BUPRENORPHINE AND NALOXONE (SUBOXONE) EFFICACY COMPARED WITH METHADONE AND CHALLENGES IN TREATING OPIATE ADDICTION

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Todd M. Carpenter

WASHINGTON STATE UNIVERSITY

College of Nursing

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Washington State University Spokane
Riverpoint Campus Library
P.O. Box 1495
Spokane, WA 99210-1495
To the Faculty of Washington State University:

The members of the Committee appointed to examine the master's project of TODD MICHAEL CARPENTER find it satisfactory and recommend that it be accepted.

Chair
Lorna Schwann

Mel Heideman

Allen Fairless
Buprenorphine and Naloxone (Suboxone) Efficacy Compared with Methadone and Challenges in Treating Opiate Addiction

Abstract

By Todd M. Carpenter, RN, BSN
Washington State University
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Chair: Lorna Schumann

Submitting to: American Journal on Addictions

Purpose: To identify the efficacy and barriers that patients face concerning treatment of opiate addiction with buprenorphine and naloxone (Suboxone) through an examination of current peer-reviewed literature comparing buprenorphine and naloxone to that of methadone and the barriers to treatment.

Conclusions: Access to treatment, social stigma, and overall treatment costs are primary barriers to persons with opiate addictions seeking treatment. Buprenorphine and naloxone treatment offers equal efficacy to the standard treatment of methadone, with pharmacologic advantages, lower cost with office-based treatment, and increased access to those seeking addiction management without the need to attend a methadone clinic and avoid the stigma associated with opioid addiction.

Implications for Practice: More research is required to examine long-term outcomes with buprenorphine and naloxone managed addiction treatment. Currently, this treatment is only
available through qualified physicians, hindering access to care. Allowing nurse practitioners to have prescriptive authority would increase access to treatment for addicts in an office-based setting.
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Introduction

Opioid drug abuse has reached epidemic proportions in society. The Diagnostic and Statistical Manual for Mental Disorders, Fourth Edition, Text Revision (DSM-IV-TR, 2000) defines opioid abuse as a maladaptive pattern of opioid use leading to clinically significant impairment or distress occurring within a 12-month period. The criteria include: interference with role fulfillment and failure to meet obligations at home, work, or school; posing a danger to one-self by repeatedly using opioids in hazardous situations, such as driving a vehicle; recurrent legal problems related to opioid use, such as crimes related to the obtaining and illegal possession of narcotics; and/or social problems stemming from continued use of opioids causing continued interpersonal and relationship problems.

Individuals who meet the criteria of opioid abuse and continue to use, may eventually become addicted to opiates. Addiction is defined by the DSM-IV-TR as having significant impairment or distress as manifested by at least three criteria and occurring in a 12-month period. The criteria are: the need for increasing doses of the opioid to achieve the initial or desired effect of the drug; the emergence of withdrawal symptoms upon opioid abstinence; persistent desire to continue, or an inability to decrease, opioid use; significant time and effort spent obtaining opioids; giving up social, occupational, and recreational activities; and/or continued opioid use despite knowledge of having persistent physical and psychological problems related to its use.

The effects of drug abuse and addiction are far reaching and devastating to the individual user, their family, and the communities that they live in. The price of addiction is high, when taking into account the toll of increased crime, emotional stress of all involved, and increased
morbidity and mortality that come along with addiction. According to the 2009 National Survey on Drug Use and Health (NSDUH), sponsored by the Substance Abuse and Mental Health Services Administration (SAMHSA), there were an estimated 1.9 million Americans twelve years and older who were current (when the survey was presented) dependent users of pain medications. Whether that was hydromorphone, oxycontin, hydrocodone or other opiates is not specified, but this does demonstrate a significant problem in the United States. Of the 1.1 million users surveyed who reported that they felt they needed treatment for their drug use problem, only 371,000 reported that they made any effort to get treatment. The barriers to treatment were not reported from the survey; however, one of the largest barriers is limited access to treatment in a primary care setting (McCance-Katz, 2004). Users who are addicted to these drugs face physical and emotional trauma. Conditions such as Hepatitis B and C, Human Immunodeficiency Virus (HIV), sexually transmitted infections, physical and emotional abuse, and liver failure are some of the common issues that addicts face (SAMHSA, 2010; Schwartz et al, 2008; Malinoff, Barkin, & Wilson, 2005). Couple that with the risk of incarceration and isolation from their social network and you get a view of what life is like as a person addicted to opiates.

It is important to consider the toll that addiction takes on society. The most current report from the National Institute of Health (NIH) estimates the financial cost of untreated opiate addiction at 20 billion dollars per year (NIDA, 2005). Consider also the impact of increased crime, increased health care costs, and increased stress on the addict's family and community.

Management of addiction has traditionally been treated with the opioid analgesic methadone, as the drug of choice since its development in the 1960s. However methadone is
known to have a high risk of overdose. Since the 1990s, the most common cause of drug overdose is opioid analgesics, surpassing cocaine and heroin poisonings. When studied between 1999 and 2002, methadone contributed to 32% of the overall hospital admissions for overdose. The other types of opioid analgesic poisonings were 54% from semi-synthetic opioids like oxycodone and hydrocodone and 13% from other synthetic opioids, such as fentanyl (Paulozzi, Budnitz, & Xi, 2006). The purpose of this paper is to examine the drug combination of buprenorphine/naloxone and its efficacy in regard to opiate addiction treatment as an alternative to methadone. The paper further explores challenges to treating opiate addiction and viable solutions to help the addicted person.

**Literature Review**

**Method**

Data Sources: Cited sources published in English were obtained through the Cumulative Index to Nursing and Allied Health Literature (CINAHL), EBSCOhost Academic Search Premier, PubMed (a service of the U. S. National Library of Medicine and the National Institutes of health), Medline via EBSCOhost, and Up to Date (Uptodate.com). Search terms used were: Buprenorphine, Opiate addiction treatment, Methadone, Barriers to opiate addiction treatment, Suboxone, Naloxone, Office based opiate treatment, and Heroin addiction management. Eighty four articles were reviewed and 26 articles selected based on their pertinence to buprenorphine and naloxone efficacy and challenges when treating addiction as an alternative to methadone.
Theoretical Framework

The Health Belief Model (HBM) guided this paper. The model offers insight into factors that help people make positive or negative health care decisions. It identifies five basic premises for behavioral change: perceived severity of the problem, perceived susceptibility to the problem, perceived benefits of behavioral change or treatment, barriers and costs of treatment or prevention, and cues to action for behavioral change (Becker & Maiman, 1975). A meta-analysis by Harrison, Mullen, and Green (1992) evaluated the relationships between four HBM dimensions (Susceptibility, Severity, Benefits and Costs) and health behavior from 16 studies that measured behavioral-related dependent variables. They concluded that the principle dimensions of the HBM had a significant influence on health behavior. In order for a person to make a health care decision, they must take these factors into consideration. Someone who is addicted to opiates must decide to seek treatment. Using the HBM to design treatment programs may maximize the effects of treatment in the areas of behavioral change and compliance.

Identifying a patient's perceived severity of their addiction will help facilitate communication and provide an opportunity to teach patients the consequences of continuing their current addiction behaviors. Many health factors (liver failure, renal failure, heart failure) need to be considered when dealing with the consequences of addiction. Also important to consider are the social consequences. Work, family, and relationships are addressed within the framework of the HBM. The provider must also evaluate the patient's perception of their susceptibility to addiction in order to judge if they see addiction as a treatable condition. When evaluating the HBM with regard to diabetes treatment compliance, Harvey and Lawson (2009) noted that acceptance of vulnerability alone to a disease was not enough of a force to lead to behavioral
change. They theorized that change would depend greater on the patient's beliefs in the effectiveness of the treatment and their ability to achieve the desired final outcome. Janz and Becker (1985) published a meta-analysis examining the HBM with regard to preventative action and behavior change. The study demonstrated that an increase in perceived susceptibility caused healthy behavioral change and preventative behaviors, but only if the subject felt that the perceived barriers were able to be overcome. With regard to addiction treatment, a greater focus should be placed on reducing perceived barriers to treatment to increase compliance and better outcomes. The HBM has been utilized to help understand preventative health measures in many different conditions requiring healthy behavior choices involving taking medications, utilization of the health care system, keeping clinical appointments, and ability to follow a prescribed treatment plan (Janz & Becker, 1984).

**Physiology and Pharmacology of Addiction and Buprenorphine**

The initial attraction to opioids is a short-term feeling of euphoria, sedation, pain relief, and an escape from life's stressors that stems from activating the reward center in the brain. Opiates bind at the mu (\(\mu\)), kappa (\(\kappa\)), sigma (\(\sigma\)), and delta (\(\delta\)) receptors that couple with G proteins. These receptors are known to have an analgesic effect on nerve transmission with regard to pain perception. The human body releases its own endogenous opioids during times of pain and stress, both emotional and physical. Activation of the \(\mu\)-opiate receptor has been shown to illicit a reduction in pain sensitivity and produce a sense of euphoria that can lead to dependence. The \(\kappa\)-opiate receptor (KOR) has also been shown to play a major role in substance dependence. Chronic opiate use triggers down-regulation of dopamine activity through the release of dynorphin, which is an opiate peptide that binds to the KOR. This blocks the release
and increases the re-uptake of dopamine in the synapse seen in the prefrontal cortex causing the symptoms of dysphoria and in the substantia nigra causing hypokinesis. This process has not been demonstrated with periodic use of opiates, but has been shown to occur with chronic use. Tolerance increases as it takes more and more of an opiate to stimulate the euphoria. The opiate activates KOR dopamine down-regulation resulting in symptoms of withdrawal such as body tremors, agitation and anxiety. Studies have shown that the KOR dynorphin release stays upregulated for several days after abstinence from drugs in a chronically dependant individual (Mysels & Sullivan, 2009). Prolonged use of opiates is also believed to induce receptor desensitization and sequestration of the receptor site leading to internalization into intracellular compartments. This leads to a net-loss of opiate receptor binding sites leading to the body needing higher and higher doses to induce dopamine release. Long-term use of opiates is also associated with increased adenyl cyclase activity which has been shown to inhibit the physiologic effects that users of opiates are after (Boothby & Doering, 2007).

Buprenorphine’s high affinity for opiate receptors and its antagonistic behavior on the KOR, breaks the cycle of increased adenyl cyclase activity and reduces symptoms of withdrawal (Boothby & Doering, 2007). Suboxone contains both buprenorphine and naloxone in a 4:1 ratio in sublingual form. Buprenorphine is a partial \( \mu \)-opiate receptor agonist and \( \kappa \)-receptor antagonist with duration of action from 3 to 44 hours to terminal half-life. As a \( \kappa \)-receptor antagonist, buprenorphine decreases many of the negative side effects that are associated with chronic opiate use (Robinson, 2006). The \( \kappa \)-receptor shares some side effects with the \( \mu \)-receptor such as anxiety, mood lability, depersonalization, decreased reality orientation, analgesia, sedation, respiratory depression, and pupil constriction (Mysels & Sullivan, 2009).
Using opiates chronically causes activation of both receptors doubling the effect seen in the individual, leading to a flood of dopamine in the synapse. Kappa receptor upregulation is the response to the chronic dopamine flood. When chronic users are removed from their drug supply, there is unopposed $\kappa$-receptor agonism leading to severe dysphoria and lethargy. The addition of a $\kappa$-receptor antagonist may alleviate some of these symptoms allowing for an easier and less severe detoxification. Buprenorphine has an extremely high affinity for antagonistic behavior at the kappa receptor site. Utilizing buprenorphine's partial agonist activity on the $\mu$-receptor and antagonistic behavior on the $\kappa$-receptor allows clinically addicted people to return to a more normalized state of dopamine regulation. This gives buprenorphine the potential to prevent them from getting high, while reducing the negative effects of withdrawal (Elkader & Sproule, 2005; Woods, & Hilaire, 2010).

The $\kappa$-receptor antagonist activity and partial $\mu$-receptor activity distinguishes buprenorphine from the standard treatment of methadone for opiate addiction. Both methadone and buprenorphine have similar physiologic effects of sedation, euphoria, analgesia and respiratory depression, but the partial agonist activity that buprenorphine has, gives it less side effects of respiratory depression, mood depression, pupil constriction, etc. The partial agonist activity also gives buprenorphine a ceiling, where the effects of the medication do not increase regardless of dosage. The partial agonist activity also lends itself to lesser withdrawal symptoms, when tapering off when compared to other opioids. Buprenorphine's high affinity for opioid receptor binding, and long half life, help the user to not feel the rush they want when using opiates, due to buprenorphine not coming off the receptor sites (Elkader & Sproule, 2005; Woods, & Hilaire, 2010).
The naloxone component of Suboxone is included in the medication to deter diversion of the drug and intravenous route administration. With the high affinity of buprenorphine to the opioid receptors, the amount of naloxone in the sublingual tablet does not interfere with the intended physiological effects of buprenorphine. Naloxone undergoes extensive first pass metabolism so the amount actually active, when given sublingually, is insignificant for opiate receptor antagonism (Woods, & Hilaire, 2010). Naloxone also has a lesser half-life at 1-2 hours compared to the 20-40 hours half-life of buprenorphine, so the chances of naloxone exhibiting its antagonistic effects on buprenorphine, when administered sublingually, are rare. However, it has been shown that Suboxone crushed and given parenterally to physically dependant opioid users caused withdrawal symptoms systemically. When given in this route the naloxone is absorbed immediately into the blood stream, has been shown to have 100% bioavailability and goes to work attaching to the opioid receptors facilitating immediate withdrawal symptoms. The buprenorphine/naloxone combination significantly reduces the risk of diversion (Malinoff, Barkin, & Wilson, 2005; Woods, & Hilaire, 2010).

**Efficacy of Suboxone for addiction treatment**

Fundala et al. (2003) studied office-based treatment of opiate addiction using a sublingual-tablet formulation of buprenorphine and naloxone. The researchers conducted a multicenter, randomized, double blind, placebo-controlled trial of 326 opiate addicted people. Subjects were randomized and given 16 mg buprenorphine and 4 mg naloxone in the combo drug of Suboxone sublingual tablets daily (n=110), buprenorphine alone at 16 mg (n=105), or the placebo (n=110) for a period of four weeks. Safety data was collected over a period of 48 weeks on 461 opiate-addicted individuals who participated in an open-label study of buprenorphine and
naloxone at daily doses up to 24 mg and 6 mg, respectively. Patients were selected based on meeting the Diagnostic and Statistical Manual (DSM-IV) criteria for opioid dependence. The patients were aged 18-59 with a mean age of 38. Patients were given their doses daily at the office with weekend doses given for the patient to take home and self administer. Patients also received up to one hour of individual counseling each week. To measure opiate abstinence, urine samples (to demonstrate opiate use and/or other abused drugs) were collected Monday's, Wednesday's, and Friday's. To measure cravings a visual analog score was recorded with a score of peak cravings over the last 24-hour period measured as 0 being "no craving", 50 being "no change", to 100 being "the worst craving I've ever had". The researchers also observed for retention in the treatment program, rates of adverse medical events, and overall feelings of improved health both subjectively viewed by the clinician and the patient. The researchers stated these were "measures of treatment efficacy."

The four-week study was terminated early due to the effectiveness of the treatment. The authors do not state how early the study was terminated, but state that the data and safety monitoring board and the Human Rights Committee of the Veterans Cooperative Studies Program Coordinating Center recommended the early termination based on the evidence demonstrating that buprenorphine and naloxone had a greater efficacy than placebo. The data showed significant improvement in opiate free urine samples in the buprenorphine/naloxone group (17.8% negative), versus the placebo (5.8%). The subjective craving score was also significantly lower for the buprenorphine/naloxone group than placebo, as well. Opiate Craving ratings went from 60-65 (on a 0-100 scale) on week zero down to 30 by week four for the Buprenorphine-naloxone group, slightly higher (1-3 points per the table) for the buprenorphine
alone group and remained at 60 for the placebo group. The study had an 82% retention rate with overall subjective views of increased health and wellness significantly better in the Suboxone group versus placebo. There was no significant difference in efficacy (see measures of treatment efficacy) between the buprenorphine alone group and the buprenorphine/naloxone group supporting the theory that naloxone does not interfere with buprenorphine effects, when taken sublingually. The percentage of negative urine samples during the open label phase went up significantly to 50-60% and closely resembles studies done on efficacy of methadone and levomethadyl acetate maintenance. With regard to treatment, there were no unexpected safety issues during the study and the adverse effects seen were those known to be associated with opiate addiction treatment. The study concluded that buprenorphine and naloxone in combination are safe and effective to treat opiate-addicted persons in an office-based setting (Fundala, et al., 2003).

A comparison study of levomethadyl acetate, buprenorphine, and methadone for opioid dependence was done over a 17-week time period with 220 randomized patients divided into groups of 55. Levomethadyl acetate, with the trade name Orlaam, is a synthetic opioid with a long duration of action, similar to methadone. One of the advantages of levomethadyl acetate, compared to methadone, is the dosing of only three times per week. The contraindication is anyone with potential risk for prolonged QT syndrome like patients with congestive heart failure, diuretic use, cardiac hypertrophy, or electrolyte imbalances for example. Ages of the participants ranged from 21 to 55 years (mean age 37). Levomethadyl acetate was dosed from 75 to 115 mg, buprenorphine from 16 to 32 mg, and high and low dose methadone was used, as well for treatment of opioid dependence. The high dose of methadone was between 60 and 100
mg, and the low dose was 20 mg. The buprenorphine and levomethadyl acetate were administered Monday, Wednesday, and Friday of each week, whereas the methadone was administered daily. Doses were increased if the patient had more than 83% attendance, with no Friday absences, and no more than 33% of opioid-positive urine tests. Their intent was to "achieve individually optimized doses and to avoid confounding comparisons between drugs by potential differences in the adequacy of the dose." Measures of efficacy were the percentage of positive urine tests, the patient's own reports of frequency of use, program retention, and patient ratings of the severity of their drug problem (Johnson, et al., 2000).

Fifty-one percent of the subjects completed the trial. High drop-out rates are not uncommon in addiction treatment. The retention numbers were 53% for the levomethadyl acetate group, 58% of the buprenorphine group, 73% of the high-dose methadone group, and 20% of the low-dose methadone group. Overall, the groups all reported a significant decrease in the amount of opioids they were using, but the low-dose methadone group had a far greater number of opiate positive urine screens, demonstrating worse efficacy, than the other three groups. The percentage of patients with at least 12 consecutive opioid-negative urine tests were 36-38% in the levomethadyl acetate group, high dose methadone, and buprenorphine group to a low of 8% on the low dose methadone group. Patients on the low dose methadone group also gave their drug problem the highest severity rating. Levomethadyl acetate severity rating was 35 on a 0-100 scale with 100 being most severe, buprenorphine was rated at 34, high dose methadone rated at 38, and low dose methadone rated at 53. Levomethadyl acetate had the lowest rate of retention, blamed for its slow period of induction for treatment of nine days. The study concluded that buprenorphine was just as efficacious (see measures of efficacy) as high
dose methadone and levomethadyl acetate. The study states that it would also add greater convenience to patients and clinic staff on every other day dosing. Treatment cost was not included in the study differential between medications (Johnson, et al., 2000).

An Australian study evaluated the efficacy of Suboxone relating to increasing quality of life, overall retention in the program, and a cost analysis looking at the difference between direct observation addiction treatment and unobserved administration of the treatment like that of an office-based program (Bell et al., 2007). Subjects (n=125) were over the age of 18, had a history of being opiate dependant for at least 12 months, and were seeking treatment for heroin addiction in four different out-patient centers with two centers located in Sydney, one in Newcastle, and one in Melbourne. Subjects were randomized as to the group of observed dosing or unobserved dosing that they were placed into. Subjects met weekly with a case-manager to have a structured interview and give a urine sample. All subjects were started on buprenorphine on day one and switched to Suboxone on day eight with the intention of minimizing drug diversion. The primary outcomes were measured by overall retention in treatment at 3 months, and heroin use as measured by urine drug screens and the Opiate Treatment Index (OTI), which is a validated questionnaire used to self-report drug use and monitor for improvement. The OTI also monitors risk behaviors, overall feelings of health and wellness, stress and anxiety, and relationship health. The costs associated with directly observed treatment, versus unobserved treatment were also measured. Costs were estimated for three months including hospital admissions, cost of medication, emergency visits, pathology testing, travel, medical treatment, and counseling (Bell et al., 2007).
The self-reported percentages of those in the study who reported no use of heroin three months after treatment were 61% of the unobserved and 45% of the observed dosed subjects. Urine results demonstrated 81% of those individuals self reporting no heroin use tested consistently negative for opioids. When urine was requested and the subject failed to produce a sample, the test was presumed positive, which brings the number of negative tests down to 61% of those in unobserved patients and 60% in observed patients. Retention in the program demonstrated 57% in unobserved dosing and 61% in observed dosing (not significantly different), showing that close observation was not a deterrent for treatment. The mean cost was significantly reduced (AU $475) for those patients that were on unobserved dosing compared to those under direct supervision. The largest cost for the directly supervised patients was overhead, at 41% of the total treatment cost. The largest cost for the unsupervised patients was the cost of buprenorphine-naloxone at 32.2% of the total treatment cost. Psychological evaluations demonstrated a significant improvement in both groups equally. Interviews done initially on all participants and at 3 months demonstrated significant improvement in their quality of life scores, equally for both groups (Bell et al., 2007).

The flaws in the study were the accuracy of self-reporting of drug use, the ability to generalize the study for outpatient settings, group size, and motivation to continue the study. Motivation was provided by the participants being told that they could have unsupervised treatment after the 3 month period, which would possibly influence overall retention. Only 131 out of 591 heroin users were recruited for the study based on some being couples, homeless, pregnant, lack of safe storage of the medication, and unstable psychiatric illness.
Buprenorphine was compared with methadone maintenance in ambulatory settings between February and April of 2001 (Giacomuzzi, 2003). Sixty-seven opioid dependent subjects enrolled in an open-label, non-randomized, two-site trial (38 subjects on methadone syrup and 29 subjects on sublingual buprenorphine), with 53 completing the study. Enrollment was based on DSM-IV criteria for opioid dependence (DSM-IV, p. 304). Efficacy was measured based on retention in the program, negative urine screening tests, negative side effects, and quality-of-life status measured using the Lancashire Quality-of-Life Profile (LQoLP), which is a structured interview with 105 questions aimed at gauging overall wellbeing. The LQoLP focuses on nine different domains to measure quality of life. Those domains are: work and education, overall quality of life, leisure time, religion, finances, living situation, legal and safety/security, family and social relations, and health. There are both subjective and objective items asked on the questionnaire with the subjective measures using a 7-point satisfaction scale ranging from "can't be worse" to "can't be better" (Lehman, et al., 1982).

Completion of the program was equal for both groups at 79%. A total of 530 random urine drug screens detecting opioids showed the buprenorphine group demonstrated significantly less consumption of opioids (P= 0.013), compared with the methadone group (73% vs. 39%). Overall quality-of-life scores were not significant except for one area of overall satisfaction in life, which the buprenorphine group scored higher (P= 0.046). The outcome measures for physical withdrawal symptoms demonstrated no significant difference between the two groups (P= 0.685). Side effects were similar between both groups with no significant difference, however after 24 weeks of treatment, the buprenorphine group demonstrated an overall decrease of stomach cramps, fatigue, tiredness, feelings of coldness, and feelings of their heart pounding.
The study concluded that buprenorphine is just as effective as methadone regarding withdrawal symptoms and effects on quality of life, but with fewer risks suggesting that pharmacologically it is a safer treatment and should result in lesser dependence than methadone (Giacomuzzi, 2003).

**Barriers to Treatment**

Given the estimated 1.1 million opioid dependent people in the United States, why is it that only an estimated 371,000 attempt to seek treatment in substance treatment programs? McCance-Katz (2004) relates this to the physiological changes that occur with addiction to opiates and the need to feed that addiction multiple times daily. Peoples’ lives become only about the addiction and not about living a "productive life." People focus more on finding the drugs and resources to obtain them and are oblivious to the price they are paying. This often results in deviant behavior, crime, and high-risk activities that could lead to an early death for some.

Schwartz et al. (2008) examined attitudes toward buprenorphine and methadone among opioid dependent individuals. They found that one of the biggest barriers for treatment of opioid addicted individuals is lack of treatment facilities and an inability to have addiction management in a primary care setting. They found in the out-patient setting that patients had a consistently more positive view of buprenorphine versus that of methadone as an aid to behavior change (p < .001). Travel distance then becomes another barrier, not to mention the stigma associated with being treated at a Methadone clinic. Methadone clinics also require patients to attend up to six days per week. Barriers to treatment can be discouraging considering travel time, cost of travel, the inability to hold a regular day job due to hours missed in treatment, and not wanting to be labeled as a drug user if anyone they know sees them going to a treatment center. Office-based
practice with buprenorphine provides a great opportunity to patients who would otherwise not be able to seek treatment based on the aforementioned barriers (McCance-Katz, 2004).

Primary care providers, nurse practitioners, psychiatrists, and specialty physicians have an important role to play when treating opioid addicted patients (McCance-Katz, 2004). People with opiate addictions have multiple medical issues other than their addiction. Many have depression, renal problems, liver problems, dental issues, and are pregnant. Addiction therefore, not only involves drug treatment in drug treatment centers, but drug treatment issues at the OB/GYN, the Gastroenterologist, the Psychiatrist, the Dentist, the Nephrologist, etc. McCance-Katz states that training in addiction for all fields of medical care is needed and would greatly enhance the care that these patients receive.

The Drug Abuse Treatment Act of 2000 (DATA) offered a solution of another treatment access point for opiate addiction. DATA allowed physicians to prescribe schedule III-V medications for addiction treatment in office-based practices. This was passed mainly due to FDA approval for buprenorphine and buprenorphine/naloxone for the treatment of opiate addiction and labeled buprenorphine as a schedule III drug. The main goal of DATA legislation was to mainstream opiate addiction treatment not only in primary care, but in mental health settings as well. In order for physicians (only physicians per DATA) to qualify to provide this type of care, they must have the ability to refer for psychosocial counseling, complete an eight-hour training course, if they are not currently certified in addiction management, and register with the secretary of the Department of Health and Human Services. This legislation does help with one hurdle of treatment access, but only time will tell if physicians feel comfortable enough to offer this service. Currently each physician is limited to taking 30 patients in treatment for the
first year and that physician may then submit a second notification of the need and intent to treat
up to a maximum of 100 patients (DATA, 2000).

**Discussion**

The evidence suggests that buprenorphine and naloxone are an effective, well tolerated
treatment for opiate addiction with efficacy comparable to the current standard treatment of
methadone. The 4:1 ratio of buprenorphine to naloxone has been shown to have similar efficacy
to methadone with reduced side effects, reduced withdrawal symptoms, and lower overall abuse
potential. Patient satisfaction appears equal to, if not greater than treatment with methadone with
an overall reduced cost to the patient versus inpatient treatment. Having office-based
administration of buprenorphine and naloxone demonstrates that this combo drug can be used
successfully in an outpatient setting at a reduced overall cost to the patients, which could allow
more to seek help. Having office-based treatment limited only to physicians however, limits the
amount that can be treated.

More research needs to be done on what barriers prevent addicts from seeking treatment.
Another question to ask is why physician assistants and nurse practitioners can prescribe
schedule III drugs for pain, but not for addiction management. Allowing independent
practitioners to prescribe Suboxone may increase access to treatment. Increasing office-based
treatment should be a priority and more research needs to be done on ways to improve access for
the opiate dependant population. Opiate abuse is happening in rural areas, as well, and by
increasing the amount of patients that can be helped by legislation allowing qualified care
providers and not just physicians, will break down one of the largest barriers for those seeking
treatment.
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