

Treating the Opioid Epidemic: Innovations for Expanding Access to Buprenorphine in the United States

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ABSTRACT

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The opioid epidemic in the United States has been a growing problem over the past two decades. There were 2.1 million people in the United States who met the clinical criteria for an opioid use disorder in 2016. Of these people, less than a third of them received evidence based treatment. This thesis focuses on one of the promising forms of treatment for opioid use disorder: medically assisted maintenance (MAT) using buprenorphine. This thesis aimed to answer the following question. How well do the innovative ways for providing medically assisted treatment using buprenorphine address the current barriers to access in the United States?

In order to answer this question, the thesis is broken into three parts. The first chapter focuses on the evidence supporting buprenorphine as an effective treatment for opioid use disorder. The second chapter focuses on identifying the current barriers to accessing buprenorphine for MAT in the United States. The third chapter focuses on four innovative methods for providing treatment with buprenorphine: project ECHO, hub and spoke, collaborative care, and hospital initiation of buprenorphine. These innovations were assessed based on their ability to address some of the key barriers to access that were identified in chapter 2 of the thesis.

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Introduction:

The opioid crisis in the United States has been a growing problem over the past two decades. While at times incredibly valuable for their analgesic properties, opioids also have habit forming properties that put the people using them at risk of developing an opioid use disorder. In 2017, an estimated 49,068 people in the US died from opioid overdoses.¹ Despite the growing national attention and attempts to reduce the damage of the opioid epidemic in recent years, the number of opioid overdoses has been growing annually, with a 28% increase in the number of overdoses between 2015 and 2016.² The opioid epidemic has also resulted in approximately 2.1 million people in the United States reaching the clinical criteria for diagnosis of an opioid use disorder (OUD) in 2016.³ Of those with an opioid use disorder, only 29.9% received evidence based treatment.⁴ The root cause of this epidemic is multifaceted and complex, which can complicate attempts to address the epidemic. While the problem of opioids is considerable, there are promising treatments for people with opioid use disorders. Pharmacological treatment of opioid use disorder, called medically assisted treatment (MAT), is one of these promising and effective form of treatment. Despite the known efficacy of this type of treatment, there continue to be problems with ensuring access to MAT for patients in the US. This thesis will focus on efforts to expand access to medically assisted treatment using buprenorphine. The thesis will attempt to answer the following question: How well do the innovative ways for providing medically assisted treatment using buprenorphine address the current barriers to access in the

¹ National Center on Health Statistics, “National Overdose Deaths from Select Prescription and Illicit Drugs,” August 2018.”

² National Center on Health Statistics.

³ SAMHSA, *Key Substance Use and Mental Health Indicators in the United States: Results from the 2017 National Survey on Drug Use and Health*

⁴ SAMHSA.

United States? This thesis will address this question in three chapters. Chapter 1 will focus on why providing access to treatment of opioid use disorder with buprenorphine is a necessary and effective response to the opioid epidemic. Chapter 2 will assess some of the barriers to accessing this form of treatment. Chapter 3 will analyze some of the innovations in providing treatment for OUD with buprenorphine and how these innovations address the current barriers to access.

Chapter 1: Why Increasing Access to MAT is a Promising Response to the Opioid Epidemic

History of the Opioid Epidemic in the United States:

Since the discovery that opioids have analgesic and sedative properties, they have had both medicinal benefits and potentially harmful habit forming properties. Opioids have been present in American medicine for most of its history. One of the earliest forms of an opioid used in US medicine was morphine. Later, heroin was developed and popularized by Bayer Pharmaceutical in 1874.⁵ At that time, its purported uses included analgesic properties, cough suppression, and treatment for morphine addiction.⁶ The current opioid crisis is not the first time that the US has experienced an opioid epidemic. In the 1880s, the United States went through its first opioid epidemic. The rate of opioid prescription had been increasing since the mid 19th century mainly due to its widespread use as treatment for cough, diarrhea, and chronic pain. The habit forming nature of the drug was poorly understood and few alternative treatments were available. By the 1920s, the number of opioid overdose deaths and new cases of opioid addictions had decreased, mainly attributable to the development of alternative treatments and an

⁵ Wilkerson et al., “The Opioid Epidemic in the United States.”

⁶ Wilkerson et al., “The Opioid Epidemic in the United States.”

increase in education amongst prescribers of the possible dangerous effects of opioid use.⁷

Although the extent of opioid prevalence had subsided by the early 20th century, the problem continued to ruminate in the background and, beginning in the 1990s, developed into one of the worst drug epidemics seen in the United States.

The opioid problem in the US began to worsen significantly in the 1990s and early 2000s. In 1986, a case study of 38 chronic pain patients claimed to show that opioids could safely be used in treatment of chronic pain.⁸ At that time, the addictive effects of newer opioids were not well understood and opioids were presented as a safe and effective treatment for chronic pain. Even when these addictive affects were better understood, the pharmaceutical companies and physicians did not effectively communicate the potential for addiction to their patients. In the 1990's a movement called "pain as the 5th vital sign" was widely popularized. The connotation of this campaign implied that pain was vital to health in the same way as other vitals such as blood pressure or body temperature. This movement incentivized doctors to aggressively treat pain and introduced pain reduction as a metric for clinical success.⁹ The rate of prescriptions for opioid more than quadrupled from 1996 to 2013. While increasing the access to opioids in an attempt to relieve pain was well intended, the increase had the unforeseen consequence of a concurrent quadrupling in the number of opioid overdoses in the United States. In 2017, 49,068 people had died from an opioid overdose and approximately 2,110,000 Americans were living with a substance use disorder related to opioids.^{10 11}

⁷ Wilkerson et al.

⁸ Portenoy and Foley, "Chronic Use of Opioid Analgesics in Non-Malignant Pain."

⁹ Wilkerson et al., "The Opioid Epidemic in the United States."

¹⁰ National Center on Health Statistics, "National Overdose Deaths from Select Prescription and Illicit Drugs," August 2018."

¹¹ Center for Behavioral Health Statistics and Quality, 2017 National Survey on Drug Use and Health: Detailed Tables.

With 2.1 million Americans who have an opioid use disorder, it is imperative that evidence based treatment for OUD is widespread and easily accessible. One promising form of treatment is medically assisted treatment with buprenorphine or a buprenorphine-naltrexone combination. The history of the opioid epidemic helps to emphasize several lessons that are important when assessing the efficacy of increasing access to this form of MAT. While opioids are an essential medication for pain management, a lack of regulation, disregard for the potential risks, and common medical practices such as the “pain as the 5th vital sign” likely contributed to the unforeseen negative consequences of increasing access to opioids. In a similar way, MAT is an essential medication for treating opioid use disorder, but it is imperative that access be implemented in a way that both maximizes the benefits of the medication and minimizes its potential risks. One of the ways to increase the benefits of MAT treatment while mitigating the risks is to implement system based supports within the medical community. There are many models of providing this type of treatment that have been develop in recent years that aim to increase access to MAT in a way that also reduces any potential negative outcomes.

Introduction to Opioid Use Disorder and Medically Assisted Treatment:

There is significant unmet need for effective treatment of opioid use disorders. Medically assisted treatment is the use of pharmaceuticals to provide treatment for an opioid use disorder. There are currently three FDA approved pharmaceutical treatments for opioid use disorder: buprenorphine, methadone, and naltrexone. Both buprenorphine and methadone are opioid agonists, and they both activate the mu-opioid receptor. Long term use of either of these medications has been shown to retain patients and reduce the occurrence of illicit drug use better

than non-pharmaceutical based programs.¹² These medications are a promising form of treatment for OUD, which has been historically difficult to treat. While these medication can be an necessary tool for recovery, it is important to acknowledge that both buprenorphine and methadone are forms of opioids. Long term use of these medications can cause physical dependence and stopping these medications can result in withdrawal symptoms. In addition, these medications are most effective when used in long term maintenance, and they do not necessarily lead to a patient weaning off of opioids entirely. Treating an opioid use disorder with opioids may sound counterintuitive, but both buprenorphine and methadone work to reduce cravings, prevent withdrawal symptoms, and reduce illicit opioid use . The effect of methadone and buprenorphine on the brain differs from the effect of other opioids such as heroin, fentanyl, or oxytocin. While buprenorphine and methadone prevent withdrawal symptoms and cravings, they do not produce the type of high or euphoric feelings that other opioids produce. Some of the confusion surrounding the use of opioid agonist treatment originates from the imprecise use of language used to describe patients with an opioid use disorder.

Colloquially, addiction is often used interchangeably with opioid use disorder and physical dependence to opioids; however, addiction, opioid use disorder, and physical dependence are not equivalent. Use of imprecise language can cause confusion when discussing the treatment of an opioid use disorder with opioid agonist maintenance. It is important to note that even though medically assisted treatment does not entail total detoxification, reversal of physical dependence, or abstinence from opioids, it can still enable recovery from an opioid use disorder. Tolerance and withdrawal, two signs of physical dependence on opioids, are possible criteria for an opioid use disorder according to the Diagnostic and Statistical Manual of Mental

¹² Substance Abuse and Mental Health Services Administration, “TIP 63: Medications for Opioid Use Disorder.”

Disorders (5th Edition), but neither of these criteria are met when a patient is taking opioids under medical supervision.¹³ If a patient is taking methadone or buprenorphine solely under medical supervision for maintenance therapy, a tolerance to the medication or withdrawal symptoms upon stopping the medication would not be criteria that could qualify them for a diagnosis of an opioid use disorder. In addition, medically assisted treatment can help to reduce the occurrence of other behaviors that can be criteria for the diagnosis of an opioid use disorder, including craving for opioids and using a greater quantity of opioids than intended.¹⁴

Opioid use disorder is defined by the Diagnostic and Statistical Manual of Mental Disorders (5th Edition), as “a problematic pattern of opioid use leading to clinically significant impairment or distress as manifested by at least two of the following, occurring within a 12-month period:

1. Opioids are often taken in larger amounts or over longer period than was intended.
2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
4. Craving, or a strong desire to use opioids.
5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
6. Continued opioids use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.

¹³ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*..

¹⁴ Substance Abuse and Mental Health Services Administration, “TIP 63: Medications for Opioid Use Disorder.”

8. Recurrent opioid use in situations in which it is physically hazardous.
9. Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance
10. Tolerance, as defined by either of the following:
 - a. A need for markedly increased amounts of opioids to achieve intoxication or desired effects
 - b. A markedly diminished effect with continued use of the same amount of an opioid.

Note: This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

11. Withdrawal, as manifested by either of the following:
 - a. The characteristic opioid withdrawal syndrome
 - b. Opioids are taken to relieve or avoid withdrawal symptoms.

Note: This criterion is not considered to be met for those individuals taking opioids solely under appropriate medical supervision.”¹⁵

Most of the criteria which the DSM-5 uses to diagnose OUD are focused the negative effects that habitual use of opioids can have on a person’s well-being or quality of life. The disorder associated with opioids occurs when a person’s use of opioids causes significant distress in their life. With medically assisted treatment, patients continue to use opioids, but they can gain more control over how their use of opioids effects their life. Medically assisted treatment with an opioid agonist does not necessarily resolve a physical dependence to opioids, but it can

¹⁵ American Psychiatric Association, *Diagnostic and Statistical Manual of Mental Disorders*.

drastically improve the patient's quality of life and reduce the distress that can be caused by an opioid use disorder.

Overview of Buprenorphine Maintenance Treatment:

Buprenorphine is an opioid agonist treatment that has been approved by the FDA for use in medically assisted maintenance treatment. Buprenorphine is a partial agonist of the mu-opioid receptor and differs in its effects from methadone. Like methadone, buprenorphine is an opiate and can reduce the physical symptoms of withdrawal along with cravings. Unlike methadone, buprenorphine is a partial agonist. Buprenorphine readily binds to the mu-opioid receptor and activates it, but increasing the dose of buprenorphine only increases the effects up to a certain point. Once a ceiling dose has been reached, increasing the buprenorphine does not increase its effects on the brain.¹⁶

Buprenorphine is used for multiple medical purposes including pain management, medically assisted withdrawal, and maintenance treatment. Buprenorphine is often administered in a form mixed with naloxone in a 4:1 ratio under the brand name Suboxone. The addition of naloxone to the formulation of the medication helps to discourage injection of the medication.¹⁷ Naloxone is a mu-opioid receptor antagonist that has a higher affinity for the receptor than buprenorphine. When used as prescribed, the naloxone in Suboxone does not enter the blood stream of the patient in a great enough quantity to cause an effect. If a patient were to administer Suboxone intravenously, the naloxone would readily enter the blood stream, bind to the mu-opioid receptors, and can cause withdrawal symptoms.¹⁸ Because these withdrawal symptoms

¹⁶ Substance Abuse and Mental Health Services Administration, "TIP 63: Medications for Opioid Use Disorder."

¹⁷ Substance Abuse and Mental Health Services Administration.

¹⁸ Substance Abuse and Mental Health Services Administration.

are often distressing and undesirable, the addition of naloxone to the formulation in Suboxone helps to discourage patients from administering the medication intravenously.

In clinical trials, treatment with buprenorphine maintenance has been shown to have superior outcomes when compared to non-pharmaceutical treatment. The Cochrane review conducted by Richard Mattick in 2014 analyzed studies comparing buprenorphine to placebo and methadone treatment. The outcomes measured in these studies included retention of patients and reduction of opioid use. The review included 31 randomized clinical trials that totaled 5430 trial participants. They found strong evidence that buprenorphine is more effective than placebo in retaining patients and reducing illicit opioid use. The study also found that for patients retained in treatment, buprenorphine was equal in its ability to suppress opioid use compared to methadone.¹⁹ There are pros and cons to using a metanalysis like the Cochrane review to assess the efficacy of buprenorphine. The large patient population included in the 31 clinical trials helps to support a conclusion that the outcomes in this study would be generalizable to the public at large. However, because of the variety in patient factors and types of outcome data that were collected across the 31 clinical trial, it can be difficult to statistically analyze the outcomes as an aggregate group.

Buprenorphine is more effective when it is used in long term maintenance therapy than when it is used at tapered doses. In a study conducted by Weiss et al. in 2011, 635 patient were assigned to a two phase clinical trial aimed at assessing the efficacy of different lengths of buprenorphine-naloxone maintenance treatment followed by weaning from treatment. The study found that patients who were put on buprenorphine-naloxone treatment for 12 weeks had a success rate of 49.2%. 8 weeks after these patients were weaned from treatment, their success

¹⁹ Mattick et al., “Buprenorphine Maintenance versus Placebo or Methadone Maintenance for Opioid Dependence.”

rate had decreased to 8.6%. These treatment outcomes occurred independently of level of counseling or presence of chronic pain as a comorbidity.²⁰ This study shows that buprenorphine is far more effective as a maintenance therapy. Buprenorphine is not as effective if used for the short term goal of weaning from all opioid agonist treatment.

In addition to clinical studies, treatment with buprenorphine has also been shown to be effective within a natural medical setting in the larger public. In Baltimore, Maryland, an increase in the availability of medically assisted treatment starting in 2000 was associated with a decrease in the number of heroin overdoses.²¹ This data is not a controlled study and does not account for possible confounding variables. However, when this data is compared to the trend of increasing opioid overdose deaths for the entire US during the same time period, the data does present compelling evidence that buprenorphine access had a positive impact in reducing overdose deaths in Baltimore, Maryland.

There is also data from other countries that have shown medically assisted treatment to be an effective way to reduce overdose deaths. One country that has been successful in reducing the number of opioid overdose deaths is France. In France, the number of overdose deaths declined by 79% from 1995-1999.²² There are many factors contributing to this decline, but one significant change in the country during that time was a 95% increase in the number of patients with an opioid use disorder receiving medically assisted treatment.²³ In France, most of the patient's receiving buprenorphine are receiving it in a primary care setting. Several aspects of the French healthcare setting have made it successful in utilizing buprenorphine as a medically

²⁰ Weiss et al., "Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence."

²¹ Schwartz et al., "Opioid Agonist Treatments and Heroin Overdose Deaths in Baltimore, Maryland, 1995–2009."

²² Fatseas and Auriacombe, "Why Buprenorphine Is so Successful in Treating Opiate Addiction in France."

²³ Fatseas and Auriacombe.

assisted treatment. All medical doctors in France can prescribe buprenorphine to their patients, and the majority of patient receiving buprenorphine treatment are prescribed by a general practitioner, not a practitioner in a specialized setting. The organization of the treatment of OUDs in a primary care setting also helps to explain the success of increasing treatment access. The French system serves as an example of the success that implementation of buprenorphine can have in mitigating the opioid epidemic. While this displays the possible benefits of increasing buprenorphine access in the United States, there are several pertinent differences between the healthcare system in the US and in France. One of the attributes of the French healthcare system that facilitates the widespread prescription of buprenorphine is full universal coverage for the treatment of opiate dependence. In addition, French primary care physicians are also supported by a preexisting network of psychosocial services that can provided for the patient free of charge.²⁴

While buprenorphine does present a viable and life changing treatment option for many patients, it is important to note that there are possible risks and consequences of increasing the access to buprenorphine. Unfortunately, in the United States there is a history of pharmaceutical companies developing and advertising wonder drugs without substantial data to fully understand the implications of widespread or chronic use. Buprenorphine has the potential for diversion, dependence and misuse. One of the most striking cautionary examples of widespread buprenorphine access is the buprenorphine epidemic that occurred in Finland.

Finland experiences a marked increase in opioid use disorders with buprenorphine as the preferred drug since the introduction of medically assisted treatment in the country in the 1990s. A study conducted by Uosakainen et al. looked at the trend in patients seeking treatment for

²⁴ Fatseas and Auriacombe, “Why Buprenorphine Is so Successful in Treating Opiate Addiction in France.”

buprenorphine misuse in Finland from 1997-2008. The study was conducted in part because of an alarming rise in the number of patients seeking treatment for misuse of high dose buprenorphine, which is the dosing that is typically used in opioid substitution treatment. The study found that around half of patients seeking treatment for opioid use disorder listed buprenorphine as their primary drug. The study also found that from the year 1997-2008, use of concurrent drugs increased amongst patients seeking treatment for buprenorphine misuse.²⁵ The authors of the study posited a few possible explanations of this increase in buprenorphine misuse in Finland. One compelling explanation was that the access to heroin had been drastically decreased while the access to buprenorphine had increased in the country. Another explanation was that the production of buprenorphine is likely to be higher quality and more safe than heroin because it is typically manufactured by a pharmaceutical company before being diverted to unintended uses.²⁶ It is important to note that the source of the buprenorphine that was misused by the patients was beyond the scope of this study. Another explanation for the misuse of buprenorphine is that patients might be treating their own withdrawal symptoms, essentially treating their OUD with buprenorphine outside of the formal healthcare system. As access to buprenorphine is expanded in the United States, it is important to learn from countries like France and Finland that have already implemented the widespread use of buprenorphine for treating OUD.

Introduction to Methadone and Comparisons to Buprenorphine:

²⁵ Uosukainen et al., “Twelve-Year Trend in Treatment Seeking for Buprenorphine Abuse in Finland.”

²⁶ Uosukainen et al.

Of the medications used for medically assisted treatment, methadone has the largest volume of empirical evidence supporting its efficacy in comparison to non-pharmacological treatments. Methadone is a synthetic opiate that acts as a full agonist of the mu-opioid receptor.²⁷ Because methadone is an agonist, it can reduce the symptoms of opioid withdrawal and reduce a patient's cravings.²⁸ As a full agonist, increasing the dose of methadone will increase the effects of the medication without a ceiling effect. Methadone is used for a variety of medicinal purposes including pain management, medically assisted withdrawal, and methadone maintenance treatment (MMT).

In clinical trials, methadone has been shown to be an effective treatment for reducing the recurrence of heroin use and cravings for illicit opioids. A study conducted by Mattick et al. for the Cochrane Database of Systematic Reviews in 2009 analyzed 11 randomized clinical trials containing a total of 1969 participants. These studies focused on the efficacy of methadone maintenance treatment compared to abstinence based treatment. This review found that MMT was more effective than non-pharmacological treatment for OUD in retaining patient compliance and reducing heroin use. The reduction in heroin use was measured both by self-reporting measures and urine samples. This study found that methadone and buprenorphine performed comparably in reducing heroin use.²⁹

Like buprenorphine, methadone is more effective as a maintenance therapy than it is as a tool for eventual detoxification. A study conducted by Karen Sees et al. and published in the Journal of American Medical Association analyzed the efficacy of methadone maintenance therapy compared to psychosocially enriched 180-day methadone-assisted detoxification. The

²⁷ Substance Abuse and Mental Health Services Administration, "TIP 63: Medications for Opioid Use Disorder."

²⁸ Substance Abuse and Mental Health Services Administration.

²⁹ Mattick et al., "Methadone Maintenance Therapy versus No Opioid Replacement Therapy for Opioid Dependence."

study found that methadone maintenance was relatively more effective than methadone-assisted detoxification in decreasing heroin use in patients.³⁰ This supports a conclusion that the most effective use of methadone is to reduce craving and prevent withdrawal symptoms while taking medication. It is less effective as a tool to reach total detoxification from opioids.

While methadone might be one of the most empirically supported MATs, it is also the most highly regulated medically assisted treatment. Methadone is a schedule II drug and can only be administered in an opioid treatment program. Under the Title 21 US Controlled Substances Act, a schedule II drug is a drug with currently accepted medical use in the US that has a high potential for abuse and may lead to severe psychological or physical dependence.³¹ ³²

³³ Restricting the use of methadone to OTPs can be a barrier for treatment access. One possible justification for this heightened surveillance of methadone treatment is the risk of diversion or harm to the patient if the medication is not used as prescribed.

The initial use of methadone can be dangerous if not intensely supervised because of the medication's lengthy and variable half-life lasting around 22 hours.³⁴ The longer half-life of methadone can pose some increase in danger for initial use because the concentration of methadone in the blood stream over time is less predictable, making it easier to accidentally reach toxic levels. This unpredictable half-life is one of the reasons that OTPs have strict training for methadone maintenance initiation and regulations for maximum dosing at the beginning of

³⁰ Sees et al., "Methadone Maintenance vs 180-Day Psychosocially Enriched Detoxification for Treatment of Opioid Dependence."

³¹ The term abuse is used in this instance to refer to the use of opioids in a manner that has not been prescribed by a medical provider. Labeling these actions as abuse is common practice in government agencies and legislature, but this term can have detrimental effects on the treatment and perception of people with an OUD³². Because of the potential harm that the use of this label can have, the term abuse will only be used when referring to government regulations or legislature in the context of this paper.

³² Kelly, Dow, and Westerhoff, "Does Our Choice of Substance-Related Terms Influence Perceptions of Treatment Need?"

³³ Title 21 US Controlled Substances Act.

³⁴ Toombs and Kral, "Methadone Treatment for Pain States."

methadone maintenance treatment. It is imperative that steps are taken to ensure that methadone maintenance treatment is used to its full potential for opioid use disorders without allowing methadone to negatively contribute to the opioid epidemic through diversions and unintended use.

There are many examples of possible risks associated with reducing the regulation of methadone. From 2002-2014, methadone related overdose deaths were strongly correlated with the rate of prescription of methadone for pain management and rates of diversion of methadone.³⁵ The regulation of methadone used for pain management varies from the regulation of methadone for MMT in that methadone can be prescribed for chronic pain in an outpatient setting by any doctor with proper Drug Enforcement Agency registration. In addition, methadone for pain management can be prescribed for multiple take home doses a day, which contrasts the restriction that methadone in MMT can only be administered once per day at an OTP.³⁶ Because methadone used in an outpatient setting is not under the same strict regulation as methadone used in MMT, it is at higher risk of diversion or unintended use. In England and Wales, a study conducted by Dr. Marteau and published in the BMJ in 2015 analyzed the comparative risk of using methadone or buprenorphine for opioid agonist maintenance treatment for opioid use disorders in England. The study found that prescription methadone had a six times higher rate of associated overdose death when compared to the risk of overdose when using buprenorphine.³⁷ It also found that although the only 36% of the overdose deaths linked to methadone occurred in patients who had received the methadone through an MAT program. This suggests that a large

³⁵ Jones et al., “Trends in Methadone Distribution for Pain Treatment, Methadone Diversion, and Overdose Deaths - United States, 2002-2014.”

³⁶ Toombs and Kral, “Methadone Treatment for Pain States.”

³⁷ Marteau, McDonald, and Patel, “The Relative Risk of Fatal Poisoning by Methadone or Buprenorphine within the Wider Population of England and Wales.”

portion of the methadone overdoses which occurred in this study resulted from diversion of methadone from MAT programs.³⁸ The regulation for methadone maintenance therapy in England and Wales differs from the regulations in the United States. Administration of the methadone doses used for MMT in England are observed by a pharmacist and are not restricted to specialize facilities.³⁹ This system of regulation varies significantly from the US system of regulation and displays the risks that are possible if regulations of methadone are reduced.

Because of the increased risk associated with prescribing methadone, buprenorphine tends to be a first line option for patients with an opioid use disorder. There are some instances in which methadone maintenance treatment might be preferable to buprenorphine treatment. As a partial agonist with a ceiling effect, buprenorphine can be a safer option for many patients. However, the ceiling effect of buprenorphine can be problematic if a patient has developed a tolerance to opioids that is higher than the ceiling for buprenorphine. In this instance, methadone would be a preferred treatment to buprenorphine. In addition, it is important to offer flexibility in treatment for patients. The patient population with opioid use disorders is diverse and complex. There is no one size fits all for opioid use disorder treatment. While buprenorphine might be a better option for one patient because of the convenience of receive it in an outpatient setting, the structure required with methadone maintenance treatment at an OTP may help some patients with compliance. Ultimately, the expansion of buprenorphine access is likely to be safer and equally effective to methadone, although the option for either buprenorphine and methadone maintenance treatment should be available to patients who require it.

³⁸ Marteau, McDonald, and Patel.

³⁹ Marteau, McDonald, and Patel.

Need for Psychological and Social Services in Addition to OBOT:

There are mixed opinions regarding the necessity of behavioral treatment for patients on OBOT. Randomized control studies comparing treatment retention and urine negative samples between groups receiving only OBOT and groups receiving OBOT with some form of behavioral treatment have had mixed results. It is important to note that negative drug testing is not the only possible way to measure the success of a treatment. Behavioral therapy may be a benefit for some patients' quality of life that cannot be measured in a urine test.

While buprenorphine is an effective treatment for people with opioid use disorder, medication alone is not enough to address the diverse set of needs for people with an opioid use disorder. In order for medically assisted treatment to be most effective, there needs to be psychological and social resources available to patients. In 2017, 45.6% of adults with a substance use disorder also had a cooccurring mental illness. In contrast, of the population without a substance use disorder, 16.7% had a cooccurring mental illness.⁴⁰ The prevalence of mental illness is a far greater for patients with a substance use disorder than it is for the population of adults without a substance use disorder. Of the adults with both a mental illness and substance use disorder, only 8.3% received treatment for both mental health and substance use.⁴¹ It may be essential to address a patient's preexisting mental illness before a substance use disorder can be addressed.

Need for Access to Buprenorphine and Other Flexible Treatments:

⁴⁰ SAMHSA, "National Survey on Drug Use and Health 2016."

⁴¹ SAMHSA.

The data presented previously supports the necessity and efficacy of providing access to buprenorphine treatment. Evidence supports that maintenance treatment with buprenorphine can be a safe, effective, and life changing treatment for patients with opioid use disorder. There is compelling evidence from both France and Maryland that increased access to buprenorphine is correlated with lower overdose death rates. In addition, there have been a multitude of studies to show that buprenorphine is safer than methadone while still being as effective in treating opioid use disorders. MAT with buprenorphine is an evidence based and necessary treatment that has the capacity to help patient with an opioid use disorder.

With over 2 million people in the United States meeting criteria for an opioid use disorder, it would be unwise to subscribe a one size fits all solution to this problem. There is just as much variation in the population of patients with an opioid use disorder as there is variation in the general public. Some patients may need the structured and controlled environment that a methadone clinic provides while others find the clinics impersonal and inconvenient. Many patients have comorbidities such as other substance use disorders, mental health disorders, or chronic pain. Some patients may wish to achieve abstinence while other patients decide to stay in MAT for the duration of their life. Buprenorphine should be accessible to all patients who want and need it, but it is not the only form of successful treatment. Other common forms of treatment include MAT with methadone, MAT with naltrexone, abstinence, social support groups, and counseling. A well rounded model for treatment must include access to a variety of treatments or have the ability to refer patients to that type of treatment.

As buprenorphine access is expanded, it is important that concurrent psychosocial therapy also be available to the patients. One study found that 93% of providers who were

prescribing buprenorphine to their patients felt that patients would benefit from counseling.⁴²

While the need for psychosocial care is notable, the access to this care is difficult to ensure. Only 36% of the providers from the study mentioned previously felt that their patients had adequate access to counseling. This means that the majority of patients who are being treated in community care clinics likely do not have access to the psychosocial care that they might feel they need. It is also important to not focus on the medication alone because the environment that a person receives medication can have a profound impact on the patient outcome. For this reason, many of the programs aimed at expanding access to buprenorphine focus on improving the available medical environments in which buprenorphine can be prescribed. One important point of analysis is the flexibility of these programs to offer other key forms of treatment to their patients. When left alone, many of these primary care providers may be unable to ensure that their patients have access to all of the resources they need for recovery. Models of systematic support and referral are one way to address some of the common barriers to treatment access and to ensure that patients have access to different types of treatment as necessary.

PDMs, Rescheduling Opioids, and the Effect on Patients with Opioid Use Disorder

One of the popular approaches to combating the opioid epidemic is to reduce the number of prescriptions for opioids. This is a logical step in trying to reduce the number of new opioid use disorders developed. Monitoring and reregulating opioids can reduce the number of prescriptions given out each year, and it also is one potential way for medical providers to identify patients that might benefit from intervention and treatment for opioid use disorder.

⁴² Lin et al., “Perceived Need and Availability of Psychosocial Interventions across Buprenorphine Prescriber Specialties.”

These strategies have been successful in reducing the number of prescriptions opioids in circulation in the United States. In fact, since 2012, the number of rate of prescriptions for opioids has been declining each year. From 2012 to 2017, the number of per capita prescriptions for opioid decreased by almost 30%.⁴³ Even though all of the effects of reducing the number of prescriptions mentioned previously are beneficial for avoiding new opioid use disorders, there is some concern that PDMPs and rescheduling opioids may have negative impacts for patients who already have opioid use disorder. Even with the reduction in opioid prescriptions, there continues to be a rise in the number of overdose deaths in the US. From 2016 to 2017, there was a 12.0% increase in the number of per capita overdose deaths involving an opioid.⁴⁴ It is concerning that as the number of prescriptions for opioids has reduced, the number of overdose deaths has continued to rise. This is only correlational data, and there could be several factors contributing to this continued rise in overdose deaths. However, there is concern that if a patient has an opioid use disorder from prescription opioids and can no longer gain access to an opioid prescription through legal means, they may seek out illegal sources of opioids such a heroin or fentanyl. There illegal sources of opioids are more dangerous and carry a higher risk of overdosing. This is not to say that a doctor should continue to prescribe opioids to patients who have an opioid use disorder, but they should have the ability to provide help or refer these patients to sources of help rather than just cutting off a patient and leaving them without support. As opioids are subject to more stringent regulation and prescription drug monitoring programs become more common, it is important that there is adequate treatment resources to address subsequent patients who may need help. The emphasis on reducing the amount of prescription opioids in circulation is a

⁴³ “U.S. Opioid Prescribing Rate Maps | Drug Overdose | CDC Injury Center.”

⁴⁴ The Henry J. Kaiser Family Foundation, “Opioid Overdose Death Rates and All Drug Overdose Death Rates per 100,000 Population (Age-Adjusted).”

beneficial step for future reduction of the opioid use disorders. Unfortunately, the reduction in the number of prescriptions since 2012 has not yet correlated with a reduction in the number of patients with opioid use disorder. This does not necessarily mean that these efforts have been ineffective, but it does show that simply reducing the supply of opioids is not enough to address the prevalence of opioid use disorders in the United States.

Chapter 2: Barriers to Access for Buprenorphine and the Need for Systemic Support

Even though buprenorphine has been shown to be a relatively safe and effective treatment for patients with an opioid use disorder, there are still large gaps in the availability and utilization of this treatment. The initial dissemination of buprenorphine has not occurred as quickly or as equally as initially intended. The gaps in treatment are important to acknowledge and address. These treatment gaps have many sources including prescriber scarcity, geographic isolation, economic disparities, and demographic inequalities. These factors can be addressed through the use of institutional systems and programs within healthcare. This chapter of the thesis aims to assess the current gaps in access to buprenorphine and the need for systems of support to close these gaps in access. FDA approval for buprenorphine as a treatment of opioid use disorders might provide legal availability to treatment, but this does not address any of the de facto barriers to access. Many of these barriers may not be addressed through the natural diffusion of MAT into medical practice and there is an need for programs that directly address these barriers.

Supply Side Restrictions on Buprenorphine Access

This section aims to assess the barriers to access that are created by a scarcity of providers in the US who are DATA waived and have the capacity to take on new OBOT patients. Increasing supply side access requires increasing the number of providers who are DATA waived, willing to prescribe buprenorphine, and have the capacity and desire to treat the maximum number of buprenorphine patients allowed. There are many factors that affect the supply of providers who are able and willing to provide this type of care for patients including FDA regulations, lack of provider interest and incentive, and the uncertainty regarding which specialty should be responsible for providing this care.

One of the major factors effecting the access to buprenorphine is its regulation under US law. Buprenorphine is a schedule III drug and can only be administered by a health care provider if they obtain a waiver. The waiver program is regulated with the Drug Abuse Treatment Act of 2000 (DATA 2000). Physicians who have met the requirement to obtain a waiver under this act are often called DATA waived physicians. Under the current iteration of DATA 2000, an MD, NP, or PA can manage a maximum of 30 patients with buprenorphine for MAT during the first year as a buprenorphine prescriber. After a year of treating 30 patients, an MD, NP, or PA can increase their maximum patients to 100 people. After one year of treating 100 patients, only a physician can increase the number of their patients to 275.⁴⁵ A physician can qualify to obtain a waiver to prescribe buprenorphine after attending an eight hour continuing education course. A physician assistant or nurse practitioner can qualify for a buprenorphine waiver following 24 hours of training.⁴⁶ Nurse practitioners and physician assistance may be required to be under the supervision of a physician who has obtained the qualifications for a buprenorphine waiver, depending on the state regulation. Both the 8 hour and 24 hour training options are available

⁴⁵ Substance Abuse and Mental Health Services Administration, “TIP 63: Medications for Opioid Use Disorder.”

⁴⁶ Substance Abuse and Mental Health Services Administration, “TIP 63: Medications for Opioid Use Disorder.”

online and free of cost through multiple site including the Providers Clinical Support System. After obtaining a waiver to prescribe buprenorphine, a medical provider can prescribe take home dosing of buprenorphine for MAT. Because increasing the number of physicians who have obtained a waiver is more cost efficient than creating new opioid treatment facilities, increasing access to buprenorphine should be relatively easier than increasing access to methadone in the United States.

As the number of DATA waived physicians increases, the number of patients that can receive buprenorphine treatment should also theoretically increase. An investigation published in JAMA found that, amongst Medicaid enrollees, a 10% increase in the number of DATA waived medical providers was associated with a 10% increase in buprenorphine prescribing rate.⁴⁷ While this may seem like an obvious correlation to establish, it also supports several fundamental ideas underpinning the efforts to increase access. The first of these ideas is that increasing the number of DATA waived physicians has the potential to increase the number of patients receiving treatment. The second fundamental idea is that there is unmet demand for buprenorphine treatment. While it is well established that there is unmet need for treatment, there are many patients who might need treatment but either want a form of treatment that is not buprenorphine or do not wish to pursue treatment. This study helps to establish that there are patients who would receive buprenorphine treatment if more providers were available to prescribe it.

One of the questions surrounding the expansion of access to buprenorphine treatment is the division of responsibility for this form of treatment amongst the fields of medicine. While addiction medicine might be the most obvious choice to carry the majority of the responsibility,

⁴⁷ Wen, Hockenberry, and Pollack, “Association of Buprenorphine-Waivered Physician Supply With Buprenorphine Treatment Use and Prescription Opioid Use in Medicaid Enrollees.”

the number of addiction specialists in the United States is too small to support the need for treatment. Although there are around 2 million patients in the United States with an opioid use disorder, there are only 5,500 physicians trained in addiction psychiatry or addiction medicine.⁴⁸ It is also important to note that opioid use disorder is not the only disorder that is considered part of the addiction specialty. There is a large number of other substance use disorders that can also put a strain on the capacity of the physicians in addiction specialties to provide care for all the patients who need it. While there are efforts to increase the number of physicians trained in addiction medicine and psychiatry, the need for treatment must be addressed in the interim. The DATA waiver program does not require the medical provider to come from a specialty, and one proposed solution to the bottle neck created by the lack of addiction specialist is to move some of the management of opioid use disorders into the primary care setting. Primary care physicians are tasked with managing many complicated chronic conditions such as diabetes, hyperlipidemia, and hypertension, with the support of a referral system for patients requiring specialty care. Many people argue that a similar system would work well for outpatient buprenorphine maintenance. Less complex patients can receive treatment from a primary care physician, while more complex cases are referred to addiction specialist. While buprenorphine can carry some risk, there are plenty of other complex medications that are often managed by primary care including insulin and anti-hypertensive medication. In the same manner that diabetes and hypertension are too prevalent in the population for endocrinologist and cardiologist to manage every case, opioid use disorder is also too prevalent to be only treated by psychiatrists and addiction specialists. In addition, opioid use disorder is not the only behavioral health condition that is commonly treated by primary care. Many primary care providers prescribe

⁴⁸ Sokol and Kunz, “Training Future Physicians to Address Opioid Crisis.”

antidepressants, mood stabilizers, and antianxiety medications to their patients. One other important implication of providing treatment for opioid use disorder in a primary care setting is that it may be able to reduce some of the stigma associated with opioid use disorder and with seeking treatment for opioid use disorder. It is possible that with the right support, primary care physicians could be able to treat many of the patients requiring OBOT.

Providing treatment for opioid use disorder through primary care physicians has several advantages. The number of primary care physicians currently practicing in the United States, including family medicine, general practice, and internal medicine, is 332,216.⁴⁹ In addition, primary care physicians are the front line of care and might be the only point of contact with the health care system for some patients. Some studies have found that patients with an alcohol or substance use disorder are more likely to initiate treatment if it is offered at a primary care setting.⁵⁰ There are several possible explanations for this phenomena. One of the most cited reasons for not entering treatment is that patients do not perceive a need for treatment and do not want others to know that they are receiving treatment.⁵¹ Receiving care at a primary care office is less likely to feel like to patient is receiving intensive care. After all, many people need to make regular appointments with their primary care provider for a range of chronic health conditions. It may be that a patient fears stigma if they are seen at or near an opioid treatment program. Another reason for this preference of treatment in a primary care setting is the convenience. Patients may feel more comfortable navigating the structure of an outpatient clinic, as this is the setting in which many other common conditions are addressed. Even though primary care is a potential area of growth for treatment of opioid use disorder, there are challenges associated with

⁴⁹ “Professionally Active Primary Care Physicians by Field.”

⁵⁰ Barry et al., “Estimating Demand for Primary Care-Based Treatment for Substance and Alcohol Use Disorders.”

⁵¹ Barry et al.

expanding the number of primary care physicians offering this treatment and ensuring quality of care.

While the number and location of primary care physicians might make them a viable option for increasing access to buprenorphine, there are many obstacles to expanding this form of treatment in primary care. In practice, increasing the treatment capacity for buprenorphine maintenance has been more complicated than simply providing free DATA waiver classes. Even though these classes can be taken for free, the time to take these classes is not compensated. Only 3% of primary care physicians were DATA waived in 2015.⁵² In addition, younger physicians were less likely to have obtained a DATA waiver.⁵³ This indicates that the physicians who are coming out of residency programs are not likely to seek out a DATA waiver. This data contrasts studies that have found that there is significant interest amongst new residents to become DATA waived. One study found that amongst the internist attending physicians and residents surveyed in the study, 66.7% had high interest in obtaining a DATA waiver.⁵⁴ The physicians were more likely to be interested in obtaining a DATA waiver if they were younger or had a strong belief that buprenorphine was an effective treatment for opioid use disorder. While this study cannot necessarily be generalized to all internists or primary care physicians, it shows that the interest in obtaining a DATA waiver is likely to be far greater than the 3% of physicians who currently are DATA waived. This indicates the need for some form of intervention within the medical community to connect interested physicians to training. Another obstacle for expanding treatment into a primary care setting is the concern that adding more strain to the

⁵² Rosenblatt et al., “Geographic and Specialty Distribution of US Physicians Trained to Treat Opioid Use Disorder.”

⁵³ Rosenblatt et al.

⁵⁴ James et al., “Interest in Prescribing Buprenorphine among Resident and Attending Physicians at an Urban Teaching Clinic.”

primary care workload would facilitate worsening provider burnout. Primary care physicians are already tasked with understanding and managing a wide variety of complex chronic and acute conditions. For many primary care physicians that already feel overwhelmed by the broad spectrum of medical conditions that they are expected to competently manage, taking an uncompensated class to expand their patient load might not be an enticing option. It is important to ensure that primary care physicians feel supported as they take on treatment of opioid use disorder in order to prevent increasing physician burn out.

In addition, simply obtaining a DATA waiver does not necessitate that the medical provider will be willing or able to take on patients needing buprenorphine treatment. A study conducted by Jones et. al. electronically surveyed 4225 clinicians who had obtained a federal DATA waiver in 2017 to determine common barriers or incentives for providers to prescribe buprenorphine after obtaining a waiver. The study found that 24.5% of the surveyed providers had not prescribed buprenorphine to a patient, even though they were legally able to. In addition, only 13.1% of the providers were prescribing close to the limit of patient's allowed by the waiver.⁵⁵ This is a major barrier to treatment. If a provider who is able to prescribed buprenorphine is not willing to prescribe it, then they do not contribute to increasing access to treatment. This article shows that simply increasing the number of DATA waived physicians is not enough to efficiently increase access. It would be unfortunate to spend tremendous effort to incentivize physicians to obtain a DATA waiver only to find that they do not use their new capacity to actually treat patients. The study found that increased patient interest, increase institutional support, and increased reimbursement were three of the incentives that providers

⁵⁵ Jones and McCance-Katz, "Characteristics and Prescribing Practices of Clinicians Recently Waivered to Prescribe Buprenorphine for the Treatment of Opioid Use Disorder."

considered most promising for increasing the number of patients receiving buprenorphine.⁵⁶ Another study found that primary care physicians cite a lack of training, poor care coordination, and inadequate institutional support as some of the major factors for not prescribing buprenorphine.⁵⁷ Many physicians may feel that the 8 hour course required to obtain a DATA waiver is insufficient to gain competence in treating a medical condition as complex and variable as opioid use disorder. The complexities caused by cooccurrence of other substance use disorders, chronic pain, and other mental health disorders, can discourage primary care physicians from initiating treatment. In addition, the connection between patients who need treatment and the physicians who can provide treatment appears to be lacking. All of these barriers decrease the potential for buprenorphine to reach its full potential in reducing the occurrence of opioid use disorder and opioid overdoses in the US.

Geographic Barriers to Access

Another problem facing access to buprenorphine treatment is geographical distribution of physicians. Rural areas tend to have less access to specialty care, including treatment for opioid use disorder. Providing quality specialty care in rural settings is not an issue isolated to opioid use disorder treatment. Rural areas tend to be further from academic hospitals and specialty care clinics. In 2017, 56.3% of rural counties in the United States did not have any physicians that were DATA waived. Rural areas also have a lower per capita access to DATA waived physicians. It can be difficult to ensure access to a DATA waived physician in a rural area for several reasons. Because rural providers are tasked with caring for patients that do not have

⁵⁶ Jones and McCance-Katz.

⁵⁷ Haffajee, Bohnert, and Lagisetty, “Policy Pathways to Address Provider Workforce Barriers to Buprenorphine Treatment.”

access to specialists, they can have practices that are already strained with complex patient loads. In addition, the number of physicians in rural areas are less than urban areas so the likelihood of one of these prescribers being DATA waived is smaller than in urban areas. Providing medical care in rural areas can be challenging, and it is important to address these geographic barriers when expanding access to buprenorphine maintenance for opioid use disorder.

One example of a state within the US that faces geographic difficulty in providing quality care for opioid use disorder is Texas. In 2017, Texas had an estimated population of 28,797,290 people dispersed over 268,596 square miles.⁵⁸ The population of Texas is concentrated in urban areas, but around 3,230,468 people in Texas live in non-metropolitan areas.⁵⁹ These non-metropolitan areas can be hours from the nearest metropolitan area when traveling by car. In the 2015-2016 National Survey on Drug Use and Health conducted by SAMHSA, it was estimated that Texas had 1,026,000 people who had misused opioid within a one month period. Of this group, 306,000 people lived in small metropolitan or non-metropolitan areas.⁶⁰ Approximately one third of people misusing opioids were located in non-metropolitan areas. While misuse of opioids is not equivalent to having an opioid use disorder, recurrent misuse of opioids is one of the possible criterium for diagnosing an opioid use disorder and is likely to be correlated with a risk for developing an opioid use disorder. In addition to the prevalence of opioid misuse outside of large metropolitan areas, the rate of opioid overdoses per 100,000 people is higher in rural communities in the US according to the Morbidity and Mortality Weekly Report release by the CDC in 2017.⁶¹ Both of these studies serve to highlight the evident need to provide access to treatment in rural communities.

⁵⁸ US Census Bureau, "State Area Measurements and Internal Point Coordinates."

⁵⁹ "Population Data (Projections) for Texas Counties, 2017."

⁶⁰ SAMHSA, "National Survey on Drug Use and Health 2016."

⁶¹ "CDC Reports Rising Rates of Drug Overdose Deaths in Rural Areas."

According to data collected by SAMHSA, there are 83 SAMHSA-certified OTP clinics which offer methadone for opioid use disorder treatment in Texas.⁶² These clinics are concentrated around areas of higher population. While there are OTPs within a reasonable distance in urban areas, many of the non-metropolitan areas are far from the nearest OTP. In addition to OTPs, there are 838 DATA waived medical providers in Texas listed in the SAMSHA database.⁶³ The distribution of these providers is similar to the distribution of the OTP clinics. The number of OTPs is geographically correlated with the concentration of the population.

Another problem facing care in a rural setting is the scarcity of supporting care such as psychosocial care. In the US, 65% of the non-metropolitan counties do not have any psychiatrists, 47% do not have psychologists, and 27% do have social workers.⁶⁴ This means that only expanding access to buprenorphine access is not enough to ensure that patients get the most effective and flexible care. Most patients would likely benefit from a multidisciplinary approach to treatment that incorporates medical professionals, behavioral health specialist, and social workers. Access to any or all of these resources is especially difficult to ensure in rural areas. It is important the providers in rural settings feel equipped and supported with the necessary resources to treat patients with a opioid use disorder.

Demographic Barriers to Access

There has been a long history in the US of disparity in treatment based on the demographic profile of the patient. In addition, this disparity has been especially apparent in the

⁶² SAMHSA, “SAMHSA Behavioral Health Treatment Facility Listing 2018.”

⁶³ SAMHSA, “SAMHSA Behavioral Health Treatment Facility Listing 2018.”SAMHSA.SAMHSA, “SAMHSA Behavioral Health Treatment Facility Listing 2018.”

⁶⁴ Larson et al., “Supply and Distribution of the Behavioral Health Workforce in Rural America.”

treatment of substance use disorders. Access to buprenorphine has been shown to be unequal amongst race and ethnicities. Counties with higher percentages of traditionally underserved minorities, such as African American and Hispanic populations, are less likely to have access to a DATA waived medical provider.⁶⁵ ⁶⁶ Another study found there is an uneven distribution of buprenorphine usage between different zip codes within a county, with higher percent wealthy white communities being more likely to use buprenorphine for treatment.⁶⁷ This same study found that there was a positive correlation between counties that had higher percent poverty with African American or Hispanic populations and the use of methadone treatment. This indicates that there is a need and demand for treatment of opioid use disorders within these communities. It is likely that many members of the communities that have a higher percent poverty or are composed of a higher percent African American or Hispanic population would want access to buprenorphine. Some have argued that the association between racial minorities and methadone has contributed to the increased regulation of methadone.

The rate of increase in the number of buprenorphine prescribers by county is not equal across counties with various ethnic demographics. Although access to buprenorphine treatment has increased over time, the rate of increase is faster for areas where less of the population is composed of Hispanic or African American residents.⁶⁸ This is problematic for ensuring access to treatment because it indicates that the demographic disparities can continue to persist or even worsen over time. It is essential that programs which focus on increasing the number of

⁶⁵ Andrilla et al., “Geographic Distribution of Providers With a DEA Waiver to Prescribe Buprenorphine for the Treatment of Opioid Use Disorder.”

⁶⁶ Abraham et al., “County-Level Access to Opioid Use Disorder Medications in Medicare Part D (2010-2015).”

⁶⁷ Hansen et al., “Variation in Use of Buprenorphine and Methadone Treatment by Racial, Ethnic and Income Characteristics of Residential Social Areas in New York City.”

⁶⁸ Hansen et al., “Buprenorphine and Methadone Treatment for Opioid Dependence by Income, Ethnicity and Race of Neighborhoods in New York City.”

buprenorphine waived providers are aware that some demographics are disproportionately underserved. Programs should aim to ensure that the increase in buprenorphine providers also occurs in areas that traditionally have less access to care.

Another important demographic factor that must be mentioned is financial barriers to treatment. In the 2017 National Survey of Drug Use and Health conducted by SAMHSA, 30.3% of the people who perceived a need for treatment of substance use disorder but did not receive it cited cost of treatment without insurance coverage as their primary barrier. The frequent doctors visits, lab work, monitoring, medication, and transportation can all be cost prohibitive for patients. Financial barriers to access are mentioned briefly here because it is a significant barrier to access; however, a full discussion concerning the causes and solutions to the issue of funding in medicine is beyond the scope of this thesis.

Patient Education and Access to Treatment

Not every patient that qualifies as having an opioid use disorder wants to enter treatment. Of the patients who needed but did not receive substance use disorder treatment in the National Survey on Drug Use and Health, 94.3% cited that they did not perceive a need for treatment.⁶⁹ It is important that patients are educated on treatment in a variety of setting in order to reduce stigma surrounding treatment seeking. While many patients would benefit from some sort of treatment and have an increase in their quality of life, it may be that the stigma surrounding treatment is too great of a barrier for them to overcome. In addition, many patients may not know that there are pharmaceutical options for treatment of opioid use disorder that are offered outside of rehabilitation facilities. If efforts were made to increase intervention and patient education it

⁶⁹ SAMHSA, “National Survey on Drug Use and Health 2016.”

would likely increase the number of patients who are interested in receiving treatment for an opioid use disorder.

Chapter 3: Innovations in Expanding Access and Quality of OBOT

The barriers presented in the previous section all highlight issues that have not been naturally addressed by the diffusion of buprenorphine into healthcare. There are clearly problems facing expanded access to buprenorphine that may not be solved without efforts that specifically target these issues. There have been several models for addressing these issues that have been proposed. Some of these models are specific to addressing opioid use disorder while other programs have borrowed models that have been effective when treating other health conditions.

Each of the following models aim to address some of the barriers to access by providing support for the DATA waived provider and the patient receiving treatment. In the following section, four models for systematic support are discussed: telemedicine, hub and spoke models, nurse care managers, and hospital initiation of buprenorphine. These tools are discussed in the context of actual programs that have been implemented in the US. While the programs discussed in this next section are by no means comprehensive, they give a good overview of the variety of strategies currently used in the US to expand access. Many of the programs discussed in the next section incorporate multiple strategies; however, each is used as an example for a specific type of innovation.

The Use of Telemedicine in OBOT: Project ECHO

Telemedicine is the use of technology, usually video conference calls, to help disseminate information remotely. The term telemedicine is typically used to describe the remote communication between medical providers and their patients; however, telemedicine has also

been employed in communication between different health care providers to disseminate information and facilitate educational programs. Technological advancements that allow for video conferences and fast reliable communication between doctors have already begun to impact medicine positively. Telemedicine has been implemented in programs addressing some of the treatment gaps in OBOT, primarily gaps in the supply of providers prescribing buprenorphine and geographical distribution of care. One of the programs which has used telemedicine to address treatment gaps is the ECHO program in New Mexico.

Project ECHO (Extension for Community Healthcare Outcomes) was first implemented in 2003 at the University of New Mexico Health Science Center. The program was designed by Dr. Sanjeev Arora in order to expand the access to quality care for patients with Hepatitis C virus (HCV). Dr. Sanjeev Arora identified a significant need for increasing quality care for HCV in the rural areas of New Mexico. He saw technology as one possible method for addressing this need. The ECHO program connects office based practices throughout the state to experts in the field of study located at teleECHO hubs, which are typically at academic hospitals. The program uses video technology to facilitate virtual seminars and helps to disseminate information on best practices to a team of community providers, increasing their ability to confidently and effectively treat complex conditions.⁷⁰

Project ECHO was shown to be effective in safely treating patients with Hepatitis C. The New England Journal of Medicine published a study that assessed the outcomes of patients that had been treated for Hepatitis C by a primary care doctor who had been in the ECHO program and compared these outcomes to patients that were treated at university medical centers.⁷¹ The study found that patients treated at clinics using the ECHO model had equal rates of sustained

⁷⁰ “Our Story | Project ECHO.”

⁷¹ Arora et al., “Outcomes of Treatment for Hepatitis C Virus Infection by Primary Care Providers.”

viral response and serious adverse events as those treated at the University of New Mexico HCV clinic. This study showed that ECHO could be safely used to implement treatment for complex conditions in clinics that were not specialized in that area of treatment. One of the explanations for the success of the program was that continuity of care and proximity of care are superior to initiating care with a new, distant provider. Because of the success of this program in HCV, it has been expanded to be used for a multitude of complex chronic conditions, including opioid use disorder.

Project ECHO for opioid use disorder is a system of regularly scheduled video conferences. Each week, multiple video conferences are held in which primary care providers can present their patient cases to experts located at a teleECHO hub. The teleECHO sessions can be conducted by an interdisciplinary team of experts including “addiction specialist, a psychiatrist, a licensed clinical social worker with addiction expertise, a psychiatric nurse or psychiatric nurse specialist, and a community health worker”.⁷² The sessions last 2 hours and include both a didactic portion and a case-based learning portion. Through presentation and discussing real deidentified cases, all of the providers in the session can learn from the input and experience of other primary care physicians and experts in the field of addiction medicine. The idea is that the providers are able to gain competency in treating a complex conditions through the ongoing training and mentorship. In additions, providers can learn from each other by hearing and discussing all of the patient cases. By using real patient cases as the basis for the teleECHO session, the doctors are exposed to the complexities that exist within the actual population of patients with an opioid use disorder.

⁷² Komaromy et al., “Project ECHO (Extension for Community Healthcare Outcomes).”

Through this model of information dissemination and doctor mentorship, the ECHO program begins to address some of the significant barriers to safely increasing buprenorphine access in outpatient office settings. The ECHO model has had success in increasing access to treatment in New Mexico. One study found that since the start of the ECHO program focused on substance use disorders, the increase in DATA waived physicians located in traditionally underprivileged areas in New Mexico increased at a rate that exceeds the rest of the United States.⁷³ This is a significant impact of this program because it contrasts the trends in growth of provider access for the rest of the United states, in which the demographic disparities have resulted in slower growth for areas that are composed of traditionally underserved populations. There is not yet conclusive data on patient outcomes relating to the ECHO model when used for treating substance use disorders, but there have been good outcomes for patients treated by ECHO clinics for other conditions, such as HCV. In addition, initial surveys have shown a promising response from health care providers involved in an ECHO program. This type of program is especially useful in states where the rural population cannot easily access specialty care due to distance from metropolitan areas.

This model has many beneficial attributes that make it a viable option for safely expanding the access to MAT with buprenorphine. The programs targets teams of providers, including a lead provider and a nurse or medical assistant. This type of model directly targets the problem of rural access. It not only allows for an increase in the number of competent DATA waived medical providers, it also allows providers to feel confident in expanding the number of patients that they can see. This helps to address the issue of DATA waived physicians who do not take on the maximum number of patients allowed by their waiver. In addition, models

⁷³ Komaromy et al., “Project ECHO (Extension for Community Healthcare Outcomes).”

such as the ECHO model allows for quality control to maintain the optimal standard of care because doctors across the state are provided with information coming from the same source. This also allows for quick dissemination of information as new data emerges and best practices change. There is also some flexibility in this model for doctors to have control over how they decide to integrate MAT with buprenorphine into their practice.

There are some possible concerns with this model of treatment for opioid use disorders. The first of these concerns is that the ECHO model does not resolve the time strain that treating opioid use disorders can have on primary care physicians. Treatment with buprenorphine can be time intensive because of the initiation and the close monitoring required to ensure the best patient care. Also, attending the ECHO video conferences takes time and physicians are not compensated for their participation. This can mean that participation in project ECHO actually creates a greater uncompensated time strain for the participating physicians. While project ECHO addresses issues of geographic access and increases the patient capacity for participating physicians, it does not ensure that the patients have access to other treatments such as methadone maintenance or counseling. Given that this program targets rural areas, it is definitely worth noting that access to some forms of treatment is better than access to no forms of treatment. However, project ECHO alone cannot solve the issues of ensuring access to a variety of recovery options. In conclusion, the strongest attributes of project ECHO are that it addresses barriers created by geographic distribution and reduces supply side restrictions caused by prescribers who feel ill-equipped to treat patients to the full capacity of their DATA waiver. Project ECHO is an effective way to use technology to increase access to treatment for opioid use disorders.

Hub and Spoke Models: Vermont, Maryland, and Rhode Island

Many of the hub and spoke models for treating OUD were developed from the Health Homes Models that were introduced under the Affordable Care Act of 2010. States were given the option to use federal funding to create Health Homes that could facilitate the coordination of care for Medicaid enrolled patients who were at risk of developing multiple chronic conditions, such as opioid use disorder. The intention of the program was to provide six key health services including comprehensive care management, care coordination, health promotion, comprehensive transitional care, individual and family support, and referral to community and social support services.⁷⁴ The programs aim to create a robust network of providers within one system that are able to provide comprehensive care. By connecting these providers into one system, care of patients can be coordinated and there can be “warm hand offs” when it is necessary to transfer a patient. In addition, patients within the system are supposed to have all of the resources in the system at their disposal. There are three states that have adopted Medicaid health home models specifically for patients with an opioid use disorder: Maryland, Vermont, and Rhode Island. While each of these programs is slightly different, they all operate within the health home model.

The Medicaid health homes in Vermont are part of a system called the hub and spoke model. The Hub and Spoke model was first popularized in Vermont and is also called the Care Alliance for Opioid Addiction. Unlike the ECHO model previously discussed, this model was originally designed as a response to the opioid epidemic in Vermont. This system divides the clinical settings that are involved in buprenorphine treatment into two categories, hubs and spokes. Hubs are typically specialty outpatient treatment programs (OTPs) that offer methadone and buprenorphine, and spokes are outpatient practices that offer buprenorphine for office-based opioid treatment (OBOT). Hubs are intended to be fully staffed with medical providers and

⁷⁴ Moses and Klebonis, “Designing Medicaid Health Homes for Individuals with Opioid Dependency.”

counselors that specialize in substance use disorder treatment. Spokes are located in primary care settings and typically are staffed with a team of providers including a DATA waived physician, nurse, and a master's level counselor. The hub and spoke program emphasizes that each of the spoke sites includes integrated psychosocial care.⁷⁵ In addition to the DATA waived physicians at the spokes, for every 100 Medicaid patients receiving OBOT there is also one nurse and a master's level behavioral health provider in a supportive role. Patients can transfer between the hub and the spoke depending on their current level of complexity and need for specialty care. Communication between the hub and the spoke concerning particular cases is conducted by a registered nurse or a case manager. Patients typically receive their initial screening at hubs. At the time of this initial screening, the hub staff determines the most appropriate level of care for the patient. Patients can continue care at the OTP hub, or they can be transferred to a spoke provider. The spoke provider continues to have access to the specialist at the hub if they require guidance.

In 2017, the Vermont Department of Health funded a preliminary evaluation of the hub and spoke model, which was conducted by Dr. Rawson at the University of Vermont Center for Behavior and Health.⁷⁶ The review collected both quantitative and qualitative data regarding the efficacy of the hub and spoke program. The patients interviewed for this study had an average history of 14 years of opioid use and were either treated with methadone at one of the hub sites or buprenorphine at a spoke site. The evaluation found that participants within the hub and spoke system in Vermont had improved in their substance use habits, including an average 96% decrease in opioid, decreased use of other substances like alcohol and tobacco, and reduction of emergency department visits. Patients in the hub and spoke model also reported having positive

⁷⁵ Korthuis et al., "Primary Care-Based Models for the Treatment of Opioid Use Disorder."

⁷⁶ Rawson, "Vermont Hub-and-Spoke Model of Care for Opioid Use Disorders: An Evaluation."

improvements in lifestyle, including a decrease in illegal activity, increased life satisfaction, and decreased instances of conflict with their family. These outcomes highlight the effect of medically assisted treatment in producing positive patient outcomes. Within this 2017 evaluation of the hub and spoke model, 40 of the participants were located at a hub site and 40 participants were located at a spoke site. This facilitated the collection of data that was useful in comparing the advantages and disadvantages of both types of sites. A common theme in the data collected was that patients at hub sites had higher satisfaction with the mental health services offered.

There are many benefits to the hub and spoke model that can be used in other states. One of the important tools of the hub and spoke model is the care coordinator and the ease of transfer from primary care settings to specialty clinics. One of the main barriers to successfully treating opioid use disorder with medically assisted treatment is patient compliance. If a patient begins to destabilize in an outpatient setting and needs to be transferred to more specialized care, then it is important that there is systematic support to ensure that the patient is successfully transferred from a spoke to a hub or vice versa. In addition, the integration of care for opioid use disorders into one system in the state of Vermont can help to ensure quality and consistency in the care provided. The hub and spoke model in Vermont has attempted to increase dissemination of information and homogeneity of care by implementing didactic video conference sessions. By using a state wide, hub and spoke system, there is an infrastructure for referring patients as well as connecting physicians to mentors and ongoing support.

One of the major advantages of this model is that all of the different resources necessary for effective and comprehensive care for a patient with opioid use disorder can be housed under the same roof. This makes it more convenient for a patient to access all of these services. It also facilitates communication between the different branches of treatment and can allow for a

multidisciplinary and holistic approach to patient care. This allows for more flexible treatment for the patient.

There have been several challenges associated with implementing Medicaid health homes for opioid use disorder. One of the identified barriers for these programs was a lack of providers willing to be a part of the care system. This type of model typically relies on preexisting OTPs within the state to act as the hubs. Community care clinics that can act as spokes can be increased through outreach, but it is more resource intensive to create new OTPs. Another barrier facing the initiation of these programs is provider burnout during times of transition. It is important that providers involved in the programs feel invested in the programs and do not feel forced into compliance and change when unnecessary.

Nurse Care Managers and Collaborative Care Team Models: The Massachusetts Model

Nurse care managers present one promising form of systematic support for the treatment of OBOT in a primary care setting. Nurse care managers are typically implemented within a collaborative care model of treatment. This model can be used to treat several chronic conditions and has been shown to be effective when used in the treatment of patients with an opioid use disorder. Collaborative care focuses on addressing the difficulty surrounding the extensive monitoring that is typically carried out during OBOT by using the nurse care manager to carry out much of the follow up. A study by Alford et. Al., conducted in 2011, showed that patients who were treated within a collaborative care model had good success with OBOT. Slightly more than half of the patients were retained in treatment at 12 months and of the patients who were retained 91.1% were abstinent from illicit opioids. Another study found that the collaborate care

model used in a primary care setting increased the number of patients receiving treatment and the number of patients who were abstinent at 6 months.⁷⁷ One example of a program that has used collaborative care to expand access to OBOT treatment is the Massachusetts program.

The model for systematic support of OBOT in Massachusetts is called the State Technical Assistance Treatment Expansion Office-Based Opioid Treatment Program (STATE OBOT-B) and relies on a collaborative care model for office base buprenorphine treatment. This model for was first implemented in community health centers in 2007. The program was developed to address five key barriers to treatment in the state. These five barriers were physician competing activities, lack of support staff, inadequate addiction expertise, payment issues, and administrative obstacles.⁷⁸ An integral part of the effort to address these issues is the use of nurse care managers. Nurse care managers are nurses who are specifically hired and trained to care for the patients receiving OBOT. The nurse care managers work closely with a DATA waived medical providers and other care team members to help alleviate some of the barriers to treatment. In addition to the nurse care managers, the program also puts an emphasis on education and training for all of the staff involved in OBOT through TTAs (Training and Technical Assistance) One of the goals of the program was to ensure treatment of traditionally underserved patients. The nurse care manager performs the initial screening and medical induction. In addition, they serve as a liaison between the patient and the DATA waived provider and stay in close contact with the patient with follow up visits to ensure that the patient is successful initiated on treatment and receiving behavioral health counseling. The Massachusetts model puts an emphasis on the entire team of health care providers involved in the treatment. On-site training was provided to the entire clinical staff with the primary purpose

⁷⁷ Watkins et al., “Collaborative Care for Opioid and Alcohol Use Disorders in Primary Care.”

⁷⁸ LaBelle et al., “Office-Based Opioid Treatment with Buprenorphine (OBOT-B).”

of reducing stigma and improving care quality for OUD patients. Community care clinics that met state standards were given a grant to fund one full time nurse care manager with the expectation that the nurse care manager would be responsible for around approximately 100 patients receiving buprenorphine. Of note, after the start of the program, 5 of the original 19 clinics that had opted to take part in this program returned their contracts because they were unable to meet the standards of the state.⁷⁹ There are several advantages of using a nurse care manager for OBOT. One of the major barriers preventing physicians from taking on buprenorphine patients is the perceived time constraint and low reimbursement. Using a nurse care manager helps to alleviate this perceived time constraint. In addition, the nurse care manager ensure consistent follow up and monitoring.

There is some preliminary data collected from 2007-2013 which indicates that the Massachusetts model can be an effective model for systematic support of OBOT. Since the implementation of this model, the number of DATA waived providers and the number of patient's receiving treatment with OBOT both increased. The patients treated within the Massachusetts collaborate care model showed good retention, with 67% of patients retained in treatment for more than 12 months. This indicates that frequent visits with the nurse care manager can be an effective alternative to being closely followed by an MD or midlevel provider.

Initiating Buprenorphine Maintenance at Hospitals

Patients have two basic forms of accessing information about treatment, either they seek this information out or someone else brings this information to their attention. Each point of

⁷⁹ LaBelle et al.

contact with the medical system is an opportunity for a health care professional to share information about opioid use disorder and treatment with the patient. One of the currently underutilized medical settings for disseminating information and initiating treatment is the hospital setting, both emergency department and inpatient. Studies have shown that intervention and initiation of treatment in hospital settings can be one way to increase a patient's likelihood to engage in treatment. Many hospitals have begun to adopt programs that focus in intervention, initiation of treatment, and referral to outpatient management with good success. This next section discusses the data supporting this type of program and the variations within hospital initiated OBOT.

This type of program takes a different approach to expanding access to treatment than the programs previously discussed. Unlike telemedicine, hub and spoke models, and collaborative care models, this program focuses only on the initiation of treatment and the ability to refer for further treatment. This type of program was included for analysis because it uses a resource which is already available, the hospital system, and creates another opportunity for intervention. An ER visit or a hospitalization might be the first time a patient comes to the realization that they would like to receive help treating their opioid use disorder. In addition, the hospital setting can provide the patient a brief break from their surroundings that might contribute negatively to their opioid use disorder. It is important to capitalize on the time that a patient spends in the hospital so that a patient is able to make their decision regarding treatment without the pressure of outside influences in their lives.

Initiation of OBOT in the hospital is intended to utilize a patient's time in the hospital to identify potential opioid use disorder, begin treatment, and connect the patient to appropriate care after they are discharged. Hospitals may be the only point of care for patients who might not

otherwise have regular contact with a medical professional. Many patient who have opioid use disorder require hospitalization for a number of reason. One common cause for hospitalization is opioid overdose. The number of emergency department visits for opioid overdoses increased 30% from 2016 to 2017. In addition, patients with an opioid use disorder may need hospitalization for a number of other health complications relating to chronic opioid use. Some patients with an opioid use disorder may be at the hospital for an unrelated health condition or acute injury. No matter the reason for a patients visit to the hospital, if they have an opioid use disorder, then their time in the hospital can be used to inform them of their treatment options and hopefully improve their future health outcome. Hospital initiation of buprenorphine typically occurs in three stages: screening, intervention, and initiation.

Screening for patients that potentially have an opioid use disorder is typically done in a questionnaire format. There are several advantages of using questionnaires. It is beneficial for screening tools to be brief and easy to use so that they can be readily implemented in the setting of an emergency department. There are a variety of concerns when a patient enters an ER and opioid use might not be the most pressing or evident problem for that patient. It is important that the screening be accurate, but not take up more time than necessary. Questionnaires are more susceptible to inaccuracy than other forms of screening such as drug screening because patients can lie or withhold information on a survey. However, there are several questionnaires that have been used successfully to identify patients who could benefit from intervention and further treatment.⁸⁰ There is also some variability in the types of patients that receive screening. It would be inefficient to screen every patient in the hospital for opioid use disorders due to time constraints and other pressing concerns. Patients who screen positive for an opioid use disorder

⁸⁰ Duber et al., “Identification, Management, and Transition of Care for Patients With Opioid Use Disorder in the Emergency Department.”

or concerning opioid use patterns are then typically given a brief intervention. If the patient is interested in starting treatment after this intervention, then the hospital can initiate buprenorphine while the patient is still in the hospital.

A study conducted by Liebschutz et al. analyzed the outcomes for patients that were initiated on buprenorphine treatment during hospitalization when compared to the patient that underwent a 5 day detoxification.⁸¹ The patients that were assigned to the buprenorphine maintenance were also linked to the hospital's primary care clinic buprenorphine OAT. The study found that patients who were induced on buprenorphine treatment in the hospital had improved outcomes in many measures including entry into buprenorphine OAT after discharge, reduced illicit opioid use, and retention in buprenorphine maintenance treatment.⁸² This study provides valuable data supporting the programs that operate within a hospital setting to initiate treatment and link patients to continued care.

Initiation onto buprenorphine treatment during hospitalization has been shown to be more effective in increasing enrollment in outpatient buprenorphine treatment than intervention and referral alone. D'Onofrio et. Al. conducted a study in 2015 in which 329 patient were assigned to three interventions: referral only, intervention and referral, or buprenorphine/naloxone initiation and referral. The study found that the patients who were initiated onto buprenorphine during hospitalization were more likely to be engaged in treatment one month after the study intervention. This indicates that while a robust referral system is essential to connect patients to care, more patient will actually follow up and seek treatment if treatment is initiated while they are still in the hospital. Initiation onto buprenorphine takes time and effort. Providing the

⁸¹ Liebschutz et al., "Buprenorphine Treatment for Hospitalized, Opioid-Dependent Patients."

⁸² Liebschutz et al., "Buprenorphine Treatment for Hospitalized, Opioid-Dependent Patients."

initiation of buprenorphine in the hospital makes the initial treatment more convenient for the patient.⁸³

While there is good data to support the implementation of this program, many hospitals have been slow to adopt a model of emergency department initiation of buprenorphine maintenance treatment. A survey of physicians working in emergency departments found that barriers to implementing this type of program include lack of patient interest, insufficient referral network, and insufficient provider comfort for prescribing buprenorphine and determining the necessary level of care.⁸⁴ Many of the patient who are identified in an emergency department as qualifying for buprenorphine maintenance treatment are not likely to be seeking treatment at the time of their hospitalization. This may explain why there is a lack of patient interest. The referral network is key for the implementation of this program. If a patient is initiated onto buprenorphine but then has nowhere to follow up for continued maintenance, then their treatment is more similar to a buprenorphine detox and release than to the start of OBOT. The insufficient provider comfort may be the most readily addressable barrier to implementing models like ER and inpatient initiation of buprenorphine. Offering education, training, and mentorship to doctors who may want to prescribe buprenorphine but feel uncomfortable with their level of competency would be an effective step towards decreasing this barrier.

Similar to many of the models assessed in this thesis, the emergency department initiation of OBOT relies heavily on coordinated transfer of patients from one point of care to another. This system cannot be successful if there is not a network of medical providers who are DATA waived, willing to prescribed buprenorphine, and can take on new patients. While the

⁸³ D’Onofrio et al., “Emergency Department–Initiated Buprenorphine/Naloxone Treatment for Opioid Dependence.”

⁸⁴ Lowenstein et al., “Barriers and Facilitators for Emergency Department Initiation of Buprenorphine.”

emergency department initiation of buprenorphine is a good model for areas with a readily available outpatient buprenorphine treatment, it does little on its own to address the shortage of physicians who are willing and able to manage a patients on buprenorphine.

Comparing Innovations

The models previously discussed each use innovative tools and organization in order to address the issues surrounding buprenorphine access in the United States. While each of these models address a variety of the barriers to access, some of the programs are better suited for addressing certain types of access barriers than others. In assessing and comparing all of these programs, the benefits and setbacks of each model can be seen more apparently, which can be informative as new models for treatment are designed and implemented.

One of the barriers that these programs begin to address is the inadequate number of providers who are DATA waived and willing to take on more patients. The two programs that addressed this issue most directly were project ECHO and the collaborative care model. Both of these programs targeted current DATA waived providers and attempted to provide the resources for the provider to treat more patients. The collaborative care model and project ECHO are distinct in several capacities. Project ECHO expands access by addressing a lack of experience and education for treatment of opioid use disorders while collaborative care addresses the perceived time strain that taking on new patients with OUD can have on a provider's schedule. Project ECHO attempts to address a need for more highly trained specialists, while the collaborative care model actually offloads a large portion of the monitoring and follow up onto the nurse care managers, who presumably have less training than the physician. These two models are similar in that they delegate care and disseminate information from a smaller group

of medical professionals to a larger group of professionals who have less training. In project ECHO, information and treatment is disseminated from a team of specialists to a primary care team so that the primary care team can make an independent decision as to the best course of treatment for their patient. The specialist team in project ECHO is not responsible for the patient care decisions. This differs from the collaborative care model because the decisions for the patient are a collaborate effort between the nurse care manager and the provider. In addition, in the collaborative care model both of the parties are responsible for the patient's care. While at first these two systems seem to be at odds, both systems increase access to buprenorphine treatment in a safe and effective way. This indicates that both of the models for expanding access are filling a need that is not currently met. The treatment of opioid addiction is similar to other chronic conditions in that a highly trained medical provider is sometimes necessary, but it is not essential that every interaction with the patient be carried out by a highly specialized MD in order to provide quality care. At the core, project ECHO and the collaborative care model actually are very similar. Both ensure that patients receive high quality care by disseminating information and responsibility to the providers with the appropriate level training for that level of care. Ultimately, it appears that project ECHO is the most effective program for increasing the capacity of DATA waived physicians in rural area. Collaborate care is better suited for urban settings.

Another consideration for evaluating these programs is the degree of strain that they can cause on the medical providers. With any change or increase in a providers practice, there is always the potential for provider burnout. As new programs are implemented, it is important to take into account ways to minimize the strain on the medical providers who participate. The programs which are more likely to cause provider strain are those that are organized and

regulated by statewide programs, such as Hub and Spoke and Collaborative Care. While statewide programs allow for closer monitoring and can facilitate consistency in the type of care offered, they can often be less flexible in their design and implementation. Project ECHO and emergency department initiation of buprenorphine are both less likely to cause physician burnout when compared to the other two programs. Both project ECHO and emergency department initiation of buprenorphine focus on giving current providers new tools for treating patients. Both of these programs give individual clinics and hospitals more autonomy in how they want to implement the use of these tools within their practice. These more flexible programs can be beneficial because it is unlikely that there is one way of implementing a program that will work well across an entire state. Physicians are able to choose how many patients to take on and in what case load they feel they can handle. This contrasts the Medicaid health home models and coordinated care models because physicians who participate become a part of a system. Providers might feel greater pressure and expectation to treat more patients because they are a part of a greater system of health care providers. In addition, clinics that cannot meet the standard set by the State are unable to participate in these programs at all. These less flexible programs can be beneficial because they may spur clinics to increase their quality of care and the resources that they offer. Project ECHO and hospital initiation of buprenorphine are both models of care that can be regulated by each individual clinic or hospital, allowing for more autonomy and flexibility. This contrasts the Medicaid health home and coordinated care models which can provide structured and consistent quality of care across the state but do not allow for as much flexibility.

In addition, there are significant differences in the delegation of the responsibility of care between the different programs. In contrast with many of the other models patient's treated

within the ECHO framework are not ever directly under the care of an expert in the field of addiction medicine. In fact, the case information presented in the ECHO telecommunication clinics is deidentified. While this allows for treatment of patients who might not have geographic access to an OTP or specialty clinic it can also reduce the ability to maintain continuity of care for patients who destabilize and require more structured care in an OTP. Under the hub and spoke model, the transfer of patients from a spoke back to a hub is intended to be a well-coordinated continuation of care. If the patient destabilizes in office based treatment and requires a more structured or intensive program, their care can be transferred to an OTP that still has contact with the spoke site. If a primary care provider in the Hub and Spoke model requests assistance from the Hub, it is likely that they will be able to discuss the patient case with a provider who actually knows and has had contact with that patient.

The programs previously mentioned have several qualities in common that are essential to their successful. All of the programs rely on providers who share a common belief in the efficacy and necessity of buprenorphine for opioid use disorder. Stigma against patients with opioid use disorder and the treatment of opioid use disorder continues to be a common issue in the United States. Without providers who are willing to manage patients with an opioid use disorder, none of these programs would function. It is also important that the entire health care team involved in the treatment are working together to increase the efficacy of buprenorphine maintenance. Another important determinant of success for these programs is the cooperation between health care providers and professionals in other disciplines in order to create continuity of quality care.

A Case from Travis County

One example of an area that could benefit by expanding access to buprenorphine is Austin, Texas. In 2016, the rate of deaths from opioid overdoses was 7.5 per 100,000 in Travis county.⁸⁵ Although this number is lower than the national average of 13.1 per 100,000 in 2016, it is likely that the number of opioid overdose deaths in Texas are underreported. According to the SAMHSA buprenorphine practitioner locator, there are currently 92 DATA waived medical providers in Travis County.⁸⁶ In addition, CommUnity Care has partnered with Integral care to provide buprenorphine as part of the hospital district for Travis county. CommUnity Care operates with a hub and spoke model of care, with the hub site located at the Dove Springs clinic in Austin. Because Travis county is a large urban area with an existing hub and spoke system, it would be beneficial to expand the capacity of the hub and spoke system by creating more hub sites that could house multidisciplinary teams focused on treating opioid use disorder. It would be important to have a more coordinated system of referral and treatment established within Travis county before attempting to implement hospital initiation of buprenorphine. One of the ways to expand the capacity of the hub and spoke model may be to integrate nurse care managers within the treatment team. While all of these programs provide some benefit in expanding access to buprenorphine, Travis county would most benefit from expanding the hub and spoke system and integrating nurse care managers into the treatment teams.

Conclusion:

Thousands of people die of opioid overdoses every year in the United States, but expanding access to buprenorphine is one of the many hopeful innovations being explored to combat this opioid epidemic. Buprenorphine has been shown to be effective in decreasing the

⁸⁵ Huang et al., “Drug Overdose and Opioid Use in Travis County.”

⁸⁶ SAMHSA, “SAMHSA Behavioral Health Treatment Facility Listing 2018.”

rates of overdose deaths, and it has helped many patients recover from opioid use disorder and improve their quality of life. There is an evident need for expansion of access to medically assisted treatment with buprenorphine. It is imperative that access to buprenorphine be safely increased in order to address the current need for opioid use disorder treatment. While buprenorphine has been FDA approved for 16 years, there continues to be limited access to this treatment. Some of the factors limiting access include a lack of DATA waived prescribers who can take on new patients, geographic barriers, limited access to flexible treatment, and demographic disparities in access. In order to ensure that buprenorphine maintenance is accessible to all people who need it for opioid use disorder, programs designed specifically for the purpose of improving OUD treatment and buprenorphine access must be implemented. The programs highlighted within this thesis can be useful tools when addressing the current barriers to access.

In conclusion, all four models are effective in addressing some of the barriers for treatment. When assessing and comparing these models, it is important to take into account the most pressing of the issues in the region being analyzed. If the issue of treatment is the geographic distances, then models that rely on the presence of a nearby OTP will be less effective in treating rural patients when compared to models such as project ECHO. This is contrasted by states that are densely populated and need better care coordination within the state. These densely populated states would likely benefit most from coordinated care models and Medicaid health home models. The emergency department initiation of buprenorphine is most likely to be effective in states which have extensive networks of treatment that a patient can be referred to upon leaving the hospital.

Ultimately, each of these models has had some success in improving access to buprenorphine while ensuring quality care. It would be wonderful to have all of these programs working in conjunction within a state; however, with limited funding and the urgency of finding solutions to reduce opioid use disorder prevalence, each state will need to make decisions as to which parts of these programs are most necessary and pressing at that time. Just as there is no one size fits all treatment for opioid use disorder, there is also no one size fits all program for expanding access to buprenorphine in the United States. The variety in demographics, funding, and geography within a region will ultimately determine which of these programs will be most beneficial in expanding access to MAT with buprenorphine

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