly controlled and regulated by federal and state agencies at a level not found in any other form of medical treatment (Lowinson et al., 2005).

One benefit of methadone is the length of its effects. Heroin works for about four to six hours, oral methadone's effects last between 24 and 36 hours. During this time period, the patient can perform normal everyday physical mental tasks without impairment (Lowinson et al., 2005). Most importantly, methadone relieves the narcotic cravings that are believed to be a major contributor to relapse (Lowinson et al., 2005).

Methadone is cost effective and appears to provide a global benefit to society (Rufener & Cruze, 1977). Methadone maintenance programs have demonstrated effectiveness in providing assistance for those attempting to change the patterns of opioid use (Joseph, Stancliff, & Langrod, 2000). Studies clearly demonstrate that methadone maintenance therapy is more effective than drug-free outpatient care in promoting sustained abstinence (Hubbard, Craddock, Flynn, Anderson, & Etheridge, 1997; O'Connor, Carroll, Shi, Schottenfeld, Kosten, & Rounsaville, 1997; Sees et al., 2000).

Hubbard et al. (1997) conducted a one-year follow up of outcomes from a large-scale drug abuse treatment study of a sample that included 10,010 clients from 96 treatment programs in 11 cities. The proportion of clients using heroin weekly or daily at one-year follow up was one third of the percentage when compared to the preadmission data. A subsample of 211 clients receiving methadone treatment showed statistically

significant decreases at the .01 level, while the outpatient drug free condition ($n = 104$) reported statistically significant positive outcomes at the .01 level.

One benefit of methadone is the treatment requires daily visits to methadone clinics, which allows those at the clinic to address other biopsychosocial factors (i.e., legal assistance, adherence to medications, self-efficacy) involved with treatment (McLellan, Woody, Luborsky, & Goehl, 1988).

Methadone maintenance does appear to have some limitations. Even with the observed effectiveness, methadone detoxification demonstrated limited long-term usefulness because of frequent relapses after detoxification. This relapse pattern appeared to be accurate independent of patient variables such as ethnicity, gender, or education level (Dole & Joseph, 1976). This was even true in patients exhibiting high levels of motivation and strong social support (Rosen & Kosten, 1995, O'Connor, et al., 1997; O'Connor & Kosten, 1998; Stine, Meandzija, & Kosten, 1998). Some patients decided to stop treatment due to intolerance for side effects, which include constipation and decreased sexual interest (Lowinson et al, 2005). Another limitation included the scarcity of clinics in rural and suburban areas (Harris, 2005). Fiellin, Rosenheck, & Kosten, (2001) suggested that methadone maintenance treatment has been significantly restricted by a lack of financial resources, local opposition to the establishment of new clinics, state licensing restrictions, and stringent federal regulations designed to prevent the medication from being diverted from its medical use and resold as a substance of abuse on the street. These regulations restrict the delivery of these medications to specialized methadone clinics often located in neighborhoods that patients did not like frequenting.

Some suggested that only 15% of the total heroin-dependent population participate in methadone treatment (Hubbard et al., 1997). They suggested these factors significantly impact adherence rates given methadone maintenance therapy requires almost daily attendance (Fiellin, Rosenheck, & Kosten, 2001). The daily trips to the methadone clinic can hamper patients' ability to work, attend school, care for children, and other essential activities (Ling, 1994). Ward, Hall and Mattick (1990) suggested that approximately half of the people admitted to methadone maintenance programs leave within the first year of treatment. The authors also noted that those who remain in treatment often continue to abuse narcotics and other drugs. Of those who attended methadone maintenance treatment programs, Ball and Ross (1991) found that 46% of patients relapse to intravenous drugs after being out of treatment for 1 to 3 months, and 82% relapse after being out of treatment for 10 or more months.

While the literature on methadone maintenance shows some efficacy, it is clear that there are variables that keep the patients from adhering to their treatment regimens. While some cognitive factors were studied in the research, self-efficacy was not directly mentioned as a possible variable in the low adherence rates observed in methadone maintenance treatment.

While no longer on the market, LAAM (levo-alpha-acetyl-methadol), which was approved by the FDA for opioid maintenance therapy in 1993, was also used as a medication treatment for opioid addiction. It is similar to methadone in that it is an opioid and can become addictive if the use is uncontrolled (Lowinson, et al., 2005). LAAM does have some benefits that methadone does not provide. LAAM blocks withdrawal effect up to 72 hours, which eliminates the required daily clinic visits (Ling et al, 1994). LAAM

can be converted to nor-LAAM and dinor-LAAM, compounds that have 48 and 96 hour half lives, long durations that appeal to some patients (Walsh, Johnson, Cone, & Bigelow, 1998; Fudala, 1996).

Clinical studies on LAAM suggest that it is comparable to methadone in reduction of heroin use, treatment retention, and patient acceptance. The patients who seem to benefit from LAAM over methadone were those who are looking for less frequent clinic visits. LAAM does have limitations. It was not safe for pregnant women to take LAAM (Ling 1994). There were struggles educating patients that the effects of LAAM will peak later than methadone and opioids (Ling, 1994). No studies on LAAM explored the impact of self-efficacy or medication adherence.

Naltrexone is an opioid antagonist that blocks the actions of opioids in the brain and blocks the "high." Naltrexone is available by prescription (Lowinson et al., 2005). The option of receiving a prescription in a private physician's office and not having to make frequent visits to clinics makes naltrexone a popular option among motivated individuals with time-consuming work schedules (Ward et al., 1999; NIDA, 1997). Because it has no psychoactive reinforcing effects, like methadone or other opioid agonists, those individuals receiving naltrexone have a low retention rate, which contributes to data showing lower effectiveness (Ward et al., 1999). The treatment is currently limited by a low interest in the population, early treatment drop-out rates, and difficulties associated with naltrexone induction (Lowinson et al., 2005). No studies on naltrexone explored the impact of self-efficacy or medication adherence.

Clonidine and lofexidine are alpha 2 agonists used primarily as anti-hypertensive agents, including opioid maintenance. Clonidine appears to blunt symptoms like

restlessness and diaphoresis (Fudala, Greenstein, & O'Brein, 2005). Jasinski, Johnson, and Kocher (1985) suggested clonodine is not well accepted in the population, as it does not produce "morphine-like" subjective effects to relieve anxiety. Fudala et al. (2005) summarized the literature on lofexidine and suggested that it is effective in suppressing some signs and symptoms of opioid withdrawal. Lofexidine has been compared to methadone in clinical studies. Bearn, Gossop and Strang (1996) found that those patients receiving lofexidine and methadone had similar rates of detoxification completion. Lofexidine and clonidine seem to produce similar effects with lofexidine being more tolerated (Fudala et al., 2005). No studies on clonidine and lofexidine explored the impact of self-efficacy or medication adherence.

Buprenorphine Treatment for Opioid Addiction

Buprenorphine, a partial agonist, is used in opioid detoxification and maintenance. The medication contains unique pharmacological properties that make it possible for the medication to be prescribed in the privacy of a doctor's office. This provides a unique alternative treatment for opioid addiction as many other treatment options require daily disbursement at a clinic. Buprenorphine comes alone and in combination with naloxone. Research suggests that buprenorphine could be appropriate for both detoxification (Krook et al., 2003) and maintenance (Stoller, Bigelow, Walsh, & Strain, 2001) treatment of individuals addicted to opioids. It does not appear that buprenorphine has a high abuse potential (Stoller, et al., 2001).

In 2002, the Food and Drug Administration (FDA) approved office based treatment of opioid addiction with buprenorphine (Mintzer, Eisneberg, Terra, MacVane, Himmelstein, & Woolhandler, 2007). The medication has demonstrated safety and

efficacy in primary care/office based environments (Fiellin, Pantalon, Pakes, O'Connor, Chawarski, & Schottenfeld, 2002; Fudala et al., 2003; Mintzer, et al., 2007).

Unlike methadone and LAAM, buprenorphine can be described as a partial agonist at the μ opioid receptor. It acts like other opioid agonists as it binds, but has higher affinity to opioid receptor sites in the brain because it blocks the "high" produced by other opioids. The combination of these two characteristics gives buprenorphine a "ceiling effect," in that increasing the dose lengthens the duration of the action without increasing the intensity of the effect (Fudala & O'Brein, 2005; Walsh et al., 1994). The combination of buprenorphine and naloxone (a pure agonist) provides a medication that is less tempting for illegal use as naloxone produces immediate withdrawal symptoms in the presence of opioids (Fudala & Obrien, 2005) Fudala and O'Brien (2005) found buprenorphine important in treatment of opioid addiction, "it may represent the most important advance in addiction medicine since the introduction of methadone substitution pharmacotherapy 40 years ago" (p. 634).

Fiellin et al. (2001) stated that buprenorphine provides advantages over methadone and other similar forms of treatment. Because of these chemical properties, buprenorphine has also shown a lower potential for the adverse effects (e.g., abuse, respiratory depression, and overdose) associated with other similar treatments (Jasinski, Pevnick, & Griffith, 1978; Walsh, Preston, Stitzer, Cone & Bigelow, 1994; Bikel, Stitzer, Bigelow, Liebson, Jasinski, & Johnson, 1998). Because it is a partial opioid agonist, the associated withdrawal syndrome is milder than with methadone. As a result, eventual tapering off the medication may be easier to accomplish with buprenorphine than with methadone. Another advantage lies in the fact that dosing can be done in the privacy of

home. This requires less frequent clinic visits and helps remove the stigma. Buprenorphine has few side effects and it is reported that the medication is well accepted by patients (Ling et al., 1994).

There are some additional advantages to buprenorphine over methadone identified in the literature. There is a lower overdose risk with buprenorphine (Bell, Butler, Lawrance, Batey, & Salmelainen, 2009), and buprenorphine is safer than methadone at induction. It is not associated with a higher risk of death when compared to methadone (Bell, Trinh, Butler, Randall, & Rubin, 2009). Maremmani and Gerra (2010) suggest that buprenorphine increases access to care, provides a safer and more appropriate treatment than methadone for some patients, and especially those patients who are concerned about visiting a methadone clinic daily. Those who participate in buprenorphine treatment are more likely to suppress illicit opioid use than those who utilize methadone. Buprenorphine may also be a more attractive alternative than methadone for recruiting individuals into treatment (Pinto, Maskrey, Swift, Rumball, Wagle, & Holland, 2010). For example, 93% of a sample of offenders who were prescribed buprenorphine while incarcerated intended to enroll in buprenorphine treatment programs once released (Awgu, Magura, & Rosenblum, 2010).

Lintzeris, Bell, Bammer, Jolley, and Rushworth (2002) found that buprenorphine was just as effective as other medications (i.e. clonidine) for detoxification. One hundred and one patients completed a day-8 research interview and 92 patients completed a day-35 research interview examining post-withdrawal outcomes. Those receiving buprenorphine (50 of 58; 86%) completed the program at a statistically significantly ($p =$ .001) higher rate than those who received other medications. Those who received

buprenorphine reported significantly lower mean withdrawal scores than those who received clonidine ($p = .016$) or combined clonidine and naltrexone ($p = .01$). Buprenorphine was more effective than clonidine and other symptomatic medications at day 8 ($p = .001$) and day 35 ($p = .02$) for short-term withdrawal. Those in the buprenorphine group also used self-reported heroin use on fewer days while in the program ($p < .001$) (Lintzeris et al., 2002).

Ling et al. (2005) compared the effectiveness of the buprenorphine/naloxone with clonidine for opioid detoxification in both inpatient ($n = 113$, 77 bup-nx) and outpatient ($n = 231$, 157 bup-nx) community treatment programs. Fifty-nine of the 77 (77%) inpatients treated with the buprenorphine/naloxone met the criterion for treatment success compared to 8 of the 36 (22%) inpatients given clonidine. Among the outpatients, 46 of the 157 (29%) of patients given buprenorphine/naloxone met the established criterion for treatment success (completion of program and opioid-free urine drug sample on last day of clinic attendance) compared to 4 of 74 (5%) of patients given clonidine. Ling and colleagues concluded that the results demonstrate clear superiority for buprenorphine/naloxone to clonidine in the management of opioid withdrawal (Ling et al., 2005).

One provider used a combination of methadone and buprenorphine in their treatment of those struggling with opioid addiction. One study (Glasper, Reed, de Wet, Gossop, & Bearn, 2005) examined the process of switching detoxification patients from methadone to buprenorphine. The Short Opioid Withdrawal Scale (SOWS) was used to measure severity of withdrawal symptoms during the transfer. They found that 21 of the 23 study participants successfully completed the facilitated transfer. The researchers

concluded that transfer from daily methadone doses of 30 to 70 mg to buprenorphine in an inpatient setting could be accomplished with relative ease (Glasper et al., 2005). They authors suggest that this process could allow for a large proportion of opioid-dependent patients to utilize buprenorphine.

Most of the research comparing known efficacious medications for opioid dependence to buprenorphine focused on maintenance and/or relapse prevention. Only one study utilized a simple buprenorphine and placebo comparison in a human trial. Kakko, Svanborg, Krek, and Heiling (2003) found that one-year retention rates for buprenorphine were significantly better than a placebo condition, with both groups receiving psychosocial treatment ($p = .0001$).

Johnson et al. (2000) conducted a 17-week randomized study of 220 patients assigned to one of four treatment groups: levomethadyl acetate, buprenorphine, and high or low dose methadone. Those who received levomethadyl acetate (89 days), buprenorphine (96 days), and high dose methadone (105 days) had mean number of days in treatment significantly higher ($p < .001$) when compared to those who received low dose methadone (70 days). Patients in those groups reported a statistically significantly higher probability of 12 or more consecutive opioid-negative urine drug screens than those who received low dose methadone ($p = .005$). The authors concluded that, compared to low dose methadone, levomethadyl acetate, buprenorphine, and high dose methadone substantially reduced the use of illicit opioids.

More recently, Wesson and Smith (2010) reviewed the literature and found "compelling clinical evidence that buprenorphine is similar to methadone in efficacy for opiate detoxification and maintenance but safer than methadone in an overdose situation"

(p. 173). They note that buprenorphine is preferred for pregnant patients; it has less abuse potential than other prescription opiates, and targets patients who would not otherwise receive treatment.

Fischer et al. (1998) followed 60 Austrian outpatients for 24 weeks receiving either sublingual buprenorphine or methadone and assessed treatment retention and illicit opioid use. The retention rate was better for the methadone group (71% for methadone compared to 38% for buprenorphine) ($p < 0.05$) but the buprenorphine group had significantly higher opioid-negative urine drug screens (35%) when compared to the methadone group (24%) ($p = .04$).

Stein, Cioe, and Friedmann (2005) examined retention rates for patients treated with buprenorphine in primary care. Patients were followed for 24 weeks. The investigators found that 59 percent of the patients completed the study. Nearly half of the drop-outs occurred in the first 30 days. Patients with opioid-positive urine-drug screens at week one were most likely to drop out of the program ($p < .01$). The variables most strongly associated with retention in treatment included abstinence during the first week of treatment, employment, and exposure to addiction counseling.

Sullivan, Chawarski, O'Conner, Schottenfeld, and Fiellin (2005) used a cross-sectional and longitudinal analysis to study the clinical characteristics and outcomes of 96 patients entering a clinical trial of buprenorphine maintenance in a primary care clinic. The buprenorphine group was compared to patients receiving methadone maintenance in an opioid treatment program. Data from this study led the investigators to conclude that office-based treatment with buprenorphine was associated with abstinence and treatment retention rates comparable to those of methadone patients. The investigators also noted

that office-based treatment of opioid dependence was associated with new types of patients entering treatment. Those receiving office-based treatment were more likely to be male ($p < 0.01$), have full-time employment ($p < .001$), have no history of methadone treatment ($p < .05$), have fewer years of opioid dependence ($p < .001$), and have lower rates of injection drug use ($p < .03$) (Sullivan, 2005). While the data from this study demonstrates similar outcomes when compared to methadone, it does suggest that buprenorphine may be able to attract a new demographic to treatment.

A treatment retention study was conducted with 61 participants from Austria, adolescents received either methadone or buprenorphine (Bell & Mutch, 2006). The participants treated with methadone experienced significantly longer retention in the first treatment episode than subjects treated with buprenorphine (m days 354 vs. 58, $p < .01$). Those treated with methadone also missed fewer days in the first month (m days 3 vs. 8, $p < .05$). Subsequent re-admission for further treatment occurred in 25% of methadone patients and 60% of buprenorphine patients. Time to re-entry was significantly shorter for buprenorphine patients ($p < .05$), however the methadone was related to prevention of premature dropout. These findings are interesting. It is unclear as to what appears to be causing these results. It is important to note that no psychological data was collected in this study. The researchers suggest that psychological data might provide insight into the differences observed.

Marsch et al. (2005) found that a greater percentage of adolescents receiving buprenorphine stayed in treatment longer relative to those who received clonidine ($p < .05$). This study did address a psychological component, as both conditions in this study

included psychotherapy interventions. The authors did not report data regarding

differences in psychological variables between groups.

Concerns have also been raised about the safety and effectiveness of

buprenorphine treatment. There is evidence that buprenorphine is abused. Moratti,

Kashanpour, Lombardelli, and Maisto (2010) found widespread IV misuse of

buprenorphine among those struggling with opioid addiction in Italy. Especially

vulnerable were those already receiving buprenorphine treatment and younger

individuals. While the potential for abuse is concerning, it should be noted that illicit use

rarely occurs in an attempt to attain euphoria. Instead, it is more common for

buprenorphine to be abused in an attempt to self-treat symptoms of opioid withdrawal,

pain and depression (Schuman-Oliver, Albanese, Nelson, Roland, Puopolo, Klinker, &

Shaffer, 2010). Patients receiving a stable dose of buprenorphine also do not appear to

show decreases in complex psychomotor or cognitive performance (Shmygalev, Damm,

Weckbecker, Berghaus, Petzke, & Sabatowski, 2011). Despite these findings, the authors

did not trust the data enough to suggest that those patients are qualified for a driver's

license.

Summary of Buprenorphine Literature

Amato et al., (2005) conducted a qualitative narrative and quantitative summary of

systematic review findings of the Cochrane Library reviews in the United Kingdom on

substitution maintenance treatments for opioid dependence incorporating 52 studies

(12,075 participants). Outcomes considered were retention in treatment, use of heroin and

other drugs during treatment, mortality, criminal activity, and quality of life. The review

reported weak evidence concluding that methadone maintenance therapy at appropriate

doses was more effective than buprenorphine in retaining patients in treatment. Contextual considerations should be made when assessing the Amato et al. (2005) study. Many of the results found in the meta-analysis were dose-dependent, the investigators cautioned that they might be skewed in favor of methadone since methadone doses given in clinical trials were likely higher than those used in clinical practice (Amato, et al., 2005). It is important to note that the study does not suggest that buprenorphine is ineffective. The authors suggest that future clinical trials should collect data on a broad range of health outcomes to increase generalizability of results.

Buprenorphine serves as an important new, cost-effective advance in opioid treatment as it has a better safety profile than pure agonists (i.e. methadone) and did not produce a clinically significant level of dependence (Polsky, Glick, Yang, Subramaniam, Poole, & Woody, 2010; Blaine, 1992). It is appropriate for both maintenance and withdrawal (Orman & Keating, 2009). It is very well tolerated when taken under medical supervision (Orman & Keating, 2009). Buprenorphine therapy has shown data suggesting that it can reduce heroin use and decrease negative addiction-related health and social problems in those struggling with opioid addiction (Fudala & O'Brien, 2005; Strain, Stitzer, Liebson, & Bigelow, 1996; Ling, 1994). NIDA gave buprenorphine a positive review in 1992 when it noted:

> Buprenorphine appears to be as effective as methadone for detoxification of heroin addicts but does not induce significant physical dependence in humans and can be discontinued without significant withdrawal symptoms. NIDA views buprenorphine as a safer, more acceptable maintenance or detoxification option for many opioid-dependent addicts. It also envisions buprenorphine as an intermediary drug (i.e.

between methadone and being drug-free) for those patients who wish detoxification from methadone (Blaine, 1992, pp. 3-4).

A summary by the United States Department of Health and Human Services – Substance Abuse and Mental Health Administration (Wilford, 2006) reviewed the literature on the effectiveness of buprenorphine treatment for opioid dependence and reached three conclusions: (a) multiple studies have shown that buprenorphine is safe and effective, positive treatment outcomes were reported for patients treated with buprenorphine in office-based settings, (b) researchers have identified some patient variables that may prove useful in identifying those patients who are most likely to benefit from buprenorphine treatment, and (c) therapeutic outcomes for office-based treatment with buprenorphine are essentially comparable to those seen in patients treated with methadone in opioid treatment programs (Wilford, 2006).

While research on buprenorphine does mention psychological variables, it does not directly address the impact of self-efficacy and medication adherence. Specifically, the research does not address the impact of the patient's self-efficacy to take the buprenorphine medication.

Psychological Variables in Treatment of Opioid Addiction

Findings from other areas of addiction suggested attendance in psychotherapy sessions increases the probability of positive outcomes (Ciraulo, Piechniczek, Buczek, & Iscan, 2003; Fiorentine, 2001; Miller, 1998). Montoya et al. (2005) evaluated the influence of weekly individual psychotherapy (cognitive-behavioral and interpersonal) attendance on treatment outcome in 90 outpatients struggling with cocaine and opioid dependence over a 70 day controlled clinical trial of sublingual buprenorphine. Their

findings suggested a significant psychotherapy by study week interaction ($p = .04$). In other words, the influence of attending psychotherapy sessions grew more pronounced as the study progressed. The authors noted that psychotherapy could improve the outcome of buprenorphine maintenance treatment for patients diagnosed with dual (cocaine and opioid) dependence for this sample. In the discussion section, the authors noted, "In this study, psychotherapy attendance seemed to have been influenced by internal factors, external factors (i.e. court mandated therapy, employment supervision) played only a small role" (Montoya et al., p. 252). They concluded that more research is needed to identify the cognitive characteristics of non-adherent cocaine and opioid dependent patients.

Some have explored reasons for prematurely leaving treatment. Retention in treatment was linked to both therapeutic involvement and motivation (Simpson, Joe, & Rowans-Szal, 1997; Joe, Simpson, & Broome, 1999; Ball, Carroll, Canning-Ball, & Rounsaville (2006). Ball et al. (2006) interviewed 24 dropouts diagnosed with cocaine or opioid addiction. These subjects reported several reasons for discontinuing the program. Specifically they noted that feelings of hopelessness, a variable negatively correlated with low self-efficacy (Sinnakaruppan, Macdonald, McCafferty, & Mattison, 2010).

Simpson, Joe, and Brown (1997) examined measures of pretreatment motivation and early therapeutic engagement (measured structured interview, TCU self-rating form and Desire for Help Scale) correlated with personal interviews at 12 months post-discharge. Several patient characteristics including being older than 35, lower injection frequency, and higher motivation were each associated with two-fold increases in favorable follow-ups on illicit drug use, alcohol use and criminal activity. The authors

suggest "more comprehensive models of patient attributes, therapeutic processes, and environmental influences are needed, and that treatment enhancement efforts should focus on such during treatment measures as interim criteria for improving post-treatment outcomes" (Simpson et al., 1997, p. 234).

Joe et al. (1999) explored retention in terms of therapeutic involvement and session attributes during the first month of treatment in long-term residential, outpatient drug free, and outpatient methadone settings. Data for the study was gathered in the National Drug Treatment Outcome Studies (DATOS) and included 1362 long-term residential patients, 866 outpatient drug free patients and 981 outpatient methadone treatment patients. Structural equation modeling revealed that motivation at intake was the strongest determinant in success. Other factors including pretreatment depression, alcohol dependence, legal pressure (mandated treatment), and cocaine use also significantly related. The study did note a high retention rate for the outpatient methadone treatment condition, with about half (54%) of patients remaining in treatment for at least a year. The authors included that intrinsic motivation played a strong role in predicting therapeutic involvement. Intrinsic motivation and high levels of self-efficacy are often positively correlated (Kavussanu & Roberts, 1996; Bandura & Schunk, 1981).

Gerra et al. (2006) compared buprenorphine therapy of 206 dually diagnosed and non-dually diagnosed patients divided into five subgroups: major depression, generalized anxiety, antisocial-borderline, schizophrenia, and substance use disorder without psychiatric co-morbidity. Buprenorphine appeared to be more effective in those patients affected by depression. Across all groups, the researchers suggested that higher doses of buprenorphine were associated with better outcome but not with better retention. This

suggests that there may be some unmeasured variables in this study that are especially important during the first phases of treatment with buprenorphine. It also suggests research on dosage and dosage changes may influence effectiveness of buprenorphine.

Kaplan (2006) also noted that adherence was the key for treatment of opioid addiction with buprenorphine. This finding was supported by Boothby and Doering (2007) when they concluded:

> Buprenorphine is an attractive option for the pharmacologic treatment of opioid dependence. Compliance and adherence to buprenorphine therapy for opioid-dependent patients remain clinical issues. Future research should focus on improving compliance and adherence to buprenorphine therapy (Boothby & Doering, 2007 p. 272).

Buprenorphine appears to be a significant advance in the treatment of opioid addiction (Wilford, 2006). Since buprenorphine is a relatively new medication, not much research exists on the impact of psychological variables on treatment outcomes. In order to maximize the positive impact of the medication researchers suggest including psychological treatment variables in further research. Special attention should be paid to the psychological variables that improve compliance to buprenorphine.

Medication Adherence

Individuals throughout health services have studied the concept of adherence to medical treatment since the time of Hippocrates (Haynes, 1979). Medication adherence is commonly defined as "the extent to which a person's behavior coincides with medical advice" (Haynes, Taylor, & Sackett, 1979, p. 1). Adherence is preferred over the term compliance as researchers in allied health professions find that the term compliance

connotes an overly authoritarian view of health care minimizing the patient's role as a decision maker in the overall treatment plan. The term adherence refers to the patient's ability to comply with a treatment plan. It involves "patient acceptance and follow-through with treatment recommendations" (DiMatteo, 2004, p. 200). The term adherence is used primarily in behavioral and allied health science literature where the term patient compliance is frequently used in medical journals and other medically oriented publications (Feinstein, 1990). The preferred term, adherence, suggests a more collaborative view of provider–patient exchanges (Eisenthal, Emery, Lazare, & Udin, 1979). Thus, many researchers perceive adherence as a "collaborative process, or interaction between patient and provider" (Waters, 1997, p. 76). Medication adherence plays a part in medical compliance, which encompassed the entire spectrum of patient responses to medical advice as well as adherence to prescription regimens (Haynes, 1979).

Medication adherence is seen a significant problem impacting the effectiveness of treatment (Balkrishnan, 2005; Osterberg & Blaschke, 2005; DiMatteo et al., 2002). Participants in clinical drug trials who failed to follow medication regimens, or placebo regimens, exhibit a poorer prognosis than subjects in the respective groups who correctly followed instructions (Horwitz & Horwitz, 1993). This problem is especially prevalent in populations who receive psychiatric treatment (Elliott, Barber & Horne, 2005). Adherence to psychopharamacotherapy remains an important part of the treatment process. Lack of adherence decreases the client's chance for immediate recovery while also reducing the probability of a positive long-term outcome (Horwitz & Horwitz, 1993). While many factors contribute to relapse from chronic illness, non-adherence to

medications is seen as the single most influential determinant of relapse (Green, 1988).

At times, researchers are not able to decipher how the many variable work in

combination to impact medication adherences. Some research on chronic conditions

suggests that many other variables, like self-efficacy, are positively correlated with

medication adherence (McCaul, Glasglow, & Schafer, 1987). Researchers need to create

instruments to measure these variables in order to assess the cause and effect

relationships involved in medication adherence.

Measurement of Medication Adherence

There is confusion about the operational definitions of treatment adherence

(Bosworth, Weinberger, & Oddone, 2006). This could be a function of the terms the

literature uses interchangeably to refer to the concept, such as: compliance, cooperation,

concordance, mutuality and therapeutic alliance. Most definitions contain aspects that

relate to patient's self-care responsibilities, patient's role in the treatment process and the

work that the health care provider and the patient do together (Bosworth et al., 2006).

There remains no consensual operational standard for what constitutes medication

adherence.

Most contemporary literature considers adherence a dichotomous variable rather

than a phenomenon with multiple dimensions (Osterberg & Blaschke, 2005). There is

danger in treating adherence as a dichotomous variable. When treated as a dichotomous

variable, the result is often a reduction in variance, which impacts the sensitivity, and

possibly reliability, of the data. Labeling a patient as "nonadherent" versus "adherent"

may also negatively impact the therapeutic relationship. To combat this danger,

Ostereberg and Blaschke (2005) suggested that medication adherence be viewed along a

continuum from 0% to more than 100% given patients sometimes take more than the

prescribed amount of medication. Rudd et al. (1989) agree and conclude that adherence is

an exceptionally variable concept. These facts lead researchers to operationally define

medication adherence as the percentage of the doses taken divided by the total number of

doses (Dunbar, 1983).

Much of the research utilizes the well-accepted definition of adherence presented

by Osterberg and Blaschke (2005), where the concept of medication adherence refers to

"the extent to which patients take medication as prescribed by their health care providers"

(p. 487). This "extent" is measured and operationally defined in various forms based on

the theoretical approach of the researcher. If the researcher takes a behavioral approach,

the researcher must measure complex actions, thoughts and emotions that may not be

observable. In these cases, self-report may provide the best data. Outcome-oriented

definitions like cure rate can be objective but may not accurately assess the complex

processes that lead to the outcomes. Process-oriented measured techniques, using

variables like appointment show rates, help the researcher understand the process but

might not reflect the ultimate goal (Bosworth et al., 2006). In the end, the operational

definition should reflect the researchers understanding of the concept and be a good fit

for the populations being researched.

Empirical Evidence on Medication Adherence

A review of literature illustrates that many studies address medication adherence

both in the United States (Osterberg & Blaschke, 2005; DiMatteo, 2004; Agarwal,

Sharma, Kumar, & Lowe, 1998; Chen, 1991; Morris & Schulz, 1992) and Great Britain

(Blackwell, 1976). Research focuses on the measurement and correlates of adherence as

well as the strategies to improve existing adherence or compliance (DiMatteo et al., 2002; Morris & Schulz, 1992).

Non-adherence results in consequences including suffering and death, diminished quality of life, provider and patient frustration, anger and hopelessness (Bosworth et al., 2006). It leads to decreased effectiveness and higher health care costs (Bosworth et al., 2006). Some estimate that nonadherence to medication regimens has resulted in 125,000 deaths per year in the United States (Peterson, Takiya, & Finley, 2003).

Given the variability in conceptual and operational definitions of adherence, it was not surprising to find that ranges for adherence range from 0% to over 100% (Haynes, McKibbon, K., & Kanani, R., 1996; Rudd, 1995; Eraker, S., Kirscht, j., & Becker, M. 1984). Patients adhere to their medication regimen totally, partially, or more often, erratically (Cramer, 1995; Fotheringham & Sawyer, 1995; Orme & Binik, 1989). Patients also initially adhere but then discontinue. Epstein & Cluss (1982) suggests that 40% of all patients receiving prescription medication took it incorrectly or not at all. Dunbar-Jacobs & Schlenk (2001) suggest adherence rates for all populations could vary between 60% and 75%. DiMatteo (2004) conducted a meta-analysis of 50 years of research in 164 studies and found that the average non-adherence rate across all diagnoses was 24.8%. DiMatteo's (2002) meta-analysis suggests there is a 26% difference between low and high adherence. For most populations, acceptable adherence rates exist at 80% and sometimes as high as 95% (Osterberg & Blaschke, 2005). The variability in the prevalence rates for adherence and non-adherence is somewhat attributed to inconsistent definition and measurement of the construct (Zygmunt, Olfson, Boyer, & Mechanic, 2002; Dolder, Lacro, Leckband, & Jeste, 2003).

Research reflects a wide variation in observed adherence ranges based on diagnosis. Differences exist in adherence between those diagnosed with physical and psychiatric diagnoses. Psychiatric diagnoses often reflect lower medication adherence when compared to those with non-psychiatric illnesses (Haynes, 1976). The average adherence rate in clinical trials is remarkably high when compared to nonclinical trials. Even so, clinical trials often report average adherence rates of only 43% to 78% among patients receiving treatment for chronic conditions like depression (Cramer, Rosenheck, Krik, Krol, & Krystal, 2003). Adherence rates in those populations with chronic conditions rarely exceed 50% (Osterberg & Blaschke, 2005: Sackett & Snow, 1979).

Average adherence rates remain higher among patients with acute conditions, when compared to those with chronic conditions (Osterberg & Blaschke, 2005). DiMatteo's (2004) meta-analysis suggests that adherence was highest for those diagnosed with HIV (88.3%), arthritis (81.2%), gastrointestinal disorders (80.4%) and cancer (79.1%). Adherence is lowest in individuals diagnosed with pulmonary disease (68.8%), diabetes (67.5%) and sleep disorders (65.5%). All of those disorders are chronic conditions. Interestingly, substance abuse data is not included in this meta-analysis nor is it included in the DiMatteo et al. (2004) meta-analysis.

Medication Adherence in Populations Struggling with Addiction

The problem of medication adherence appears especially salient among individuals diagnosed with both substance use disorders and mental illness (Benarde & Mayerson, 1978; Chewning & Sleath, 1996; McLane, Zyzanski, & Flocke, 1995). While some suggest that no connection exists between substance abuse and medication adherence (Kovasznay et al., 1997), a majority of others find that current or past

substance abuse positively correlates with poor treatment and medication adherence (Benarde & Mayerson, 1978; Drake & Wallach, 1989; Kashner, Radr, & Rodell, 1991; Owen, Fischer, Booth, & Cuffel, 1996).

Magura et al. (2002) attempted to explain the reasons medication adherence remained poor among substance abuse populations. The authors suggested that the lifestyle of the substance abuser impacts medication adherence. Substance abusers tend to lead disorganized lifestyles making adherence a challenge. More directly, substance abuse leads to impaired judgment leading the patient to make generally unhealthy choices, essentially forgetting to take his/her medication (Sowers, 1997). Those who self-medicate prior to treatment prefer self-medication to the medications prescribed (Sowers & Golden, 1999). Additionally, recovering persons with dual diagnoses can be persuaded by 12-step program staff or self-help groups to stop taking any medications (Zweben & Smith, 1989).

Drug addiction is a complex problem that involves many variables. While there is some disagreement in the research, most research supports the view that medication adherence is a problem in populations struggling with addition. Differing opinions exist for the reasons for the low level of adherence. A greater understanding of those underlying variables that lead to low adherence may lead to treatment modalities that increase medication adherence in populations struggling with addiction.

Medication Adherence in Opioid Treatment

There is limited data on medication adherence for medications designed to assist in reducing opioid use. Haskew, Wolff, Dunn and Bearn (2008) find that 38 (42%) methadone patients were either partial (3-27 days of adherence) or poor adherers (0, 1,

and 2 days of adherence) in the last month. They suggest that new approaches encouraging adherence are necessary to improve opioid treatment programs. Trafton, Humphreys, Harris, and Oliva (2007) find that opioid dependent patients who attend clinics are more compliant with guidelines for methadone dosing and psychosocial treatment. Those patients consistently adhere to all treatment guidelines, including medication guidelines, had reductions in heroin use and greater improvement in mental health when compared to those who attend clinics that were less compliant. This appeared to support a biopsychosocial approach to treatment.

Only one study addresses adherence in patients receiving buprenorphine-naloxone treatment for opioid addiction. Fiellin et al. (2006) conducted a 24-week randomized, controlled trial with 166 patients in three treatment conditions: (1) standard medical management and once-weekly medication dispensing, (2) standard medication management and (3) thrice-weekly medication dispensing, and enhanced medical management and thrice-weekly medication dispensing. They found that a variety of weekly regimens involving counseling and buprenorphine-naloxone appears to be equally effective in reducing opioid use among dependent patients as measured by patient self-report and testing of opioid negative urine samples. All three treatments show a decrease in the mean self-reported frequency of opioid use (95 percent confidence interval, 5.1 to 5.5) at baseline to 1.1 days (95 percent confidence interval, 0.9 to 1.3) during induction to 0.4 day (95 percent confidence interval, 0.2 to 0.7) during maintenance ($p < .001$ for the comparisons of induction and maintenance with baseline), but there are no significant differences among the three groups ($p = .73$) or among the treatments over time ($p = .83$). The overall mean percentage of days on which patients adhere to buprenorphine-

naloxone was 71 plus/minus 22 % (range, 7 to 100), and the mean percentage did not

differ significantly among the groups ($p = .87$). The percentage of days of adherence did

correlate significantly with the percentage of opioid-negative urine specimens and the

mean number of consecutive weeks of abstinence from opioids ($r = .30$ and $r = .35$ across

all groups $p < .001$). Patients who adhere to their medication were more likely to remain

drug free regardless of treatment schedule. The study suggests that medication adherence

is a very important variable in reducing opioid use with populations receiving

buprenorphine-naloxone treatment. It also suggests that the use of urine drug screens as a

measure of adherence is a valuable tool in research. The article concluded with the

following sentence; "the variability in buprenorphine-naloxone adherence highlights the

need to both measure adherence in future research and encourage adherence in practice in

order to reduce to the potential misuse of the medication and to improve treatment

outcomes (pp. 373-374).

The research provided very little insight into the impact of medication adherence

in opioid treatment. The research did seem to highlight the importance of accurate

measures of adherence as well as an increased understanding of the variables that

contribute to adherence. Bosworth and Voils (2006) suggested that, to understand

adherence, researchers and practitioners should look at theoretical models to gather

insight into adherence behavior. They suggested a good starting point for theoretical

understanding is Social Learning Theory and the role of self-efficacy as it applies to

medication adherence.

Self-Efficacy

Bandura suggests that human behavior is much more than the sum of past associations and/or consequences (Bandura, 1977). Specifically, Bandura's social learning theory suggests that an individual's cognitions, among other personal variables, impacts behavior (Bandura, 1989). Bandura (1986) proposes a model of triadic reciprocal causation in which behavior, personal attributes (i.e. internal cognitive processes), and external environmental influences all work together to influence behavior.

> The relative influences exerted by these interdependent factors differ in various
> settings and for different behaviors. There are times when environmental factors
> exercise powerful constraints on behavior, and other times when personal factors are
> the overriding regulators of the course of environmental events (Bandura, 1977, p.
> 10).

As environmental influences shape an individual's behavior, the behavior, in turn, shapes the environment. During this process, the individual uses cognition to monitor and/or shape his or her own behavior (Bandura, 1995). According to the theory, an individual's cognitive processes play an important role in determining behavior.

One of the cognitive processes at work is the individual's belief about his or her own abilities. Bandura (1995) proposed that an individual's level of motivation, affective states, and behaviors are rooted more in what he or she believes than in what is objectively the case. He calls this construct self-efficacy. Bandura identified general self-efficacy as, "the belief in one's capabilities to organize and execute the courses of action required to produce given attainments" (Bandura, 1997, p. 3). He believes that change is possible, and the impetus for change is often an individual's belief system. Self-efficacy

does not necessarily represent a general trait, however. Self-efficacy is domain specific and refers to the self-assessment of one's ability and degree of confidence in performing a specific task or activity (Bandura 1977, 1997). Bandura (1989) reports that stressful life situations create opportunities in life where behavior is influenced by self-efficacy. His research indicates that people with high levels of self-efficacy perceive threatening circumstances as more manageable. These individuals develop cognitive and behavioral strategies to reduce fear and increase the potential for success.

Since an individual's health is partially determined by reactions to stress, self-efficacy impacts the general health of an individual (Bandura, 1989). Bandura (1977) suggests self-efficacy is a cognitive mechanism that mediates behavior change, whereas stress is often seen as a barrier to change. "Among the mechanisms of personal agency, none is more central or pervasive than an individual's self-efficacy" (Bandura, 1995, p. 2).

Sources of Self-Efficacy

Bandura (1977, 1986) defines four sources of self-efficacy beliefs: personal accomplishments or mastery experiences (i.e. previous success with abstinence), vicarious experiences (i.e. watching others successfully complete treatment), verbal persuasion and emotional arousal (i.e. hearing others discuss their recovery). Mastery experiences include accomplishments and performance results. Bandura (1986) notes that successes raise efficacy expectations while failures reduce it.

Observing the experiences of others influences the self-efficacy of the individual, especially if the characteristics of the model being observed closely resemble the characteristics of the learner. Verbal persuasion influences those with mild mastery self-

efficacy doubts. Mastery self-efficacy resembles a dynamic set of domain specific self-beliefs (Brandon, Herzog, Irvin & Gwaltney, 2004). Vicarious experiences include behaviors adopted from role models. Verbal persuasion can occur directly from a role model or from another in the environment. Emotional arousal can influence decision-making. These decisions influence future perceptions of self-efficacy. Given the critical importance of behavior change in the treatment of addiction, Bandura's theory of self-efficacy is a highly useful model for understanding human behavior in populations struggling with addiction.

Measurement of Self-Efficacy in Addiction

Researchers highlight the importance of self-efficacy in cognitive models of addiction (Beck, Wright, Newman, & Liese, 1993; Marlatt, 1985). However, applying self-efficacy theory to behavior change in populations struggling with addiction is not an easy task. Theoretically, the levels of self-efficacy will change given the multiple possible domains involved. An individual's self-efficacy for abstinence in a social situation might be different than the same individual's self-efficacy for abstinence when alone. The self-efficacy for drug of choice can be different. The self-efficacy for type of treatment may also show individual differences. Since self-efficacy is theoretically domain specific, Bandura argues that there should be multiple measurements of self-efficacy in addiction.

Some researchers disagree with Bandura and fail to differentiate among the theorized forms of self-efficacy and define self-efficacy applied to all addiction situations as "the belief or perceived confidence in one's ability to effectively manage a high-risk situation" (Sitharthan, Soames, Kavanagh, Sitharthan, & Hough, 2003, p. 352).

DiClemente, Prochaska and Gibertini (1985) suggest that making a distinction between types of self-efficacy is not necessary. They suggest that the data points to a general self-efficacy rather than many separate, situation specific categories in substance use populations. DiClemente's (1986) later research notes that measurement tools may differ but there are important similarities in the findings. That is, variability exists in the measurement of the construct but alternate methods of measurement still result in significant relationships between self-efficacy and behavior change in populations struggling with addiction (DiClemente, 1986).

While definitions and domain specific types of self-efficacy vary in the literature, most research in this area often utilizes abstinence self-efficacy. Abstinence self-efficacy refers to "confidence in the ability to abstain use" (Gwaltney, Shiffman, & Sayette, 2005, p. 651). The literature indicates that self-efficacy is an important variable in treatment of those suffering from addiction. This research base started with valid and reliable tools designed to measure self-efficacy. Some of the tools that gather this type of data include the 12-item Readiness to Change Measure (Rollnick, Heather, Gold, & Hall, 1992), the University of Rhode Island Change Assessment (URICA) (McConnaughty, DiClemente, Prochaska, Velicer, 1989), the Stages of Change Readiness and Treatment Eagerness Scale (SOC-CRATES) (Miller & Rollnick, 1991) and the 20-item Alcohol Abstinence Self-Efficacy Scale (DiClemente, Carbonari, Montgomery, & Hughes, 1994). In general, these measures assess the individual's self-efficacy for abstinence and/or confidence in coping skills for high-risk relapse situations.

Self-Efficacy in Addiction

Marlatt, Baer and Quigley (1995) note that self-efficacy theory provides a complex but applicable model that assists researchers and practitioners in understanding both the "development of addictive habits and the behavior change process involving the cessation of such habits and maintenance of abstinence" (p. 289). Bandura (1986) theorizes that higher self-efficacy positively impacts treatment outcomes among those who desire to quit smoking. In 1995, Bandura addresses the issue of self-efficacy as it applied to substance use. He notes that self-efficacy is particularly important during the cessation of substance use. Bandura also suggests that stronger self-efficacy beliefs are associated with a greater probability of achieving and maintaining abstinence (Bandura, 1995). In 1997, Bandura devotes portions of his work to the study of self-efficacy and addiction.

Viewed from the model of triadic reciprocal causation, each of the three classes of casual interactants – environmental factors, the self-system, and behavioral competencies - contribute to the long-term control of substance abuse. As we have already seen, skills and strategies are quickly abandoned if people lack the strength of self-efficacy to stick with them through tough times (Bandura, 1997, p. 293).

Bandura applies his existing mechanisms for increasing self-efficacy to populations struggling with addiction. Bandura (1977) identifies sources of self-efficacy specific to those struggling with drug addiction, including past experiences with the behavior (e.g., prior attempts to quit or cut down on substance use), vicarious experiences and verbal persuasion or encouragement (e.g., exposure to supportive sober role models

that often occur in group therapy), and level of arousal, impulsivity and distress (e.g.,

learning how to deal with triggers).

Bandura's concept of self-efficacy is adopted by others and expanded in the study

addiction. Marlatt (1985) proposes that self-efficacy increases when patients learn to

identify high-risk situations and cope with them effectively. He believes that self-efficacy

was highly domain specific and proposed five types of self-efficacy based on different

stages of the process.

Marlatt et al. (1995) believes that an individual utilizes different types of self-

efficacy during different stages of addiction. The researchers propose five types of

efficacy beliefs specifically applied to populations struggling with addiction. Each

category reflects unique domain specific situations. The first two categories apply before

the initiation of substance use. The first category is resistance self-efficacy (i.e. ability to

avoid use prior to first use). Refusal of the offering of a drink exemplifies resistance self-

efficacy. Prevention programs often focus on resistance self-efficacy (Bentrim-Tapio,

2004). The second category is harm-reduction self-efficacy (i.e. risk reduction efficacy

following first use), which becomes important when attempts to prevent initiation of

substance use fail and the goal shifts to reducing intake and/or harm from use of

substances.

The third, fourth, and fifth categories of self-efficacy apply after the initiation of

substance use. The third category represents action self-efficacy (i.e. ability to achieve a

goal of abstinence or controlled use). Once a pattern of addictive behavior is established,

the individual enters a static state. Increasing this third category of self-efficacy is used to

propel the individual out of the static, addictive behavior and into a changed and sober

lifestyle. Coping self-efficacy (efficacy to cope with relapse crisis), the fourth category, includes a person's confidence in his or her ability to resist relapse. The fifth stage represents recovery self-efficacy, defined as restorative coping following relapse episodes. This type of self-efficacy is specifically part of the challenge for long-term sobriety after the cessation of the addictive behavior. Marlatt, et al. (1995) notes that coping self-efficacy focuses on an individual's ability to resist relapse while recovery self-efficacy involves the individual's reactions following a lapse or relapse episode. A person with high recovery self-efficacy returns to utilizing coping strategies after a relapse. The theorized categories of self-efficacy appear to describe the domain specific recovery process for individuals with addictions. While the model needs empirical evaluation, it does theoretically support Bandura's notion that each type of self-efficacy is unique to the specific domain. In order to provide empirical support for the multiple types of self-efficacy proposed by Marlatt and Bandura, we need to assess multiple types of self-efficacy in the treatment process.

Empirical Support for Self-Efficacy in Populations Struggling with Opioid Addiction

Bandura himself tested his theory on populations struggling with opioid addiction in 1987. Bandura, O'Leary, Taylor, Gauthier and Gossard (1987) assessed the relationship between self-efficacy and pain control. The study included 36 men and 36 women from an introductory psychology course. Each individual was selected to one of three conditions. One condition learned cognitive methods of pain control, a second condition received a placebo, and a third condition received no intervention. The findings of this study suggest that cognitive training strengthened self-efficacy assisting the subjects to both withstand and reduce pain. The placebo group increased self-efficacy to

withstand pain. In all treatment conditions, higher self-efficacy to withstand pain resulted in longer periods of endurance for mounting pain. No significant differences were seen between men and women.

Hser (2007) studied 242 males addicted to heroin for more than 30 years in the California legal system. Multiple interviews were conducted over time; the interview in 1985/1986 (eleven years after first collection) was the latest to collect self-efficacy data. Self-efficacy for abstinence was significantly higher among the recovery group (n = 104, m = 3.8/2.9 sd = .6/1.0) than the non-recovery group (n = 138, mean 2.9; p < .01). The data suggested Hispanic heritage, psychological distress and self-efficacy significantly predicted recovery status at 10 years.

Reilly et al. (1995) studied 74 participants (50 males and 24 females) enrolled in a 180-day methadone treatment program at a Veterans Affairs Hospital. They utilized the phase approach to methadone maintenance treatment: collecting self-efficacy data for abstinence at the intake, initiation of stabilization phase and initiation of taper. They found that self-efficacy increased at the start of the stabilization phase $F(2, 146) = 45.97$, p <.001), did not change at a statistically significant level across the stabilization phase $F(2, 146) = 1.33$, $p = .27$, and decreased across the taper phase $F(2, 90) = 5.37$, $p = .01$. The researchers found that changes in all stages coincided with changes in illicit opioid use. Self-efficacy ratings at day 30 did predict the number of positive urine screens across the stabilization phase ($r = -.51$, $p < .001$). For both the stabilization and taper phases, self-efficacy predicted variance in opioid use above the variance accounted for by demographic characteristics. A $R2$ change = .16, $p < .01$) vs. .12 for demographics was observed in the stabilization phase. A $R2$ change = .16, $p < .01$) vs. .27 for the

demographics in the taper phase. Reilly et al. (1995) did not find any significance in the demographic data gathered. They did discuss previous treatment as a variable that should be addressed in future research.

El, El, Sheikh, & Bashir (2004) compared self-efficacy levels of 105 individuals struggling with heroin addiction and those struggling with alcohol addiction in Saudi Arabia. The findings suggested that those struggling with alcohol addiction report higher self-efficacy to cope effectively with high-risk substance use situations when compared to the same self-efficacy measures with an addiction to heroin. Since self-efficacy has been correlated with success in treatment, these results suggest that self-efficacy may be a very important variable to address in treatment of opioid addiction. The authors also noted that sobriety is a factor that should be included in any study of self-efficacy in opioid addiction. They also focused a great deal on the influence of the medication taper on self-efficacy, finding that changes in medication influence the patient's level of self-efficacy.

In summary, research supports social learning theory, and specifically self-efficacy, as important components in understanding populations struggling with addiction. Limited research exists on the relationship between self-efficacy and opioid addiction, however. The research that does exist suggested gender, previous treatment, medication changes and sobriety are variables of interest for this population. Particular demographic and treatment variables have been found to be correlated with self-efficacy and types of addiction including age, marital status, education level, and employment status (De Gees et al., 1995; Moynihan, Roehling, LePine, & Boswell, 2003). That research suggests that those with marriage partners and those with higher levels of

education may display higher levels of self-efficacy (De Gees et al., 1995; Moynihan, Roehling, LePine, & Boswell, 2003).

Self-Efficacy and Medication Adherence

Medication-taking behavior is seen as a complex interaction of biological, psychological and social factors (Ogedegebe, Mancuso, Allegrante, & Charlson, 2003). According to Bandura, self-efficacy is one of the psychological factors that impacts medication adherence (Bandura, 1982). The empirical support for the application of social learning theory, specifically self-efficacy, to treatment adherence has been accumulated over the past 20 years (Bosworth & Voils, 2006). The theoretical model has been applied to exercise (Jeffery, French, Rothman, 1999; Marcus, Rakowski, & Rossi 1992), contraceptive use (Grimley, Riley, Bellis, & Prochaska, 1993), and smoking (Plummer, et al., 2001; Clark, Rakowski, Kviz, & Hogan, 1997). Self-efficacy has been shown to predict medication adherence in individuals diagnosed with chronic diseases (Oleary, 1985; Ogedegebe, Mancuso, Allegrante, & Charlson, 2003). McCann, Clark, and Lu (2008) saw self-efficacy as a "cornerstone of medication adherence" (p. 333).

Measurement of Self-Efficacy for Medication Adherence

While there may be disagreement in the specific types of self-efficacy for overall treatment, self-efficacy for adherence to medications represents a domain specific form of self-efficacy that may impact the treatment process and outcome. Domain specific self-efficacy refers to the self-assessment of one's ability and degree of confidence in performing a specific task or activity (Bandura 1977, 1997). In this case, the task is adhering to the specific medication regimen.

Only one study addresses self-efficacy specifically for adherence to a medication

regimen. Ogedegbe, Mancuso, Allegrante and Charlson (2003) created the Medication

Adherence Self-Efficacy Scale (MASE) to measure and identify situations in which

patients expressed self-efficacy in adhering to prescribed medications. The purpose of the

MASE is to evaluate self-efficacy for medication adherence in those struggling with

hypertension. The data are used to assist clinicians and researchers in identifying

situations in which patients have low self-efficacy in adhering to prescribed hypertensive

medications. The conceptual development of the MASE was based on the findings from

open-ended interviews of 106 patients. The questions were created to elicit patient

experiences with taking antihypertensive medications. Responses were recorded

verbatim, coded, and sorted into nine qualitative categories describing barriers and

facilitators of medication adherence. An initial 43-item self-efficacy questionnaire was

created, which was administered to another group of 72 patients for item analyses. For

each of the situations listed, patients rated how sure they are that they can take their blood

pressure medications: Not at All Sure, Somewhat Sure and Very Sure. Items are scored

from 1 (Not at All Sure) to 3 (Very Sure). A total mean score on the measure was

calculated by averaging across responses to all items. Higher scores indicate a greater

level of self-efficacy (Ogedegbe et al, 2003).

At the end of this initial phase, 21 of the 43 items fulfilled the minimum item-total

correlation coefficient value of 0.5 and minimum kappa value of greater than 0.4. The

remaining 22 items did not meet these criteria. Of these, five items were retained for their

clinical significance. The five items retained reflected cost of medications, side effects,

and frequency of dosing, all of which have been shown to be significant predictors of

medication adherence. The Cronbach alpha for the entire 26-item scale was 0.95

(Ogedegbe et al, 2003).

An exploratory principal components factor analysis performed on the 26 items of the final MASE revealed a five-factor solution using the minimum Eigen value criteria $\geq$ 1. These five factors accounted for about 93% of the total variance. Results of this factor analysis suggest that the final MASE is a one-dimensional scale, with the majority of the items loading on factor 1. The mean self-efficacy score was 2.50 for all patients (Ogedegbe et al, 2003).

Literature Summary

Opioid addiction is a problem that negatively impacts the lives of many Americans. The history of treatment for opioid addiction includes the use of many maintenance medications. Burprenorphine is a fairly new medication that has shown efficacy in the maintenance and detoxification of opioid addiction. The effectiveness of the medication lies, in part, in the patient's ability to adhere to the prescribed medication regimen. There are many factors that influence the medication adherence of the patient. Self-efficacy impacts many aspects of addiction treatment, with medication adherence being one of those factors. Self-efficacy is domain specific, with levels and types of self-efficacy differing in different domains of our lives. It follows that self-efficacy for medication adherence represents a very specific domain. Only one measure, the MASE, measures self-efficacy for medication adherence (Ogedegbe et al., 2003). The MASE is designed for populations struggling with hypertension.

To date, no study has examined self-efficacy to adhere to buprenorphine medication for the treatment of opioid addiction. A measure of self-efficacy for buprenorphine regimen adherence will enable future research to investigate the impact of

self-efficacy on pharmacotherapy treatment for opioid addiction. This study is designed

to adapt the MASE for use in opiate addiction treatment and evaluate the reliability and

validity of the resulting instrument which was named the Self-Efficacy for Medication

Adherence—Buprenorphine scale (SEMA-B).

CHAPTER THREE

METHOD

To fully evaluate the psychometric properties of an instrument, researchers

normally examine multiple forms of test reliability and validity. Commonly accepted

forms of reliability include inter-rater, test-retest (temporal), parallel-forms, and internal

consistency, while common forms of validity include content, criterion-related, and

construct. Newer approaches such as generalizability theory and item-response theory are

now also commonly utilized. While a thorough examination of an instrument will address

most of these forms of reliability and validity, initial analyses of new instruments

typically rely on a smaller number of forms of reliability and validity. It is very common

for internal consistency reliability, temporal reliability, and construct validity to be

included in the initial analysis of an instrument. The present study took this approach.

These analyses were also similar to those undertaken in the development of the MASE,

the parent instrument for the SEMA-B (see Ogedegebe, Mancuso, Allegrante, &

Charlson, 2003).

Participants

Participants for this study were recruited from an Opiate Recovery Program at a

comprehensive mental health treatment hospital in the Midwestern United States. An

employee of the facility recruited volunteers when they checked in for their psychiatric

appointment. Participants needed to be adult patients in the recovery program, and no

exclusionary criteria were used in the recruitment of the study participants. Inclusion

criteria included the following:

1. Participants needed to be willing to the complete informed consent documentation to participate in this study.

2. Participants needed to be receiving buprenorphine treatment for opioid addiction at the hospital.

A total of 121 patients participated in the study (76 male, 45 female). The mean age of the sample was 31.6 (*SD* = 11.2). Twenty-seven participants (22%) were currently married, 71 (58.7%) were separated, 15 (12.4%) were divorced and 8 (6.6%) were single or never married. Out of the total sample, 14 (11.6) had completed some high school, 42 (35.5%) finished high school or equivalent, 42 (34.7%) completed some college, 15 (12.4%) completed college, 5 (4.1%) had a graduate education and 2 (1.7%) did not answer and information regarding educational attainment was missing from the medical file. Eighty (66%) were currently employed.

With regard to employment, 41 (34%) of the participants were currently unemployed. One hundred and four (86%) had participated in substance abuse treatment within the past 5 years (14% had not participated in treatment in the past 5 years). Forty-two (34.7%) had a positive drug screen for an opiate other than buprenorphine during the current treatment episode, indicating that the participant was abusing some other type of opiate while taking buprenorphine. The average number of treatment appointments attended, which included medication appointments as well as individual and group counseling sessions, was 13.12 (*SD* = 12.8). Fifty-six (46.3%) of the patients had a change in buprenorphine dosage in the past 6 months compared to 65 (53.7%) who continued on the same dose over that time frame.

Measures

Demographic and Treatment History Data Recording Form

The demographic data recording form included items related to gender, age, marital status, education level, employment status, past substance abuse treatment experience, urine drug screen results, number of substance abuse treatment appointments attended in last 6 months, and medication changes in the last 6 months. A copy of this form is found in Appendix B.

Self-Efficacy for Medication Adherence – Buprenorphine (SEMA-B) Scale

This dissertation study involved adapting the Medication Adherence Self Efficacy Scale (MASE) (Ogedegbe et al., 2003) scale for use with patients in substance dependence treatment who receive buprenorphine for the treatment of opioid addiction. The purpose of the MASE scale is so clinicians and researchers can identify situations in which patients have low self-efficacy in adhering to prescribed medications for treating hypertension. It was created using open-ended interviews with 106 patients to elicit their experiences with taking antihypertensive medications. The initial subject population consisted of hypertensive patients aged 20 to 83 (mean age = 56). Concepts from categories were formatted into an initial 43-item self-efficacy questionnaire, which was administered to another group of 72 patients for the analyses. For each of the situations listed, patients are asked to rate how sure they are that they can take their blood pressure medications with a three-point Lykert scale. The scale contains the following options: not at all sure, somewhat sure, and very sure. After statistical analysis, 26 items were retained. The mean self-efficacy score was 2.50 for all patients. Those with controlled

blood pressure had slightly higher mean self-efficacy scores than those patients with uncontrolled blood pressure (2.54 vs. 2.48, $p > 0.05$) (Ogedegbe et al., 2003).

The first phase of adapting the MASE to the SEMA-B for patients taking buprenorphine for opioid addiction involved a rewriting of the questionnaire items. To accomplish this, the MASE was given to three licensed practicing psychiatrists who had completed training specific to dispensing buprenorphine. This training involved meeting one of seven criteria for consideration as a buprenorphine provider, criteria that guaranteed a baseline of competence and licensure in medicine and research, specifically in addiction. Additionally the psychiatrists who participated in this study had to be willing to meet the following three criteria: (1) Participation as an investigator in one or more clinical trials leading to the approval of a narcotic drug in Schedule III, IV, or V for maintenance or detoxification treatment; (2) Training or other such experience as determined by the physician's state medical licensing board; and (3) training and other such experiences as determined by the United States Secretary of Health and Human Services.

In addition to the review of the MASE by three licensed psychiatrists specifically trained for prescribing buprenorphine, the MASE was also given to three former patients who had completed treatment for opioid addiction and had been prescribed Suboxone (the brand name for buprenorphine) as part of that treatment. Both the psychiatrists and the patients were asked to reword the MASE items so that they were relevant for Suboxone. They were also asked to provide feedback on the face validity of the items.

The three psychiatrists and three former opioid addiction patients suggested the following changes to the MASE so that the instrument could be used to assess self-

efficacy for maintaining adherence to Suboxone treatment. First, the initial prompt ("How confident are you that you can take your blood pressure medications") was changed to "How confident are you that you can take your buprenorphine as prescribed?" Second, item 21 ("If they make you want to urinate while away from home") was deleted. Both the psychiatrists and patients believed that excessive urination is not a side effect buprenorphine. Third, item 25 ("Always remember to take your blood pressure mediations") was changed to "Always remember to take your buprenorphine." No additional changes to MASE items were suggested. Because the changes suggested by these psychiatrists and former patients were not significant enough to distinctly change the instrument, the research team was in agreement that no pilot testing of the new SEMA-B was needed.

Procedures

Protection of Human Subjects and Informed Consent

The researcher obtained institutional review board approval for human subjects protection from both Marquette University and the Inpatient/Outpatient Treatment Facility where patient recruitment took place. The consent forms with all the institutional signatures were kept with the researcher at all times in preparation for institutional review of the study.

Participation in this study was voluntary. All participants were provided the opportunity to refuse participation without concern for prejudicial treatment from the treatment facility. The participants also had the right to terminate participation at any time, refuse to provide information, and ask for clarification about the study. The

information regarding the study was read to all participants. Written information on how to contact the investigator during the study was also provided.

Data Collection

A facility researcher who was specifically trained in conducting research collected all data for the study. The researcher interviewed each participant and also reviewed the participant's medical file to gather information that was not provided during the interview or that the participant was unsure about. The study data were then de-identified before being provided to the present writer for analysis.

Those willing to participate in this study were screened according to the inclusion criteria. The participants were then provided a brief explanation from the administrative assistant using the following script: "We are conducting a research study on a tool to help people remember to take their Suboxone medications. It will take you about 15 minutes to complete this tool. Would you be interested in participating? [If "Yes,"] I will let the researcher know that you have agreed and she will be out to see you shortly."

No participant took longer than 20 minutes to complete the demographic questionnaire and the SEMA-B, with some finishing in as few as 8 minutes. Most participants completed the forms during the first week of their treatment in the facility. Temporal (test-retest) data were also collected for 30 of the participants. This occurred 2 to 4 days after the first administration of the instrument.

CHAPTER FOUR

RESULTS

Results will be reported first for the self-reported responses to the questionnaire items regarding the participants' treatment history. This will be followed by the results of the internal consistency, temporal stability, and factorial validity analyses of the SEMA-B.

Participants' Treatment History

Seventeen participants (14%) had not participated in any form of substance abuse treatment in the previous 5 years. Forty-two participants (34.7%) had a positive drug screen for an opiate other than buprenorphine during the current treatment episode, indicating that they were abusing opiates and relapsed while receiving treatment. The average number of treatment appointments attended during the duration of the present treatment was 13.12 ($SD = 12.8$). Treatment appointments attended included all medication appointments as well as individual and group counseling sessions. Twenty of the thirty patients who completed the temporal stability data took the first SEMA-B in the first week of treatment. It was not possible to establish exactly how many of those patients completed the first SEMA-B prior to their first doctor's appointment. A conservative estimate of 4 was provided. Fifty-six (46.3%) of the patients had a change in buprenorphine dosage in the past 6 months, raising the possibility that the test-retest data may show changes in self-efficacy if the data were collected at or around a change in medication dosage.

Reliability

### Item Analysis and Internal Consistency

Reliability was assessed using both internal consistency and temporal reliability

analyses. Table 4.1 includes the mean self-efficacy scores, standard deviations, item-total

correlations, and the Cronbach alpha coefficient if the item is deleted. Mean self-efficacy

scores for the individual items were generally high, ranging from 1.84 to 2.86 and with

only 1 item below 2.0 on the 1-to-3 scale. The Cronbach alpha for all 25 items was .88.

The item-to-total correlation coefficients for the individual items ranged from .21 to .64.

Nine items (1, 2, 4, 8, 9, 10, 15, 21, 23 and 24) had item-total correlations less than the a

priori cut-off of .40, however. Therefore, the remaining 16 items were retained for the

final version of the new SEMA-B instrument. The Cronbach alpha coefficient for this 16-

item version of the instrument was .87. The mean total scores on the SEMA-B were

relatively high and were negatively skewed (see Figure 4.1), suggesting that the patients

generally reported high levels of self-efficacy for maintaining adherence to the

buprenorphine medication regimen.

Table 4.1

Mean self-efficacy scores and standard deviation, item-total correlations, and Cronbach

alpha if item deleted (CITC) (*n* = 121)

Item	Mean	SD	CITC
1. When you are busy at home	2.83	.40	.38
2. When you are at work	2.48	.73	.29
3. When there is no one to remind you	2.86	.37	.42
4. When you worry about taking them for the rest of your life	2.32	.67	.37
5. When they cause some side effects	2.48	.56	.54
6. When they cost a lot of money	2.06	.75	.44
7. When you come home late from work	2.60	.64	.44
8. When you do not have any symptoms	2.42	.70	.58
9. When you are with family members	2.67	.60	.39
10. When you are in a public place	2.59	.62	.36
11. When you are afraid of becoming dependent on them	2.26	.67	.55
12. When you are afraid they may affect your sexual performance	2.22	.76	.57
13. When the time to take them in between meals	2.80	.51	.49
14. When you feel you do not need them	2.34	.69	.46
15. When you are traveling	2.76	.45	.31
16. When you take them more than once a day	2.73	.52	.50
17. If they sometimes make you tired	2.55	.61	.58
18. If they always make you tired	2.26	.73	.64
19. When you have other medications to take	2.74	.56	.45
20. When you feel well.	2.68	.58	.44
21. Get refills for your medications before you run out	2.60	.60	.21
22. Make taking your medications part of your routine	2.84	.37	.55
23. Fill your prescriptions whatever they cost	2.25	.75	.33
24. Always remember to take your Suboxone medications	2.81	.43	.39
25. Take your Suboxone medication for the rest of your life	1.84	.83	.56

Figure 4.1
Histogram of SEMA-B Total Mean Scores
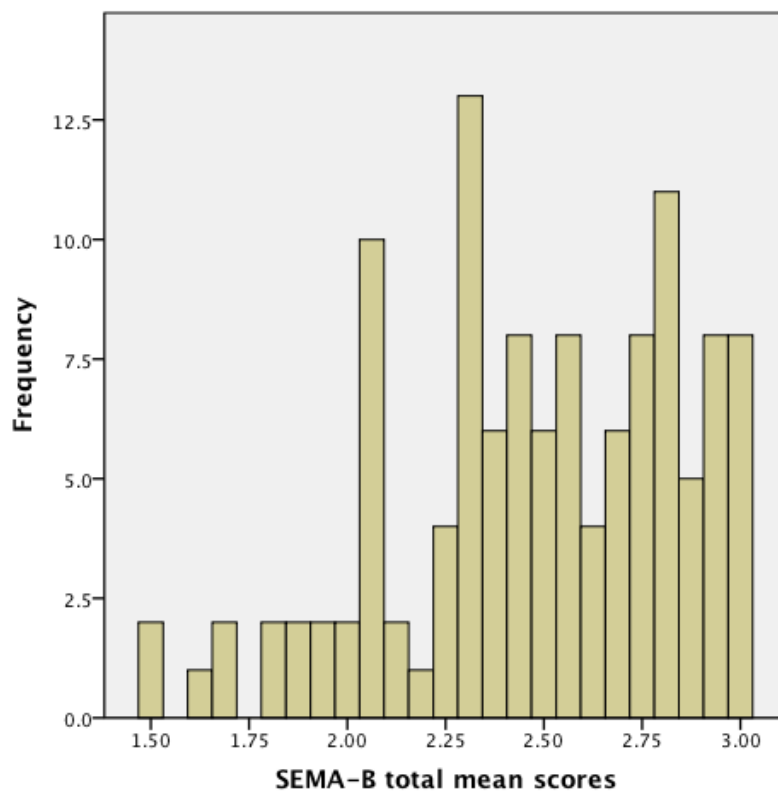
Temporal Stability

The temporal stability of the SEMA-B scores was also evaluated by having

patients retake the SEMA-B two to four days after the initial data collection. This interval

was chosen as it maximized the potential that the patents would complete the retest prior

to their second appointment. The two-to-four day interval allowed the researcher a

chance to interact with the patients at a treatment group session and request follow-up

data. The mean score for the pretest was 2.48 (SD = 3.67) and the mean score on the

posttest was 2.40 (SD = 3.67). The test-rest correlation coefficient for the 30 patients who

participated in this part of the study was $r(30)$= .77, p = .001. The Pearson correlations

for individual items ranged from .02 to .80 with 10 of the items showing significance at the .001 level. The results of the temporal stability analysis are in Table 2.

The test-retest coefficients for three of the SEMA-B items (i.e., 16, 19, and 22) are particularly low (i.e., < .30). There are two possible explanations for the very low temporal reliability of these items. First, there is a great deal of cognitive and emotional instability that occurs with patients in the first week of opiate recovery. The majority of the participants in this study completed the SEMA test and retest administrations during the first week of treatment, and it is likely that some of the variable responses to these three items in particular might vary based on their very recent entry into treatment. Second, many of the participants completed the SEMA and demographic form before starting their buprenorphine regimen but completed the retest after their first appointment with the psychiatrist and after they started taking their buprenorphine medication. This too may have affected their responses to these three items in particular because they all deal with the routine of taking the medicines on a daily basis. An examination of the mean scores for these three items found that all three had risen at statistically significant levels ($p <. 001$) at retest.

Table 4.2

Temporal stability Pearson correlations for the SEMA-B

Item	Pearson
3	.79*
5	.57*
6	.60*
7	.71*
8	.35
11	.71*
12	.57*
13	.30
14	.76*
16	.20
17	.35
18	.62*
19	.02
20	.50*
22	.17
25	.65*

* denotes significance at the .001 level

Factorial Validity

An exploratory principal components analysis with Varimax rotation was

performed on the scores from the SEMA-B. This analysis revealed a four-factor solution

based on Eigen values of $\geq$ 1.0. These four factors accounted for 67.25% of the total

variance. All items loaded on at least one factor at the .40 level. The process followed for

naming the factors emphasized the items within each factor that had the highest factor

loading (see DeVellis, 2003; Child, 2006)). Those factors were named *Management of*

Fear, Adherence to Regimen, Fitting into Daily Schedule, and *Maintaining Adherence*

when Symptom Free.

Eight items (5, 6, 11, 12, 14, 18, 22, and 25) loaded on factor 1, with all eight of

those loadings being the strongest loading on any factor. Six of the items on this factor,

including six of the top 7 strongest loading items, are in some way related to fear, and

this factor was subsequently labeled *Management of Fear*. The fears that these items refer

to are related to either the medication itself and/or its possible negative side effects.

Specifically, these five items address: fear of dependence on the medication, fear of

impact on sexual performance, fear of taking the medication for the rest of one's life, fear

of fatigue, fear of any possible side effects, and fear of not being able to afford the

medication.

Three items (16, 17, and 19) loaded on factor two. Two of these items, including

the strongest loading in the factor, concerned dosage and dosing schedule, and so this

factor was labeled *Adherence to Regimen*. Two items (7, 13) loaded on factor 3. These

items address how other aspects of life (work, eating schedules) may impact the

medication adherence, and so this factor was labeled *Fitting into Daily Schedule*. Three

items (3, 8, 20) loaded on factor 4. Two of those items focus on the necessity of taking

the medication when the patient is not experiencing symptoms, and so this factor was

labeled *Maintaining Adherence when Symptom Free*. These results suggest that the

SEMA-B has an underlying structure that includes multiple facets of self-efficacy.

Table 4.3

Factor loadings

Item		Factor		
	1	2	3	4
3	.04	.06	.42	.61
5	.55	.21	.11.	.25
6	.61	-.02	.44	-.33
7	.05	.36	.64	.05
8	.37	.14	.37	.54
11	.79	.04	.01	.18
12	.67	.13	.20	.17
13	.15	.20	.76	.21
14	.56	.08	-.08	.05
16	.08	.67	.43	.08
18	.59	.58	.03	.08
19	.01	.82	.18	.13
20	.26	.12	.03	.72
22	.52	-.04	.39	.24
25	.63	.24	.03	.17

Relationship of SEMA-B Scores to Demographic and Treatment History Variables

The literature review in Chapter Two suggested that some demographic and treatment history variables may have significant relationships with self-efficacy for medication adherence for opioid addiction treatment. Only one of these variables (gender) was found to have a statistically significant effect on the SEMA-B scores in the present study, however. An independent samples t-test found that men obtained statistically significantly lower SEMA-B scores ($M = 2.43$, $SD = .39$) than the women in the study sample ($M = 2.56$, $SD = .31$), $t(119)= -1.96$, $p = .05$. This suggests that men in the study sample showed a significantly slightly lower level of self-efficacy (at $p = .05$) for maintaining adherence to Suboxone treatment compared to the women in the sample.

Table 4.4

SEMA-B Mean (Standard Deviation) by Demographic and Treatment Variable Groups

Demographic or Treatment Variable	N	Yes	No
Gender*	76/45	2.43 (.39)	2.56 (.31)
Employment	80/41	2.44 (.39)	2.56 (.31)
Past Treatment	104/17	2.48 (.36)	2.42 (.40)
Positive Urine Screen	42/79	2.41 (.32)	2.51 (.39)
Medication Changes	56/65	2.52 (.35)	2.45 (.38)

* The male group is in the "yes" column and the female group is in the "no" column.

Table 4.5

SEMA-B by Marital Status

Marital Status	N	Mean (SD)
Married	27	2.52 (.37)
Separated	71	2.45 (.37)
Divorced	15	2.58 (.38)
Single	8	2.45 (.28)
Total	121	2.48 (.37)

Table 4.6

SEMA-B by Education Level

Education Level	N	Mean (SD)
Less than high school graduate	14	2.47 (.40)
High school graduate	43	2.46 (.42)
Some college	42	2.45 (.32)
College graduate	15	2.55 (.37)
Post college schooling	5	2.54 (.27)
Unknown	2	2.72 (.22)
Total	121	2.48 (.37)

CHAPTER 5

DISCUSSION

Overview

The purpose of this study was to develop and evaluate the psychometric

properties of the Self-Efficacy for Medication Adherence - Buprenorphine (SEMA-B)

scale. The SEMA-B items were repeated verbatim or adapted from the items in the

Medication Adherence Self-Efficacy (MASE) scale. The MASE items were evaluated by

three psychiatrists and three former opiate addiction patients, all of whom had experience

with prescribing or taking buprenorphine. All six individuals provided feedback on the

face validity of the items. One MASE item concerned the side effect of urination related

to taking hypertensive medication and was consequently deleted as it is not a side effect

of buprenorphine medication. All the other changes to the MASE items involved

adapting the language so it refers to opiate medication instead of hypertensive

medication.

The study data were collected from 121 patients at a large inpatient/outpatient

substance abuse treatment center in a medium-sized city in the Midwest. Participants

completed the SEMA-B and a demographic form. Thirty participants completed the

instrument a second time between 2 and 4 days after the initial administration of the

questionnaire. A researcher employed by the treatment facility collected the data and a

de-identified dataset was provided to the present writer for analysis.

The reliability of the SEMA-B was assessed using internal consistency and

temporal reliability analyses. The Cronbach alpha coefficient for all 25 items was .88.

Mean self-efficacy scores for the individual items ranged from 1.84 to 2.86 and standard

deviations ranged from .37 to .83, and the item-to-total correlation coefficients for all 25 items ranged from .21 to .64. Sixteen items had item-to-total correlation coefficients greater than the cutoff value of .40. These 16 items were then retained for the new instrument, the SEMA-B. The Cronbach alpha coefficient for the 16 items in the SEMA-B was .87, suggesting a reasonably strong level of consistency across the items for assessing self-efficacy for buprenorphine medication adherence. While the internal consistency analysis did suggest the items consistently measure the same construct, it did not have the power to evaluate unidimensionality of the SEMA-B. As a result, a factor analysis of the items was also subsequently conducted.

An exploratory principal components analysis with Varimax rotation performed on the SEMA-B revealed a four factor solution with Eigen values of ≥ 1.0. The four factors accounted for 67.25% of the total variance. The results indicate that the SEMA-B has an underlying structure with multiple dimensions of self-efficacy. This result highlights a difference when compared to the original SEMA for hypertension scale, which suggested a unidimensional scale. The SEMA-B factors were named *Management of Fear, Adherence to Regimen, Fitting into Daily Schedule*, and *Maintaining Adherence when Symptom Free.*

The SEMA-B items were also evaluated for temporal reliability. The mean score on the initial administration of the instrument was 2.48 with a standard deviation 3.67. The mean score of the retest was 2.40 with a standard deviation of 3.67. The test-rest correlation coefficient for 30 participants was $r\,(30) = .77, p = .001$, suggesting that SEMA-B scores are reasonably consistent over time.

The review of literature suggested there would be significant differences observed in the demographic and treatment variables. The data in this study did not show the differences found in other research. Only one demographic variable, gender, showed a statistically significant relationship with the mean scores on the SEMA-B $t(119) = -1.96$, $p = .05$. This result suggests that men in the study showed a slightly lower level of self-efficacy for maintaining buprenorphine adherence (at $p = .05$) when compared to women on the SEMA-B. It is very possible that the lack of variance in scores obtained in this study contributed to the lack of relationships found between the SEMA-B scores and the demographic and treatment variables.

These analyses suggest the SEMA-B is similar to the MASE, the model instrument for the SEMA-B. Cronbach alpha for the MASE was .95 compared to .87 for the SEMA-B. A factor analysis of the MASE found a five-factor solution that accounted for 93% of the total variance, and most of the items loaded on the first factor of the MASE. This led the creators of the MASE to infer that the scale was unidimensional. It should be noted that the MASE factor analysis contained an unrotated solution. The factor analysis of the SEMA-B used a varimax rotation that found a four-factor solution that accounted for 67.25% of the total variance. The four factors that emerged were each interpretable based on the content of the individual items. Therefore, unlike the MASE, these initial data suggest the SEMA-B measures a multidimensional construct.

The different factor structures of the MASE and the SEMA-B are inconsistent with the theoretical conceptualization of self-efficacy as presented by Bandura (Bandura, 1977, 1982, 1989). Bandura suggested that self-efficacy is specific to particular behaviors, and that self-efficacy in one domain can be distinctly different than self-

efficacy in other domains, even when those domains are relatively similar. This appears to be the case when comparing the factor structures of the MASE and SEMA-B. It is possible that self-efficacy for maintaining adherence to hypertension medication is unidimensional while self-efficacy for maintaining buprenorphine adherence is more complicated and multidimensional. Future research will be useful for verifying the differences found thus far.

Limitations

An important limitation of the present study is its small sample size. A minimum of 10 participants per item is suggested for the internal consistency and factor analyses conducted in this study (Child, 2006). That guideline would suggest a sample of 250 participates for the present study, much more than the 121 who participated. Recruitment of additional participants proved to be too difficult given the constraints present in the treatment program, however, and data collection was consequently discontinued. The sample of 121 participants was sufficient for providing reasonably reliable estimates of reliability and factorial validity for purposes of an initial evaluation of a fairly uncomplicated instrument, though the sample size was certainly not ideal. A larger sample likely would have led to greater variation in scores and a larger number of statistically significant relationships with patients' treatment history and demographic variables.

Possibly the most significant limitation of this study is the negatively skewed distribution of the scores. The limited heterogeneity in scores likely resulted in diminished reliability estimates and associations with the demographic and treatment

history variables. This likely impacted the variance accounted in the factor analysis as well.

The review of the literature in Chapter Two suggested that there may have been additional personal and psychiatric history variables (e.g., co-occurring disorders) that may have been related to self-efficacy for maintaining buprenorphine treatment. These variables would have been included if not for limitations imposed by the treatment center's institutional review board, which was not willing to provide the present researcher access to the medical record. In addition, the treatment center researcher who collected all of the study data also had limited time to devote to the present study. It would have been particularly helpful if treatment outcome data (e.g., relapse, treatment continuation, work and social functioning) could have been collected to further evaluate the role of self-efficacy at the beginning of treatment in the eventual effectiveness of treatment.

Clinical Implications

The SEMA-B is a very easy instrument to administer, yet it can provide medical providers with important information about a variable widely viewed as important to treatment outcomes. The self-report format makes it easy to complete while the patient is waiting for his or her appointment. The scoring is straightforward and can easily be self-scored if desired. The SEMA-B can be included in the initial assessment battery to help identify opiate addiction treatment patients who may have low self-efficacy for adhering to a medication regimen for buprenorphine.

Reilly et al. (1995) studied changes in self-efficacy levels during the taper process for those taking maintenance medication for opioid addiction. The current study focused

on self-efficacy levels during the first stages of treatment. No studies have examined the predictive value of self-efficacy at the beginning of treatment, however, and so clinicians will need to rely on their own experience to predict possible obstacles to treatment adherence based on a patient's reported self-efficacy. If a patient's self-efficacy is low, for example, clinicians can utilize established treatments such as motivational interviewing to enhance self-efficacy and address barriers to treatment adherence. Other interventions such as individual therapy, group therapy, partner support, employment, sponsorship within the recovering community, and the reinforcement of adherence behaviors can also be used to improve self-efficacy for treatment adherence. Clinicians can also readminister the SEMA-B multiple times to track self-efficacy changes over the course of treatment.

Having low self-efficacy for maintaining buprenorphine treatment is very relevant for engaging in this type of treatment. The item responses on the SEMA-B can identify possible obstacles to self-efficacy. The principal components analysis of the SEMA-B revealed four areas that may represent obstacles for adhering to the treatment regimen for buprenorphine: fear of side effects or characteristics of the medicine itself, maintaining the medication regimen, the timing of the doses, and maintaining the medication after one has been abstinent for a period and symptom free. A practitioner can review specific item responses to identify concerns that are impacting patient self-efficacy. Those with low self-efficacy in specific areas can receive appropriately tailored treatment plans (i.e., motivational interviewing) to maximize the likelihood of medication adherence.

Suggestions for Future Research

Future research on the SEMA-B should replicate the results observed in this study, particularly given the relatively small sample size that was available. It is recommended that other forms of validity be addressed, including predictive and concurrent validity. Bandura (1997) noted that other populations struggling with addiction (e.g., alcohol, nicotine) have used self-efficacy to predict treatment outcomes (Bandura, 1997). The predictive validity of the SEMA-B should be evaluated to replicate those findings in the population with opiate addiction. Concurrent validity using well-established abstinence self-efficacy measures could help differentiate the self-efficacy for medication adherence from general abstinence self-efficacy. Possible comparison assessments include, but are not limited to: the Drug Avoidance Self-Efficacy Scale (DASES) and the Alcohol Abstinence Self-Efficacy Scale (AASES). This will allow researchers to assess the need to tailor self-efficacy instruments to population and situation, as Bandura suggests.

This study utilized Classical Test Theory. Future research could utilize item response theory to further assess the underlying constructs of the instrument. An item response theory analysis might also include the full 25-item SEMA-B because some of the items in the full version may be significant in ways that were not detected in the present study.

Most of the data gathered in the present study were collected in the first week of treatment. Future research should evaluate whether there are differences in self-efficacy for medication adherence at later stages of treatment. Some research suggests that self-efficacy levels fluctuate during the opioid recovery treatment process (Reilly et al.,

1995). Collecting self-efficacy data across the various stages of treatment stages would allow an opportunity to examine these issues in detail. A more detailed examination of self-efficacy across the treatment process is particularly important in cases where clinicians are considering a tapering off of the Suboxone medication. Some patients appear to need Suboxone or an alternative pharmacological treatment over the very long term or relatively permanently, but other patients can be considered for a discontinuation of the medication. Self-efficacy for maintaining one's sobriety without taking the medication is a critically important clinical issue in these cases, but it appears not to have been examined in the research literature to date.

Finally, and perhaps most importantly, a change in the scoring of the SEMA-B may result in greater dispersion of scores. This will help with the major limitation of this study, the negatively skewed total mean scores. Future research could explore the potential benefit of including at least a four-point scale instead of the three-point scale in the current SEMA-B in order to increase variance in responses (e.g., with possible anchors of "not sure," "somewhat sure," "mostly sure," and "very sure").

Conclusions

The importance of self-efficacy has been researched across multiple domains of behavior, including in populations struggling with addiction. Medication adherence is seen as an important variable in treatment outcomes. Buprenorphine is a medication for opioid withdrawal and maintenance that is quite effective when used as prescribed. A patient's self-efficacy to adhere to buprenorphine as prescribed had not been measured or researched until this study. The study created a scale (SEMA-B) that shows acceptable

psychometrics and is worthy of further analysis. In the future, the SEMA-B can be used

to assess self-efficacy for buprenorphine medication adherence.

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Appendix A. Self-Efficacy for Medication Adherence Scale - Buprenorphine

Self-Efficacy for Medication Adherence Scale - Buprenorphine

Situations come up that make it difficult for people to take their medications as prescribed by their doctors. Below is a list of such situations. We want to know your opinion about taking your buprenorphine (Suboxone) under each of them. Please indicate your response by checking the box that most closely represents your opinion. There are no right or wrong answers. For each of the situations listed below, please rate how sure you are that you can take your buprenorphine medication ALL OF THE TIME.

Please respond to each situation with one of the following responses:
Not at all Sure, Somewhat Sure, Very Sure

Situations

1. When you are busy at home	Not at all Sure	Somewhat Sure	Very Sure
2. When you are at work	Not at all Sure	Somewhat Sure	Very Sure
3. When there is no one to remind you	Not at all Sure	Somewhat Sure	Very Sure
4. When you worry about taking them for the rest of your life	Not at all Sure	Somewhat Sure	Very Sure
5. When they cause some side effects	Not at all Sure	Somewhat Sure	Very Sure
6. When they cost a lot of money	Not at all Sure	Somewhat Sure	Very Sure
7. When you come home late from work	Not at all Sure	Somewhat Sure	Very Sure
8. When you do not have any symptoms	Not at all Sure	Somewhat Sure	Very Sure
9. When you are with family members	Not at all Sure	Somewhat Sure	Very Sure
10. When you are in a public place	Not at all Sure	Somewhat Sure	Very Sure
11. When you are afraid of becoming dependent on them	Not at all Sure	Somewhat Sure	Very Sure
12. When you are afraid they may affect your sexual performance	Not at all Sure	Somewhat Sure	Very Sure
13. When the time to take them is between your meals	Not at all Sure	Somewhat Sure	Very Sure
14. When you feel you do not need them	Not at all Sure	Somewhat Sure	Very Sure
15. When you are traveling	Not at all Sure	Somewhat Sure	Very Sure
16. When you take them more than once a day	Not at all Sure	Somewhat Sure	Very Sure
17. If they sometimes make you tired	Not at all Sure	Somewhat Sure	Very Sure
18. If they always make you tired	Not at all Sure	Somewhat Sure	Very Sure
19. When you have other medications to take	Not at all Sure	Somewhat Sure	Very Sure
20. When you feel well	Not at all Sure	Somewhat Sure	Very Sure

**Please rate how sure you are that you can carry out the following tasks
ALL OF THE TIME:**

21. Get refills for your medications before you run out	Not at all Sure	Somewhat Sure	Very Sure
22. Make taking your medications part of your routine	Not at all Sure	Somewhat Sure	Very Sure
23. Fill your prescriptions whatever they cost	Not at all Sure	Somewhat Sure	Very Sure
24. Always remember to take your Suboxone medications	Not at all Sure	Somewhat Sure	Very Sure
25. Take your Suboxone medication for the rest of your life.	Not at all Sure	Somewhat Sure	Very Sure

Appendix B. Data Collection Tool

Data Collection Tool

SEMA-B Study

Gender: M   F

Age: _____

Marital Status: M S D Sep

Education Level: _____

Employment Status: employed   not

Past substance abuse treatment history (last 5 years)

_____

_____

Urine Drug Screen: (Results since starting Suboxone)

_____

Number of Substance Abuse Treatment Appointments Attended (last 6 months)

_____

Medication Changes (Suboxone dose changes the last 6 months)

_____