Medication-Assisted Drug Abuse Treatment: A Quantitative Analysis of Access to Suboxone Treatment for Low-Income Heroin and Opioid Abusers in the United States

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I have adhered to university policy regarding academic honesty in completing this assignment.

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Abstract

In 2007, the cost of illicit drug use in the United States was nearly $200 billion. This cost included criminal prosecution, lost productivity, and healthcare expenses (National Drug Intelligence Center [NDIC], 2011). Today, heroin and prescription opioid abusers, who make up 10% of illicit drug users in the United States, account for nearly 37% of those costs (Birnbaum, et al., 2011, NDIC, 2011; U.S. Department of Health and Human Services [HHS], 2013; American Society of Addiction Medicine [ASAM], 2016). Abstention from heroin and opioid abuse has been shown to fail in up to 90% of those individuals that attempt to fight their addictions through a detoxification program, even when counseling is provided (Hunt & Bespalec, 1974; Hubbard & Marsden, 1986; Fiellin, 2006). However, there are treatment options available that include medications that curb one's appetite for heroin and prescription drugs. Along with accompanying social services counseling, these options form a class of treatment known as medication-assisted treatment (MAT). MAT options have been shown to be effective at stopping heroin and opioid abuse. One MAT medication, Suboxone, was approved for use in 2002. Unlike methadone (the most commonly used MAT medication), Suboxone offers treatment flexibility for heroin and opioid abusers and it is less addictive. Additionally, Suboxone has less severe withdrawal side effects than methadone (Center for Substance Abuse Treatment [CSAT], 2005; Orman & Keating 2009; Polsky, et al., 2010; Canadian Agency for Drugs and Technologies in Health [CADTH], 2013; Sittambalam, Vij, & Ferguson, 2014; Volkow, 2014; Peddicord, Bush, & Cruze, 2015).

Popular literature suggests that there is a barrier to Suboxone treatment for low-income heroin and opioid abusers (Harmon, 2011; U.S. Attorney's Office, 2014; Cherkis, 2015; Healy, 2015; Sharon, 2015; Svrluga, 2015). While academic literature provides support that Suboxone is an effective treatment option for heroin and opioid abuse, there are not many studies dedicated to addressing the issue of access to the medication for low-income residents. This study assumed a post-positivist worldview to examine this issue through a quantitative content analysis framed by the social determinants of health. The study used IBM's SPSS software to perform multi-variable linear regression analysis tests to determine whether a barrier to access to Suboxone (dependent variable) is related to income status (independent variable) in the United States and whether there is a relationship between region, income status, and access to Suboxone treatment in the country as well. Data collected represents state-level indicators for the year 2014 for all 50

states and the District of Columbia. The data came from the databases of the Centers for Disease Control and Prevention, the Substance Abuse and Mental Health Services Administration, and the U.S. Census Bureau. Factors of race, ethnicity, age, gender, population size, and number of heroin-and-opioid-related overdose deaths were controlled for (Merriam, 2009; Szafran, 2012).

Findings from this study showed that income status does not have a statistically significant effect on access to Suboxone treatment at the region or state-level ($p = 0.050$). Instead, population (at the state level) and the number of heroin-and-opioid-related overdose deaths (at the regional and state levels) were identified as significant predictors of access to Suboxone treatment ($p = 0.050$). Further research into the role of heroin-and-opioid-related overdose deaths is suggested in order to determine the temporal sequence of the deaths and access to Suboxone treatment and to address any health disparities or health policy issues that might arise from the results of such an investigation. Research into the effectiveness of Suboxone treatment and the effectiveness of other methadone-alternative treatments (such as naltrexone) in addressing addiction for low-income heroin and opioid abusers is also suggested.

Keywords: access, addiction, heroin abuse, low-income, medication-assisted treatment (MAT), methadone, opioid abuse, social determinants of health (SDOH), Suboxone, treatment, United States

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Introduction

Illicit drug use is an ongoing epidemic within the United States. In 2007, at $194 billion, the cost of illicit drug use was higher than the costs associated with smoking, obesity, or diabetes (National Drug Intelligence Center [NDIC], 2011). Furthermore, ongoing illicit drug use can lead to other chronic and acute medical conditions in addition to lessening one's quality of life. Heroin and prescription opioid abuse (typically referred to as 'heroin and opioid abuse' in literature) is a subset of illicit drug use with substantial economic and personal costs. Only about 1 in 10 illicit drug users in the U.S. abuses heroin and/or opioids (American Society of Addiction Medicine [ASAM], 2016). However, with an estimated annual expense of $56 - $72 billion, heroin and opioid abuse account for up to 37% of illicit drug abuse costs in the nation (Birnbaum, et al., 2011, NDIC, 2011; U.S. Department of Health and Human Services [HHS], 2013). Furthermore, research shows that prescription drug users are more likely to abuse heroin during their lifetimes (Volkow, 2014). Research also shows that heroin abuse is linked to increased exposure to and incidences of kidney disease, liver disease, cardiovascular disease, hepatitis C, and HIV (National Institute on Drug Abuse [NIDA], 2012). These comorbidities place an increased burden on the health care system and result in more costs.

Detoxification from heroin and opioid abuse alone has been shown to be ineffective in reducing relapse rates among abusers (Hunt & Bespalec, 1974; Hubbard & Marsden, 1986; Fiellin, 2006). However, medication-assisted treatment (MAT) for such abuse has been shown to be effective. From the 1970s through 2002, methadone was the only approved medication option for MAT available to heroin and opioid abusers. Then, in 2002, the FDA approved another medication—Suboxone—for treatment of the addiction (Center for Substance Abuse Treatment [CSAT], 2005). Suboxone, as indicated by its DEA scheduling, has a lower potential

for abuse than methadone (CSAT, 2005; Volkow, 2014). In many cases, Suboxone has been shown to be as effective at treating heroin and opioid addiction as methadone in addition to being more cost-effective (Orman & Keating 2009; Polsky, et al., 2010; Canadian Agency for Drugs and Technologies in Health [CADTH], 2013; Sittambalam, Vij, & Ferguson, 2014; Peddicord, Bush, & Cruze, 2015).

Popular literature suggests that access to Suboxone is being compromised for low-income heroin and opioid abusers. In several states, physicians are forcing patients to pay solely out-of-pocket for monthly Suboxone appointments; and they are altogether refusing to see patients with Medicaid. Additionally, it has been hypothesized that a lack of access to Suboxone among low-income heroin and opioid abusers has increased the likelihood of diversion of the medicine (Harmon, 2011; U.S. Attorney's Office, 2014; Cherkis, 2015; Healy, 2015; Sharon, 2015; Svrluga, 2015). In 2003, U.S. police reported 90 seizures of Suboxone that was illegally obtained; by 2010, they reported 10,500 illegal Suboxone seizures (Partnership for Drug Free Kids, 2014). Since Suboxone produces diminished stimulation of opioid receptors, street use (especially intravenous use) of the drug could easily result in an overdose when patients do not feel an intense response following initial consumption. In some cases, individuals who previously took Suboxone as a recreational drug have formed addictions to heroin, which elicits a much more intense response in opioid receptors than does Suboxone (Yokell, Zaller, Green, & Rich, 2011; Partnership for Drug Free Kids, 2014). This risk of Suboxone diversion, therefore, also burdens the public health community.

Still, there is not enough academic research to support or refute claims that there is a lack of access to Suboxone treatment for low-income heroin and opioid abusers. Since heroin use typically affects individuals who make less than $20,000 per year (Jones, Logan, Gladden, &

Bohm, 2015), investigating these claims is important. Therefore, the researcher used a quantitative content analysis method to analyze data and determine if a barrier to access to Suboxone based on income level exists. The researcher used IBM's SPSS software to conduct a series of multi-variable linear regression analyses on data collected from the databases of the U.S. Census Bureau, the Centers for Disease Control and Prevention (CDC), and the Substance Abuse and Mental Health Services Administration (SAMHSA).

Statement of the Problem

Heroin and opioid abuse predominantly affects U.S. citizens between the ages of 18 – 25 and those making less than $20,000 a year (Back, Payne, Simpson, & Brady, 2010; HHS, 2013; Jones, Logan, Gladden, & Bohm, 2015; SAMHSA, 2015). Relapse rates following detoxification treatment range from 52 – 90% (Hunt & Bespalec, 1974; Hubbard & Marsden, 1986; Fiellin, 2006). There is a treatment protocol, known as medication-assisted treatment (MAT) to address heroin and opioid abuse. Diversion issues were widely observed due to the highly addictive nature of methadone, the first medication available for MAT in the United States. In 2002, a new medication for MAT—Suboxone—was approved for use in treating heroin-and-opioid addicted patients. Suboxone is less addictive than methadone and, therefore, produces less of a risk for diversion (CSAT, 2005; Volkow, 2014). However, media and government reports suggest the presence of a barrier to access to Suboxone treatment for low-income heroin and opioid abusers (Harmon, 2011; U.S. Attorney's Office, 2014; Cherkis, 2015; Healy, 2015; Sharon, 2015; Svrluga, 2015). This claim threatens the potential for Suboxone to have a positive impact on a group that could greatly benefit from it. Still, there is a lack of academic research that is explicitly focused on the relationship between income status and access to Suboxone treatment.

Purpose of the Study

The researcher's purpose in this study is to conduct a quantitative content analysis to determine if there is a relationship between income status and access to Suboxone treatment in the United States. Specifically, this study will attempt to answer two questions. The first question is: Controlling for age, race/ethnicity, gender, population size, and number of heroin and opioid overdoses, what is the relationship between income status and access to Suboxone treatment in the U.S.? The second question is: What effect does region have on the relationship between income status and access to Suboxone treatment in the U.S.?

Significance of the Study

If a relationship exists between being low-income and having less access to Suboxone treatment, then a call to action for public health officials to investigate the topic further would be needed. Furthermore, if income status is identified as a barrier to care, the presence of a health inequity in heroin and opioid abuse treatment might be imminent. Such an inequity would need to be addressed in order to avoid higher health care costs for treating low-income heroin and opioid abusers for comorbidities such as hepatitis, cardiovascular disease, and HIV (NIDA, 2012).

Theoretical Perspective

The social determinants of health will be used to address this research topic. This framework was first introduced by former U.S. Surgeon General David Satcher. The social determinants of health acknowledge the importance of social factors (such as income status) and structural factors (such as access to medical treatment) in the provision of care to disadvantaged populations. This framework suggests that there is an inherent link between one's social

upbringing and circumstances and the systematic policies put into place that affect that individual. Moreover, the framework purports that structural factors, such as laws, educational systems, and the availability of services, can influence social factors, such as income and health status, in one's life (Dean & Fenton, 2010; Satcher, 2010). As it pertains to this research study, having a structural barrier to access to Suboxone treatment might keep low-income heroin and opioid abusers impoverished and in poor health. The population might remain impoverished due to the lack of opportunity to try new medication-assisted treatments that allow them to be more coherent and less dependent on illicit drugs. If they lack coherency, they might not be able to obtain jobs that pay enough to keep them out of poverty, if they are able to obtain employment at all. A structural barrier in access to Suboxone could also prevent heroin and opioid abusers from achieving improved health statuses (a social factor) as they continue to abuse drugs. Furthermore, rising costs from comorbidities related to opioid and heroin abuse might further limit these individuals' abilities to gain financial independence to move past poverty into more desirable, affluent, and healthy circumstances.

Research Method

The researcher assumed a post-positivist worldview to conduct a quantitative analysis of secondary data sources. Information on income status, Suboxone physicians, age, race/ethnicity, gender, population size, and heroin and opioid overdoses was gathered from the U.S. Census Bureau, the Substance Abuse and Mental Health Services Administration (SAMHSA), and the CDC WONDER database. All data was collected at the state-level for the year 2014. A series of multi-variable linear regression analysis tests were performed using SPSS to answer the research questions for this study (Szafran, 2012). No sampling procedure was used for this study since all 50 states and the District of Columbia were included.

Assumptions and Limitations

This study assumes a post-positivist worldview to try to determine, quantitatively, if there is a barrier to access to Suboxone treatment for low-income heroin and opioid abusers when controlling for several factors. One major assumption for this study is that an access barrier to Suboxone treatment that is related to income status can be analyzed using state-level data. If the relationship is best-analyzed using a smaller unit of data, such as county-level data or city-level data, there might not be any statistically significant information to report at the state-level. Additionally, an assumption is made that all data sources used in this study will provide accurate data for all variables of interest in the year 2014. If data sets are inaccurate, any relationship between the independent and dependent variables in this study might be overstated or understated. Furthermore, an assumption is made that the relationship between income and access to Suboxone treatment is linear. If the relationship is not linear, no significant findings will be produced from this study (Szafran, 2012).

Another limitation of this study is that access to methadone treatment among low-income U.S. residents is not being considered. There is a possibility that access issues exist for both methadone treatment and Suboxone treatment within low-income populations. However, since Suboxone is the less-addictive, more cost-effective treatment option (Orman & Keating 2009; Polsky, et al., 2010; Canadian Agency for Drugs and Technologies in Health [CADTH], 2013; Sittambalam, Vij, & Ferguson, 2014; Peddicord, Bush, & Cruze, 2015), the findings for access to methadone treatment are not necessarily needed to draw conclusions about income status and access to more effective medications to treat heroin and opioid abuse.

Summary

The purpose of this study is to determine if low-income heroin and opioid abusers have barriers to access to Suboxone treatment for their addictions at the state- and region-levels. The presence of such barriers would represent a health inequity that would require intervention by public health officials. The issue will be examined using a post-positivist worldview and a quantitative content analysis of secondary data (Merriam, 2009). Additionally, the issue will be examined through the social determinants of health framework, with income status representing a social determinant and access to Suboxone treatment representing a structural determinant (Dean & Fenton, 2010 and Satcher, 2010). Data was collected from the U.S. Census Bureau, SAMHSA, and the CDC WONDER databases. Then, a series of multi-variable linear regression analyses using IBM's SPSS software were performed to answer the research questions. Factors of age, race/ethnicity, gender, population size, and number of heroin and prescription opioid overdoses were controlled for (Szafran, 2012). The major assumptions in conducting this research are that state-level data can be used to assess the relationship between income status and access to Suboxone treatment and that the relationship between income and access to Suboxone treatment is linear. Another assumption is that the data sources used for this study are accurate. Inaccurate data could limit the findings of this research by overestimating or underestimating the relationship between the independent and dependent variables.

Literature Review

Illicit drug use is a costly epidemic in the United States. In 2007, the cost of illicit drug use, including lost productivity, health care costs, and criminal prosecution was $194 billion. These costs exceeded national costs (including lost productivity) for treatment of diabetes ($174 billion), smoking ($157 billion) and obesity ($147 billion) during the same year (NDIC, 2011). Health-wise, illicit drug use can lead to chronic and terminal illnesses that further impact one's quality of life and further increase the costs associated with such behavior. Heroin and opioid abuse is a subset of illicit drug use that affects 2.5 million U.S. citizens (Volkow, 2014). The estimated yearly cost of heroin and opioid abuse in the United States is between $56 billion and $72 billion (about 28% - 37% of total illicit-drug-related costs for the nation) (Birnbaum, et. al., 2011; HHS, 2013). Additionally, research shows that heroin and opioid abuse increase one's exposure to serious diseases including hepatitis C, the human immunodeficiency virus (HIV), liver disease, kidney disease, and cardiovascular disease—the latter of which costs $316 billion per year in health care costs and lost productivity (NDIC, 2011; NIDA, 2012).

Recognizing that abstinence was an ineffective method to resolving heroin and opioid drug abuse for most abusers, new methods of treating these patients have been developed. These methods are known as medication-assisted treatment (MAT) options (CSAT, 2005). Since 2002, Suboxone, a potent, clinically proven drug for use in MAT, has been approved by the FDA for use with heroin-and-opioid-addicted patients. However, there are concerns that income status presents a barrier to access to Suboxone treatment for low-income heroin and opioid abusers. This concern, while highly vocalized in popular media (Harmon, 2011; U.S. Attorney's Office, 2014; Cherkis, 2015; Healy, 2015; Sharon, 2015; Svrluga, 2015), has yet to be addressed in-depth in academic research. Addressing the issue of a potential income-related barrier to access

to Suboxone treatment is essential to addressing the social determinants of health related to the drug addiction epidemic and drug addiction treatment. Observations that Suboxone-access barriers exist in areas with large proportions of low-income residents might present a call to action for public health officials to review the protocols for issuing Suboxone-prescribing licenses. On the other hand, observations that Suboxone-access barriers do not exist might support a position that the Suboxone-prescribing licensing procedures in the United States do not represent a negative social determinant of health for heroin and opioid abusers.

In the proceeding sections of this chapter, the researcher will discuss the various elements related to this research topic. Those elements include: an overview of heroin and opioid abuse in the United States; the mandate for insurance coverage of drug abuse treatment under the Patient Protection and Affordable Care Act of 2009 (ACA); treatment options for heroin and opioid abuse; and the treatment of heroin and opioid abuse with Suboxone. Additionally, a critique of currently available academic research on the topic of medication-assisted treatment for heroin and opioid addiction will be discussed. Lastly, the theoretical framework of the social determinants of health will be presented and discussed as it relates to access to Suboxone treatment for low-income heroin and opioid abusers in the United States.

Heroin and Opioid Abuse in the U.S.

There are a total of 21.5 million illicit drug users in the United States. Of these, 586,000 are heroin abusers and 1.9 million are opioid abusers (ASAM, 2016). On a larger scale, U.S. heroin and opioid abusers make up about 9% of the world's heroin and opioid abusers (Volkow, 2014). Heroin was first introduced to the United States in 1898 as a cough suppressant for tuberculosis patients; today, it is an illegal substance with no approved medical use (CSAT, 2005). It is a drug that is synthesized from morphine and it binds to opioid receptors in the brain,

inducing feelings of euphoria once consumed (NIDA, 2014). The drug may be smoked, injected, or inhaled (NIDA, 2014). In 2014, 10,564 U.S. citizens died of heroin overdoses (ASAM, 2016). Research has shown that heroin usage is highest among individuals who: are non-Hispanic, Whites, are male, are ages 18-25, earn less than $20,000 in annual income, and live in areas with more than 1 million residents (Jones, Logan, Gladden, & Bohm, 2015).

Prescription drugs used to treat acute and chronic pain form a class of drugs referred to as opioids. These drugs also bind to opioid receptors and can induce euphoria when consumed. Prescription drug abusers consume prescription drugs like Vicodin, OxyContin, and Percocet for non-medical reasons. Generally, these drugs are taken orally. Each year, approximately $72.5 billion are spent on prescription painkillers. In 2013, U.S. residents consumed almost 100% of the world's supply of Vicodin and 81% of the world's supply of Percocet (Volkow, 2014). In 2014, 18,893 U.S. citizens died of opioid overdoses (ASAM, 2016). Opioid abusers are primarily ages 18 – 25, female, and of Native American or non-Hispanic, White descent (Back, Payne, Simpson, & Brady, 2010; HHS, 2013; SAMHSA, 2015). Studies have shown that prescription drug users are more likely to abuse heroin, presumably when their access to prescription opioids is reduced or when their funds are low (Volkow, 2014). Since heroin can be consumed intravenously, prescription opioid abusers who become addicted to heroin are more susceptible to HIV and Hepatitis C than other, non-heroin drug abusers (NIDA, 2012).

Affordable Care Act Coverage of Drug Abuse Treatment

Until recently, treatment for drug abuse in the United States was largely uncovered by commercial insurance plans (Horgan & Merrick, 2001). Additionally, state-funded and federally-funded insurance plans offered limited coverage for drug abuse treatment. This limited coverage included short-stay detoxification programs, drug abuse counseling sessions, and, in

some instances, MAT for heroin and opioid abusers (CSAT, 2005). However, these circumstances changed when, in 2010, the Patient Protection and Affordable Care Act of 2009 (ACA) named substance abuse coverage as of the ten "elements of essential health benefits (ONDCP, n.d., par. 2)". This provision marked a new era of addressing the issue of drug treatment. Under this mandate, substance abuse counseling and various treatment options are available to—and covered for—drug abusers, including heroin and opioid abusers (ONDCP, n.d.).

Treatment Options for Heroin and Opioid Abuse in the U.S.

Prior to the passage of the ACA, there were treatment options for heroin and opioid abusers, but different levels of coverage for them under private and government-funded plans. The first treatment option available was the detoxification program. Drug detoxification programs for opioid abuse have been available since the early 1900s. These programs typically involve treatment in a facility with medical staff supervision while patients abstain from using drugs altogether (CSAT, 2005). However, research has shown that 52 - 75% of heroin abusers and nearly 90% of opioid abusers relapse (or revert back to drug abuse) within one year of being released from a detoxification program, even with continued counseling (Hunt & Bespalec, 1974; Hubbard & Marsden, 1986; Fiellin, 2006). So, in the early 1970s, public health experts developed a new program, called the methadone treatment program, for heroin and opioid abusers (CSAT, 2005).

Methadone is a controlled substance on Schedule II of the DEA's prescribing list. Schedule II substances have approved medical uses, but are highly addictive. When taken orally, methadone can limit heroin and opioid cravings for up to 36 hours without impairing an individual's social functioning. A methadone treatment program, known as methadone

maintenance treatment (MMT) includes administering a daily dose of methadone to patients along with group therapy and drug addiction counseling (CSAT, 2005). There are complaints about methadone treatment programs, including the stringent attendance requirements and the adverse side effects of methadone treatment withdrawal. MMT requires heroin and opioid abusers to report to a methadone clinic each day to receive their daily doses of the medication. For individuals with jobs or other responsibilities, this requirement can prove cumbersome. If too many days are missed from the MMT program, patients can be dismissed from the program instantly, without any period of gradual withdrawal from methadone (Krambeer, von McKnelly, Gabrielli, & Penick, 2001). Non-gradual methadone withdrawal induces withdrawal symptoms similar to those of heroin or opioid withdrawal, including vomiting, excessive sweating, muscle aches, and abdominal cramping (NLM, 2013). To avoid the discomfort associated with withdrawal, individuals might relapse to heroin and/or opioid abuse as a result of being banned from participating in an MMT program (Krambeer et al., 2001).

In 2002, a new group of MAT options became available. These options included Subutex (buprenorphine) treatment and Suboxone (a buprenorphine and naloxone compound) treatment (Volkow, 2014). Subutex and Suboxone are the first drugs to be approved for use in treating drug addiction under the Drug Addiction Treatment Act of 2000 (DATA2000). DATA2000 enables physicians meeting certain qualifications to treat patients' drug addictions using Schedule III, IV, and V drugs outside of methadone-clinic-based settings (SAMHSA, n.d.). Subutex and Suboxone are Schedule III drugs. Scheduling for these drugs indicates that the propensity to become addicted to the medications is lower than that of Schedule II drugs, such as methadone. These two drugs are known as partial agonists. Partial agonists bind to the opioid receptors in the brain, but produce a diminished response. Suboxone's ingredient of naloxone

further works to curb misuse of the drug by limiting the feeling of euphoria that can be experienced when taking the medication (Volkow, 2014). For this reason, these drugs, and Suboxone especially, are less strictly regulated than methadone. The less strict regulation has its benefits, including less stringent attendance requirements and less severe withdrawal symptoms for patients (CSAT, 2005; Volkow, 2014). Still, there are fears that diversion (or misuse) of these drugs is fatal since the diminished response after consumption might more easily lead to an overdose (Yokell, Zaller, Green, & Rich, 2011; Partnership for Drug Free Kids, 2014).

Treatment of Heroin and Opioid Abuse with Suboxone

Like methadone treatment, Suboxone treatment is still controlled. Unlike methadone treatment, Suboxone treatment can be administered on an outpatient basis, via a take-home prescription, with monthly (instead of daily) follow-ups with a physician in the physician's office. However, physicians are limited in the number of heroin-and-opioid abusing patients they can treat with Suboxone. That number is either 30 or 100 patients depending on the number of years the physician has been certified to issue Suboxone prescriptions. Physicians within their first year of certification are limited to treating 30 patients; physicians in their second and subsequent years of certification can treat up to 100 patients (SAMHSA, n.d.). While methadone has an out-of-pocket expense of $4,700 annually per patient, Suboxone has a $6,000 annual out-of-pocket expense per patient (NIDA, 2012; BupPractice, 2016). Although Suboxone costs more annually per patient, the decreased risk of addiction might provide a cost-effective benefit for nationwide health care expenses related to drug abuse (Polsky, et. al., 2010; CADTH, 2013).

In recent cases, it has been observed that Suboxone-prescribing physicians abstain from accepting insurance payments (which can be much lower) in favor of out-of-pocket-paying patients to earn more money for providing Suboxone treatment to patients addicted to heroin and

opioids. In some instances, Medicaid-participating physicians have billed patients instead of billing Medicaid for services rendered or they have refused to see Medicaid patients altogether (U.S. Attorney's Office, 2014). Suboxone is not only covered by Medicaid in many states (Rinaldo, 2008), but it has also been shown to be more effective than detoxification and safer and more practical than methadone treatments for addressing heroin and opioid addiction. If Suboxone-prescribing physicians are, in fact, discriminating against patients based on their ability to pay for this service, the issue must be addressed to restore equity in access to this treatment.

Review of Related Literature

This section will discuss studies completed to determine the effectiveness and implications of using MAT to treat heroin and opioid abuse. The studies included for review consist of studies related to methadone treatment, studies related to Suboxone treatment, and studies regarding issues of access to MAT for heroin and opioid abusers.

Studies on Methadone. Methadone maintenance treatment (MMT) has long been questioned as replacing one morbidity (heroin or opioid addiction) with another morbidity (methadone addiction). However, Sorensen, et al. (2009) concluded that, when controlling for psychiatric history, criminal justice pressure, and length of stay in a treatment program, MMT patients had illicit-opioid-abuse relapse rates that were "indistinguishable (p. 100)" from the illicit-opioid-abuse relapse rates of patients in residential therapeutic communities (TCs) for heroin and opioid abusers. The study followed 125 MMT patients and 106 TC patients for a 24-month period to track, among other factors, illicit drug relapse, alcohol use, and HIV risk behavior. This study supports claims that MMT is an effective intervention in treating heroin and opioid addiction. Another study done in 2010 found that supervised methadone treatment

resulted in a substantial decline in methadone-related deaths from 1993 to 2008 in England and Scotland (Strang, Hall, Hickman, and Bird, 2010). These findings indicate the benefit of supervised dosing for methadone patients. In a clinical trial consisting of 225 participants, Ling, Wesson, Charuvastra, and Klett (1995) found that high-dosage methadone treatment was more effective than low-dosage methadone treatment or low-dosage Suboxone treatment with respect to opioid use, opioid cravings, and opioid program retention. These results are controversial since health experts warn of the dangers of diversion, overdoses, and addiction related to high-dosage methadone treatment. Modesto-Lowe, Brooks, and Petry (2010) found that high doses of methadone could lead to respiratory arrest and Torsades de Pointes, a ventricular arrhythmia that is potentially deadly. Collectively, these studies help identify both scientific support of-and serious causes for concern for- methadone maintenance treatment for heroin and opioid abuse.

Studies on Suboxone. Since Suboxone was approved by the FDA, several studies have been conducted to determine the drug's standalone effectiveness in treating heroin and opioid addiction as well as its comparative effectiveness against methadone maintenance treatment. Finch, Kamien, and Amass (2007) reported that, in a sample of 72 patients, Suboxone treatment of 2 – 24 mg per day was effective in treating a group of heroin abusers. This study was based on chart reviews of the patients at the commencement of Suboxone treatment in an office setting. The sample included primarily White, employed patients. Sittambalam, Vij, and Ferguson (2014) found that among 220 heroin abusers, mostly African Americans, Suboxone levels of 16 – 32 mg were optimal. The 4-year study found that emergency room visits for all 220 participants decreased by 23% after one year while hospital stays decreased by 45%. Quality of life was also improved for all participants. However, it is important to note that only 16.8% of program participants remained in the program for at least three months.

McKeganey, Russell, and Cockayne (2013) concluded that Suboxone treatment resulted in significantly less days of heroin use than methadone treatment for 71 patients that were studied. However, limitations of this study include small sample size and non-randomized selection of participants. Later, in a systematic review of available studies and trials comparing Suboxone treatment to methadone treatment, Peddicord, Bush, and Cruze (2015) concluded that:

> Suboxone and methadone are both proven to be effective treatment options. Both medications have unique risks and benefits, and the research does not indicate that one medication is a better option than the other. This decision must be based on an individual basis after reviewing important patient factors such as health status and access to the medication (para. 3).

The researchers also concluded that since, on average, Suboxone is more expensive than methadone, cost might play a role in which treatment a patient receives.

Studies on access to treatment for heroin and opioid addiction. There are few studies that were found that explicitly address the issue of access to medically-assisted treatment for heroin and opioid addiction. Dick, et al. (2014) conducted a study of access to methadone and Suboxone treatment for prescription opioid abuse from 2002 – 2011. The researchers found that the number of counties with treatment shortages fell from 48.6% in 2002 to 10.4% in 2011. The researchers concluded that "[p]olicy makers should focus their efforts on further increasing the number and geographical distribution of physicians, particularly in more rural counties… (p. 1028)." Saloner and Karthikeyan (2015) issued a letter stating that "[e]xpanding access to substance use treatment among individuals with opioid use disorders (OUDs) may be an important strategy for reducing harmful use (p. 1515)." This recommendation was made following interviews with 6,670 respondents who identified as opioid abusers in the 2004 – 2013 National Surveys of Drug Use and Health. The interviews asked each respondent if he/she sought addiction treatment, what kind of addiction treatment was sought, and the place of service

for that treatment. Neither of these studies focused on income status as a factor in barriers to access to addiction treatment.

Gap in Knowledge. In the aforementioned studies, much information is provided supporting the clinical basis for treating heroin and opioid addiction with medication-assisted treatment options. However, in each of the studies discussed, a lack of emphasis is placed on access to care and its relation to income status. One reason for the lack of emphasis might be that many of the studies concerned with effectiveness were performed using convenience sampling, where patients were already enrolled in some kind of MAT program. Additionally, in clinical trials, patients were provided with treatment irrespective of their abilities to pay for it. Due to this lack of emphasis, the issue of access to MAT treatment—specifically Suboxone—and income status is not thoroughly addressed using available, peer-reviewed literature. This topic is important to study since low-income individuals are more susceptible to heroin and opioid addiction (Jones, Logan, Gladden, & Bohm, 2015). Therefore, if they seek treatment, barriers to that care based on their income would represent a health inequity. The goal of this study is to investigate the relationship between income status and access to the MAT treatment option of Suboxone. Addressing access-to-care issues, if any are found, would be beneficial to containing and/or shrinking the epidemic of heroin and opioid abuse in the United States.

Theoretical Framework

When discussing access to a treatment and its potential link to economic status, the social determinants of health present an appropriate framework for discussing the issue. Social determinants of health (SDOH) are a set of attributes first introduced by former U.S. Surgeon General David Satcher (2010). SDOH are "circumstances in which people grow, live, work,

socialize, and form relationships, and …the systems put in place to deal with illness, all of which are, in turn, shaped by political, social, and economic forces (Dean & Fenton, 2010, p. 1)."

SDOH include two categories of attributes: social determinants and structural determinants. Social determinants include (Dean & Fenton, 2010),

> Economic and social conditions that influence the health of people and communities as a whole, and include conditions for early childhood development, education, employment, income and job security, food security, health services, and access to services, housing, social exclusion, and stigma (p. 1).

In this study, income status represents a social determinant of health. If a barrier to access to Suboxone treatment is related to low income status, being low-income would be a negative social determinant of health for heroin and opioid abusers in the U.S.

Structural determinants include "those physical, social, cultural, organizational, community, economic, legal, or policy aspects of the environment that impede or facilitate efforts to avoid disease transmission (Dean & Fenton, 2010, p.1)." In this study, structural determinants would be policies governing Suboxone licensing and the availability of Suboxone treatment for heroin and opioid abusers. If economic situations and policies in-place for Suboxone treatment encourage a barrier to access to treatment for low-income heroin and opioid abusers, those situations and policies can be seen as negative structural determinants of health related for heroin and opioid addiction.

Dependent variable. *Access to Suboxone treatment.* The dependent variable in this research is access to Suboxone treatment, which was measured by the number of providers of Suboxone treatment within a given state.

Independent variable (IV1). *Income status.* The independent variable in this research is income status, which refers to the annual earnings of individuals.

Moderating variables. *Number of overdoses, population size, and Medicaid coverage*. Moderating variables often influence the relationship between independent and dependent variables (MacKinnon, Krull, & Lockwood, 2000). The number of heroin and opioid overdoses in a given state might affect the magnitude of the relationship between income status and access to Suboxone treatment. For example, states with higher rates of heroin and opioid overdoses might have greater access to Suboxone treatment. Population size might also affect the magnitude of the relationship between the independent and dependent variables in this study. For example, states with larger populations might have greater access to Suboxone treatment than states with smaller populations. Medicaid coverage of Suboxone treatment might also affect the relationship between being low-income and having access to treatment. For example, if a patient is low-income and has Medicaid insurance, but Medicaid does not pay for Suboxone treatment, then that patient's access to such treatment might be limited. These variables will need to be considered in this study.

Confounding variables. *Age, race/ethnicity, and gender*. Confounding variables can typically change the magnitude and/or direction of the relationship between the independent variable and the dependent variable (MacKinnon, Krull, & Lockwood, 2000). In this study, age, race/ethnicity, and gender might influence the relationship between income status and access to Suboxone. So, these variables will also be considered in this study.

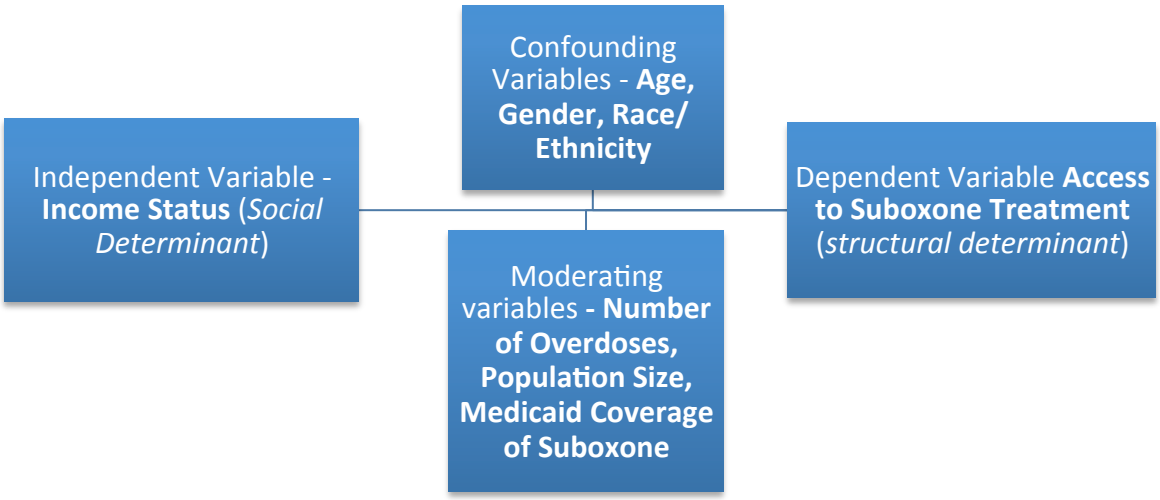

Figure 1. Theoretical framework for income status and access to Suboxone treatment.

Summary

Heroin and opioid abuse are costly addictions for the patients they affect and the general public. In addition to the billions of dollars per year attributed to heroin and opioid abuse, the disorders result in higher susceptibility to equally—if not more—costly diseases and conditions such as liver disease, kidney disease, hepatitis, HIV, and cardiovascular disease (NDIC, 2011; NIDA, 2012). While detoxification is an option, studies show that it is not as effective as medication-assisted interventions for this type of addiction. Moreover, while methadone maintenance treatment is a viable solution for treating heroin and opioid addiction, Suboxone treatment has been shown to be more viable and less addictive (Volkow, 2014). However, the question of whether access to Suboxone presents a treatment barrier for low-income heroin and opioid abusers has yet to be addressed by available academic literature. This research study intends to address that knowledge gap by investigating the topic quantitatively through the

perspective of the social determinants of health. The research methodology for this study is presented in the next chapter.

Research Methods

Government reports and popular news articles provide evidence of a systematic barrier to Suboxone treatment for low-income U.S. residents (Harmon, 2011; U.S. Attorney's Office, 2014; Cherkis, 2015; Healy, 2015; Sharon, 2015; Svrluga, 2015). While dismissing these claims could prove irresponsible on the part of public health officials, accepting them without additional evidence is equally irresponsible. Although individual experiences cannot be ignored, they do not fully represent a greater understanding of what is occurring nationwide among low-income heroin and opioid abusers seeking medically-assisted treatment for their addictions. This research study assumes a post-positivist worldview to investigate the claims made that access to Suboxone MAT is hindered due to one's income status. Assuming such a worldview is integral to objectively examining the circumstances surrounding access to Suboxone treatment in the United States (Merriam, 2009).

In this chapter, the research methodology for this quantitative study will be explained. First, the research questions and accompanying hypotheses for testing those questions will be presented. Then, the setting for the research project and the data sources to be used will be discussed, followed by an examination of the ethical considerations for this research. A discussion of the research design, including data collection protocols and operational definitions of variables will also be presented. Lastly, the data analysis strategy for answering the research questions will be discussed before concluding the chapter with a summary.

Research Questions

The research questions for this study are designed to comment on access to Suboxone interventions for low-income heroin and opioid abusers. Examining access to these resources among low-income patients will allow the researcher to draw conclusions regarding barriers to

Suboxone treatment within the United States and, specifically, to discover if there is a relationship between access to Suboxone MAT and income status. Overall, researching these questions will identify if there is a statistically significant barrier to access at all and, if there is, the magnitude of that barrier. Based on the findings of this research, public health officials can further investigate the issue and propose methods for addressing the barriers, if applicable. Furthermore, this investigation, if warranted, could reduce the magnitude of the heroin and opioid epidemic in the United States among low-income drug abusers.

Research question one. Controlling for age, race/ethnicity, gender, population size, and number of heroin and opioid overdoses, what is the relationship between income status and access to Suboxone treatment in the United States?

Null hypothesis one: Controlling for age, race/ethnicity, gender, population size, and number of overdoses, there is a positive relationship between being low-income and having access to Suboxone treatment in the United States.

Alternative hypothesis one: Controlling for age, race/ethnicity, gender, population size, and number of overdoses, there is a negative or no relationship between being low-income and having access to Suboxone treatment in the United States.

Research question two. How is the relationship between income status and access to Suboxone treatment affected by U.S. region?

Null hypothesis two: U.S. region does not have an effect on the relationship between income status and access to Suboxone treatment.

Alternative hypothesis two: U.S. region does have an effect on the relationship between income status and access to Suboxone treatment.

Setting

The setting for this research is the United States of America. The heroin/opioid epidemic in the United States has remained a public health issue for decades. In addition to the healthcare costs and lost productivity costs associated with heroin and opioid abuse, these addictions also lead to violence and criminal activity (NDIC, 2011). With a 52 – 90% relapse rate for heroin/opioid abusers within one year of being released from detoxification programs (Hunt & Bespalec, 1974; Hubbard & Marsden, 1986; Fiellin, 2006), it is imperative that effective treatment be provided to curb the craving for heroin and prescription opioids. Investigating the issue of access to effective treatment, specifically Suboxone, for low-income heroin and opioid abusers could save billions of dollars in healthcare costs, lost productivity, and criminal prosecution costs in the United States.

Data Sources

The data for this study came from several government sources. Demographic information, including age, race/ethnicity, gender, and population size, was obtained from the U.S. Census Bureau; this information is based on annual estimates for the civilian population. The classification of each state into a region utilized the regional groupings used by the U.S. Census Bureau. Regional groupings may be found in Appendix A. Information on Suboxone providers was obtained through the Substance Abuse and Mental Health Services Administration (SAMHSA), a branch of the U.S. Department of Health and Human Services. SAMHSA has a database containing the number of Suboxone providers that treat 30 or 100 patients, by state. Lastly, information on heroin and opioid overdoses was obtained from the CDC Wide-ranging Online Data for Epidemiologic Research (WONDER) database. The codes used to indicate heroin-and-prescription-opioid-overdose-related deaths can be found in Appendix B.

All data collected was for the year 2014, which is the most recent year for which all data is available from each data source previously named. Using data from the latest-available year allows the results of this study to have relevance in addressing any issues related to income status and access to Suboxone while they are still likely prevalent in the country.

Ethical Considerations

Although this research project does not use human subjects, there are still ethical considerations that can be taken in handling the data and in interpreting results from the data based on two of the three principles of the Belmont Report: beneficence and justice. Beneficence refers to having the welfare of participants in mind while conducting research. The intended purpose of this research is to determine if an issue of access to care exists for low-income heroin and opioid abusers. Within this context, the welfare of heroin and opioid abusers is being considered. Determining that an access problem exists would present a call to action for public health officials to re-assess the issuance of Suboxone-prescribing licenses and to focus on regulating physicians in possession of such licenses. Justice refers to avoiding undue burdens on one group (U.S. Department of Health, Education, and Welfare, 1979). One might argue that finding a correlation between low-income and less access to Suboxone treatment might place an undue burden on taxpayer dollars to pay for Suboxone treatment for low-income heroin and opioid abusers. The researcher counters that taxpayers already spend an exorbitant amount of money on care for low-income heroin and opioid abusers as a result of the illicit drug use (NDIC, 2011). So, paying for a treatment that will reduce the overall cost burden of heroin and opioid abuse (with respect to comorbidities, lost productivity, and criminal prosecution) would not place a heavier undue burden on taxpayers (U.S. Department of Health, Education, and Welfare, 1979).

Lastly, if a barrier to access to Suboxone treatment for low-income heroin and opioid abusers exists, investigations could be launched by government agencies to determine underlying problems with the current provision of care to these patients. These investigations might lead to a redistribution of resources and/or revocation of Suboxone-prescribing licenses. These consequences might affect Suboxone treatment options for higher-income heroin and opioid abusers. However, it is the researcher's stance that, if done correctly, there will be minimal disturbance in the provision of care to those patients since such a disruption would be in contrast to the purpose of redistributing resources in the first place.

Research Design

To conduct this research, first, information was gathered from each of the previously identified secondary data sources in the Data Sources section of this chapter. Namely, income status, age, race/ethnicity, population size, and region data were retrieved from the U.S. Census Bureau; the number of Suboxone physicians in each state was retrieved from the SAMHSA database; and the number of heroin and prescription opioid overdose deaths in each state was extracted from the CDC WONDER database. A sampling method was not used for this study since the study involves data from all 50 states and the District of Columbia.

Income status is the independent variable for this research. The variable, which is continuous, is represented by the percentage of adults in each state that live within 200% of the federal poverty level (FPL) (or adults making $23,340 or less in 2014) (Assistant Secretary for Planning and Evaluation [ASPE], 2014). Access to Suboxone treatment is the dependent variable. This continuous variable was determined by the number of Suboxone prescribers (for 30 patients or 100 patients) that each state had. Age is a continuous variable that was represented by the percentage of residents in each state between the ages of 18 and 25.

Race/Ethnicity is also a continuous variable. For this research, race/ethnicity was represented by the percentage of the population that was non-Hispanic and White. Gender is a continuous variable that was represented by the percentage of males in a given state. Population is a continuous variable that was be measured by the number of residents. Number of overdoses is also a continuous variable. This variable was represented by the number of heroin and prescription opioid overdose deaths as reported using the cause of death codes listed in Appendix B. Lastly, region is a categorical variable that was used to group state data into regions of the United States (Szafran, 2012). A list of states, by region, can be found in Appendix A. All information was gathered at the state-level for the year 2014. Although Medicaid coverage of Suboxone was identified as a confounding variable in the theoretical framework for this research (Figure 1), since 39 out of 50 (78%) states provided Medicaid coverage for Suboxone since 2008, this variable was not controlled for in this study (Rinaldo, 2008).

As all information of interest was gathered, it was entered into an Excel spreadsheet. Each row in the Excel file represented data for a different state. The first column of each row contained the name of the state to which all additional data in the row corresponded. Once all data was gathered, the Excel spreadsheet was used to define variables and input the data into the statistical programming software IBM SPSS. SPSS was available, free-of-charge, on the Trinity Washington University campus; the software was also available for rent for six months through the Trinity Software Purchasing Store for $59.98 (Trinity DC, 2016). One week after the completion of initial data entry, the SPSS data was reviewed and compared against the Excel spreadsheet to ensure data entry accuracy prior to analyzing the information.

Validity of the data used in this research study was preserved by using appropriate operational definitions. For example, age was measured by the percentage of residents in each

state that are between the ages of 18 and 25. This age group is the most susceptible to heroin and opioid abuse (Back, Payne, Simpson, & Brady, 2010; HHS, 2013; SAMHSA, 2015; Jones, Logan, Gladden, & Bohm, 2015). However, the validity of the heroin and opioid overdose data might have been compromised by the coding system used. The CDC WONDER database has switched to using ICD-10 codes instead of ICD-9 codes for the data it displays. However, until October 1, 2015, ICD-9 codes (which are less specific) were used to code heroin and opioid overdose deaths. Since ICD-10 codes must be used to retrieve the data now, the numbers reported for this variable might be lower than the numbers that would have been reported using the less-specific ICD-9 codes (Szafran, 2012; CDC, 2015; Centers for Medicare and Medicaid Services [CMS], 2016). Additionally, if state-level data is inappropriate for assessing the relationship between income status and Suboxone, then the validity of this data is compromised.

By explaining the operational definitions for the variables in this study, reliability is improved. Using these definitions, future researchers will be able to extract the same information from the named databases to conduct similar analyses. One issue with reliability in this study is the classification of causes of death. If the classification system for coding causes of death changes in the future, the reliability of the data collected using the methodology from this study might be compromised (Szafran, 2012).

Data Analysis Strategy

Once all data were entered and confirmed in SPSS, descriptive statistics such as mean, median, mode, and variance were discussed as appropriate for the data set. Then, a multi-variable linear regression analysis test was performed to determine the statistical significance or insignificance between income status and access to Suboxone treatment in the United States, controlling for age, race/ethnicity, gender, population size, and the number of heroin and opioid

overdoses. Next, a series of multi-variable linear regression analysis tests were performed to evaluate the same relationship for each region. Lastly, results from the analyses were used to answer the research questions for this study (Szafran, 2012).

Summary

In order to obtain an objective indication of the presence or absence of barriers to Suboxone treatment for low-income heroin and opioid abusers in the United States, this study assumes a post-positivist worldview in gathering data and conducting analyses of that data (Merriam, 2009). The two main questions of concern in this study are: 'What is the relationship between income status and Suboxone treatment availability in the U.S.' and 'What effect does region have on this relationship'. Several data sources were used to extract this information for analysis. These sources include the U.S. Census Bureau, the Substance Abuse and Mental Health Services Administration, and the CDC WONDER database. All data used was from the year 2014, which provides the most recent data available on the topic. The ethical principle of beneficence was upheld by keeping the welfare of heroin and opioid abusers in mind during this study. The ethical principle of justice was upheld by avoiding placing undue burdens on any one group of people affected by this research. After data were gathered, descriptive statistics procedures as well as a series of multi-variable linear regression tests were performed to address the research questions (Szafran, 2012). The results of these analyses are provided in the next chapter.

Findings

After gathering data, entering the data into SPSS, and validating the SPSS data entries, a means procedure was performed on the data set, followed by multi-variable linear regression analysis tests. The results from SPSS were then used to describe and make inferences from the data. The proceeding sections of this chapter will describe the sources used for the data set for this study and the general characteristics of the data set used in this study. The proceeding sections will also provide an overview of the results produced by the multi-variable linear regression analysis performed on the data. Lastly, a summary of the data presented will conclude this chapter.

Data Set

The data used in this study were retrieved from three sources. Data on age, gender, income status, population, race and ethnicity, and region were obtained from the U.S. Census Bureau. Information on the number of Suboxone providers within each state was obtained from the Substance Abuse and Mental Health Services Administration. Lastly, information on the number of heroin and opioid overdose-related deaths was obtained from the CDC WONDER database. The data were grouped together, by state, to form the aggregate data set used to conduct this study.

U.S. Census Bureau data. Regional groupings for this study utilized the census regional groupings as defined by the U.S. Department of Commerce, Economics, and Statistics Administration (U.S. Census Bureau, n.d., *Census regions and divisions*). Income status information was retrieved from the 2014 Current Population Survey (CPS), which was released as part of the 2015 Annual Social and Economic Supplement report. The Current Population Survey is a joint initiative between the U.S. Bureau of Labor Statistics and the U.S. Census

Bureau. The survey provides individual-level data on employment and unemployment for noninstitutionalized U.S. residents and enlisted members of the Armed Forces living within the United States. The 2014 CPS sampled 94,000 households over the course of one year (January 2014 through December 2014) to obtain data for estimating key demographics for the entire U.S. population (U.S. Census Bureau, 2015b).

Information used for the variable 'population size' was retrieved from the National and State Populations Estimate data set, which is maintained by the U.S. Census Bureau's Population Estimates Program (PEP). These population estimates are used as controls in other Census Bureau surveys, including the CPS. The estimates are done using the most recent decennial census numbers as a base. Then, migrations (both national and international) and births are added to the base number and deaths are subtracted from it. Birth and death information is retrieved from the National Center for Health Statistics (NCHS) and the Federal-State Cooperative for Population Estimates (FSCPE). NCHS provides information from birth certificates and death certificates at a national level; FSCPE reports the same events at a state or lower geographical level. State-level information on domestic migration is retrieved from IRS tax exemptions, changes in Medicare enrollments, and changes in yearly characteristics of age, sex, race, and other demographics. Information on international immigration is retrieved from the three-year American Community Survey (U.S. Census Bureau, n.d., *Methodology for the United States population estimates*).

Data for variables of age, gender, and race and ethnicity were collected from the American Community Survey. The ACS is an annual nationwide survey that collects data on demographics, socio-economics, and housing. ACS data files are published in 1-year, 3-year, and 5-year formats. However, the 2012 – 2014 ACS data set will be the last set to include a 3-

year report of ACS findings. The Census Bureau recommends that users obtaining data from the ACS focus on percentages, rates, averages, and medians of the data instead of focusing on actual numbers. The Bureau emphasizes that a survey is best used as a tool for estimating distributions of characteristics. ACS estimates for 2014 are based on data collected from January 1, 2014 to December 31, 2014 (U.S. Census Bureau, n.d., *American Community Survey*).

Substance Abuse and Mental Health Services Administration data. Information on the number of Suboxone providers was collected from the Substance Abuse and Mental Health Services Administration database. The database keeps track of the number of DATA-certified Suboxone providers in each state. The information provided in this database is sorted by state, year, and the maximum number of patients each provider can treat with Suboxone (30 patients for first-year Suboxone providers or 100 patients for providers who have been treating patients with Suboxone for two or more years) (SAMHSA, n.d.).

Centers for Disease Control data. Information on the number of heroin and opioid overdose-related deaths was obtained from the Multiple Cause of Death (MCD) database, which is available via the CDC WONDER website. The information in the MCD database is retrieved from death certificates of U.S. residents. A single underlying cause of death and multiple additional causes of death can be extracted from this database by several demographic groupings, including state of residence. The cause of death codes used for this study may be found in Appendix B. Researchers using data from the MCD database agree not to report any state-level data for cases where less than 10 observations are made (CDC, n.d., *About multiple*). No such instances were observed in this study.

Data set overview. All fifty U.S. states and the District of Columbia were included in this study, for a total of 51 cases. The raw data for all cases can be found in Appendix C. Values

for all variables were recorded for each case; there were no missing values. Twelve states (23.53%) are located in the Midwest region of the United States. Nine states (17.65%) are located in the Northeast region of the country. Seventeen states (33.33%) are located in the South region of the country. And, thirteen states (25.49%) are located in the West region of the country. Appendix A shows the state compositions for each region. Table 1 (below) shows several additional descriptive characteristics for the data set compiled for this study.

Table 1. *Descriptive statistics for data set.*

	Subox-oneMD (#)	FPL200 (%)	Overdoses (#)	PopSize (#)	Pop18to25 (%)	PopMale (%)	PopWhite-NonHispanic (%)
N Valid	51	51	51	51	51	51	51
Missing	0	0	0	0	0	0	0
Mean	67.57	N/A[b]	322.43	6,252,216.78	N/A[b]	N/A[b]	N/A[b]
Median	44.00	31.0000	214.00	4,413,457.00	11.0100	49.2300	73.3900
Mode	23[a]	34.50[a]	39	None	10.79[a]	48.43[a]	22.97[a]
Std. Dev.	74.108	6.10932	314.335	7,123,931.621	.81769	.82179	16.11494
Range	345	26.70	1,392	38,218,347	4.68	4.85	70.79
Min	2	20.10	15	584,153	9.61	47.34	22.97
Max	347	46.80	1,407	38,802,500	14.29	52.19	93.76
Sum	3,446	N/A[b]	16,444	318,863,056	N/A[b]	N/A[b]	N/A[b]
% 25	19.00	27.6000	66.00	1,634,464.00	10.8000	48.7500	57.2600
50	44.00	31.000	214.00	4,413,457.00	11.0100	49.2300	73.3900
75	91.00	36.7000	441.00	7,061,530.00	11.4500	49.6800	81.4400

a. Multiple modes exist. The smallest value is shown.
b. This variable is a percentage. Therefore, the descriptive statistics of mean and sum are not appropriate for this variable.

Dependent variable (access to Suboxone treatment). In 2014, there were a total of 3,446 Suboxone physicians (SuboxoneMD) practicing in the United States. The mean number of

Suboxone physicians per state was approximately 68 physicians. The most frequently occurring numbers of Suboxone physicians for this data set (mode) were 23 physicians and 44 physicians. Half of the states had 55 or fewer Suboxone physicians in 2014 while 75% of the states had 91 or fewer Suboxone physicians in 2014. Wyoming had the least number of Suboxone physicians (2) while New York had the largest number of Suboxone physicians (347). A range of 345 physicians and a standard deviation of 74.108 indicate a high level of variance in the values for this dependent variable (Szafran, 2012).

Independent variable (income status). Income status (FPL200) was measured using the percentage of residents in a given state that had incomes within 200% of the federal poverty level in 2014. The most frequently occurring values for this variable were 34.5% and 38.5%. Half of the states had 31% or less of their residents living within 200% of the federal poverty level while 75% of the states had 36.7% or less of their residents living within 200% of the federal poverty level. New Hampshire has the lowest percentage of residents living within 200% of the federal poverty level (20.10%) while Mississippi had the highest percentage of residents living within 200% of the federal poverty level (46.80%). A range of 26.70 percentage points and a standard deviation of 6.10932 indicate moderate variance in the values for this independent variable (Szafran, 2012).

Moderating variables (number of overdoses and population size). There were a total of 16,444 heroin and opioid overdose-related deaths (Overdoses) in the U.S. in 2014. The mean number of overdose-related deaths in 2014 was approximately 322 deaths. The most common number of overdose-related deaths was 39 (in Alaska and in the District of Columbia). Half of the states had overdose-related deaths of 214 or fewer people while 75% of the states had overdose-related deaths of 444 or fewer people. North Dakota had the least number of overdose-

related deaths (15) while Ohio had the largest number of overdose-related deaths (1,407). A range of 1,392 deaths and a standard deviation of 314.335 indicate a high level of variance in the values for this moderating variable (Szafran, 2012).

In 2014, there were an estimated 318,863,056 residents in the United States. The mean state population in 2014 (PopSize) was approximately 6,252,217 people. Half of the states had a population size of 4,413,457 or fewer residents while 75% of the states had a population size of 7,061,530 or fewer residents. Wyoming had the smallest number of residents (584,153 people) while California had the largest number of residents (38,802,500 people). A range of 38,218,347 residents and a standard deviation of 7,123,931.621 indicate a high level of variance in the values for this moderating variable (Szafran, 2012).

Confounding variables (age, gender, and race/ethnicity). Adults ages 18 to 25 (Pop18to25) most frequently comprised 10.79%, 10.94%, 10.95%, 10.99%, and 11.43% of the residents in a given state in 2014. Half of the states had a population between the ages of 18 and 25 that represented 11.01% or less of the total state population while 75% of the states had a population between the ages of 18 and 25 that represented 11.45% or less of the total state population. Maine had the lowest percentage of adults ages 18 to 25 (9.61%) while the District of Columbia had the highest percentage of adults ages 18 to 25 (14.29%). A range of 4.68 percentage points and a standard deviation of 0.81769 indicate a low level of variance in the values for this confounding variable (Szafran, 2012).

The most frequent compositions of male residents (PopMale), by state, in 2014 were 48.43%, 48.72%, 49.67%, and 49.68%. Half of the states had a male population of 49.23% or less in 2014 while 75% of the states had a male population of 49.68% or less in 2014. The District of Columbia had the lowest percentage of males in its population (47.34%) while Alaska

had the highest percentage of males in its population (52.19%). A range of 4.85 percentage points and a standard deviation of 0.82179 indicate a low level of variance in the data for this confounding variable, too (Szafran, 2012).

Lastly, half of the states had a population of non-Hispanic, White residents (PopWhiteNonHispanic) that comprised 73.39% or less of the total population for the state while 75% of states had a population of non-Hispanic, White residents that comprised 81.44% or less of the total population for the state. Hawaii had the lowest percentage of non-Hispanic, White residents (22.97%) while Maine had the highest percentage of non-Hispanic, White residents (93.76%). A range of 70.79 percentage points and a standard deviation of 16.11494 indicate a moderate level of variance in the data for this confounding variable (Szafran, 2012).

Data Analysis Strategy

The strategy for analyzing the data that were retrieved, including a discussion of multi-variable linear regression and the measurements used for analysis, are discussed.

Tests and measurements. A multi-variable linear regression analysis was used to analyze the data collected to answer the research questions presented for this study. Regression analysis, in general, is one of the strongest statistical analysis tests available to researchers to begin to show causation. Multi-variable linear regression can be used to determine the magnitude, direction, and strength of the relationship between a set of independent variables and a dependent variable. Multi-variable linear regression testing considers the effect of one independent variable on a dependent variable when all other identified independent variables are held constant. As more independent variables are added to a model, spurious relationships can be exposed, leading a researcher closer to unearthing the true statistical significance of the

relationship between dependent and independent variables. The test is ideally performed using continuous (as opposed to categorical) variables (Szafran, 2012).

The correlation coefficient, R, is the square root of R-square. This value provides the level of association between observed and predicted values of the dependent variable. R is a continuous variable that ranges from 0 to 1. The closer R is to 1, the stronger the relationship is between the independent and dependent variables. Appendix D shows a table of correlation coefficients and the corresponding relational strength between an independent variable and a dependent variable that is indicated by a given R value (Szafran, 2012).

The coefficient of determination, R-square, is the value in a multi-variable linear regression model that indicates the percentage of variance in the dependent variable that can be explained by the independent variables in the model. The adjusted R-square is an estimate of R-square that accounts for the addition of unnecessary independent variables into the model. R-square values and adjusted R-square values indicate an overall measure of the strength of the entire model; they do not indicate strengths of association between the dependent variable and any one independent variable (Szafran, 2012).

Lastly, the level of significance (or p-value) represents the value at which a null hypothesis can be rejected in favor of an alternate hypothesis. The threshold for this study is a level of significance of 5.00% (p-value = 0.050). This level of significance will indicate that the researcher can be sure that the values produced by the model will accurately predict the behavior of the dependent variable approximately 95% of the time. Models and variables with significance levels above 5.00% will be considered statistically insignificant for this study. Models and variables with significance levels at or below 5.00% will be considered statistically significant for this study (Szafran, 2012).

Data Analysis

The results from multi-variable linear regression analysis are discussed, first by all states, then by regions. Tables 2 – 5 show the results of the multi-variable linear regression model for all state-level data collected. The model was used to assess the relationship between income status (independent variable: FPL200) and access to Suboxone treatment (dependent variable: SuboxoneMD). Factors of age (variable: Pop18to25), gender (variable: PopMale), heroin and opioid overdose-related deaths (variable: Overdoses), population size (variable: PopSize), and race and ethnicity (variable: PopWhiteNonHispanic) were controlled for. Overall, the model is statistically significant ($p = 0.000$, see Table 4).

The model shows a very strong relationship between the independent variables and the number of Suboxone providers available in each state ($R = 0.867$, see Table 3). Additionally, in this model 71.9% of the variance in the dependent variable can be explained by the independent variables (Adjusted R-Square = 0.719, see Table 3). Of the independent and control variables in this one-tailed test, Table 5 shows that two variables were statistically significant: population size ($p = 0.002/2 = 0.001$) and the number of heroin and opioid overdose-related deaths ($p = 0.001/2 = 0.000$). Income status ($p = 0.841/2 = 0.4205$), age ($p = 0.845/2 = 0.4225$), gender ($p = 0.270 / 2 = 0.135$), and race and ethnicity ($p = 0.468/2 = 0.234$) were statistically insignificant in determining the number of Suboxone physicians available in a given state (Szafran, 2012).

In this model, Table 5 shows that overdose-related deaths have a stronger effect on Suboxone physician availability (Beta = 0.475) than does population size (Beta = 0.434). The model predicts that for every additional resident in a state, the number of Suboxone physicians will be increased by 0.000004514. In practical terms, this estimate means that for every 221,534 residents in a given state, one additional Suboxone physician is expected to be available in that

state. The model also predicts that for every additional heroin and opioid overdose-related death, the number of Suboxone physicians in a given state will be increased by 0.112. In practical terms, this estimate means that for every nine heroin and opioid overdose-related deaths in a given state, one additional Suboxone physician is expected to be available in that state (Szafran, 2012). Graphical representations of the relationship between income status and overdose-related deaths and between income status and population size can be found in Appendix E.

Table 2. *Variables entered/Removed for all state-level data*

Model	Variables Entered	Variables Removed	Method
1	Overdoses, FPL200, Pop18to25, PopWhiteNon Hispanic, PopMales, PopSize[b]		Enter

a. Dependent Variable: SuboxoneMD
b. All requested variables entered

Table 3. *Model summary for all state-level data*

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.867[a]	.752	.719	39.305

a. Predictors: (Constant), Overdoses, FPL200, Pop18to25, PopWhiteNonHispanic, PopMales, PopSize

Table 4. *ANOVA table for all state-level data*

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	206624.099	6	34437.350	22.291	.000[b]
	Residual	67976.411	44	1544.918		
	Total	274600.510	50			

a. Dependent Variable: SuboxoneMD
b. Predictors: (Constant), Overdoses, FPL200, Pop18to25, PopWhiteNonHispanic, PopMales, PopSize

Table 5. *Multi-variable linear regression coefficients for all state-level data*

		Unstandardized Coefficients		Standardized Coefficients		
Model		B	Std. Error	Beta	t	Sig.
1	(Constant)	377.896	399.637		.946	.350
	FPL200	.201	.992	.017	.202	.841
	Pop18to25	1.385	7.026	.015	.197	.845
	PopWhiteNonHispanic	.290	.396	.063	.731	.468
	PopMales	-8.444	7.562	-.094	-1.117	.270
	PopSize	4.514E-6	.000	.434	3.228	.002
	Overdoses	.112	.031	.475	3.555	.001

a. Dependent variable: SuboxoneMD

Regional multi-variable linear regression analysis results. ***Northeast region.*** Tables 6 – 8 show the parts of the model produced by performing a multi-variable linear regression analysis test on data from the Northeast region. The model for the Northeast is not statistically significant ($p = 0.077$, see Table 8). Therefore, factors measured for the states in this region do not present a remarkable relationship (Szafran, 2012).

Table 6. *Variables entered/Removed for northeast region*

Model	Variables Entered	Variables Removed	Method
1	Overdoses, FPL200, Pop18to25, PopWhiteNonHispanic, PopMales, PopSize[b]		Enter

a. Dependent Variable: SuboxoneMD
b. All requested variables entered

Table 7. *Model summary for Northeast region*

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.987[a]	.974	.895	36.573

a. Predictors: (Constant), Overdoses, FPL200, Pop18to25, PopWhiteNonHispanic, PopMales, PopSize

Table 8. *ANOVA table for Northeast Region*

ANOVA[a]						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	98811.089	6	16468.515	12.312	.077[b]
	Residual	2675.133	2	1337.567		
	Total	101486.222	8			

a. Dependent Variable: SuboxoneMD
b. Predictors: (Constant), Overdoses, FPL200, Pop18to25, PopWhiteNonHispanic, PopMales, PopSize

Midwest region. Tables 9 – 12 show the multi-variable linear regression model produced for the Midwest region. The model for this region is statistically significant (p = 0.005, see Table 11). The model shows a very strong relationship between the independent variables and the number of Suboxone physicians available (R = 0.972, see Table 10). Additionally, in the model 87.7% of the variance in the dependent variable (R Square) is explained by the independent variables (Adjusted R Square = 0.877, see Table 10). Table 12 shows that, of the independent and control variables in this two-tailed test, one variable was statistically significant: the number of heroin and opioid overdose-related deaths (p = 0.021). Income status (p = 0.174), age (p = 0.435), gender (p = .0.345), population size (p = 0.388), and race and ethnicity (p = 0.087) were statistically insignificant in predicting the number of Suboxone physicians available for states in this region (Szafran, 2012).

The Midwest model predicts that for every additional heroin and opioid overdose-related death, the number of Suboxone physicians in a given state will be increased by 0.102. In practical terms, this estimate means that for every 10 heroin and opioid overdose-related deaths in a given state, one additional Suboxone physician is expected to be available in that state. This estimate is slightly lower than the estimate of the effect of overdose-related deaths on Suboxone physician availability at the national-level (Szafran, 2012).

Table 9. *Variables entered/Removed for Midwest region*

Model	Variables Entered	Variables Removed	Method
1	Overdoses, FPL200, Pop18to25, PopWhiteNon Hispanic, PopMales, PopSize[b]		Enter

a. Dependent Variable: SuboxoneMD
b. All requested variables entered

Table 10. *Model summary for Midwest region*

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.972[a]	.944	.877	19.346

a. Predictors: (Constant), Overdoses, FPL200, Pop18to25, PopWhiteNonHispanic, PopMales, PopSize

Table 11. *ANOVA table for Midwest region*

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	31475.306	6	5245.884	14.016	.005[b]
	Residual	1871.361	5	374.272		
	Total	33346.667	11			

a. Dependent Variable: SuboxoneMD
b. Predictors: (Constant), Overdoses, FPL200, Pop18to25, PopWhiteNonHispanic, PopMales, PopSize

Table 12. *Multi-variable linear regression coefficients for Midwest region*

		Unstandardized Coefficients		Standardized Coefficients		
Model		B	Std. Error	Beta	t	Sig.
1	(Constant)	-1575.284	1253.887		-1.256	.265
	FPL200	3.570	2.254	.231	1.583	.174
	Pop18to25	-8.863	10.441	-.139	-.849	.435
	PopWhiteNonHispanic	3.154	1.484	.367	2.125	.087
	PopMales	26.268	25.188	.277	1.043	.345
	PopSize	5.110E-6	0.000	.378	.944	.388
	Overdoses	.102	0.038	.797	2.709	.042

a. Dependent variable: SuboxoneMD

South region. Tables 13 – 16 show the multi-variable linear regression model produced for the South region. This model is statistically significant (p = 0.001, see Table 15). The model shows a very strong relationship between the independent variables and the number of Suboxone physicians available (R = 0.925, see Table 14). Additionally, in the model 77% of the variance

in the dependent variable (R Square) is explained by the independent variables (Adjusted R Square = 0.770, see Table 14). Table 16 shows that, of the independent and control variables in this two-tailed test, one variable was statistically significant: the number of heroin and opioid overdose-related deaths (p = 0.050). Again, income status (p = 0.593), age (p = 0.450), gender (p = 0.395), population size (p = 0.559), and race and ethnicity (p = 0.106) were statistically insignificant in predicting the number of Suboxone physicians available in the South region (Szafran, 2012).

The model for the South region predicts that for every additional heroin and opioid overdose-related death, the number of Suboxone physicians in a given state will be increased by 0.183. In practical terms, this estimate means that for every six heroin and opioid overdose-related deaths in a given state, one additional Suboxone physician is expected to be available in that state (Szafran, 2012). This estimate would result in a 63.39% increase in available Suboxone physicians over the number of physicians predicted at the national-level and a 79.41% increase in available Suboxone physicians over the number of physicians predicted in the Midwest region based on the same variable (Overdoses).

Table 13. *Variables entered/Removed for South region*

Model	Variables Entered	Variables Removed	Method
1	Overdoses, FPL200, Pop18to25, PopWhiteNon Hispanic, PopMales, PopSize[b]		Enter

a. Dependent Variable: SuboxoneMD
b. All requested variables entered

Table 14. *Model summary for South region*

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.925[a]	.856	.770	22.942

a. Predictors: (Constant), Overdoses, FPL200, Pop18to25, PopWhiteNonHispanic, PopMales, PopSize

Table 15. *ANOVA table for South region*

ANOVA[a]						
Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	31312.838	6	5218.806	9.916	.001[b]
	Residual	5263.279	10	526.328		
	Total	36576.118	16			

a. Dependent Variable: SuboxoneMD
b. Predictors: (Constant), Overdoses, FPL200, Pop18to25, PopWhiteNonHispanic, PopMales, PopSize

Table 16. *Multi-variable linear regression coefficients for South region*

		Unstandardized Coefficients		Standardized Coefficients		
Model		B	Std. Error	Beta	t	Sig.
1	(Constant)	653.489	1034.595		.632	.542
	FPL200	.710	1.288	.091	.551	.593
	Pop18to25	9.733	12.381	.178	.786	.450
	PopWhiteNonHispanic	1.655	.931	.477	1.778	.106
	PopMales	-18.311	20.618	-.203	-.888	.395
	PopSize	1.513E-6	.000	.217	.604	.559
	Overdoses	.183	.058	.974	3.186	.010

a. Dependent variable: SuboxoneMD

West region. Tables 17 – 20 show the multi-variable linear regression model produced for the West region. This model is also statistically significant (p = 0.001, see Table 19). The model shows a very strong relationship between the independent variables and the number of Suboxone providers available (R = 0.973, see Table 18). In the model 89.5% of the variance in the dependent variable (R Square) is explained by the independent variables (Adjusted R Square = 0.895, see Table 18). However, in this two-tailed test, no individual variables produced a significant impact on the number of Suboxone physicians available. Income status (p = 0.431), age (p = 0.965), population size (p = 0.242), gender (p = 0.646), overdose-related deaths (p = 0.463), and race and ethnicity (p = 0.838) were all statistically insignificant in the model for the

West region. These findings indicate that there might be some interaction variable that was not used in this model that could better explain the relationship between the independent variable, the controls, and the dependent variable for this region (Szafran, 2012).

Table 17. *Variables entered/Removed for West region*

Model	Variables Entered	Variables Removed	Method
1	Overdoses, FPL200, Pop18to25, PopWhiteNon Hispanic, PopMales, PopSize[b]		Enter

a. Dependent Variable: SuboxoneMD
b. All requested variables entered

Table 18. *Model summary for West region*

Model	R	R Square	Adjusted R Square	Std. Error of the Estimate
1	.973[a]	.948	.895	26.580

a. Predictors: (Constant), Overdoses, FPL200, Pop18to25, PopWhiteNonHispanic, PopMales, PopSize

Table 19. *ANOVA table for West region*

Model		Sum of Squares	df	Mean Square	F	Sig.
1	Regression	76600.195	6	12766.699	18.071	.001[b]
	Residual	4238.882	6	706.480		
	Total	80839.077	12			

a. Dependent Variable: SuboxoneMD
b. Predictors: (Constant), Overdoses, FPL200, Pop18to25, PopWhiteNonHispanic, PopMales, PopSize

Table 20. *Multi-variable linear regression coefficients for West region*

Coefficients[a]						
		Unstandardized Coefficients		Standardized Coefficients		
Model		B	Std. Error	Beta	t	Sig.
1	(Constant)	442.862	791.220		.560	.596
	FPL200	-1.878	2.225	-.109	-.844	.431
	Pop18to25	.599	13.208	.005	.045	.965
	PopWhiteNonHispanic	-.103	.483	-.025	-.214	.838
	PopMales	-7.572	15.680	-.067	-.483	.646
	PopSize	4.772E-6	.000	.591	1.297	.242
	Overdoses	.114	.145	.378	.784	.463

a. Dependent variable: SuboxoneMD

Summary

This chapter reviewed the sources for the data set compiled for this study and the findings from that data set as retrieved from SPSS. The study included a total of 50 U.S. states and the District of Columbia, for a total of 51 cases. Regional groupings of the states were assigned based on the regional classifications of the U.S. Department of Commerce, Economics, and Statistics Administration. Income status information was collected from the Current Population Survey (CPS). Information on age, gender, and race and ethnicity was retrieved from the American Community Survey (ACS). Data on Suboxone providers was collected from the SAMHSA online database. Data on population size was retrieved from the National and State Populations Estimate data set. Lastly, information on heroin and opioid overdose-related deaths was collected from the Multiple Cause of Death CDC WONDER database. There were no missing data points for any case. All data used were collected for the year 2014.

Information from a means procedure in SPSS showed a high level of variance among cases for: the number of Suboxone providers available (SuboxoneMD), the number of heroin and opioid overdose-related deaths (Overdoses), and population size (PopSize). Moderate levels of variance were observed for: income status (FPL200) and race/ethnicity (PopWhiteNonHispanic). Low levels of variance were observed for variables of age (Pop18to25) and gender (PopMale). Multi-variable linear regression analysis was performed to summarize the relationship between the independent, moderating, confounding, and dependent variables in this study. Nationally, the model produced indicated that population size and the number of heroin and opioid overdose-related deaths are statistically significant in estimating the number of Suboxone physicians in a given state. Regionally, the models produced indicated that, depending on the region, the number of heroin and opioid overdose-related deaths is the only identified statistically significant

variable in determining the number of Suboxone physicians in a given state. The next (and final) chapter will discuss these results as they pertain to the research questions of interest in this study. Also, in the next chapter, implications of the findings and recommendations for future studies will be presented.

Discussion

In this chapter, the research questions posed for this critical analysis study of secondary data will be discussed. Those research questions will be used as a guide to interpreting the data of the multi-variable linear regression models that were produced in SPSS to explore the relationship between income status and access to Suboxone treatment for low-income heroin and opioid abusers within the United States. First, the questions for this study will be reviewed and the answers to those questions, as indicated by the statistical analyses performed, will be provided. Then, conclusions based on the findings from this study will be discussed. Next, recommendations for future research and implications of this study will be presented. Finally, a summary of the study in its entirety will be provided.

Research Questions

There were two research questions posed for this study to explore the relationship between income status and access to Suboxone treatment for low-income heroin and opioid abusers within the United States. Those two questions were designed to answer the overall question of whether or not there is a bias against low-income heroin and opioid abusers in relation to having access to Suboxone treatment for their addictions. Answering these questions will allow the researcher to compare claims made in popular media regarding an income-based access barrier to Suboxone treatment to objective, state-level data that have been statistically analyzed. A confirmation of income status as a barrier to access to Suboxone treatment would present a call to action to public health officials to intervene and to reduce the health inequity that would exist. A failure to confirm those claims would raise demands for further proof of an income-based barrier to access to Suboxone treatment. Additional findings obtained through this

investigation might further help to explain disparities in access to Suboxone care within the United States.

Research question one. Controlling for age, race/ethnicity, gender, population size, and the number of heroin and opioid overdoses, what is the relationship between income status and access to Suboxone treatment in the United States?

It was hypothesized that, controlling for age, race/ethnicity, gender, population size, and the number of heroin and opioid overdoses, there would be a negative or no relationship between income status and access to Suboxone treatment in the United States. This alternate hypothesis was tested against the null hypothesis that, controlling for the same factors, there is a positive relationship between income status and access to Suboxone treatment in United States. Table 5 shows that income level (FPL200) increased the number of Suboxone physicians by 0.201 for each percentage increase in the number of residents living within 200% of the federal poverty level. This finding is in-agreement with the null hypothesis. More importantly, since that estimate is not statistically significant ($p = 0.841/2 = 0.421$), the researcher must accept the null hypothesis. At a significance level of 5% ($p = 0.050$) there is not enough evidence to suggest that income status has a negative or no impact on access to Suboxone treatment within the United States. The lack of a relationship between the two variables in this data set can also be seen in the graph provided in Appendix E.

Research Question Two. How is the relationship between income status and access to Suboxone treatment affected by U.S. region?

It was hypothesized that, controlling for age, race/ethnicity, gender, population size, and the number of heroin and opioid overdoses, region would have an effect on the relationship between income status and access to Suboxone treatment in the United States. This alternate

hypothesis was tested against the null hypothesis that, controlling for the same factors, region would not have an effect on the relationship between income status and access to Suboxone treatment in U.S. states. Table 8 shows that the overall model for the Northeast region was not significant ($p = 0.077$). Table 12 shows that income status ($B = 3.570$) was not a significant predictor of access to Suboxone treatment in the Midwest region ($p = 0.174$). Table 16 indicates that income status ($B = 0.790$) was not a significant predictor of access to Suboxone treatment in the South region, either ($p = 0.593$). Lastly, Table 20, also indicates that income status ($B = -1.878$) was not a significant predictor of access to Suboxone treatment in the West region ($p = 0.431$). Based on these findings, the researcher must again accept the null hypothesis. At a significance level of 5% ($p = 0.050$) there is not enough evidence to suggest that region has an effect on the relationship between income status and access to Suboxone treatment within the United States (Szafran, 2012).

Conclusions

Using state-level information extracted from databases of the U.S. Census Bureau, the Centers for Disease Control and Prevention, and the Substance Abuse and Mental Health Services Administration, there is a lack of evidence to support the claim that access to Suboxone treatment within the United States is compromised for low-income residents. Furthermore, when looking at the data on a smaller, regional scale, there is still a lack of evidence to support the claim that being low-income negatively impacts access to Suboxone treatment for heroin and opioid abusers within the United States. Additionally, the linear regression models produced by SPSS estimate that income status (as defined in this study), albeit statistically insignificant, would increase the number of Suboxone physicians on a national level and regionally, with the

exception of the West region (in which income status is predicted to decrease the number of Suboxone physicians that are available).

Recommendations and Implications

This study focused on state-level data to determine the size and magnitude of the relationship between income status and access to Suboxone treatment for low-income heroin and opioid abusers within the United States. Future research might consider analyzing the same variables at the metropolitan-area level or city-level using a random sampling technique. Performing such an analysis might provide stronger evidence to support the claim made by popular media that there is a barrier to Suboxone treatment for low-income heroin and opioid abusers. Performing such an analysis might also provide stronger evidence to refute that claim. Additionally, the linear regression model for the West region, which was significant overall ($p = 0.001$) did not indicate that any identified independent variable was statistically significant in determining the dependent variable. This occurrence might indicate that there is some other variable that was not controlled for in this study that has an effect, at the region-level, on the relationship between income status and access to Suboxone treatment (Szafran, 2012). Future research might be dedicated to identifying that additional variable to help provide statistical significance to at least one independent variable in the model. Lastly, this study does not consider the effectiveness of Suboxone treatment among low-income heroin and opioid abusers, nor does it consider access to or the effectiveness of other medical treatments for low-income heroin and opioid abusers, such as naltrexone (which is not a controlled substance) (Volkow, 2014). These areas of study present additional opportunities for future research on the topic of treatment options for heroin and opioid addiction for low-income patients.

The findings of this study indicate that there is a lack of evidence at the state-level to show that low-income status has a negative impact on access to Suboxone treatment within the United States. This conclusion reflects positively on the DEA and its current Suboxone-prescribing guidelines. Furthermore, the findings from this study suggest that there is not an access-related health inequity present for low-income heroin and opioid abusers who seek treatment for their addiction with the drug Suboxone. Additional findings from the study show that population size and the number of heroin and opioid overdose-related deaths at the state-level have a positive relationship with access to Suboxone treatment. Additionally, at the national-level, where population size and the number of overdoses were both identified as statistically significant factors within the linear regression model, the number of heroin and opioid overdose-related deaths had the larger effect on estimating the number of Suboxone physicians available. This occurrence is deserving of further investigation. First, the temporal sequence between heroin and opioid overdose-related deaths and the availability of Suboxone treatment would need to be determined. If it is discovered that increased access to Suboxone treatment precedes increased overdose-related deaths, further monitoring of patients taking Suboxone might be required. Alternatively, if it is discovered that Suboxone treatment increases in response to increases in overdose-related deaths, health officials might want to determine a more proactive means of disseminating effective care to heroin and opioid abusers in addition to researching the possible social causes of the overdose deaths (e.g.: unable to obtain treatment, ineffective treatment received in the past, etc…). Such an approach would be desired to reduce the number of overdose-related deaths that could have been prevented had effective treatment been available prior to the death(s) in-question.

Summary

The purpose of this critical analysis study was to determine if there is a barrier to access to Suboxone treatment for low-income heroin and opioid abusers living within the United States. A post-positivist worldview was assumed to conduct this quantitative study and determine, objectively, if an income-based barrier to care exists. To conduct this investigation, secondary data from the year 2014 were collected from the databases of the U.S. Census Bureau (namely, the American Community Survey, the Current Population Survey, and the National and State Populations Estimate data set), the U.S. Centers for Disease Control and Prevention (namely, the Multiple Cause of Death database), and the Substance Abuse and Mental Health Services Administration (namely, the DATA-certified Suboxone providers database). Data from these secondary sources were used to determine the impact of low-income status (the percentage of residents living at or below 200% of the federal poverty level in a state) on access to Suboxone treatment (the number of physicians authorized to treat Suboxone patients in a state). Factors of age (the percentage of residents between the ages of 18 and 25 in a state), gender (the percentage of male residents in a state), overdoses (the number of heroin and opioid overdose-related deaths in a state), population (the number of residents in a state), and race/ethnicity (the percentage of non-Hispanic, White residents in a state) were controlled for. A region was also recorded for each state. Using the collected data, a series of multi-variable linear regression models were produced in SPSS to answer the research questions for this study.

The first research question for this study was: Controlling for age, gender, population size, race/ethnicity, and overdoses, what is the relationship between income status and access to Suboxone treatment within the United States? Results from the model for this data (see Table 5) show that, at a 95% confidence level, there is no statistically significant relationship between

income status and access to Suboxone treatment in the United States. However, there are statistically significant relationships between population size and access to Suboxone treatment and overdoses and access to Suboxone treatment. Moreover, for every additional 221,534 people in a state, the number of Suboxone physicians is expected to increase by one physician; and for every nine heroin and opioid overdose-related deaths in a state, the number of Suboxone physicians is expected to increase by one physician (Szafran, 2012).

The second research question for this study was: Controlling for age, gender, population size, race/ethnicity, and overdoses, what effect does region have on the relationship between income status and access to Suboxone treatment within the United States? One model was produced for each region: Northeast, Midwest, South, and West. After interpreting all models, it was concluded that region did not have a statistically significant effect on the relationship between income status and access to Suboxone treatment, either. However, heroin and opioid overdose-related deaths were identified as statistically significant factors influencing access to Suboxone treatment in the Midwest and South regions. In the Midwest, for every 10 heroin and opioid overdose-related deaths, the number of Suboxone physicians is expected to increase by one physician. In the South, for every six heroin and opioid overdose-related deaths, the number of Suboxone physicians is also expected to increase by one physician (Szafran, 2012).

Although none of the null hypotheses were rejected in this study, the lack of evidence supporting the existence of a barrier to Suboxone care for low-income heroin and opioid abusers is a welcomed finding. This finding indicates that, at the state-level, the DEA's process for issuing Suboxone-prescribing licenses does not appear to present a health inequity for low-income heroin and opioid abusers. Examining the data from a smaller unit of analysis, such as metropolitan areas or cities, might reveal results in support of the findings of this study, or in

contradiction to the findings of this study. Additionally, further research to determine the effectiveness of Suboxone treatment for low-income heroin and opioid abusers might be beneficial. Research to examine access to and the effectiveness of non-controlled heroin and opioid addiction medication (such as naltrexone) for low-income heroin and opioid abusers might also be beneficial. Lastly, further investigation into the temporal sequence of heroin and opioid overdose-related deaths and access to Suboxone treatment might provide additional guidance for public health officials to closely monitor Suboxone treatment interventions or to become more proactive in administering effective medically-assisted care to those who are addicted to heroin and/or prescription opioids.

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Appendices

Appendix A: Regional groupings for U.S. states

(U.S. Census Bureau, n.d., *Census regions and divisions*)

NORTHEAST REGION	
▪ Connecticut ▪ Maine ▪ Massachusetts ▪ New Hampshire ▪ New Jersey	▪ New York ▪ Pennsylvania ▪ Rhode Island ▪ Vermont
SOUTH REGION	
▪ Alabama ▪ Arkansas ▪ Delaware ▪ District of Columbia ▪ Florida ▪ Georgia ▪ Kentucky ▪ Louisiana ▪ Maryland	▪ Mississippi ▪ North Carolina ▪ Oklahoma ▪ South Carolina ▪ Tennessee ▪ Texas ▪ Virginia ▪ West Virginia
MIDWEST REGION	
▪ Illinois ▪ Indiana ▪ Iowa ▪ Kansas ▪ Michigan ▪ Minnesota	▪ Missouri ▪ Nebraska ▪ North Dakota ▪ Ohio ▪ South Dakota ▪ Wisconsin
WEST REGION	
▪ Alaska ▪ Arizona ▪ California ▪ Colorado ▪ Hawaii ▪ Idaho ▪ Montana	▪ Nevada ▪ New Mexico ▪ Oregon ▪ Utah ▪ Washington ▪ Wyoming

Appendix B: ICD-10 Multiple cause of death codes for Heroin and Opioid overdoses

(CDC, n.d., *Multiple cause of death*)

PRIMARY CODES (DRUG POISONING)

- X40–X44
- X60–X64
- X85
- Y10–Y14

SECONDARY CODES (HEROIN OVERDOSE)

- T40.1

SECONDARY CODES (OPIOID OVERDOSE)

- T40.2
- T40.3
- T40.4

Appendix C: Raw Data Set for Access to Suboxone Study

(SAMHSA, 2016; U.S. Census Bureau, 2015a; U.S. Census Bureau, 2014; CDC, n.d., *Multiple cause of death*; U.S. Census Bureau, n.d., *ACS demographic and housing estimates*; U.S. Census Bureau, n.d., *Census regions and divisions*)

State	Region	FPL200	SuboxoneMD	Pop18to25	PopWhiteNonHispanic	PopMale	PopSize	Overdoses
Alabama	South	39.30%	52	11.19%	66.19%	48.49%	4,849,377	188
Alaska	West	27.90%	18	11.60%	61.94%	52.19%	736,732	39
Arizona	West	40.60%	44	11.29%	56.21%	49.67%	6,731,484	324
Arkansas	South	40.00%	15	10.95%	73.39%	49.11%	2,966,369	62
California	West	34.90%	306	11.67%	38.45%	49.68%	38,802,500	1,047
Colorado	West	29.50%	46	11.01%	68.99%	50.18%	5,355,866	325
Connecticut	Northeast	22.00%	57	10.82%	68.82%	48.74%	3,596,677	327
Delaware	South	29.00%	19	10.94%	63.69%	48.41%	935,614	82
District of Columbia	South	32.10%	12	14.29%	35.84%	47.34%	658,893	39
Florida	South	38.90%	177	10.20%	55.81%	48.88%	19,893,297	873
Georgia	South	35.80%	69	11.27%	54.34%	48.83%	10,097,343	388
Hawaii	West	27.80%	12	10.03%	22.97%	50.36%	1,419,561	29
Idaho	West	31.30%	9	10.84%	82.81%	50.12%	1,634,464	34
Illinois	Midwest	30.80%	67	10.97%	62.29%	49.06%	12,880,580	897
Indiana	Midwest	34.50%	54	11.45%	80.30%	49.23%	6,596,855	316
Iowa	Midwest	27.40%	7	11.57%	87.10%	49.58%	3,107,126	63
Kansas	Midwest	30.20%	23	11.43%	76.76%	49.71%	2,904,021	116
Kentucky	South	39.50%	127	10.93%	85.37%	49.19%	4,413,457	342
Louisiana	South	44.40%	52	11.41%	59.33%	48.91%	4,649,676	121
Maine	Northeast	31.00%	47	9.61%	93.76%	48.90%	1,330,089	70
Maryland	South	22.90%	115	10.68%	52.62%	48.43%	5,976,407	695
Massachusetts	Northeast	28.30%	197	11.76%	74.28%	48.43%	6,745,408	704
Michigan	Midwest	31.90%	97	11.43%	75.81%	49.09%	9,909,877	655
Minnesota	Midwest	23.40%	42	10.59%	81.44%	49.68%	5,457,173	214
Mississippi	South	46.80%	20	11.58%	57.26%	48.55%	2,994,079	66

State	Region	FPL200	SuboxoneMD	Pop18to25	PopWhiteNonHispanic	PopMale	PopSize	Overdoses
Missouri	Midwest	27.50%	36	11.02%	80.12%	49.00%	6,063,589	541
Montana	West	32.40%	3	10.99%	86.73%	50.23%	1,023,579	36
Nebraska	Midwest	29.40%	13	11.34%	80.49%	49.67%	1,881,503	19
Nevada	West	37.60%	14	10.34%	51.50%	50.37%	2,839,099	157
New Hampshire	Northeast	20.10%	21	10.79%	91.28%	49.34%	1,326,813	243
New Jersey	Northeast	25.40%	78	10.14%	56.85%	48.75%	8,938,175	434
New Mexico	West	41.20%	44	11.15%	38.91%	49.51%	2,085,572	181
New York	Northeast	33.60%	347	11.47%	56.53%	48.46%	19,746,227	889
North Carolina	South	36.00%	75	10.79%	64.09%	48.72%	9,943,964	596
North Dakota	Midwest	24.00%	3	13.96%	86.60%	50.91%	739,482	15
Ohio	Midwest	34.50%	199	10.80%	80.11%	48.89%	11,594,163	1,407
Oklahoma	South	35.80%	27	11.31%	67.02%	49.53%	3,878,051	210
Oregon	West	31.80%	53	10.55%	77.04%	49.46%	3,970,239	234
Pennsylvania	Northeast	28.40%	193	10.94%	77.88%	48.84%	12,787,209	715
Rhode Island	Northeast	27.60%	23	12.46%	74.54%	48.40%	1,055,173	118
South Carolina	South	36.70%	42	10.98%	63.85%	48.62%	4,832,482	186
South Dakota	Midwest	29.80%	4	11.16%	83.04%	50.26%	853,175	23
Tennessee	South	39.10%	117	10.92%	74.64%	48.72%	6,549,352	364
Texas	South	37.20%	112	11.48%	43.53%	49.63%	26,956,958	652
Utah	West	29.60%	36	12.85%	79.34%	50.27%	2,942,902	163
Vermont	Northeast	23.20%	23	11.87%	93.53%	49.25%	626,562	50
Virginia	South	26.00%	91	10.95%	63.14%	49.15%	8,326,289	441
Washington	West	30.30%	123	10.67%	70.39%	49.91%	7,061,530	286
West Virginia	South	40.90%	44	10.45%	92.49%	49.33%	1,850,326	165
Wisconsin	Midwest	27.00%	39	10.99%	82.21%	49.65%	5,757,564	272
Wyoming	West	26.80%	2	11.10%	84.10%	51.02%	584,153	31

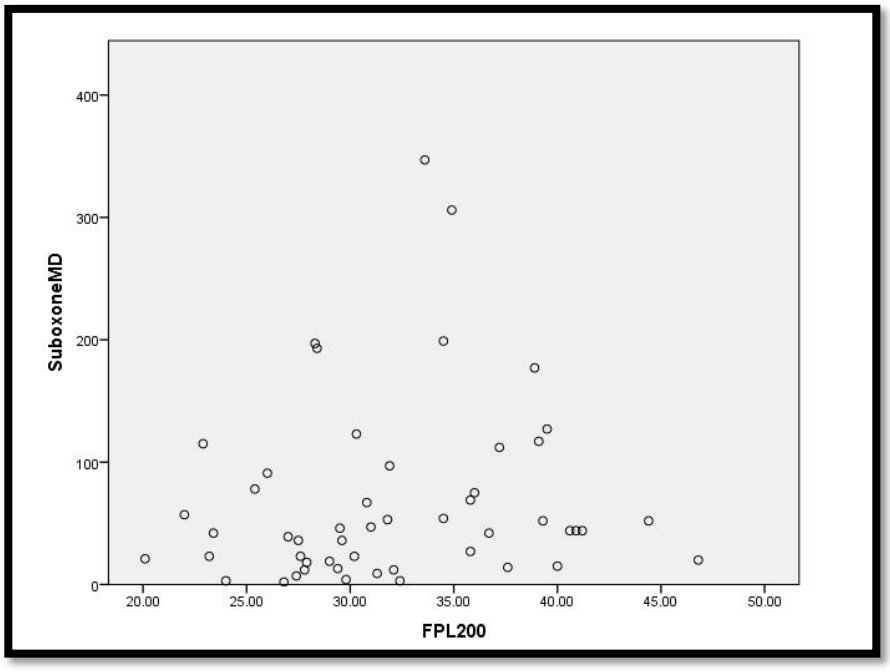
Appendix D: Correlation Strengths Table

(Szafran, 2012, p. 199)

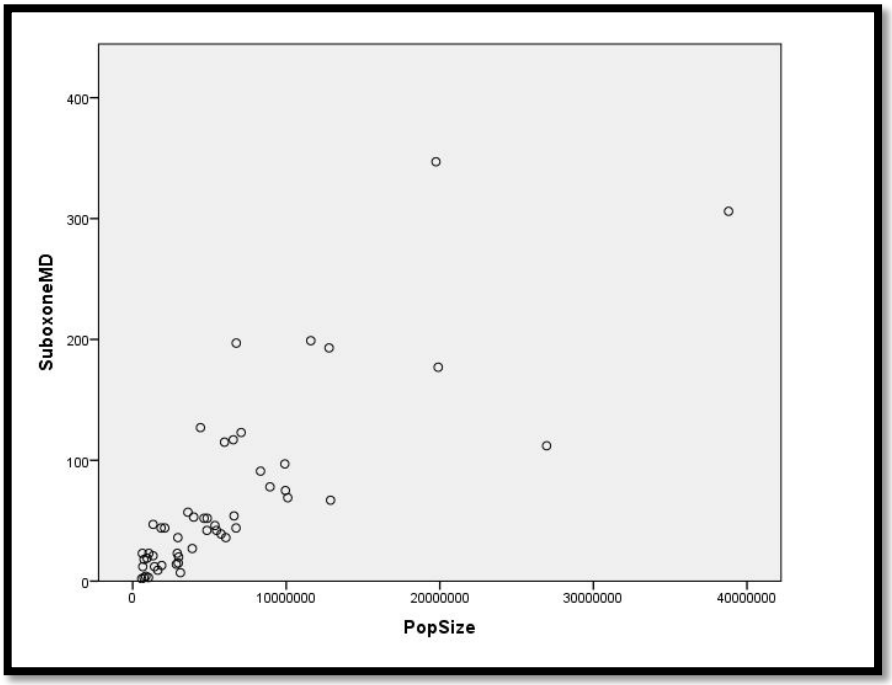
Absolute value of correlation coefficient is:	**Strength of Correlation**
0.000	No relationship
0.001 – 0.199	Weak
0.200 – 0.399	Moderate
0.400 – 0.599	Strong
0.600 – 0.999	Very Strong
1.000	Perfect relationship

Appendix E: Correlation Graphs at the National Level

Graph A: Income Status (FPL200) and Access to Suboxone Treatment (SuboxoneMD)



Graph B: Population Size (PopSize) and Access to Suboxone Treatment (SuboxoneMD)



GraphC: Heroin and Opioid Overdose-related Deaths (Overdoses) and Access to Suboxone Treatment (SuboxoneMD)