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Hospital-Based Buprenorphine-Focused Interventions for the Treatment of Opioid Use Disorder:
A Scoping Literature Review and Case Study

BY

Richard Bottner, PA-C





A doctoral project submitted to the faculty of the Medical University of South Carolina
in partial fulfillment of the requirements for the degree
Doctor of Health Administration
in the College of Health Professions

Hospital-Based Buprenorphine-Focused Interventions for the Treatment of Opioid Use Disorder:
A Scoping Literature Review and Case Study

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Richard Bottner, PA-C

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Acknowledgements

I would like to express sincere appreciation to my committee for their dedication, thoroughness, and guidance. To Amber Baysinger, MD, PhD, thank you for the amazingly in-depth subject matter expertise and editorial skills you have always brought to our work. I have learned so much from you and look forward to collaborating again soon. To Jillian Harvey, PhD, thank you for the many conversations and focusing my energy (that is no easy task!) It feels like just yesterday we were speaking on the phone about the program before I applied. To Jami Jones, MHA, PhD, thank you for the commitment and encouragement during this process. To Chris Moriates, MD, thank you for your attention to detail and ongoing mentorship. I am forever grateful for all you have done and continue to do in support of my professional development. Thank you all for your unwavering support and belief in me.

I would like to offer heartfelt gratitude to the incredible group of healthcare professionals who make up the B-Team family. None of this work would be possible without you. I have never had the privilege before to be part of such a cohesive, caring, and wonderful group of people. You inspire me every day and have taught me so much about leadership and the importance of interprofessional care. I am also deeply appreciative to the many addiction medicine and substance use disorder experts I have met over the last several years. Thank you for accepting me into this fascinatingly complex world and continuing to teach me something new each day.

There are many organizations that have encouraged and supported this work. I am grateful to Dell Medical School at the University of Texas at Austin, Dell Seton Medical Center, Integral Care, Community Care, and Communities for Recovery. Thank you to the PA Foundation for their financial support of our work three years ago and again through a scholarship for this project. Thank you to the Medical University of South Carolina for their

institutional support and hosting such an excellent academic program. To my classmates, it has been an incredible journey filled with tons of laughs and maybe a few tears. I can't wait to see what the future holds.

Finally, I am deeply grateful to my family for their extensive and unwavering support over the years, especially my mom. Thank you all for your encouragement and patience! This will probably be the last degree, but we'll see. Lastly, to my fiance Lisl, I could not have made it through this process without you. I have a camping trip or two to make up to you.

Abstract of Dissertation Presented to the
Medical University of South Carolina
In Partial Fulfillment of the Requirements for the
Degree of Doctor of Health Administration

Hospital-Based Buprenorphine-Focused Interventions for the Treatment of Opioid Use Disorder:
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Chairperson: Jillian Harvey, PhD
Committee: Jami Jones, MHA, PhD
Amber Baysinger, MD, PhD
Christopher Moriates, MD

The United States continues to struggle to find meaningful solutions to the opioid epidemic. Because they save lives, medications for the treatment of opioid use disorder (OUD), such as buprenorphine, are recommended to be made available in all practice settings. Yet the treatment of opioid use disorder appears to be rarely offered during hospitalization. However, a 220-bed academic hospital in Texas achieved this goal without the presence of an addiction medicine consultation service. This study sought to illuminate this growing area of work through an extensive literature review and case study of the program in Texas. For the case study, key informant interviews took place of stakeholders engaged in the program in addition to document review from the program's inception. Over 4,500 computer files and over 9,400 emails were reviewed from November 2017 to December 2019. Eleven key informant interviews were conducted. The findings show key areas for integration of OUD treatment within the walls of U.S. hospitals including stakeholder engagement, executive support, interprofessional collaboration, widespread education, stigma reduction, advocacy and institutional policy reform, and sharing of patient stories. As a result, a dedicated group of interprofessional hospital-based healthcare professionals working in a consultative model is one feasible method of increasing access to life-saving treatment and harm reduction for patients with opioid use disorder and likely substance use disorders as a whole.

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Chapter 1: Introduction

Hospital-Based Buprenorphine-Focused Interventions for the Treatment of Opioid Use Disorder:
A Scoping Literature Review and Case Study

The United States is facing an alarming public health crisis. An average of 130 people die every day across the nation from opioid poisonings (United States Centers for Disease Control and Prevention, 2018b). In 2017 alone, over 47,000 individuals died from opioid misuse (National Institute on Drug Abuse [NIDA], 2019). In 2016, 950,000 people were using heroin and an additional 150,000 people tried heroin for the first time (U.S. Department of Health and Human Services [DHHS], 2018a). By the same year, over \$500 billion had been lost from the economy due to acute hospitalization, rehabilitation, criminal justice costs, and lost productivity since the start of the epidemic in the late 1990s (DHHS, 2018a).

Prevention is not Enough

There has been a tremendous amount of work to decrease the supply of prescription opioids, such as oxycodone, with hopes that diversion for illicit use will also decrease. These efforts include prescribing smaller doses of opioids with less frequency and increasing utilization of prescription drug monitoring programs. These strategies appear to be achieving a reduced total amount of opioids prescribed across the country since 2010 (Hoots et al., 2018). However, despite these efforts, the number of opioid-related deaths continue to sky-rocket. For example, deaths related to the highly-potent opioid fentanyl increased by over 40% from 2013 to 2017 (Katz, 2017). By focusing mostly on prevention efforts such as appropriate prescribing, overdose deaths are expected to decrease by only 5% by the year 2025 (Chen et al., 2019). Therefore, prevention efforts must be balanced with increasing access to treatment of opioid use disorder (OUD), bolstering of harm reduction efforts and policies, and development of pathways to facilitate long-term recovery. The Institute for Healthcare Improvement [IHI] recommends five

system-level strategies for ending the opioid epidemic including screening, treatment, education, and reducing harm, in addition to appropriate prescribing (Botticelli et al., 2019).

Buprenorphine is an effective treatment for OUD and is equally effective to methadone, another widely used but highly regulated medication (Mattick, Breen, Kimber, & Davoli, 2014). Buprenorphine partially activates the brain's opioid receptors enough to prevent withdrawal and cravings for many patients, but not to the extent that it causes respiratory depression (Mattick, Breen, Kimber, & Davoli, 2014). The medication's less-restrictive federal regulations may make it an ideal intervention to support patients on their journey to recovery in the hospital and the community.

Treatment of Opioid Use Disorder in the Hospital

Hospitalization is a reachable moment and an ideal time to offer patients access to buprenorphine and harm reduction. Between 1993 and 2014, there were almost 2 million hospitalizations stemming from opioid misuse (Song, 2017). Patients are often admitted for several days to several weeks for sequelae of OUD such as endocarditis and spinal abscesses. These patients may not be actively seeking treatment and, therefore, are not necessarily assisted by community programs or other public health programs. Up to 30% of patients with substance use disorders leave the hospital against medical advice because of stigma, inadequate control of cravings, and fear of mistreatment (Ti & Ti, 2015). Such patients are more likely to be readmitted within 30 days of discharge (Walley et al., 2012). Moreover, 80% of patients who are “detoxified” from heroin during hospitalization will return to heroin use after discharge if not provided treatment, which may include initiation of a medication such as buprenorphine (Chutuape et al., 2001).

Patients started on buprenorphine during hospitalization are more likely to enter outpatient treatment, stay in treatment longer, and have more drug-free days compared to those offered only a referral (Liebschutz et al., 2014). Patients receiving buprenorphine are also less likely to be readmitted at 30 and 90 days for reasons related to OUD (Moreno et al., 2019).

Buprenorphine therapy contributes to reduced overall healthcare costs, including total cost related to hospitalizations (Mohlman et al., 2016). Patients who begin buprenorphine in the emergency department are less likely to use illicit drugs or enter inpatient drug rehabs, as opposed to outpatient treatment, versus those provided a referral and no medication to treat OUD (D’Onofrio et al., 2017). Offering buprenorphine in the emergency room is also cost-effective (Busch et al., 2017).

Barriers to Treating Addiction

There are several barriers to starting buprenorphine therapy during hospitalization. These can be divided into three domains: patient, clinician, and system. Patients are often confused and misinformed about the role of medications for treating OUD. They may believe that these medications “replace one addiction with another” (Hassamal et al., 2017a).

Clinicians may feel that they lack the clinical knowledge to start treatment for patients with OUD and that this service is better offered by behavior health specialists (Hassamal et al., 2017a). This may be partly because medical educators have historically excluded training around addictions or their treatment during early formal education (Association of American Medical Colleges [AAMC], n.d.). There is also stigma against patients with OUD. For example, stigmatizing language in the medical record influences the behavior of medical trainees and subsequent prescribing patterns (Goddu et al., 2018).

From a systems standpoint, there is often an absence of protocols and overall institutional support for treating OUD in the hospital setting (Hassamal et al., 2017a). Twelve-step and fellowship programs often advocate for total pharmacologic abstinence, which includes medications for the treatment of OUD such as buprenorphine (Brico, 2017).

Moreover, the regulatory environment for prescribing buprenorphine is complex and restrictive. The Drug Addiction Treatment Act of 2000 (DATA 2000) provides the statutory authority for physicians to prescribe buprenorphine for the treatment of OUD (GovTrack, 2020b). One of its goals was to increase access to buprenorphine therapy in primary care settings. The legislation requires completion of an eight-hour course in most cases. Ten years after the law was passed, only 2% of eligible prescribers had completed the training necessary to offer treatment, and only 6% of this tiny number were internal medicine or family medicine physicians. Half of the counties in the United States had no buprenorphine prescribers during this period (Rosenblatt et al., 2015a).

Problem Statement

Because they save lives, medications for the treatment of OUD, such as buprenorphine, are recommended to be made available in all practice settings (National Academy of Medicine [NAM], 2019). There are over 6,000 hospitals in the United States (American Hospital Association, 2019), yet treatment of substance use disorders appears to be rarely offered during hospitalization (Naeger et al., 2016).

While pieces of buprenorphine programs have been described in the literature, there does not appear to be an in-depth description of the entire build and implementation process – especially in an institution which does not have an addiction medicine consultation service. In

this author's experience, most hospitals lack the presence of such a service. A scalable model to provide buprenorphine treatment in hospitals without formal addiction services is warranted.

Study Objective

To further analyze the issue of offering buprenorphine treatment in the hospital setting and contribute to this growing practice, a literature review will be completed to examine evidence-based practices of buprenorphine therapy and a case study will be performed to share the experience of how a single 220-bed academic hospital in central Texas promoted the importance of treatment and overcame the barriers mentioned above.

Research questions

- 1) How did a single 220-bed academic institution in Texas implement an in-hospital buprenorphine treatment program?
 - a. What were the implementation barriers?
 - b. How were these barriers overcome?
 - c. How does interprofessionalism contribute to program effectiveness?

Population

In 2017, the primary academic hospital for adult non-pregnant patients in a 2-million person metropolitan area of Texas began working on a strategy to offer buprenorphine therapy for patients with a possible diagnosis of OUD admitted to the hospital for medical reasons. This interprofessional collaboration was led by a physician assistant and included a nurse, social worker, pharmacist, chaplain and incorporated physicians from varying disciplines including internal medicine, psychiatry, and palliative care. The group worked together to form a consultation service that assists hospital-based primary care teams to identify patients with OUD, start and maintain buprenorphine therapy during hospitalization, provide warm handoffs to

outpatient addiction programs, and reduce institutional stigma regarding substance use disorders.

The stakeholders of this program include patients with OUD, hospital-based clinicians, outpatient care providers, hospital administrators, payers, and policymakers.

Chapter 2: Scoping Literature Review

Literature Review Preface

The overarching purpose of this paper is to discuss and analyze the impact of the opioid epidemic on hospital systems, and potential interventions these entities may implement to decrease morbidity and mortality, improve patient and staff satisfaction, and help patients on their journey to long-term recovery. This will be accomplished by first exploring the literature relevant to opioid use disorder treatment which will be followed by a case study specific to a single hospital's experience in this realm.

In the author's experience, integrating hospital-based solutions requires knowledge of the opioid epidemic including opioid-related epidemiology and pharmacokinetics of buprenorphine. Since long-term care is provided in the outpatient setting, an understanding of this environment is important as well. While basic knowledge was required to institute the single-center program for hospitalized patients described later, advocating for system-wide and state and national change to support patients with opioid use disorder during hospitalization requires a deeper understanding and appreciation of the many issues and technicalities promoting or hindering such progress. The following literature review seeks to illuminate these areas including the historical context of the opioid epidemic, basic opioid physiology, epidemiology, role of medications to treat opioid use disorder, importance of hospital-based treatment, and the many barriers to developing systems of care for patients with substance use disorders, including opioid use disorder.

History of the Opioid Epidemic

Opioids have been utilized across the world for centuries to treat a variety of medical symptoms ranging from cough suppression to pain management. As early as the 1850s, physician-prescribed opioid use was widespread throughout the United States. During the first part of the 20th century, improved medical technologies brought new forms of analgesia to the marketplace such as aspirin and the reliance on opioids (primarily morphine) began to subside. However, after World War II and subsequent international conflicts such as the Vietnam War, opioids were increasingly used by physicians to treat pain, while nonmedical heroin use also became more prevalent (Kolodny et al., 2015).

Initial reports and beliefs were that prescription opioids were unlikely to be addictive. Porter and Jick (1980) wrote to the editor of the *New England Journal of Medicine* that among 39,946 hospitalized patients who received opioids, only four had subsequent diagnoses of addiction. The authors conclude the one-paragraph letter by stating "the development of addiction is rare in medical patients with no history of addiction" (p. 123). Portenoy and Foley (1986) published an article in *Pain* describing 38 cases of patients who had been prescribed opioids for extended periods of time, some for greater than four years. The authors concluded this as "evidence that opioid medications can be safely and effectively prescribed to selected patients with relatively little risk of producing the maladaptive behaviors which define opioids abuse" (p. 184). However, the authors also noted that since a paucity of data existed at the time, such treatment should be "pursued cautiously", and additional long-term studies would be needed to evaluate the potential for opioid misuse. Despite the many weaknesses of the case series and the authors own concerns about external validity, the results were widely cited over the next several years as conclusive "evidence" of opioid safety (Kolodny et al., 2015). By 2017,

the Porter and Jick letter had been cited 439 times in peer-reviewed literature as evidence that opioid-related addiction was rare (Leung et al., 2017).

Around the same time, an increasing focus on pain emerged within the medical community. In 1995, the American Pain Society (APS) launched the “Pain is the Fifth Vital Sign” campaign and promoted the notion that pain should be monitored and treated in a fashion similar to blood pressure (Deweerd, 2019). In 1998, APS and the American Academy of Pain Medicine published a joint consensus statement stating in part “the undertreatment of pain in today’s society is not justified” (Haddox et al., 1998, p. 102). While the authors write “it is imperative that this statement not be misconstrued as advocating the imprudent use of opioids” (p. 98), they also concluded the risk of addiction to opioids is low, occurrence of respiratory depression is rare, and physiologic tolerance is poorly studied and non-concerning. By 2000, the Department of Veterans Affairs promoted the “Pain is the Fifth Vital Sign” campaign and the Joint Commission included it as part of its new Pain Standards (Baker, 2017; Booss et al., 2000). Simultaneously, pharmaceutical companies began promoting opioid prescribing.

In the 1990s, Purdue Pharma started aggressively marketing OxyContin as a safe long-term treatment of chronic pain (Kolodny et al., 2015). At the time, the medical community was largely unaware of the addictive nature of opioids, and the physician spokespeople hired by Purdue downplayed the risks by citing the studies from Porter and Jick (1980) and Portenoy and Foley (1986). In the absence of known or popularized alternatives for the treatment of acute or chronic pain, opioid prescribing continued to rise as the focus on patient satisfaction increased in hospitals and private practices (Deweerd, 2019). The heroin market was also rapidly evolving concurrently to the rise of prescription opioids. Together, these market forces resulted in larger quantities of illicit opioids available on the underground market at increasingly lower prices

(Kolodny et al., 2015). See Figure 1 for a timeline of events leading up to the current opioid epidemic.

Three Waves of the Opioid Epidemic

The timeline of the opioid epidemic is often described in terms of the “three waves.” The first wave began in the 1990s and was related primarily to prescription opioids (United States Centers for Disease Control and Prevention, 2018b). During this time, opioid prescriptions increased by more than 300% (Adams & Giroir, 2019). Contrary to the earlier widely-cited reports, more recent evidence suggests that up to 12% of patients who are started on an opioid medication by their healthcare provider will develop an opioid use disorder (NIDA, 2019).

The second wave began in 2010 when the extended-release *OxyContin* was reformulated to deter its misuse. Unfortunately, this had an unintended consequence of driving people misusing primarily *OxyContin* to heroin (Cicero et al., 2012). The increase of opioid pill misuse during the first wave and the subsequent beginning of widespread heroin use in the second wave has been referred to as the “intertwined epidemics” (Unick et al., 2013).

The third wave began in 2013 and is marked by when heroin started to be adulterated with fentanyl, a synthetic (laboratory-made) opioid. By 2015, the number of overdose deaths related to heroin surpassed that of pills for the first time (Ciccarone, 2019). From 2013 to 2014, the number of specimens testing positive for fentanyl by law enforcement increased by 426%, which coincided with a 79% increase in overdose deaths linked to these synthetic opioids during the same period (Gladden et al., 2016). The third wave continues at the time of publication. See Figure 2 for a graphical interpretation of the three waves.

Ongoing Litigation

Healton et al. (2019) reports much of the opioid litigation to date has been led by state attorneys general. In March 2019, Oklahoma settled a \$270 million lawsuit against Purdue Pharma. In addition, an Oklahoma judge demanded Johnson and Johnson to pay \$572 million in damages related to their role in the opioid crisis. The judge outlined how such money should be spent within the state, which was immediately followed by rebuke from state legislators and the passing of a unanimous bill emphasizing their role in appropriations. In September 2019, Purdue Pharma announced a \$10 billion settlement with 2,000 government-related plaintiffs including federal stakeholders and 24 states. The company filed for bankruptcy shortly after. Some believe opioid settlements should be modeled after the \$206 billion tobacco settlement of the 1990s. However, less than 3% of these dollars were spent on tobacco prevention as expected.

Basic Opioid and Addiction Physiology

Opium is derived from poppy seeds and has been documented as early as 3400 BC. Opiates refer specifically to naturally occurring substances, primarily morphine and codeine. There are three primary physiologic receptors that are activated by opioids (“opioid receptors”): mu, kappa, and delta. The term “opioid” is used to describe substances that act at these receptors and may be natural or synthetic (such as fentanyl.) Much of the sought-after functions as well as adverse effects associated with opioids occur at the mu receptor including analgesia, respiratory depression, and sedation. Activation of the receptor initially results in pain relief but can quickly progress to decreased rate of breathing and death if opioids are misused in higher than clinically appropriate doses (Providers Clinical Support System [PCSS], 2018).

Full agonist pharmacotherapies completely activate the mu receptor. The extent to which this activation occurs is based on the concentration, potency, and amount of the drug

administered. Morphine, hydrocodone (Norco[®]), hydromorphone (Dilaudid[®]), fentanyl, methadone, and heroin are all examples of full agonist opioids. Partial agonists also activate the mu receptor, but to a lesser degree. An example is buprenorphine (Suboxone[®].) Antagonists attach to the mu receptor and prevent other medications (such as the full agonists mentioned previously) from binding to it. Examples include naloxone (Narcan[®]) and naltrexone (Vivitrol[®]) (Trescot et al., 2008).

Opioids of all types may lead to a sense of euphoria or “feeling high”. Volkow et al. (2016) describe that not all patients who are introduced to opioids experience euphoria. For those that do, long-term use supports ongoing release of dopamine from the brain’s reward pathway resulting in an increased desire to use opioids. At the same time, the area of the brain responsible for anxiety and fear becomes blunted. Thus, escalating use of opioids stimulates the desire to use more while dimming appreciation for potential consequences of ongoing use.

Of note, the complete physiology and neurobiochemistry of opioid-related analgesia and addiction is complex and beyond the scope of this paper.

Definitions of Opioid Use Disorder and Addiction

The *Diagnostic and Statistical Manual of Mental Disorders: 5th Edition* (“DSM 5”) defines opioid use disorder (OUD) as a pattern of opioid use within 12 months that results in loss of control, physiologic changes, and consequences including missed obligations and medical problems (American Psychiatric Association, 2019). Specifically, a diagnosis of OUD must include at least two factors in a 12-month period such as unsuccessful efforts to reduce use and taking larger amount than intended. A complete list of criteria can be found in Figure 3.

Implications of Clinical Definitions

The DSM 5 was released in 2013, almost twenty years after DSM IV. The updated document contains significant changes within the addiction realm including OUD. Prior to DSM V, “substance abuse” and “substance dependence” were considered separate diagnoses. These are now collectively referred to as “substance use disorders”. DSM 5 also includes the presence of cravings as a criterion for the disorder. In addition, OUD as a result of heroin and OUD as a result of prescription opioid pills are now considered separate diagnoses. These distinctions are important because they influence screening and treatment plans, as well as epidemiological reporting. For example, when DMS 5 criteria are applied as opposed to DMS IV criteria, the prevalence of OUD from 2002 to 2012 increases by 0.1% across the entire U.S. population, which could increase prevalence by tens of thousands (Glasheen et al., 2016; Hasin et al., 2013). This may have implications on public health policy and funding for clinical interventions.

There is also a distinction between addiction and dependence strictly from a physiologic perspective. Importantly, patients with a dependency to opioids do not necessarily have an addiction to opioids. The American Society of Addiction Medicine (2019) defines addiction as a:

Treatable, chronic medical disease involving complex interactions among brain circuits, genetics, the environment, and an individual’s life experiences. People with addiction use substances or engage in behaviors that become compulsive and often continue despite harmful consequences. Prevention efforts and treatment approaches for addiction are generally as successful as those for other chronic diseases. (para. 1)

This updated definition was released to reflect addiction as a chronic disease of the brain and to acknowledge the scientific and policy advances that have resulted in increased opportunities for long-term remission and recovery. Addiction has also been referred to as “the 5 ‘C’s” or “chronic

disease with impaired control, compulsive use, continued use despite harm, and craving for the substance(s) to which the patient is addicted” (Heit, 2009, p. 19).

Physical dependence describes a physiologic state in which the sudden cessation and absence of a substance leads to a withdrawal syndrome. Tolerance is a reduced response to a substance after repeated exposure. Over time, tolerance results in the need for escalating doses of a substance to achieve the same effect (Herron & Brennan, 2015). Dependence and tolerance are expected physiologic outcomes of certain classes of medications, including opioids.

Epidemiology

Mortality from Opioid Overdoses

The opioid epidemic has resulted in an exponential increase in the number of unintentional deaths secondary to opioid poisoning¹. An average of 130 people die every day across the United States from an opioid overdose (United States Centers for Disease Control and Prevention, 2018b). Opioid-related mortality throughout the country increased 22-fold between 1979 and 2015 (Alexander et al., 2018). From 2001 to 2016, deaths related to opioid overdoses increased by 345%. One of every five deaths for men 24 to 35 years old during this time were attributed to opioids (Gomes et al., 2018). Figure 4 shows opioid mortality by age over time. In 2016 alone, over 1.1 million total years of life were lost to opioid overdoses in the country and in 2017 over 47,000 individuals died from opioid poisoning (Gomes et al., 2018; NIDA, 2019).

Between 1959 and 2014, life expectancy in the United States increased year over year. However, life expectancy declined each year between 2014 and 2017, with much of this decline explained by opioid overdoses (Woolf & Schoomaker, 2019). In 2017, one of every six hearts

¹ Editorial note: This section contains a large amount of mortality data. The opioid epidemic has resulted in a staggering number of deaths. While presented here as scientific data, this paper would be amiss if the loss of individual life was not recognized. These deaths must not be reduced to numbers printed on paper.

donated for transplantation was a result of an overdose death, and in 11 states, one of every five donor hearts were a result of an overdose (Phillips et al., 2019). In contrast, less than 1% of donor hearts were related to overdoses in 2000.

Of the 3,142 counties in the United States, 24% are considered to have comparatively high rates of mortality secondary to opioid overdoses (Haffajee et al., 2019). Opioid overdoses secondary to prescription pills have affected the country relatively evenly, compared to heroin overdoses which have dominated in the northeast and Midwest (Ciccarone, 2019). Rural communities have higher odds of opioid misuse, which also occur at younger ages compared to urban areas. Mortality is higher in these areas as they are considered "treatment deserts for opioid misuse" (Palombi et al., 2018, p. 649).

The increase in overdose deaths related to opioids is a direct result of the rise of opioid misuse. From 2007 to 2016, over 37 million people reported having misused an opioid medication at least once and over two million individuals reported a dependency to opioids (Kreek et al., 2019). In 2017, 1.7 million people carried the diagnosis of OUD and over 652,000 individuals had an addiction specifically to heroin (NIDA, 2019). Of 2,916 patients with available toxicology records who died of an opioid overdose in Massachusetts between January 2013 and December 2015, 80% who had oxycodone in their system did not have a prescription for the medication (Walley et al., 2019). Figure 5 shows national mortality from opioid overdoses between 1999 and 2017.

In 2018, the number of deaths in the U.S. attributed to drug overdoses fell by 4.1%. While there were slightly fewer deaths related to heroin, deaths related to synthetic opioids such as fentanyl increased by 10% (United States Centers for Disease Control and Prevention, 2020). Approximately 96% of deaths from opioid overdoses are unintentional (Olfson et al., 2019).

Origin and Role of Heroin and Fentanyl

Fentanyl is produced entirely in a laboratory setting and, unlike heroin, requires no plant materials. The vast majority of illicit fentanyl in the United States is manufactured in China and arrives in the U.S. through packages shipped from internet sales and networks that traffic drugs from Mexico and Canada. Fentanyl arriving in the United States directly from China via mail is over 90% pure compared to fentanyl that is trafficked through Mexico or Canada, both of which have an average purity less than 10%; presumably the latter is adulterated before arriving in the U.S. to achieve greater profits (Drug Enforcement Agency [DEA], 2018). In 2016, 90% of heroin in the United States originated from Mexico. Overall, heroin and fentanyl have increased in potency and purity over time, in particular during the third wave which is associated with the stark increase of overdose-related mortality (Ciccarone, 2019).

However, the increase in mortality related to heroin overdoses cannot be linked entirely on the transition from heroin to heroin mixed with fentanyl. Unick and Ciccarone (2017) describe the robust introduction of fentanyl into the marketplace began in 2013, but heroin overdoses were already rising at that time in most parts of the country. The authors postulate one explanation is that since injecting drugs is a learned skill, as more individuals acquire this knowledge, the number of people able to act in an instructional role increases which ultimately spreads opioid misuse by injection. Another possibility suggested by the authors is that younger people who use heroin may have deeper and stronger opioid dependencies because of their exposure to prescription opioids before heroin, as opposed to their older counterparts whose entry to opioid misuse was strictly heroin decades prior. Heroin provides a more potent, less expensive, and easier-to-access alternative to opioid pills obtained by prescriptions through “doctor shopping”, taken from family or friends, or purchased from the street (Ciccarone, 2019).

Impact of Opioid Overdoses on Hospitals

Hospitalizations related to opioid misuse increased more than 150% from 1993 to 2012 (Agency for Healthcare Research and Quality [AHRQ], 2014). More than one in ten patients with OUD are readmitted to the hospital within 30 days of discharge (Merchant et al., 2020). Song (2017) found approximately 1.9 million hospitalizations occurred secondary to opioid misuse between 1993 and 2014. Figure 6 shows the trend of hospitalizations related to opioid poisonings. Patients in these hospitalizations are on average younger compared to patients hospitalized for other reasons (30 years old vs 48 years old), more likely to have Medicaid (40% vs 19%) or be uninsured (17% vs 5%), and live in areas of the nation in the lowest 25% of household income (32% vs 25%). Figure 7 shows opioid-related hospitalizations by insurer.

According to Song (2017), 20 deaths occurred for every 1,000 opioid-related hospital admissions in 2014 compared to 4.3 deaths for every 1,000 opioid-related admissions in 2000. Figure 8 shows the trend of in-hospital mortality from opioids compared to other causes. Notably, Song revealed the overall rate of hospitalization remained constant during this time with the mortality increase reflecting the potency of opioids in the marketplace, heroin and fentanyl in particular.

Song (2017) also found the majority of patients nationwide with Medicare who were hospitalized for opioid misuse were younger than 65, with nearly all Medicare beneficiaries in this group receiving Social Security Disability Insurance (SSDI). A similar conclusion was reported by Peters, Durand, Monteiro, Dumenco, and George (2018) who found that hospitalizations in the U.S. related to opioid misuse among SSDI beneficiaries increased to 25% in 2013 from 12% in 1998.

Hospitalizations related to heroin overdose increased more than 20% in most of the country from 2012 to 2014. In the South Atlantic and East South Central census regions, hospitalizations related to heroin overdose increased by 122% and 111%, respectively. Figure 9 shows the trend in hospital admissions related to opioid overdoses separated by prescription opioids and heroin and divided by geographic region.

Emergency departments (EDs) have an increasing role in treating patients with OUD. In 2017, a third of all opioid-related encounters in Indiana's EDs represented repeat visits for opioid-related reasons, compared to 9% in 2012 (Balio et al., 2020). Many patients hospitalized in the ED for opioid-related reasons die a short time after discharge. For example, among 11,557 patients seen in Massachusetts emergency departments for an opioid overdose between July 2011 and September 2015, 635 (5.5%) died within one year, 130 (1.1%) died within one month, and 29 (0.25%) died within two days (Weiner et al., 2019). Figure 10 shows the mortality rate in the first 30 days among patients discharged from Massachusetts' emergency departments.

Costs of the Opioid Epidemic

The economic impact of opioid misuse and opioid poisoning is astounding. The misuse of opioids costs the United States over \$75 billion annually when taking into account acute healthcare, drug rehabilitation, lost productivity, and the impact on the criminal justice system (Florence et al., 2016). By 2016, a total of \$504 billion had been spent on services related to OUD (DHHS, 2019). Overall, patients with OUD cost the healthcare system a minimum of eight times more than patients without the diagnosis (White et al., 2005).

The Society of Actuaries found the total economic burden from opioid misuse was over \$630 billion between 2015 and 2018. This estimate included \$200 billion on healthcare costs, \$253 billion on lost lifetime earnings secondary to premature death, \$39 billion on criminal

justice, and over \$90 billion related to lost productivity (Davenport et al., 2019). Others estimate the opioid epidemic as a whole has cost upwards of \$2.5 trillion (Council of Economic Advisers, 2019). In a sample of 647 hospitals nationwide, opioid overdoses resulted in costs of \$1.94 billion with over 60% being paid for by public programs. When extrapolated to all hospitals nationwide, costs are estimated at \$11.3 billion annually, representing 1% of all hospital expenditures (Premier, 2019).

Infectious Complications of Intravenous Drug Use

There are numerous infectious complications associated with intravenous drug use including hepatitis C, human immunodeficiency virus (HIV), skin and soft tissue infections, spinal abscesses, and sexually transmitted infections (PCSS, 2018). The infectious complications of OUD have risen so extensively that there are now calls for infectious disease specialists to sub-specialize in addiction medicine during fellowship training (Serota et al., 2019).

Prior to the opioid epidemic, many acute hepatitis C infections were a consequence of blood transfusions or contaminated equipment before implementation of today's screening technologies (Liang & Ward, 2018). Incidence of acute hepatitis C declined until 2009 when it began rising secondary to the increasing prevalence of intravenous drug use (United States Centers for Disease Control and Prevention, 2019d; Zibbell et al., 2018). From 2004 to 2014, the incidence of acute hepatitis C infections increased by 133%. The increase was more dramatic for those 18 to 29 years old and 30 to 39 years old, who had increased incidence rates of 400% and 325%, respectively (Zibbell et al., 2018). Seventy-five percent of patients with acute hepatitis C are expected to develop chronic hepatitis C (Spearman et al., 2019). Chronic hepatitis C can develop into serious health complications for many patients including cirrhosis, hepatocellular

carcinoma, and decompensated liver disease - all which have high rates of mortality (Spearman et al., 2019).

The overall incidence of HIV related to intravenous drug use decreased from 40% in 1990 to 6% in 2015 (Dawson & Kates, 2018). However, there is concern this trend may reverse as the opioid epidemic continues (O'Hara, 2016). One in every ten new HIV diagnoses is now attributed to intravenous drug use (CDC, 2019c).

In January 2015, the Indiana State Department of Health began an investigation related to 11 new cases of HIV in a county of 4,200 people. The outbreak resulted from syringe-sharing among individuals injecting prescription oxycodone. By April 2015, 135 people in the county were newly diagnosed with HIV (Conrad et al., 2015). Over 200 counties in 26 states are at risk for a similar outbreak (Van Handel et al., 2016). In addition, opioid misuse is associated with higher-risk sexual encounters such as unprotected sex, which increases the risk of transmitting hepatitis C, HIV, and other sexually transmitted infections (Zule et al., 2016).

Infective endocarditis is a potentially life-threatening infection of the heart. There are several etiologies for this infection including intravenous drug use where a syringe inserted through the skin introduces bacteria from its surface to the bloodstream. In some cases, the bacteria travels to the heart via the bloodstream where it grows on one of the heart's valves (Jameson et al., 2018).

Infective endocarditis secondary to drug use doubled across the United States from 2002 to 2016 (Kadri et al., 2019). The incidence is greater in certain parts of the country. For example, Pennsylvania experienced a 238% increase in cases of endocarditis related to intravenous drug use between 2013 and 2017 (Meisner et al., 2019). Compared to patients with endocarditis not associated with drug use, patients with OUD-related endocarditis are more likely to have

hepatitis C, cirrhosis, and HIV and are more likely to require valve surgery, have longer lengths of stay in the hospital, and have higher hospitalization costs (Kadri et al., 2019). Patients with endocarditis secondary to drug use have a mean age of 38 years compared to 70 years for patients with non-drug use related endocarditis (Kadri et al., 2019). Figure 11 shows the trend of endocarditis incidence rates for drug-related and non-drug-related infections.

Infectious complications of OUD have also increased utilization of expensive diagnostic tools. At a large urban hospital in Massachusetts from 2005 to 2015, the use of MRI to investigate back pain for patients with a history of intravenous drug use (IVDU) increased substantially from less than 0.1% to 0.9% (Almeida et al., 2019). A prior study showed 40% of patients in a single emergency room with history of IVDU had spinal infections on MRI (Colip et al., 2018). In Washington, cases of epidural spinal abscesses related to IVDU increased by more than 300% between 20012 and 2016 (Blecher et al., 2019).

Additional research is needed to investigate other infectious complications of OUD. For example, it has been suggested that opioid exposure increases the risk of community-acquired pneumonia (Edelman et al., 2019). In addition, patients with OUD admitted to the hospital for trauma may be more likely to develop pneumonia and superficial and organ space infections (Agrawal & Amos, 2017).

Opioid Use Disorder Among Pregnant Patients

Childbirth is another common hospital touch-point for patients with OUD. Rates of OUD noted during delivery hospitalization quadrupled between 1999 and 2014 (Haight et al., 2018). According to the, pregnant patients with OUD are at risk for numerous complications including preterm delivery, miscarriage, and delivering infants with low birth weight (American College of Obstetricians and Gynecologists [ACOG], 2019). ACOG further identifies potential infectious

disease exposures for the fetus including HIV, hepatitis C, and blood borne bacterial infections. They also note infants may be born with potentially severe withdrawal symptoms known as neonatal abstinence syndrome (NAS). Opioids are the leading substance use disorder for which patients seek treatment during pregnancy (Jumah, 2016).

The incidence of NAS throughout the United States increased over 425% between 2004 and 2014, resulting in one baby born with NAS in the country every 15 minutes (Jilani, 2019). In 2014, Medicaid paid for the care of 82% of all NAS cases at a cost of \$462 million. This cost represented 7% of all birth-related Medicaid expenditures (Winkelman et al., 2018). In 2016, NAS was documented in 6.7 of every 1,000 in-hospital births representing a total cost of \$573 million. Medicaid paid for 83% of these births (Strahan et al., 2019). The proportion of NAS cases in rural areas to total cases in the country increased from 13% in 2003 to 21% in 2012 (Villapiano et al., 2017).

Opioid Use Disorder in Criminal Justice

In 2016, there were over 4.5 million people on probation or parole in the United States (Bureau of Justice Statistics, 2018). Up to 80% of these individuals are thought to have a substance use disorder (Marlowe et al., 2016). Approximately 35% of all people in the United States who use heroin have been estimated to become incarcerated at some point (Boutwell et al., 2007). Between 22% and 34% of individuals who are seen in urban, suburban, and rural drug courts have a diagnosis of OUD (Marlowe et al., 2016). Over 60% of jail inmates in the United States meet criteria for drug use disorders and over 25% of inmates report a history of heroin or illicit opioid use. Six-percent of all inmates report actively using heroin or illicit opioids at the time of arrest (Bronson et al., 2017). For example, in North Carolina and Washington State,

inmates are 40 times and 13 times more likely to experience a death related to drug overdose within two weeks of release, respectively (Binswanger, 2019; Ranapurwala et al., 2018)

Racial Disparities of the Opioid Epidemic

From 1979 to 2015, opioid mortality for White patients increased from 0.44 deaths per 100,000 people to 12 deaths per 100,000 people, or 10% annually (Alexander et al., 2018). Over the same time frame, opioid mortality for Black patients increased an average of 6% annually ultimately reaching 6.6 deaths per 100,000 people (Alexander et al., 2018). However, distinct trends are noted within the three epidemiologic waves of the opioid epidemic. Figure 12 shows trends in opioid-related mortality for White and Black people.

Alexander et al. (2018) reported opioid-related deaths were more common among Black people from 1979 to the mid-1990s, but the rate by which mortality increased was the same between Black and White people. This first wave was driven by heroin. During the second wave, from the mid-1990s to 2010, the authors describe mortality skyrocketed in the White community while remaining stable in the Black community. Much of the initial stark increase of opioid mortality for White people was related to prescription opioid pain medications (Paulozzi et al., 2006).

From 2010 to 2015, mortality increased by 30% in both racial groups and was driven by heroin, prescription opioids, and synthetic opioids (Alexander et al., 2018). From 2013 to 2017, the largest proportion of patients who died from opioid overdose were White; however opioid overdose deaths increased by over 60% among Black patients in this timeframe, the largest relative increase across all racial groups (Scholl et al., 2019). Of patients who died from an opioid overdose in 2017, 78% were White and 12% were Black (Keiser Family Foundation, 2019a).

Unick et al. (2013) showed hospital admissions for prescription opioid overdoses increased 750% for White patients between 1993 and 2009 compared to 330% for Black patients and 320% for Hispanic patients. During the same study period, admissions for heroin overdose steadily declined for Black people but increased for White people with the number of admissions for White patients surpassing that of Black patients for the first time in 2008.

The opioid epidemic has devastated American Indians more than any other racial group. From 1999 to 2015, mortality related to opioid overdoses increased in this group by over 500% (*Opioids in Indian Country - Beyond the Crisis to Healing the Community*, 2018). However, the number of opioid-related deaths in this community is likely even higher. From 1999 to 2011, 40% of death certificates for American Indians or Alaska Natives were incorrectly attributed to another race (Rothwell et al., 2016). When corrected in Washington State from 2013 to 2015, the number of opioid overdose deaths among American Indians increased by 40% (Joshi et al., 2018).

Several reasons for these racial disparities have been suggested. Despite the contribution of subjective pain scales in increasing the number of U.S. opioid prescriptions in the 1990s, biases within the medical community led to discriminatory practices by which Black patients received fewer opioid prescriptions (Om, 2018). For example, 31% of White patients who presented to an emergency department for a pain-related chief complaint between 1993 and 2005 received an opioid prescription, compared to 23% of Black and 24% of Hispanic patients presenting for the same reason (Pletcher et al., 2008). In an extensive systematic review including over 150 papers from 1990 to 2009, White patients were more likely to receive opioid therapy during hospitalization or opioid prescriptions for acute pain, chronic pain, or cancer pain (Anderson et al., 2009). White patients also received higher average daily opioid doses.

Opioid overdoses, in addition to suicide and liver disease secondary to alcohol, have contributed to the increase in midlife mortality of White people since 2000, particularly among those without college degrees. This is in contrast to decreasing mortality among Black people and Hispanic people in the same age group. These “deaths of despair” have been attributed to long-term cumulative disparities in specific geographic areas of the country such as Appalachia with specific challenges in labor, marriage, childhood and clinical outcomes (Case & Deaton, 2017).

Co-occurring Substance Use Disorders and Role of Occupation

While many patients have OUD as their sole substance use disorder diagnosis, some patients have co-occurring substance use and behavioral health diagnoses. Approximately one-third of patients with OUD admitted to the hospital have an additional substance use disorder (Merchant et al., 2020). In 2013 and 2014, patients in Maryland with co-occurring substance use disorders were six times more likely to die after a visit to the emergency room than those who used the ER for any other reason (Krawczyk et al., 2020). Among patients who died from opioid overdoses in Massachusetts, 83% had at least one additional substance on their post-mortem toxicology report (Barocas et al., 2019). Thirty-six percent of patients tested positive for cocaine. Just under half of patients in the sample had non-stimulant substances in addition to opioids. Of these, 18% tested positive for alcohol and 21% tested positive for benzodiazepines. Figure 13 shows the pooled results of this toxicology data.

Patients with specific occupations are also more at risk for opioid misuse. For example, construction workers and those employed in mines are more likely to use non-prescription opioids, marijuana, and cocaine (Ompad et al., 2019). Changes in local job markets may increase the risk of OUD. For instance, in U.S. counties reliant on manufacturing where an automotive

assembly plant had recently closed, mortality secondary to opioid overdose was 85% higher relative to manufacturing counties without such a workforce change (Venkataramani et al., 2019).

Epidemiologic Challenges of Opioid Use Disorder

The validity of opioid overdose mortality data may be limited. In many states, death certificates documenting the cause of death in a drug poisoning do not indicate the specific drug that resulted in the death. In some cases, county resources are insufficient to conduct thorough investigations such as costly autopsies or post-mortem toxicology tests. In other cases, the specific drugs that led to a death were known but were not entered into the electronic tracking system. Ruhm (2017) found when these factors were applied to 2014 CDC opioid mortality data, every state was likely to have higher mortality related to opioid misuse than what was originally reported. In some states this difference was stark. For example, Pennsylvania overdose deaths may have been underestimated by more than half. Nationally, opioid mortality rates may be underestimated by as much as 24%.

Boslett et al. (2020) evaluated over 630,000 cases of drug overdose decedents from the National Center for Health Statistics between 1999 and 2016. Of these, over 20% did not classify which primary drug led to the death. Using predictive modeling, the researchers attributed almost 100,000 additional deaths to opioids, representing a 28% increase in overall opioid deaths. In a prior study, the researchers found under-resourced counties were more likely to have deaths recorded with unclassified overdoses (Boslett et al., 2019).

From a hospital perspective, epidemiologic data start at the bedside. Clinicians document diagnoses and care plans, which are then coded by specialists. These codes are transmitted to local, state, and federal authorities and used for incidence and prevalence reporting. Jicha, Saxon,

Lofwall, & Fanucchi (2019) found “injection drug use” was documented in more than half of cases although the specific diagnosis was actually opioid use disorder. These cases were ultimately coded as general substance use disorders and not opioid use disorders. The implications of poor documentation and inaccurate coding in this patient population is poorly understood but is likely to have large public health consequences when deciding how to utilize resources.

Role of Treatment and Harm Reduction

The opioid epidemic has resulted in a myriad of policy changes at local, state, and federal levels. The vast majority of these efforts have focused on responsible and appropriate prescribing of opioids, while largely neglecting the role of treatment and the need to address the social conditions that often result in illicit drug use (Kertesz & Gordon, 2019). Policy and educational efforts over the past decade appear to be slowly reducing opioid prescription rates. However, this reduction may also be inadvertently increasing use of non-prescription opioids, such as heroin and fentanyl, as well as overdose death rates from these more potent opioids (Katz, 2017). By focusing only on appropriate prescribing, overdose deaths are expected to decrease by only 5% by the year 2025 (Chen et al., 2019). Therefore, these prevention efforts must be balanced with increased access to treatment for OUD and increasing use of harm reduction strategies.

The Institute for Healthcare Improvement (Botticelli et al., 2019) recommends five system-level strategies for responding to the opioid epidemic:

1. Screening for OUD.
2. Treating individuals with OUD.
3. Training stakeholders about OUD and how to reduce stigma.
4. Reducing harm related to substance use disorders as a whole.

5. Altering opioid prescribing practices to better balance benefits and risks.

Medications for the Treatment of Opioid Use Disorder

Medication-assisted treatment (MAT)² describes the approach of using specific pharmacologic therapies to treat OUD. Medication-assisted treatment improves patient mortality related to OUD, decreases the risk of life-threatening infections associated with intravenous drug use, increases the length of time spent actively participating in treatment, and decreases criminal activity related to illicit opioid use (Caldiero et al., 2006; Larochelle et al., 2018; Teesson et al., 2006). The goal of treatment is long-term recovery, defined as “a process of change through which people improve their health and wellness, live self-directed lives, and strive to reach their full potential” (SAMHSA, 2019a, Para 2). Yet some patients elect for a harm reduction approach, which will be discussed later.

Three Mainstay Medications

There are three FDA-approved medications for the treatment of OUD: buprenorphine, methadone, and naltrexone.

Buprenorphine. Buprenorphine is a partial agonist opioid. It attaches to the mu receptor and incompletely activates it. This unique property allows buprenorphine to control cravings and treat opioid withdrawal with a significantly lower risk of adverse effects such as respiratory depression and euphoria. Buprenorphine also has a ceiling effect. As the dose is increased, so is the therapeutic effect, but only to a certain limit. After that point, additional doses do not result in increased action or adverse effects (PCSS, 2018). Buprenorphine also has extremely strong

² There is ongoing discussion in the addiction medicine community about the appropriateness of the term “medication-assisted treatment” or “MAT.” The term and its implications will be discussed later in this paper. However, given that the vast majority of the references cited throughout this paper use this term, “medication assisted treatment” is used throughout. It should be noted the recommended term for this type of treatment is likely to change in the near future.

affinity for the mu receptor. It binds more strongly to the receptor than most other opioids. Thus, if a patient uses illicit opioids while simultaneously using buprenorphine, those illicit opioids will have less effect (Orman & Keating, 2009).

It is possible, although uncommon, for buprenorphine to provide limited euphoria when used intravenously. Therefore, when used for the treatment of OUD, buprenorphine is typically prescribed as a combination product of buprenorphine and naloxone which is administered buccally or sublingually. If a patient uses the buprenorphine-naloxone product intravenously, the naloxone component blocks buprenorphine's ability to act on the brain's mu receptors and therefore limits, if not eliminates, euphoria. Buprenorphine monotherapy (buprenorphine without naloxone) for the treatment of OUD is primarily used only in pregnancy (PCSS, 2018).

Methadone. Methadone is a full agonist opioid. It completely binds to the mu receptor and fully activates it (PCSS, 2018). Much of the medication is stored in fat cells which results in an extended half-life compared to other opioids, as much as 60 hours. Methadone's full agonist activity contributes to its efficacy as a treatment for OUD, but also leads to its potentially dangerous adverse effect profile. Methadone used inappropriately can result in death (United States Substance Abuse and Mental Health Services Administration [SAMHSA], 2018b).

Buprenorphine and methadone are on the World Health Organization's list of essential medicines (Herget, 2005).

Naltrexone. Naltrexone is an antagonist at the mu receptor. It blocks the effects of illicit opioids and is thought to reduce cravings through remodeling of molecular neurobiology (SAMHSA, 2018b). The oral formulation of naltrexone is not recommended for the treatment of OUD secondary to poor treatment adherence (PCSS, 2018). Extended-release naltrexone administered as a monthly intramuscular injection has been shown to be as effective as

buprenorphine, however its high cost has resulted in limited clinical application (Lee et al., 2018).

Precipitated withdrawal and transitioning between treatments. Due its strong affinity for the mu opioid receptor, buprenorphine must be initiated at the appropriate time. A patient must be experiencing mild to moderate opioid withdrawal before buprenorphine is administered. If administered too early for a patient with otherwise frequent opioid exposure, existing opioids occupying the mu receptor will be immediately and fully displaced. This will result in a worse-than-normal withdrawal syndrome. While not considered directly dangerous for most people, patients are less likely to resume care with buprenorphine after experiencing a precipitated withdrawal. This side effect is uncommon and easily mitigated when buprenorphine is administered in appropriate clinical settings (PCSS, 2018).

Secondary to its long half-life, methadone must be tapered when discontinuation is desired. Transitioning from methadone to buprenorphine is more technically complicated. However, researchers have described cases of micro-dosing buprenorphine during hospitalization as a means to transition from methadone to maintenance buprenorphine (Klaire et al., 2019; Lee et al., 2020; Raheemullah & Lembke, 2019; Terasaki et al., 2019). Further study of micro-dosing is needed, in particular, in the outpatient setting.

Prescribing trends. In 2017, 518,155 patients were engaged in treatment of OUD using one of the three MAT medications (Kreek et al., 2019). Of these, 74% of patients were prescribed methadone, 22% buprenorphine, and 4% naltrexone. This represents an 18% increase in total patients receiving MAT compared to 2015. Buprenorphine prescribing increased 83% between 2015 and 2017, compared to 11% for methadone and 129% for naltrexone. However,

relative naltrexone prescribing is still very low, representing less than 25,000 patients (Kreek et al., 2019).

Overall efficacy. In its landmark document *Medications for Opioid Use Disorder Save Lives*, the National Academy of Medicine reported:

Medication-based treatment is effective across all treatment settings studied to date.

Withholding or failing to have available all classes of FDA-approved medication for the treatment of opioid use disorder in any care or criminal justice setting is denying appropriate medical treatment. (National Academy of Medicine, 2019, p. S-3)

Wakeman et al. (2020) evaluated over 40,000 insured individuals with OUD between 2015 and 2017. Patients were engaged in one of six mutually exclusive treatment pathways including buprenorphine or methadone therapy, naltrexone therapy, inpatient detoxification, intensive behavioral health, non-intensive behavioral health, or no treatment. Among this cohort, treatment with buprenorphine or methadone resulted in a 76% reduction in opioid overdoses at three months and a 59% reduction at twelve months. Such treatment was also associated with a 32% and 26% reduction in acute care needs at three months and twelve months, respectively. Importantly, the authors found treatment with buprenorphine or methadone was superior to no treatment or treatment absent of these pharmacotherapies (Wakeman et al., 2020).

Buprenorphine Efficacy

Treatment of acute withdrawal. Symptoms of opioid withdrawal are widely recognized to include subjective and objective factors including elevated pulse rate, diaphoresis, pupil size, irritability, gastrointestinal upset, runny nose, and gooseflesh skin. While the first opioid withdrawal scale was published by Kolb and Himmelsbach in 1938, this required close observation for over 24 hours to document clinical elements such as calorie intake. Today, the

severity of opioid withdrawal is measured by the Clinical Opiate Withdrawal Scale (“COWS scale”) (Himmelsbach, 1942; Wesson & Ling, 2003). Until recently, patients experiencing acute opioid withdrawal were offered medically-assisted withdrawal, commonly referred to as detoxification (“detox”), or non-opioid pharmacotherapy used primarily as supportive treatment. These include clonidine for anxiety, loperamide for diarrhea, ondansetron for nausea and vomiting, and hydroxyzine for goosebumps and sweating, among others (PCSS, 2018).

Despite the use of adjunctive medications used in supportive treatment, studies have shown improved detoxification with buprenorphine. Ling et al. (2005) evaluated the effectiveness of buprenorphine versus clonidine across 344 patients in inpatient and outpatient treatment settings. Patients were placed on a two-week withdrawal protocol. At day 14, 77% of patients receiving buprenorphine from the inpatient setting were still engaged and providing opioid-negative urine drug screens, compared to 22% of those receiving clonidine. For the outpatient group, 29% of those receiving buprenorphine were still engaged compared to 5% of those prescribed clonidine (Ling et al., 2005).

Srivastava, Njoroge, & Sommer (2019) randomized patients in the emergency department to receive buprenorphine or clonidine to treat opioid withdrawal. Patients were provided a discharge prescription for the respective medication and referral to an outpatient addiction clinic. One month later, 62% of patients who received buprenorphine were still engaged in treatment, compared to 8% in the clonidine group. Patients receiving buprenorphine therapy have significantly lower cravings scores. Even at doses between 0.6mg and 1.2mg daily, today considered less efficacious for the treatment of OUD, buprenorphine is superior to clonidine in relieving many of the subjective and objective symptoms of opioid withdrawal (Nigam et al., 1993; PCSS, 2018).

Maintenance treatment. For every two patients with OUD, only one needs to be treated with buprenorphine to prevent ongoing illicit opioid use (Raleigh, 2017). This is referred to as the “number needed to treat” ratio. In comparison, 44 patients need to be treated with aspirin to prevent one patient from having a myocardial infarction (Sanmuganathan, 2001). Thomas et al. (2014) performed a sweeping systematic review of studies between 1995 and 2012 focusing on buprenorphine maintenance therapy; the authors found the “evidence clearly shows that buprenorphine maintenance therapy has a positive impact compared with placebo on retention in treatment and illicit opioid use” (p. 11). Buprenorphine therapy is associated with reduced incidence of syringe sharing, intravenous drug use, and subsequent reductions in intravenous-drug-related HIV (Edelman et al., 2014; Sullivan et al., 2008).

Fudala et al. (2003) administered a multicenter, randomized, placebo-controlled trial of 326 patients to determine efficacy of buprenorphine for maintaining abstinence from illicit opioids and self-reported control of cravings. The trial was terminated early because of overwhelming evidence that buprenorphine was superior to placebo. Fiellin et al. (2008) followed 53 patients engaged in buprenorphine therapy for five years. Patient satisfaction with buprenorphine treatment had a mean score of 91%. Over 90% of the 1,100 urine drug screens performed during the study period revealed ongoing abstinence from illicit opioids.

Kakko, Svanborg, Kreek, & Heilig (2003) performed a placebo-controlled study in Sweden evaluating buprenorphine therapy for the treatment of OUD. The authors compared outcomes for twenty patients who received buprenorphine maintenance therapy with twenty patients who were provided buprenorphine detoxification for six days followed by placebo. The authors found 75% retention in the buprenorphine maintenance group vs 0% in the placebo group. Interestingly, all twenty of the control group participants left the study within the first

three months due to positive urine drug screens. Four patients in the control group died during the treatment period versus none of the patients receiving buprenorphine (Kakko et al., 2003). Findings in other placebo-controlled studies further supported the use of buprenorphine to treat OUD in terms of treatment retention and negative urine drug screens (Ahmadi et al., 2004; Ling et al., 1998; Schottenfeld et al., 2008). Even dosing buprenorphine as low as 2mg daily was superior to placebo in maintaining patients in long-term treatment (Mattick, Breen, Kimber, & Davoli, 2014).

Home dosing. Initiation of buprenorphine therapy has historically taken place in the clinic setting, however initiation at home may be becoming more common. In a study of 72 buprenorphine prescribers in New York in early 2016, 65% were providing home inductions (Kermack et al., 2017). Bell et al. (2007) found no difference in the number of days patients abstained from heroin, regardless of whether they participated in daily clinic dosing or unobserved home dosing with a weekly prescription. Patients were followed from buprenorphine initiation for a period of twelve weeks.

Buprenorphine in pregnancy. The American College of Obstetricians and Gynecologists recommends the use of buprenorphine during pregnancy for the treatment of OUD (American College of Obstetricians and Gynecologists, 2019a). There is no known increased risk of birth defects with the use of buprenorphine in this setting (SAMHSA, 2018a).

Buprenorphine Treatment Retention

Facilitating ongoing buprenorphine treatment and how long such treatment should last are areas of ongoing research. In a sample of over 4,000 buprenorphine prescribers, 88% stated buprenorphine should be used indefinitely assuming ongoing patient benefit (Jones & McCance-Katz, 2019). In a sample of over 350 patients in Massachusetts engaged in buprenorphine

therapy over five years, 40% remained in treatment for a full year (Shcherbakova et al., 2018). Among 650 patients started on buprenorphine and tapered after 12 weeks, less than 7% continued to abstain from illicit opioid use, suggesting longer treatment is better (Weiss, 2011). For most patients, recurrence of opioid misuse occurs within 30 days of treatment cessation. Higher buprenorphine maintenance doses may be associated with higher likelihood of recurrence, although higher buprenorphine doses likely signifies more severe opioid dependence in the first place (Bentzley et al., 2015).

Importantly, while sobriety is often the target goal of clinicians, providing periodical treatment also has benefit. Stein (2003) was one of the first researchers to show decreasing the frequency of intravenous drug use may have benefit, even if total abstinence is not achieved. In Rhode Island, utilization of emergency room services was followed among over 230 patients enrolled in either an opioid agonist treatment program or a syringe exchange program. A strong association was found between frequency of self-reported heroin injections and healthcare utilization. Patients in the syringe exchange program were more likely to visit the emergency department. However, when controlled for frequency of injections, the differences in healthcare utilization between the methadone treatment and syringe exchange cohorts became statistically non-significant (M. Stein, 2003).

Reasons for attrition. Tofighi et al. (2019) describe many of the reasons patients may stop treatment. Discontinuation of buprenorphine therapy may occur due to challenges entering treatment or paying for treatment. Other patients may discontinue treatment after being exposed to peers who are actively using substances during group therapy sessions. Some patients identify the “financialization” of their care as a reason they discontinue treatment; feeling as though maintenance buprenorphine treatment is primarily based on a profit motive of clinics. Other

patients decide to taper themselves off of buprenorphine therapy and do so on their own more quickly than recommended. Patients may become frustrated with more frequent follow-up intervals after positive urine drug screens and may also face administrative discharges from buprenorphine programs. Some patients may not tolerate buprenorphine or may have better outcomes in the highly structured daily dosing environment of a methadone program. For example, Alford et al. (2011) describes a program where patients are started on buprenorphine therapy but transferred to a methadone program if three consecutive urine drug screens are positive for illicit opioids or if there is concern for medication misuse and a desire for daily observed medication administration.

Patients engaged in treatment sometimes continue to experience cravings and are often in close proximity to triggers such as widespread availability of heroin in their neighborhoods or home environments. Interacting with social networks associated with drug use also increases the risk for recurrence. Rigid treatment programs also inhibit access to employment opportunities and promote discontinuation (Truong et al., 2019). Co-occurring substance use disorders also increase the chance patients discontinue buprenorphine therapy. For example, patients with OUD co-occurring with methamphetamine use disorder are less likely to initiate treatment during hospitalization, are less likely to be retained in long-term treatment, and may have buprenorphine therapy stopped by clinicians secondary to non-opioid drug use. (Englander et al., 2019; Tsui et al., 2020).

Duration of treatment. There is limited data as to when tapering and ultimately discontinuing buprenorphine treatment should be done. However, doing so at an inappropriate time increases mortality and healthcare utilization (Sordo et al., 2017). Williams, Samples, Crystal, and Olfson (2019) evaluated post-treatment outcomes among almost 9,000 Medicare

patients between 2013 and 2017 who received buprenorphine therapy for at least 60 days. The sample was divided into four cohorts based on length of treatment retention: 6-9 months (46%), 9-12 months (27%), 12-15 months (17%), and 15-18 months (10%). Among all cohorts, the six-month period following treatment cessation was considered high-risk from the perspective of healthcare utilization. Within six months of treatment discontinuation, the average rate of emergency department visits was 45%, with each cohort having a greater than 10% chance of an inpatient admission. In each cohort, 5% of patients experienced an overdose within six months (Williams et al., 2019). These findings are summarized in Figure 14. Over 50% of buprenorphine prescribers in a study by MacDonald, Lamb, Thomas, and Khentigan (2016) reported a goal of patients stopping treatment at some point. Interestingly, the prescribers compared buprenorphine maintenance therapy to other behaviorally-related maintenance medications such as lithium. The latter is seldom discontinued once the treatment goal is achieved.

Connery and Weiss (2020) discuss how buprenorphine therapy itself is only one component of recovery. The degree to which patients are successful once the medication is tapered also relies on other components undertaken during recovery: lifestyle and identity changes, relational modifications, building personal and family connections, and addressing physical health. Unlike alcohol use disorders for which harm reduction strategies can be used to mitigate immediate risk during an acute recurrence of the disease (such as avoiding driving a vehicle), similar strategies cannot be used for OUD; patients cannot self-administer naloxone after an overdose (Connery & Weiss, 2020). However, as will be discussed later in this paper, harm reduction strategies improve outcomes over the extended course of addiction chronicity. In 2017, Scott Gottlieb, Commissioner of the Food and Drug Administration, “strengthened labeling for the MAT drug buprenorphine to emphasize that patients may require treatment

indefinitely and should continue treatment for as long as they benefit and as long as the use of MAT contributes to their intended treatment goals” (Food and Drug Administration [FDA], 2017, para 2).

During hospitalization. Patients started on buprenorphine therapy during hospitalization may have lower rates of follow-up after discharge because those patients were not necessarily seeking treatment at the time they entered the hospital for a medical diagnosis. Such medical illness may take priority in the immediate post-discharge period over that of a substance use diagnosis. Retention in a post-hospital discharge program after the first few months may also require more interventions and wrap-around services than medication dispensing (Liebschutz et al., 2014).

Buprenorphine versus Methadone for Treatment of Opioid Use Disorder

In the hospital setting, patients provided detoxification with buprenorphine are more likely to complete a detoxification protocol than patients provided methadone (Blondell et al., 2007). Giacomuzzi et al. (2003) studied 53 patients over six months, 30 of which were treated with buprenorphine and 23 who were treated with methadone. Quality of life measures had no difference between the two groups. Patients prescribed buprenorphine were less likely to experience withdrawal symptoms and were less likely to use illicit opioids. Buprenorphine and methadone have been found to be equally efficacious in treating the psychoactive components of OUD including mood and anxiety disorders and other psychiatric syndromes (Maremmani et al., 2011). Many of the studies comparing methadone to buprenorphine called for doses of buprenorphine between 2mg and 11mg, in regimens other than daily dosing such as alternate-day dosing, and for short durations – all considered ineffective today (Kosten et al., 1993; Mattick et al., 2003; Pinto et al., 2010). Currently, optimal buprenorphine dosing is 16mg daily for most

patients for as long as benefit is received. This may be several years in some cases. (PCSS, 2018). Buprenorphine cannot be compared to methadone without taking these important factors into account.

Two Cochrane reviews of patients with OUD treated with 16mg or greater of buprenorphine showed similar outcomes compared to methadone (Mattick et al., 2014; Nielsen et al., 2016). In an analysis of private insurance pharmaceutical claims for almost 4,000 patients from 2005 to 2012, a median daily dose of 15.7mg resulted in a 41% decreased chance of psychiatric hospitalization and 23% reduction in total healthcare costs (Clay et al., 2014). Hser et al. (2016) followed almost 800 patients randomized to buprenorphine versus methadone over five years. Mortality rates were indifferent between the two groups, and patients receiving buprenorphine therapy reported using heroin an average of 1.4 more days per month compared to those receiving methadone treatment. However, the authors comment that improved systems infrastructure for buprenorphine therapy may improve treatment adherence.

Buprenorphine has greater efficacy in pregnancy compared to methadone. As a result of the Maternal Opioid Treatment: Human Experimental Research Study (MOTHER Study), Jones et al. (2010) discovered infants born to mothers being treated with buprenorphine had less severe neonatal abstinence syndrome. Figure 15 shows infants required less morphine treatment for symptom management, had shorter stays in the neonatal intensive care unit, and shorter overall hospital stays compared to infants born to mothers treated with methadone. The results were so stark the study was stopped early.

During incarceration, patients receiving buprenorphine are more likely to continue treatment during their time in jail and are more likely to enter opioid treatment after release than patients receiving methadone. Further, there does not appear to be a difference in post-

incarceration return to illicit opioid use, re-arrests, or re-incarceration for patients prescribed buprenorphine versus methadone (Magura et al., 2009; Moore et al., 2019).

As will be discussed later, the regulatory environment of buprenorphine may make it the ideal pharmacotherapy to treat OUD for many patients, especially considering the more stringent regulatory environment of methadone and similar comparative effectiveness.

Regulatory Environment

Drug Addiction Treatment Act of 2000. Passed in 1970, the Controlled Substances Act separates medications which can be purchased over-the-counter, referred to as “legend drugs”, from medications which can only be obtained with a prescription from a qualified provider, referred to as “scheduled drugs” (DEA, n.d.-b). Prescription drugs are placed on lists ranging from Schedule V down to Schedule I based on how likely the drug is to be addictive compared with its appropriate medicinal use. Schedule V is considered to be the least addictive, whereas Schedule I is considered to be the most addictive and with the least medical benefit. Schedule I drugs are completely illegal and may never be produced, distributed, or prescribed in the United States. Heroin is a schedule I drug. Schedule II drugs include legal opioids, which may be prescribed by qualified providers. In most states, Schedule II drugs require additional compliance monitoring. Schedule III through Schedule V drugs still require a prescription but are less scrutinized than those on Schedule II. (DEA, n.d.-b).

The Narcotic Addict Treatment Act of 1974 prohibits the use of scheduled drugs to treat OUD outside of clinics specifically licensed by the federal government to do so. This law led to the proliferation of opioid treatment programs (OTPs), commonly referred to as “methadone clinics”, throughout the rest of the century (Kleber, 2008). Once buprenorphine was developed and classified as a schedule III drug, it would have been restricted in a similar manner without

the passage of additional legislation. In 2000, Republican Senator Orrin Hatch and Democratic senators Joe Biden and Carl Levin introduced the Drug Addiction Treatment Act (GovTrack, 2020b). The legislation specifically permits physicians to prescribe Schedule III through Schedule V medications for the treatment of OUD. Effectively, this permits buprenorphine, a Schedule III drug, to be prescribed for patients with OUD. To qualify, physicians must be board-certified in addiction medicine, have participated in the original buprenorphine studies, or complete an 8-hour training course designed for physicians about safely prescribing buprenorphine (DEA, n.d.-a).

By increasing the number of prescribers able to treat OUD with buprenorphine, policymakers hoped that access to buprenorphine treatment would improve. The overall strategy was to supplement the low number of physicians who had addiction medicine board certification with primary care providers. Those clinicians who complete the eight-hour training receive a second DEA license number beginning with an X, and therefore the process has become known as obtaining an “x-waiver” (DEA, n.d.-a; SAMHSA, 2018).

Additional legislation. On July 22, 2016, President Barrack Obama signed the Comprehensive Addiction and Recovery Act (CARA) into law (Congress.gov, 2016). CARA provided the temporary legal authority for physician assistants (PAs) and advanced practice nurses (APNs) to prescribe buprenorphine for the treatment of OUD, however these practitioners were required to complete 24 hours of additional training compared to the eight hour training required of physicians (Gardner & Ashford, 2016). The Substance Use-Disorder Prevention That Promotes Opioid Recovery and Treatment for Patients and Community Act (SUPPORT for Patients and Communities Act) was signed into law by President Donald Trump on October 24, 2018, making permanent the ability of PAs and APNs to prescribe buprenorphine for the

treatment of OUD (Congress.gov, 2018). The disparity in training hours between PAs and APNs and physicians remains.

Patient limits. The laws and regulations pertaining to the x-waiver restrict the number of patients a single prescriber may treat with buprenorphine for OUD at one time. Originally, prescribers could treat a maximum of 30 patients concurrently in the first year of having an x-waiver and then apply to the federal government to treat 100 patients followed by another application to treat 275 patients (DEA, n.d.-a). However, as of 2018, the SUPPORT Act allows prescribers to immediately prescribe buprenorphine for up to 100 patients in the first year. Yet, this is not done automatically. Prescribers must still apply for this increase after receiving the initial permission to treat 30 patients (Congress.gov, 2018).

Emergency department x-waiver exception. The emergency department has an explicit exception. Emergency medicine physicians are able to dispense buprenorphine for up to three days while a patient works to gain access to a treatment program. The patient is required to visit the ED each day during the three-day period (DEA, 2005).

Prescriber trends and current x-waiver landscape. As of April 2020, there are 85,042 practitioners who have completed the x-waiver training. Of these, 73% of practitioners can prescribe for only 30 patients concurrently compared to 100 or 275 concurrent patients for the remaining (SAMHSA, 2020). Again, any prescriber who is authorized to prescribe buprenorphine for 30 patients may also prescribe for 100 patients after completing a brief application process, which does not appear to be occurring for reasons described later. Fewer than 5% of eligible U.S. practitioners have an x-waiver (NEJM, 2018). As will be described shortly, many of those with an x-waiver also do not prescribe buprenorphine at all or at anywhere near the patient limit.

One of the primary goals of the x-waiver legislation was to increase utilization of buprenorphine in primary care. In Massachusetts, the majority of buprenorphine prescribers shortly after the DATA 2000 legislation was passed were in primary care (Walley et al., 2008). From 2006 to 2014, there was a 767% increase in ambulatory visits involving the prescribing of buprenorphine for OUD. This represents a 840% increase in visits with primary care and a 285% increase in visits with psychiatry (Wen et al., 2019). Figure 16 shows buprenorphine prescribing trends by specialty between 2006 and 2014. However, between October 2013 and October 2016 only 20% of patients with OUD seen in primary care received buprenorphine (Lapham et al., 2020).

Prior to December 2016, 23 million Americans lived in 1,436 counties without a buprenorphine prescriber. Between the passing of CARA in December 2016 and March 2019, there was a 111% increase in the total number of x-waivered providers in the United States. A majority of the increase (56%) in rural counties came from PAs and APNs (Barnett, Lee, & Frank, 2019). Scope of practice laws for PAs and APNs vary by state and are controversial (Diamond, 2016). Notably, treatment capacity for buprenorphine therapy for OUD was significantly higher in areas with full practice authority for PAs and APNs (Barnett et al., 2019). Figure 17 shows the growth of buprenorphine treatment capacity among nurse practitioners and PAs separated by scope of practice regulations.

There has been minimal uptake of the x-waiver within psychiatry and addiction medicine settings. Jones and McCance-Katz (2019) collected responses from 4,225 recently waived providers in April of 2018. Less than 12% of respondents had a board certification in addiction psychiatry or addiction medicine. Seventy-six percent of respondents reported prescribing buprenorphine at least once for the treatment of OUD. Obtaining the waiver is only the first step.

To make an impact on the opioid epidemic, those who receive the x-waiver must still actively take steps to treat patients with OUD by prescribing buprenorphine. Limitations of the x-waiver system will be discussed later in this paper.

Between 2004 and 2011, the total dosing weight of buprenorphine prescribed in opioid treatment programs increased by over 2,300% (Stein et al., 2015). There were 71 treatment programs utilizing buprenorphine in 2004 compared to 348 by 2011. Importantly, this represents an uptake in buprenorphine prescribing specifically within opioid treatment programs. While this is likely beneficial, opioid treatment programs are addiction-specific practice settings entirely separate from the primary care setting. Despite this growth of buprenorphine treatment in the outpatient setting, the medication's use in hospitals may be far less.

Hospital-Based Treatment

Hospitalization may be an ideal opportunity to offer patients with OUD access to treatment. There are over 6,000 hospitals in the United States (American Hospital Association, 2019). The majority of patients with previous substance use before hospitalization will return to that behavior after discharge if treatment has not been initiated (Chutuape et al., 2001). Among patients using heroin who are only provided detoxification, 80% will return to illicit opioid use within 30 days (Chutuape et al., 2001). Buprenorphine induction in the hospital setting leads to increased completion of inpatient medical therapies and ultimate transition to outpatient substance use treatment (Trowbridge et al., 2017).

Inpatient Hospitalization

Relevance of treatment to hospitalization. Substance use disorders are prevalent among patients who present to the hospital and may have direct implications on overall care delivery. Of over 700 patients admitted to a Boston hospital, 17% had at least one substance use

diagnosis documented at discharge. During the 21-month study, patients with drug-related diagnoses were more likely to visit the ED and more likely to be readmitted within 30 days of discharge. Even when adjusted for age, sex, presence of depression, insurance type, homelessness, and Charlson score (index of co-morbidity severity), patients with drug use were 1.7 times more likely to be readmitted to the hospital (Walley et al., 2012).

Moreno et al. (2019) performed a retrospective analysis of readmission data among 470 patients with OUD who were admitted to Massachusetts General Hospital between October 2011 and September 2016. Overall, approximately 20% of patients were readmitted within 30 days and 32% of patients were readmitted within 90 days. Patients receiving buprenorphine therapy were 53% less likely to be readmitted within 30 days and 41% less likely to be readmitted within 90 days. In another study, patients who maintained buprenorphine therapy for one year were 70% less likely to be admitted to the hospital for any cause (Shcherbakova et al., 2018).

Despite evidence that providing access to substance use disorder treatment as part of hospitalization is clinically and administratively efficacious, such access is seldom afforded (Naeger et al., 2016). Of almost 37,000 privately-insured patients from 2011 to 2014 who presented to a hospital for an opioid-related reason, only 17% were engaged in outpatient substance use disorder treatment within 30 days of discharge; despite about 80% of patients having a physical health outpatient visit and 34% having a behavioral health visit within 90 days prior to hospitalization. In this study, engagement was defined as attending two follow-up treatment appointments within 30 days of discharge. Patients admitted for an opioid overdose had lower odds of being engaged in SUD treatment after discharge compared to other substance-related diagnoses such as alcohol use disorder (Naeger et al., 2016).

Efficacy of treatment initiation during hospitalization. Parran et al. (1994) were among the first to report using buprenorphine in the hospital setting. The researchers administered subcutaneous buprenorphine strictly to manage opioid withdrawal among 65 patients, 97% of whom reported favorable experience. However, all patients were then provided a rapid taper over six days as opposed to long-term treatment, which was not possible because the DATA 2000 regulations for buprenorphine maintenance did not occur until 2000.

Aszalos, McDuff, Weintraub, Montoya, and Schwartz (1999) reported efforts to initiate treatment of OUD during hospitalization. The authors were part of an inpatient consultation service specific to substance use disorders. Prior to launching their study, patients experiencing opioid withdrawal were provided methadone detoxification during hospitalization and referred to treatment at discharge. A majority of patients did not attend the follow-up appointment. Faced with increasing ED presentations and readmissions related to consequences of OUD, the health system funded an in-hospital ambulatory methadone treatment program. Over a 14-week period in 1997, 67 patients using heroin were referred to the methadone treatment program. All patients accepted. As a condition of entering the program, patients were required to visit the in-hospital ambulatory methadone treatment area and meet with the staff prior to hospital discharge, and then report back the next day. After six months, 58% of patients were still engaged in the treatment program (Aszalos et al., 1999).

Shanahan, Beers, Alford, Brigandi, & Samet (2010) also initiated methadone therapy with the goal of long-term maintenance therapy as opposed to sole detoxification and withdrawal mitigation. Of 203 patients initiated on methadone from 2002 to 2005 at a single hospital, 82% presented to the follow-up clinic after discharge and 35% enrolled in long-term treatment. Of note, the program lacked enrollment guidelines, and patients were encouraged to present to the

clinic regardless of their desire to continue methadone therapy. Moreover, urine drug screens were not required as part of treatment. Although this program was methadone (and not buprenorphine) focused, it demonstrated the utility of initiating treatment during acute hospitalization; the authors were among the first to describe hospitalization as a “reachable moment” to treat OUD (Shanahan et al., 2010).

Hospitalization is indeed a reachable and treatable moment for patients with OUD. Pollini, O’Toole, Ford, and Bigelow (2006) studied the evolution of readiness to change among 353 patients with substance use disorders over the course of inpatient hospitalization. Over three quarters of those patients had a diagnosis of OUD, and over 40% were admitted for an infectious process likely related to intravenous drug use. Sixty-eight percent of patients recognized substance use as a major reason for their hospitalization, and 72% reported treatment for drug use was important. On admission, 51% of patients were in the precontemplative stage for change, 33% were in the contemplative stage, and 16% were in the action stage. Forty-four percent of patients increased from precontemplation or contemplation to a higher level of change-readiness over the course of hospitalization. Predictors of improved readiness to change included concern that one might get sick again and need repeat hospitalization, concern about one’s overall physical health, and being “tired of using” drugs (Pollini et al., 2006).

There are numerous examples in the literature of successfully initiating buprenorphine treatment during acute hospitalization. Suzuki et al. (2015) provided a case series of 47 patients with OUD who were treatment-naïve and initiated on buprenorphine during hospitalization in 2013 and 2014. None of the patients were seeking treatment at the time of hospital admission. In these cases, the psychiatry consultation service provided the support for medical staff related to buprenorphine induction and stabilization over the entire course of hospitalization. Attempts

were made to identify outpatient buprenorphine prescribers and to secure an appointment before discharge. If an appointment was secured, the psychiatry service wrote a bridge prescription from discharge until the follow-up appointment. If an appointment was not scheduled, the psychiatrist wrote up to a four-week prescription with instructions for the patient to continue seeking a local buprenorphine prescriber. The duration of the outpatient prescription was determined subjectively by the psychiatrist based on several factors including stable housing, available support systems, and presence of acute or chronic pain. All 47 patients received a prescription for buprenorphine. Forty-seven percent of patients filled a buprenorphine prescription within two months, although it's unclear if those patients were filling the prescription from hospitalization or from an outpatient provider. Fifty-nine percent of patients who were referred to a specific clinic continued treatment after discharge compared to 39% of patients who were provided a prescription but no referral, however these differences were not statistically significant (Suzuki J et al., 2015).

Liebschutz et al. (2014) were the first to evaluate the efficacy of inpatient buprenorphine induction while following patients longitudinally at a hospital-affiliated outpatient treatment clinic. In their single-center study, 139 treatment-naïve patients with OUD were randomized into two groups: those provided detoxification with a buprenorphine taper (n=67) and those provided full buprenorphine initiation with linkage to treatment at discharge (n=72). Seventy-two percent of the patients in the linkage group entered outpatient treatment affiliated with the study hospital within six months of discharge compared to 12% of patients in the detoxification group. At six months after entry, 17% of patients in the linkage group were still engaged in such treatment compared to 3% of those in the detoxification group. Of note, an additional 15 patients in the detoxification group and three patients in the linkage group entered some form of treatment

during the study period (methadone, buprenorphine, or inpatient detoxification), but these patients sought care outside of the hospital system and their entry into treatment was documented by self-report in follow-up interviews. Thus, the overall rate of successful early post-discharge interventions during the study period may be considered 76% for the linkage group and 34% for the detoxification group. Patients in the linkage group had lower mean and median days of illicit opioid use per 30 days compared to the detoxification group (8 vs 14 and 4 vs 15, respectively) Liebschutz et al. (2014) explained. In a follow-up study, Lee, Liebschutz, Anderson, and Stein (2017) explored predictors of patients entering treatment after discharge. Patients with previous history of buprenorphine treatment were 3.5 times more likely to attend their first appointment and stay engaged in treatment for a longer period of time. A longer length of hospital stay was also associated with greater likelihood of entering treatment.

Trowbridge et al. (2017) evaluated 319 patients seen over 26 weeks as part of an addiction medicine consult service at a single study site. Seventy-eight percent of patients had a diagnosis of OUD. Buprenorphine therapy was started during hospitalization for 40 treatment-naïve patients. Of these patients, 39%, 27%, and 18% continued to receive treatment at one month, three months, and six months, respectively. The researchers could only closely follow patients who participated in the hospital's outpatient clinic and were aware of at least two additional patients engaged in treatment within 180 days. The authors noted their study built upon the research by Liebschutz et al. (2014), who had substantial funding for their study and access to research staff. These resources may have facilitated follow-up. However, Trowbridge et al. shared their "follow-up rates [being] similar shows that starting agonist therapy in-hospital and linking patients to on-going outpatient care is feasible in real world situations, not just well-controlled experiment settings" (p. 3).

Inpatient addiction medicine consultation. Addiction medicine consult services improve engagement in longitudinal care for patients with substance use disorders, improve patient experience during hospitalization, and likely reduce the total cost of in-hospital care (Englander et al., 2019; Hyshka et al., 2019; Priest et al., 2019; Priest & McCarty, 2019a, 2019b). The work by Trowbridge et al. (2017) is “real world”, but it also reflects outcomes in the presence of a funded, staffed, and dedicated addiction medicine consultation service. While “hospitals have largely been overlooked as a setting ripe for the delivery of specialized addiction care” (Braithwaite & Nolan, 2019, p.252), such sub-specialist care is often cost-prohibitive. Yet, many aspects of addiction-related care may be delivered by primary care teams such as hospitalists and emergency medicine physicians. Some of these are described in Table 1.

Englander et al. (2018) described how Oregon Health and Science University launched the Improving Addiction Care Team (IMPACT) in 2015, an interprofessional addiction medicine consultation service that focuses on substance use disorders, including OUD and the prescribing of buprenorphine. Previously, hospital medicine practitioners felt ill-equipped to address substance use disorders, which adversely impacted patient care, created a volatile working environment, and led to staff burnout. Once IMPACT launched, providers felt the program “legitimized addiction as a treatable disease... and humanized care by treating withdrawal, directly communicating about SUD, and modeling compassionate care” (p. E3). Interestingly, after IMPACT implementation, one staff member commented the service became viewed as “the easy solution to everything, we look around say, boy, this looks hard let’s call [the IMPACT Team]. We need the ability for IMPACT to build competence in the organization and not carry the whole load, but build all of our capabilities” (p. E3).

Treatment in the setting of related infections. As noted previously, infections related to OUD are increasing at alarming rates. These infections may be treated in the hospital setting without addressing the underlying cause: opioid use disorder. For example, fewer than 10% of patients with a diagnosis of infective endocarditis secondary to injection drug use who were evaluated at a large academic tertiary care center in Boston were referred for MAT, despite its clear availability in the region (Rosenthal et al., 2016).

Referral to addiction-related treatment has been shown to reduce mortality for patients with infective endocarditis related to IV drug use (Rodger et al., 2018). Among 108 charts reviewed at the University of Kentucky HealthCare hospital of patients with OUD admitted between 2012 and 2015, 60% had endocarditis, 25% had osteomyelitis or septic arthritis, and 8% had a skin or soft tissue infection. Among the cohort, the primary care teams recommended counseling and cessation for 83% of patients – not MAT. Only 7% of discharge summaries mentioned pharmacotherapy for the treatment of OUD; however, no patients were provided direct referral or follow-up appointments pertaining to treatment of OUD (Jicha et al., 2019).

Emergency Department

The emergency department (ED) is a critical setting for initiating treatment of substance use disorders. A visit to the “emergency department represents a critical, time-sensitive point at which initiating lifesaving treatment is possible” (D’Onofrio, McCormack, & Hawk, 2018, p. 2489). D’Onofrio et al. (2015) conducted a randomized control trial of 329 patients with OUD at the Yale New Haven ED from April 2009 through June 2013. Patients were randomized to one of three groups: referral to an outpatient treatment program only (n=104), a Screening, Brief Intervention, and Referral to Treatment (SBIRT) intervention (n=111), and initiation of buprenorphine with referral to an outpatient clinic (n=114). In the buprenorphine group, patients

were treated immediately in the ED if symptoms of withdrawal were observed. Otherwise, patients were provided buprenorphine for home-based initiation. Follow-up was arranged at a hospital-based primary care clinic for the first 10 weeks of treatment and then transferred to a community-based addiction clinic or tapered based on patient preference. After 30 days, 78% of patients provided buprenorphine in the ED were engaged in treatment, compared to 45% in the SBIRT group, and 37% in the referral-only group. In addition, only 11% of patients provided buprenorphine required subsequent inpatient addiction-related treatment, compared to 35% of patients in the SBIRT group and 37% in the referral-only group (D'Onofrio et al., 2015).

In a follow-up study, D'Onofrio et al. (2017) described outcomes among the same patient population after two, six, and twelve months. After two months, 74% of patients in the buprenorphine group were engaged in treatment compared to 53% in the SBIRT group and 47% in the referral group. However, after six and twelve months, the differences in treatment engagement between the two groups were not statistically significant. Of note, patients were engaged in the hospital-based clinic for the first ten weeks after discharge. After ten weeks, patients were transferred to other clinics. As such, the authors concluded the results at six and twelve months were attributed to variation in outpatient clinic engagement after the first ten weeks and not on reduced long-term efficacy of ED-initiated buprenorphine treatment (D'Onofrio et al., 2017).

Buprenorphine initiation is also feasible in community and rural emergency departments. One such hospital in rural New York enrolled 62 patients in buprenorphine treatment during an ED visit for opioid withdrawal (Edwards et al., 2020). Over 80% of patients attended the follow-up visit with 69% and 53% engaged in care at 30 and 90 days, respectively. Importantly, based on a retrospective chart review, even patients who are provided buprenorphine therapy for

withdrawal symptoms and not ultimately engaged in a long-term treatment plan may be less likely to return to the ED for opioid-related diagnoses within 30 days compared to patients treated with traditional withdrawal medications such as clonidine (Berg et al., 2007). Further study is needed.

Kaucher et al. (2019) performed a retrospective analysis of patients provided ED-based buprenorphine inductions at Denver Health Medical Center between May 2017 and October 2018. During the study period, 807 patients were coded as having opioid withdrawal, “abuse”, or dependence. Of these, 219 (27%) patients were initiated on buprenorphine therapy. Three-quarters of patients attended their follow-up appointment and 49% were still engaged in treatment after 30 days. Just under 60% of ED inductions in this program were performed by physician assistants or nurse practitioners (Kaucher et al., 2019).

Hu, Snider-Adler, Nijmeh, and Pyle (2019) described a pilot program in four Canadian emergency departments over an eight-month period in 2017. During this period, 43 patients were provided up to 8mg of buprenorphine during a visit to the ED in addition to a next-day appointment at a “rapid access addiction clinic”. Seventy-one percent of patients visited the ED in the 12 months prior to entering the study with 57% of the visits related to substance use. The authors found that 88% of patients with OUD were interested in starting buprenorphine during their visit to the ED with understanding this was on the condition of following-up at an addiction medicine clinic within 24 hours. Of these, 54% attended the initial appointment and 35% were still engaged in treatment at six months. Patients who remained in treatment were less likely to visit the ED during the study period for reasons related to OUD (Hu et al., 2019).

Jails and Prisons

Medication-assisted treatment has tremendous benefit for incarcerated populations and particular relevance for this paper as patients with acute medical problems may be temporarily transferred from the setting of incarceration to a nearby hospital (Huh et al., 2018). For example, a person with OUD who is arrested and placed in jail may soon experience severe opioid withdrawal or need a hospital-based intervention such as an incision and drainage of a deep skin and soft tissue infection. The immediate post-incarceration period is dangerous for patients with OUD secondary to the risk of use recurrence and overdose (Binswanger, 2019; Ranapurwala et al., 2018). Providing treatment of OUD during incarceration may be beneficial for quality of life such as reducing withdrawal and cravings and clinical outcomes upon release including reducing mortality. For such treatment to start during hospitalization, a jail or prison must have the ability to continue such a care plan after hospital discharge. Walsh and Long (2019) recommended offering buprenorphine for incarcerated patients as one of three main approaches necessary to overcome the opioid epidemic. Jail and prison-based opioid treatment programs, while rare, have been shown to be clinically effective and reduce recidivism. Marsden et al. (2017) identified over 15,000 patients with OUD released from 39 different prisons in England over a three-year period. Fifty-seven percent of patients were provided methadone or buprenorphine during incarceration. In the first 28 days after release, opioid agonist therapy provided during incarceration was associated with a 75% reduction in all-cause mortality and 85% reduction in mortality related to drug overdoses.

In the United States, patients who are referred for buprenorphine maintenance therapy after being released from incarceration have similar treatment retention rates compared to patients referred from the community (Lee et al., 2012; Wang et al., 2010). Over 90% of patients

started on buprenorphine during incarceration in Puerto Rico were engaged in outpatient treatment within 30 days of release (Garcia et al., 2007). Re-arrest among patients in California with OUD treated with buprenorphine was less likely over a five-year observation period compared to patients treated with methadone (Evans et al., 2019). In exit interviews with patients randomized to methadone or buprenorphine at a New York City jail, over 90% of patients who participated in buprenorphine therapy reported an intention to enroll in a post-incarceration drug treatment program, compared to 44% of patients receiving methadone. Patients receiving methadone therapy were more likely to experience uncomfortable side effects. All of the inmates who received buprenorphine endorsed they would recommend the medication to others (Awgu et al., 2010). In a prior randomized study at the same facility, approximately half of patients randomized to buprenorphine therapy during incarceration reported to their first outpatient follow-up treatment appointment after release compared to 14% of patients randomized to methadone during incarceration (Magura et al., 2009). In a qualitative study of recently released inmates with OUD, the overall attitude towards buprenorphine was positive (Fox et al., 2015). However, patients expressed concern about having "forced detoxification" from previous methadone treatment during incarceration. As a result, some patients disfavored the use of a medication to treat OUD, but all felt buprenorphine would be a good treatment option to reduce the risk of re-incarceration (Fox et al., 2015). This study sheds light on the importance of having protocols in place not for only starting new treatment, but also for continuing and maintaining treatment for patients already engaged in a plan of care at the time of arrest (Fox et al., 2015).

Drug Cost and Cost Effectiveness

Drug cost. As of November 2019, the average wholesale price (AWP) of Suboxone® was \$10.27 per 8m-2mg sublingual film with a typical target daily dose of 16mg (UpToDate, 2019a). A generic formulation of Suboxone® was approved in June 2018 (FDA, 2018). Buprenorphine-naloxone generic sublingual films are available with an AWP between \$8.79 and \$9.23 (UpToDate, 2019a). The AWP of methadone solution is \$0.14 - \$0.63 per 10mg dose, with OUD typically treated between 80mg and 120mg daily (UpToDate, 2019b). The AWP of extended-release naltrexone for intramuscular injection is \$1,570.80 per monthly administration (UpToDate, 2019c).

Haffajee & Frank (2020) reported that Indivior, the manufacturer of Suboxone®, was accused in 2019 of manipulating various federal laws and regulations to inflate the price of its brand name medication, including when Suboxone® received orphan-drug status. This designation is awarded to pharmaceutical companies who petition the FDA to restrict generic formulations for a specific period of time to recoup costs of drug development for rare diseases. Suboxone® was initially awarded a 7-year orphan-drug period based on their application. This resulted in more than \$1 billion in profits which the company ultimately lost in a court settlement with the federal government. Generic drug manufacturers were also successful in petitioning the FDA to remove the orphan-drug status from Suboxone®. This may bring stability and lower prices to the buprenorphine market (Haffajee & Frank, 2020).

Medication pricing is a complex topic largely because the price of buprenorphine surpasses the price of methadone. Notably, while the medication cost is higher, buprenorphine treatment as a whole may be less expensive for healthcare systems than methadone, which may ultimately make it more affordable for patients. This potential cost savings is due to less stringent

regulations, reduced cost of dispensing, fewer laboratory screening tests, and the overall decreased administrative burden of buprenorphine in the primary care setting versus operating an opioid treatment program for methadone (Clay et al., 2014; Ronquest et al., 2018; Rosenheck & Kosten, 2001).

Murphy et al. (2018) described buprenorphine as being less expensive than extended-release naltrexone (ERN.) The authors reported that ERN costs an average of \$5,317 more than buprenorphine over a 24-week period. The cost difference was largely driven by the washout period required for ERN initiation. As such, the increase in cost is not associated with an increase in quality of life or drug-free years. Roberts et al. (2018) reported the cost of a 30-day supply of buprenorphine stabilized among private insurers between 2003 and 2015. Out-of-pocket costs for patients decreased from \$67 to \$32. Importantly, this data did not include patients participating in public programs or the uninsured. Even for patients with private insurance, many have high deductible health plans. The median spending for a 30-day supply of buprenorphine in 2015 was \$335, which may prohibit many patients from participating in treatment.

Cost effectiveness. King, Sainski-Nguyen, and Bellows (2016) evaluated the cost-effectiveness of buprenorphine versus methadone over one year in the United States data. On average, methadone delivered from a federally-regulated opioid treatment program cost \$450 more annually compared to buprenorphine administered in primary care. Schackman, Leff, Polsky, Moore, and Fiellin (2012) performed a cost-effectiveness analysis of buprenorphine in the primary care setting and incorporated key variables including medication cost, physician and nurse time, lab testing, and patient costs such as travel time and transportation cost. In their analysis, 24 months of buprenorphine therapy in a primary care setting cost \$7,700 dollars, a cost

justified by its improved quality of life compared to no treatment (Schackman et al., 2012). Also, in the emergency department setting, buprenorphine therapy has been found to be cost-saving compared to direct referral and traditional “detoxification” medication regimens (Busch et al., 2017).

Hsu, Marsteller, Kachur, and Fingerhood (2019) evaluated outcomes of the Comprehensive Care Practice (CCP) in Baltimore, Maryland, a program which offers insight into a model where buprenorphine treatment is fully integrated into the primary care setting. The program provides primary care to patients with substance use disorders who have Medicaid. Patients receive care for diseases such as diabetes, hypertension, HIV, and hepatitis C while simultaneously receiving treatment for substance use disorder. All clinicians in the practice are able to deliver primary care and prescribe buprenorphine for OUD. The authors conducted a comparative effectiveness analysis among two patients groups: those who received buprenorphine at CCP and those who received buprenorphine care elsewhere in Maryland. In the control group, buprenorphine was typically prescribed by a sole practitioner in a primary care clinic – one with whom the patient did not have a primary care relationship, only a buprenorphine-prescribing relationship (Hsu et al., 2019).

Between 2008 and 2012, 131 patients receiving Medicaid participated in buprenorphine therapy at CCP compared to 867 patients receiving Medicaid in other Maryland clinics (Hsu et al., 2019). Treatment retention after six months was 79% in the CCP group and 61% in the non-CCP group. As expected, the CCP group had higher pharmaceutical expenditures on buprenorphine secondary to increased retention in treatment. However, the CCP group had fewer acute hospital stays, and when hospital stays occurred, they cost less on average. Importantly, the

CCP group's total healthcare costs were \$4,554 lower than the non-CCP group. (Hsu et al., 2019).

Kessel, Castel, and Nemecek (2018) evaluated commercial insurance claims among patients with OUD. Among this population, 48 (7%) patients were provided a long-term buprenorphine care plan, 241 (37%) were provided buprenorphine detoxification services, and 359 (55%) were provided no MAT at all. Among those provided a long-term buprenorphine care plan, none required detoxification services within four months. In the same time frame, an 80% reduction in medical hospitalizations was noted. In comparison, 50% of patients provided only detoxification required another detoxification within four months, and only a 7% reduction in medical hospitalizations was achieved. As expected, total pharmacy costs for patients participating in a long-term buprenorphine care plan increased by 97%. However, total outpatient costs were reduced by 19% in this group compared to an increase of 24% among patients who received no OUD treatment (Kessel et al., 2018). In an Australian randomized study of 119 patients engaged in buprenorphine maintenance treatment, unobserved home dosing dispensed on a weekly basis cost 22% less than daily in-office dosing, and made no difference on clinical outcomes (Bell et al., 2007). In another Australian study, methadone and buprenorphine delivered in primary care settings were both found to be cost-effective (Harris et al., 2005). Premkumar, Grobman, Terplan, and Miller (2019) found buprenorphine to be more cost-effective in treating mother-baby dyads during pregnancy compared to methadone or a detoxification program.

Cost research limitations. There is much variability and numerous limitations in the approaches used to study cost-effectiveness among patients with OUD. Such factors include the number of patients engaged in treatment, duration of time spent in treatment, number of disease

recurrences during the course of treatment, cost of individual doses, practice settings where the medications are administered, extent to which non-clinical economic criteria are included such as the impact on social service use and criminal justice expenditures, variable impact of OUD treatment on other co-occurring SUDs, outcomes of harm reduction programs in particular syringe exchange programs, perspectives incorporated (health system vs societal), models deployed (Markov, transmission dynamic, etc.), country of study, regulations around who can prescribe, socioeconomic factors, evolving prescriber and patient attitudes towards MAT, and available funding mechanisms for patients to receive treatment which often vary on a state and regional basis or availability of such treatment programs to begin with (Barnett et al., 2001; Connock et al., 2007; King et al., 2016; Rosenheck & Kosten, 2001; Schackman et al., 2012)

Perhaps most importantly, the cost effectiveness when buprenorphine is administered as a widespread, routine and standard component of primary care delivery has not been studied. There are also no cost-effectiveness analyses incorporating physician assistant and advanced practice nursing prescribing since the passage of CARA in 2016. Given how quickly the opioid epidemic has evolved, it is likely that results of the above-mentioned studies, many of which were based on data from earlier parts of the epidemic, would be different if performed today.

Barriers to Care for Patients with Opioid Use Disorder

Exploring barriers to MAT in the hospital and in the general medical community is an important step in providing treatment to all patients who will benefit. Numerous barriers exist to the widespread adoption of buprenorphine therapy by physicians. These include lack of awareness about buprenorphine, inadequate training around addiction and buprenorphine within medical schools or in continuing medical education, minimal or absent institutional support, challenges with care coordination, provider stigma for patients with OUD, perceived time

limitations, complex and insufficient reimbursement including time-intensive prior authorizations, inadequate access to recovery support services beyond pharmacotherapy and brief office-based counseling, unaffordable long-term treatment options for patients, inadequate clinical space, concern about diversion, and burdensome federal and state regulations which result in onerous work related to compliance (Andraka-Christou & Capone, 2018; Ashford et al., 2018; Haffajee et al., 2018; Jones & McCance-Katz, 2019; Kermack et al., 2017; Louie et al., 2019; National Academies of Sciences, Engineering, and Medicine, 2020).

Nurse practitioners and physician assistants face similar barriers to that of physicians (Andrilla et al., 2019). In addition, the United States Government Accountability Office (2020) reports some pharmacies may choose not to stock or dispense buprenorphine and may treat patients OUD rudely. Transportation to clinic appointments and to pharmacies may also be limited for some patients. Many of the barriers to increasing buprenorphine access are summarized in Figure 18.

Flavin et al. (2020) assessed buprenorphine availability and characteristics among counties with the highest overdose death rates within ten states with the highest opioid mortality. The authors cold-called clinics based on the online SAMHSA Buprenorphine Practitioner Locator, which is one of the main recommended methods by which the federal government recommends patients identify buprenorphine treatment providers. Of approximately 500 buprenorphine providers listed, 60% could be reached, and less than 40% of the total actually offered buprenorphine (versus other therapies.) Of the 173 clinics offering buprenorphine, 25% did not accept insurance and only 63% accepted Medicaid. Wait time for an appointment ranged from 1 to 120 days with a mean wait of 17 days. Seventy-two percent of providers did not have

any appointments available and 38% of listings with phone numbers had incorrect numbers listed (Flavin et al., 2020).

Nutt (2013) postulated that many laypeople and policymakers misunderstand addiction because they have experimented with alcohol and drugs recreationally at some point in their lives. Their ability to cease at-will may reinforce the idea that those with substance use disorders and other forms of addiction can similarly and easily stop on their own. Rather, for patients with substance use disorder, addiction “is not a lifestyle choice, but an unrelenting compulsive behavior that blights their lives” (p. 494). Numerous barriers to buprenorphine exist even in Ohio, a state with the highest mortality from opioid overdoses, second only to Virginia (United States Centers for Disease Control and Prevention, 2019b). Molfenter et al. (2019) studied the barriers among 18 Ohio policymakers responsible for creating and implementing substance use disorder policy and allocating public funds. Paying for buprenorphine therapy was an issue statewide prior to Ohio’s Medicaid expansion under the Affordable Care Act and subsequent establishment of coverage for outpatient buprenorphine therapy. The policy leaders noted that several treatment providers in the community felt prescribing buprenorphine was “giving a drug to an addict” or “replacing one drug for another” (p. 274), but this had improved over time because “once the client is on [buprenorphine], it becomes so much easier to treat them” (p. 275.) The county executives also expressed concern about diversion, although they believed that the risk of buprenorphine diversion stemmed almost entirely from for-profit drug treatment programs and not ones receiving public funds, the latter of which were required to follow more strict state and county guidelines and regulations (Molfenter et al., 2019).

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In a study shortly after DATA 2000 was passed, over 80% of general practice psychiatrists reported being uncomfortable prescribing buprenorphine in an office-based setting. Yet, only 40% of addiction psychiatrists felt similarly (West et al., 2004). Subsequently, researchers found those with board-certification in addiction medicine may be more accepting of prescribing buprenorphine in addition to practitioners in urban settings and those with previous experience working with patients who have an opioid use disorder; barriers to prescribing buprenorphine in primary care include concern of disrupting office workflows, personal competence, and inadequate availability of specialist support when needed (Becker & Fiellin, 2006). The deaths resulting from these barriers are the “inevitable result of treating addiction as a disease in a system that is not equipped to do so successfully, in a society that often pays mere lip service to the idea that people with substance use disorders need care instead of judgment” (Brown, 2020, p. 209).

Role of Stigma in Opioid Use Disorder

Nora Volkow, the Director of the National Institute on Drug Abuse writes “people working in health care should be made aware that stigmatizing people who are addicted to opioids or other drugs inflicts social pain that not only impedes the practice of medicine but also further entrenches the disorder” (Volkow, 2020, p. 1290). In a review of 51 articles of opioid-related stigma, McCradden, Vasileva, Orchanian-Cheff, and Buchman (2019) discovered four main typologies of opioid-related stigma: self-stigma internalized by patients, stigma against

methadone and buprenorphine treatment, stigma of opioid use related to chronic pain, and stigma existing within healthcare settings. Increased stigma is inversely associated with poor health outcomes by decreasing and delaying access to care (Biancarelli et al., 2019). Often due to stigma on the part of healthcare professionals, patients with OUD may defer seeking care for medical conditions until such circumstances are serious or life-threatening. Once treatment is sought, patients are likely to downplay their substance use history out of fear that revealing it will impact the quality of care received (Biancarelli et al., 2019).

Definition of stigma. The modern word “stigma” comes from the term “stizein”, which was a mark burned onto the skin of slaves to signify their low place in the social hierarchy in ancient Greece (Link & Phelan, 2001). Jacobsson & Arboleda-Flórez (2002) described stigma as a:

Social construct whereby a distinguished mark of social disgrace is attached to others in order to identify and to devalue them. Thus, stigma and the process of stigmatization consist of two fundamental elements: the recognition of the differentiating ‘mark’ and the subsequent devaluation of the person. (p. 25)

Goffman (1963) defined stigma as “an attribute that links a person to an undesirable stereotype, leading other people to reduce the bearer from a whole and usual person to a tainted, discounted one” (p. 11). Stigmatization begins with stereotyping, or creating damaging and often inaccurate beliefs about a group (Corrigan & Nieweglowski, 2018). This most often occurs through labeling and language. Generally, stereotypes are unavoidable in societies and are often learned at an early age. The stereotype itself does not create marginalization. Rather, prejudice and ultimate discrimination does. Prejudice occurs when a stereotype leads to fear and shame generated by society, and internalized blame by those being prejudiced. Subsequent discrimination occurs

when these feelings lead to disparate opportunities such as decreased access to healthcare, unavailability of employment, and reduced ability to secure safe and affordable housing (Corrigan & Nieweglowski, 2018). Stereotypes include beliefs that individuals with substance use disorders are dangerous, hopeless, or dirty. These beliefs generate prejudice, or feelings such as fear, anger, or disgust which are ultimately translated to discrimination such as denial of healthcare, employment opportunities, and dehumanization (Nieweglowski et al., 2018). This is further explored in Table 2.

Self-stigma. Self-stigma occurs when patients with substance use disorders experience reduced self-efficacy stemming from perceived devaluation and discrimination. It results in the “why try effect” which greatly limits goal achievement and the ability to thrive in society (Corrigan & Rao, 2012). Internalized stigma on the part of patients with substance use disorders leads to decreased motivation to access treatment and a perception of minimal social supports. Such stigma also leads to increased levels of depression and anxiety (Akdağ et al., 2018). Figure 19 shows the model of self-stigma and how it translates into practice. When there is a lack of stigma in treatment programs, patients feel encouraged to adhere to care plans. Conversely, being identified as an “addict” leads to increased ostracism and results in pushing patients back towards drug cultures where they may feel more respected and engaged by peers (Crapanzano et al., 2018). Greater degrees of self-stigma result in extended stays in residential treatment programs, possibly due to heightened fears of life outside of these centers (Luoma et al., 2014). Self-stigma is associated with social withdrawal and isolation, reduced interpersonal communication, participation in fewer recreational activities, decreased employment, and diminished feelings of competence and independence (Can & Tanrıverdi, 2015).

Language and labels. Patients labeled as “drug addicts” are more stigmatized by the general public compared to those experiencing an “opioid use disorder” (Goodyear et al., 2018). Unfortunately, “health care practitioners, and many lay people, refer to people with opioid use disorder as ‘junkies’... Who would use similar terms about a patient with diabetes and an elevated hemoglobin A1C level?” (Olsen & Sharfstein, 2014, p. 1394). The term “substance abuser” and “opioid addict” are seen as strongly negative compared to “person with a substance use disorder” and “person with an opioid use disorder. The term “relapse” is also viewed negatively (Ashford et al., 2018).

A dichotomy exists between how patients speak about themselves and the external labels which may reinforce stigma. Pivovarova & Stein (2019) evaluated the language preferences of over 250 patients in a Massachusetts opioid treatment program. The term “addict” was the most used by patients when speaking about themselves or fellow patients. Slang such as “junkie” was used by less than 15% of patients. The preferred terms for patients to be called by clinical providers or the public was “person who uses drugs”, “person with a heroin addiction”, and “person with a heroin dependence”. Ashford, Brown, McDaniel, & Curtis (2019) found similar results. Patients in recovery did not have a negative attitude towards the term “addict” and “substance abuser” whereas those employed in the health professions possessed a negative attitude towards these terms. In a follow-up study, Ashford, Brown, & Curtis (2019) found the term “substance abuser” and its alternative “person with a substance use disorder” both had negative association among those impacted by SUDs, but the latter was perceived more positively overall. Positive and negative terminology is summarized in Table 3.

Language choice in the medical record effects the care patients receive. Goddu et al. (2018) found residents and medical students who read stigmatizing language in the medical

record were less likely to prescribe medication for pain. Residents also had more negative attitudes compared to medical students, suggesting that stigma in medical culture serves as negative reinforcement over time, and could be related to repeated exposure of stigmatizing terminology in health records. Tension was also described when quotation marks were used to quote patients about their substance use. While some readers viewed this as empathetic, most felt it was a hidden signal regarding socioeconomic status or insincere histories (Goddu, Anna et al., 2018).

Medication Assisted Treatment. The term “medication assisted treatment” is widely used in healthcare, policy, and peer-reviewed literature. However, the term faces scrutiny. Robinson and Adinoff (2018) argue calling methadone, buprenorphine, and naltrexone “medication-assisted” therapy implies that pharmacotherapy might be secondary to some other sort of treatment, without promoting what that primary treatment might be. This may inadvertently reinforce the invalid idea that medication is secondary to strictly counseling or abstinence-only support. The American Society of Addiction Medicine National Practice Guidelines state that “it is unclear whether added psychosocial treatment improves patient outcomes... and are sometimes minimally needed” (Kampman & Comer, 2015, p. 366) for patients receiving treatment with methadone. There are mixed results for patients receiving treatment with buprenorphine. The guidelines further state that any psychosocial interventions are recommended concurrently with pharmacotherapy. Overall, the terms “medication-assisted recovery” and “long-term recovery” have significantly more positive association in relation to reduced stigma than “medication-assisted treatment” (Ashford et al., 2018).

Health professionals. Health professionals in general have a negative attitude toward patients with substance use disorders. Desire to work with this patient population is consistently

lower than other chronic diseases such as diabetes and other behavioral health diagnoses such as depression (van Boekel et al., 2013). Johansson and Wiklund-Gustin (2016) described a pattern of “multifaceted vigilance” among nurses, which acknowledges the perceived challenging nature of encountering patients with substance use disorders in the hospital. Nurses sometimes struggle with balancing the desire to build relationships with patients with the need to be attentive and watchful towards hospital policies and their own stigma towards this patient population. Nurses who work specifically in pain management describe patients with substance use disorders as “difficult” and “noncompliant” but also recognize the need for individual and holistic treatment (Morley et al., 2015).

Conscious and unconscious biases may create disparities among patients with OUD in regards to treatment of other chronic diseases. For example, patients undergoing consideration for liver transplants are often told to discontinue buprenorphine or methadone therapy before they can be listed, despite a lack of scientific evidence that such therapy is contraindicated and an abundance of evidence that discontinuing therapy early is risky (Wakeman et al., 2018). Patients may be denied repeat valve repair surgeries related to endocarditis, despite the ethics of such practice being called into question (Aultman et al., 2018). This approach be related to public reporting requirements of valve replacement which began in January 2013. These measures have led to improved quality but decreased access to valve replacement surgery for all patients, especially those with severe co-morbid conditions (Kimmel et al., 2019).

Stigma in pregnancy. Extensive stigma is felt by pregnant women with OUD in the pre-natal and post-natal period (Howard, 2015). Mother’s experienced reduced self-efficacy after delivery and shame regarding prolonged hospitalizations that are often required secondary to neonatal abstinence syndrome. As Howard et al. (2018) explained:

Staff members attend to their infants less often, communicate less, and are more stringent in enforcing hospital rules because of their addiction histories... [the] perception of unequal treatment made mothers feel frustrated, anxious, and stressed... conversely, when staff members were not judgmental and treated the mothers as equals, mothers felt respected and empowered, and this greatly enhanced their confidence in caring for their infants” (p. 764).

Pregnant patients are often hesitant about buprenorphine therapy because of judgement and the potential for negative consequences. These patients often prefer detoxification, despite acknowledgement of increased fetal risk. Pregnant patients may feel that participating in buprenorphine therapy puts them at increased risk of punitive interactions with social services (Ostrach & Leiner, 2019). Nursing students feel particularly conflicted when caring for patients with OUD on maternity wards, with much of this conflict stemming from the attitudes expressed by clinical preceptors (Lewis & Jarvis, 2019).

Abstinence-based treatment. There are differences in ideology between those who support the use of MAT and those who support treatment and recovery without the use of medications. These opposing views have been described as “two warring factions” (Goodnough, 2018). The sentiment often shared is that when patients take a medication for the treatment of OUD, they are never truly abstinent or sober. Patients receiving buprenorphine therapy face such abstinence-only conversations from parents, friends, colleagues, and perhaps most importantly, clinical staff (Hadland et al., 2018). This view is often held within “abstinence-only”, 12-step, and fellowship communities such as Narcotics Anonymous (NA) who feel that pharmacotherapy is “replacing one addiction for another.”

Narcotics Anonymous is structured around 12 principles referred to as the “Twelve Traditions of Narcotics Anonymous.” Two of these principles conflict with the organization’s opinion of MAT. Tradition number 3 states “the only requirement for membership is a desire to stop using.” Tradition number 10 states “Narcotics Anonymous has no opinion on outside issues; hence the NA name ought never be drawn into public controversy” (Narcotics Anonymous, 1988). The program promotes itself as supporting only total abstinence, and while medications “may be valid” at certain times, they should be used with “extreme caution.” White (2011) states NA’s “philosophy of complete abstinence is rooted in the collective experience of its members that all past half measures resulted in pain and tragedy in spite of great and repeated assertions of personal will” (p. 12).

White (2011) argued that while abstinent-based therapy is a tenant of NA’s national platform, the organization does not actively oppose MAT outside of its own organization. For example, NA does not promote anti-MAT campaigns or participate in lobbying activities for the purpose of decreasing access to MAT. Importantly, NA states that patients engaged in MAT are welcome to meetings. However, this policy exists at the national level and individual groups are permitted and encouraged to create their own local rules. Many choose to exclude those on MAT, and local chapters who allow patients on MAT often impart bias and promote a culture which incorporates anti-MAT views. White (2011) explains this stance is not because NA is “anti-MAT” but rather because the organization does not view MAT as being completely abstinent. Complete abstinence is a cornerstone of NA participation. However, this policy may alienate people who would likely benefit from the group’s otherwise supportive environment. As Walsh and Long (2019) state, this arises:

From the misconception that FDA-approved medication is the same as uncontrolled illicit drug use; From the misconception that physical dependence (a physiological homeostatic process) is the same as an OUD; From the misconception that OUD is the same as all other substance use disorders rather than recognizing that a single lapse to illicit opioid use can lead to death, and, finally; From the misconception that OUD is a moral issue best treated by suffering rather than a life-threatening medical condition best treated by health practitioners with expertise and a toolkit of evidence-based treatments. (p. 3).

The root of NA's view on non-pharmacologic interventions stems from a similar philosophy in the very early days of its sister organization Alcoholics Anonymous (AA) (White, 2011). In the 1960s, Bob Dole, the lead investigator of the original clinical trials for methadone, was asked by Bill Wilson, the founder of AA, to join its board. In an editorial later, Dole (1991) recalled questioning AA executives about his involvement since his research was focused on pharmacotherapy and not abstinence. Executives insisted on his engagement since the "objectives were parallel – namely providing the best treatment available to sick persons" (p. 751). Dole commented that he joined the board because the AA founders "were acutely sensitive to the danger of the Fellowship being distorted by aggressive persons with dogmatic opinions" (p. 751). Just prior to Wilson's death, Dole recalled one of their final interactions:

At the last trustee meeting that we both attended, [Wilson] spoke to me of his deep concern for the alcoholics who are not reached by AA, and for those who enter and drop out and never return. Always the good shepherd, he was thinking about the many sheep who are lost in the dark world of alcoholism. He suggested that in my future research I should look for an analogue of methadone, a medicine that would relieve the alcoholic's

sometimes irresistible craving and enable him to continue his progress in AA toward social and emotional recovery (p. 751)

These interactions from decades ago show an original acceptance to integrate pharmacotherapy into support groups, however such collaboration has dwindled over the years. While AA has expressed that it has no position on the use of medications, the issue remains controversial within NA (Alcoholics Anonymous, 2018). In an editorial addressing stigma toward MAT (not specifically by the fellowship community) entitled *Being Explicit About Decisions: Prescribe Medications for Opioid Use Disorder on the Basis of Proven Effectiveness, Not Beliefs*, Barocas and Saitz (2019) write:

We should evaluate treatment for opioid addiction as we do for other chronic medical diseases, by assessing efficacy, costs, risks, and the likelihood of success, and not on the basis of beliefs, which partly underlie regulations that restrict access. As with many other chronic disorders, OUD treatment comes in several forms and is often lifelong. Basing medical decisions on beliefs about medications does nothing to help the growing pool of those with OUD, who if untreated are likely to fall victim to an overdose (p. 2).

The scientific evidence supports MAT as a key component of a plan for treatment and success. As White (2011) states, “it is time to shed the fixation on methadone and buprenorphine and to begin to nest these medications within a rich service menu and vibrant recovery culture that can nurture the larger physical, cognitive, emotional, relational, and spiritual processes of long-term recovery” (p. 11).

Ambivalence toward MAT within local chapters continues (White, 2011). In its document *Narcotics Anonymous and Persons Receiving Medication-Assisted Treatment*, the organization recognizes Tradition 3, which requires the desire to stop using at the time of

meetings, and not abstinence. However, the document also promotes the idea that “cleanliness” may only be obtained through total abstinence. The document stresses “abstinence” and “membership” in NA are not synonymous, and people may attend meetings at various stages of long-term recovery (Narcotics Anonymous, 2016).

In response, new groups are forming which are inclusive of peer support and MAT. Krawczyk et al. (2018) describe one such group: the Ability, Inspiration, and Motivation (AIM) program. Established in 2010 as an alternative to fellowship groups which exclude pharmacotherapy for OUD, the goal of the program is “to promote respect, wellness and recovery through peer support and education by allowing participants to share their unique paths to recovery” (p. 406). AIM is comprised of three foundational elements. The environment is respectful of all patients seeking recovery and designed to reduce shame and secrecy around pharmacotherapy by increasing confidence and self-esteem. The program also incorporates a holistic approach to health. In addition to groups and counseling around substance use disorders, the program promotes healthy behavior around nutrition and chronic illnesses. Finally, spirituality, story-telling, and celebration are successful components from other existing groups that have been integrated into AIM.

Another example is Medication-Assisted Recovery Anonymous (MARA). Similar to other national fellowship organizations, MARA incorporates meetings that rely on a series of principles and milestones referred to as Twelve Traditions and Twelve Steps. However, the organization is comprised of “people who believe in the value of medication as a means to recovery” (MARA, 2019, para 4).

Addiction as a chronic illness. Calls for addiction to be treated as a chronic medical disease have existed for decades (Stein & Fleischman, 1998). Substance use disorders are akin to

other chronic diseases including diabetes, cancer, and heart disease because they are driven by genetic and environmental factors (NIDA, 2005). McLellan et al. (2000) argue that while patients with addiction often experience a recurrence of the disease and challenges adhering to the care plan, similar findings exist across other chronic diseases. For example, fewer than 60% of patients with diabetes and fewer than 40% of patients with hypertension or asthma fully adhere with the pharmacologic components of their care plans, and fewer than 30% of patients in these groups adhere with behavioral modifications such as diet and weight loss. This results in up to 50% of patients with diabetes and up to 70% with hypertension or asthma requiring additional medical care annually to regain control of symptoms. The “similarities in heritability, course, and particularly response to treatment raise the question of why medical treatments are not seen as appropriate or effective when applied to alcohol and drug dependence” (p. 1694). Figure 20 compares rates of disease recurrence among those with substance use disorders with other chronic medical conditions.

Discharges against medical advice. Patients with substance use disorders may leave against medical advice (AMA) because they are stigmatized by hospital staff, receive inadequate pain control, have insufficient management of withdrawal symptoms, or experience hospital restrictions (McNeil et al., 2014; Simon et al., 2019). In this author’s experience, such clinical barriers are deeply rooted in institutional stigma, which ultimately results in AMA discharges. In a study of over 400,000 hospitalizations related to OUD, 13% of patients left the facility against medical advice (Merchant et al., 2020). The odds of leaving AMA are based on several factors including the type of substance use disorders (Table 4).

Of over 1,900 patients in Pennsylvania with drug use related infective endocarditis (DURE) between 2013 and 2017, 16% left the hospital AMA (Meisner et al., 2019). Of 202

patients treated for DURE in three Canadian acute care hospitals, 17% left the hospital AMA (Rodger et al., 2018). Among 108 patients admitted to the University of Kentucky HealthCare hospital with infectious complications of OUD including endocarditis and osteomyelitis, 14% left AMA. On inpatient medical wards “it is critical to optimize care in these settings to prevent AMA [discharges and] to successfully retain patients in treatment” (Lail & Fairbairn, 2018, p. 422).

General public. People with substance use disorders are often seen as reckless, unreliable, undeserving, and threatening, and they may be viewed as intense and hopeless individuals who are to blame for all of their psychosocial and medical issues (Nieweglowski et al., 2019). The public generally feels anger, pity, and dread when asked about individuals with substance use disorders and withholds opportunities from them (Nieweglowski et al., 2019). For many laypeople, substance use disorders are intimately linked to other alarming public health conditions such as HIV, hepatitis C, and driving under the influence – all of which are also stigmatized. Substance use disorders are considered by many to be a moral failing and a condition within the direct control of the person experiencing the illness (Livingston et al., 2012).

Kennedy-Hendricks et al. (2017) surveyed a national sample of over 1,000 adults regarding their attitudes towards patients with prescription-based OUD. Interestingly, 30% of the respondents identified as having direct experience with OUD through close friends, family members, or themselves. Over 75% of respondents felt individuals with OUD were to blame. The majority endorsed creating social distance from people with OUD and felt it was appropriate for employers to have discriminatory hiring practices. Of note, the responses from those with experience of OUD were more negative, in particular regarding self-discipline and hiring

practices. In a nationally-representative sample of over 2,600 participants, Goodyear, Haass-Koffler, and Chavanne (2018) found that patients who experienced addiction after receiving an opioid from a friend were highly stigmatized compared to those who experienced addiction after receiving an opioid prescription from their doctor.

Livingston, Milne, Fang, and Amari (2012) describe stigmatizing attitudes of substance use disorders as being widespread, endorsed by popular culture, and embedded in federal, state, and local policies that criminalize, and ultimately marginalize those using substances. The authors stress that criminalization of substance use disorders leads to exclusionary processes that continue to widen the social divide between those with substance use disorders and those without. The authors conclude that “social processes and institutions that are created to control substance use may, in actuality, contribute to its continuance” (p. 40).

There appears to be less stigma in communities afflicted most by the opioid epidemic. For example, after the Virginia State Health Commissioner declared a public health emergency in November 2016, 80% of Virginians supported increasing availability of treatment centers and 70% supported residential housing for those in recovery, even if these resources were located in their own community (Cook & Worcman, 2019). This contradicts the philosophy known as “Not in My Back Yard” or (NIMBY) where communities generally support advancements for marginalized citizens such as those with substance use disorders, so long as such advancements do not occur in their own communities. This phenomenon is driven by deeply-rooted stigma (Furr-Holden et al., 2016).

Structural Racism

Much of the structural racism that exists in relation to systems of care for patients with substance use disorders is linked to the War on Drugs declared by President Nixon in the 1970s

(Santoro & Santoro, 2018). Policies mandated during this time criminalized the possession of cocaine and resulted in the mass incarceration of individuals from racial minority groups. Further, the media often portrayed dealers as individuals from Black and Latinx communities whereas White people were portrayed as “addicts” in need of help (Santoro & Santoro, 2018). This persistent messaging resulted in widespread misinformation and grave discrimination in minority communities (Hansen et al., 2016).

Compared to White patients, Black patients are less likely to receive opioid prescriptions for acute or chronic pain (Om, 2018; Pletcher et al., 2008). These findings were the basis of a *New York Times* article that sought to frame this discriminatory practice as being protective against opioid poisonings in non-White communities (Frakt & Monkovic, 2019). Khatri et al. (2019) followed this with an opinion piece stating, in part, that “calling racial bias protective is misguided and harmful” (para 3). The authors concluded that “racism in health care still exists and is by definition harmful, and to suggest otherwise will stop us from developing effective strategies to help all Americans struggling with addiction” (para 10).

It is possible that significantly more Black people have died from illicit opioids being covertly added to cocaine by dealers than has been reported (James & Jordan, 2018). Therefore, the narrow focus of attention and resources on OUD specifically, as opposed to substance use disorders as a whole including cocaine, further reduces access to care and likely contributes to disproportionate opioid mortality among Black people.

The national narrative around OUD among policymakers and the media has often been around opioid poisonings of middle and upper class White people (James & Jordan, 2018). This “marginalization of Black people is highly consistent with a pattern of framing addiction affecting people of color as a pathological shortcoming to be answered by militarized policing

and involvement of the criminal justice system, in lieu of treatment” (James & Jordan, 2018, p. 404). In fact, White patients are 35 times more likely to receive treatment for OUD compared to patients of other racial groups (Lagisetty et al., 2019). The many facets of structural racism and marginalization of minority communities must be fully dismantled to provide appropriate, evidence-based, and effective care to all patients who may benefit from it.

X-Waiver as a Barrier and Reduced Access to a Buprenorphine Prescriber

There are two hypocrisies in the current regulatory environment pertaining to opioids: no special training or government-mandated certification is required to prescribe opioids, and the regulations of prescribing methadone or buprenorphine for the treatment of OUD do not apply when the *exact same* medications are prescribed for the treatment of chronic pain (Davis & Carr, 2019; Waters, 2019). Haffajee et al. (2019) reported of the 3,142 counties in the United States, 46% lack any provider able to prescribe any pharmacologic treatment for OUD. Over 70% of rural counties lack a treatment provider. Such disparate availability of buprenorphine is associated with increased mortality at the county level (Jones et al., 2018).

Licensed to treat vs actively treating. Increasing the number of providers who have the x-waiver does not necessarily translate to increased treatment access. In a “secret shopper” telephone survey, Beetham, Saloner, Wakeman, Gaye, and Barnett (2019) called 469 providers listed as having an x-waiver on the SAMHSA website across the six states with the highest burden of opioid overdoses. Of these providers, only 54% were accepting new appointments for patients receiving Medicaid funds. Overall, half were not accepting new patients or had an extended waitlist, regardless of insurance type.

Andrilla, Coulthard, and Larson (2017) surveyed over 1,500 physicians in rural areas registered with the DEA to prescribe buprenorphine. Overall, the most common cited reasons for

not incorporating buprenorphine therapy into daily practice were perceived time constraints, concern about medication diversion, and lack of access to additional behavioral health support services in rural areas. Prescribers also reported concern about attracting patients with substance use disorders to their practice. Almost one in five respondents also expressed concern about available office space and staff and one of every ten self-identified as having stigma towards patients with OUD (Andrilla et al., 2017). In a follow-up study, Andrilla, Moore, & Patterson (2019) found that retail pharmacies in rural areas may treat patients poorly when picking up buprenorphine prescriptions and some pharmacies refuse to stock the medication at all. Importantly, the authors also found that the “vast majority of family practice physicians reported that adding this service did not attract new drug users to their practice, instead, patients with substance use disorders were already in their practice and were simply not receiving the full level of care they needed” (p. 119).

In Washington State, less than 30% of physicians who participated in a x-waiver training went on to receive the official DEA certification and prescribe buprenorphine. The most common cited reason for not prescribing was the perceived need for additional wrap-around behavioral health services. Over 80% of the respondents were family medicine physicians (Hutchinson et al., 2014).

Patient limits. In addition to the x-waiver creating a limitation for providers who may prescribe buprenorphine for OUD, each x-waived provider is also limited by the number of patients they may treat concurrently. No other FDA-approved medication has such a restriction (Blum et al., 2016). Such patient limits may create unnecessary barriers to care, especially in rural areas where there may be a single prescriber available for an entire patient population (Waters, 2019). Notably, it took 18 years after the passage of DATA 2000 for the SUPPORT Act

in 2018 to increase the patient limit from 30 concurrently in the first year of having an x-waiver to 100 (National Association of State Alcohol and Drug Abuse Directors, 2019). However, the impact of increasing patient limits may be limited since most x-waived prescribers do not approach their patient limit.

Among over 3,000 buprenorphine prescribers from seven states with the highest number of x-waived providers, more than 20% treated 3 or less patients, and less than 10% treated more than 75 patients (Stein et al., 2016). The median monthly census was 13 patients. In a study of over 4,000 waived providers from across the United States, Jones and McCance-Katz (2019) found among prescribers with a 30-patient limit, the mean monthly census was 10.8 patients with a median of six patients. Among prescribers with a 100-patient limit, the mean monthly census was 28.4 patients with a median of 25 patients. Finally, among prescribers with a 275-patient limit, the mean monthly census was 95.8 patients with a median of 90 patients.

X-waiver process. Over a decade after DATA 2000 was signed into law, only 2% of physicians in the country had obtained an x-waiver, and only 6% of this small number were internal medicine or family medicine physicians (Rosenblatt et al., 2015b). Over half of the country's counties had no physician with an x-waiver, with the majority of these being in rural areas, some of the hardest hit by the opioid crisis (Rosenblatt et al., 2015b). As such, there are now calls for state policy changes allowing pharmacists to prescribe buprenorphine (Crabtree et al., 2017).

The “x the x-waiver” campaign. There is a growing “x the x-waiver” movement to deregulate buprenorphine and allow providers to prescribe it like any other controlled substance. The Mainstreaming Addiction Treatment Act of 2019 (H.R. 2482) introduced in the U.S. House by Representative Paul Tonko (D-NY) in May 2019 would eliminate the need for an x-waiver to

prescribe buprenorphine, essentially deregulating the medication for the treatment of OUD (Tonko et al., 2019). As of April 2020, the bill has 109 co-sponsors, including 88 Democrats and Republicans (GovTrack, 2020a). A similar bill exists in the U.S. Senate introduced by U.S. Senator Margaret Hassan (D-NH). As of April 2020, it has four co-sponsors, including two Democrats and two republicans (GovTrack, 2020c).

Proponents argue that regulations are typically enacted to safeguard the general population, yet buprenorphine is safer than commonly prescribed opioids. The process of obtaining an x-waiver discourages new prescribers. Even when a prescriber is interested, it may be challenging for that prescriber to convince colleagues to also obtain the x-waiver. This may create dangerous gaps in care during periods of time when the prescriber is not available. The x-waiver process may reinforce stigma by creating a sense that buprenorphine treatment so unsafe or somehow risky that it requires such a specialized training. Deregulation may help integrate buprenorphine into the primary care setting (Fiscella et al., 2019; Fiscella & Wakeman, 2019; Woodruff et al., 2019). Buprenorphine has been found to be safe, effective, and with x-waiver elimination, potentially highly accessible (Berk, 2019).

The American Society of Addiction Medicine (Jarvis, 2019), American Medical Association (Madara, 2018), Society of General Internal Medicine (Bass, 2019), Society of Hospital Medicine (Frost, 2019), American Pharmacists association (Menighan, 2019), American College of Medical Toxicology and American College of Emergency Physicians (Marino et al., 2019), National Council for Behavioral Health (Ingolia, 2019), and the PEW Charitable Trusts (Connolly, 2019) all support deregulating buprenorphine. Berk et al. (2019) argue that removing the x-waiver would increase utilization of buprenorphine treatment by hospital medicine providers.

A letter signed by 39 state attorneys general calling for legislation to reverse the need for an x-waiver certification was sent to U.S. congressional leadership (Stein et al., 2019). The directors of 23 state health departments have also petitioned U.S. Health and Human Services to deregulate buprenorphine (Smith et al., 2019). While the directors noted legislative changes would be ideal, they also suggested a possible regulatory remedy. The “three-day emergency rule” which allows emergency medicine physicians to prescribe buprenorphine three days in a row without an x-waiver could be expanded to include all prescribers and the period of time increased to up to four weeks. This might provide an important bridge while patients find and enter long-term treatment.

Support for deregulating buprenorphine in the manner suggested by the pending federal legislation is not unanimous. Weimer, Tetrault, and Fiellin (2019) argue the x-waiver system is meant to supplement the often minimal and sometimes absent addiction medicine content within health professions curricula. As such, the regulation guarantees specific topics are taught in a standardized fashion across the nation. Expanding access without thought into mandated education or a plan for quality assurance may be detrimental. The authors propose numerous approaches to increasing access to buprenorphine within the current regulatory framework including modifying the topics of x-waiver training to be more practical and discipline-specific based on current evidence, compensating providers for their time to participate in the training, universally incorporating training regarding OUD treatment within all healthcare professions, limiting Drug Enforcement Agency oversight, creating mentorship programs, and expanding the number of addiction medicine fellowships (Weimer et al., 2019).

Davis and Carr (2019) described numerous other policy approaches to decreasing mortality related to OUD and increasing access to treatment. These include deregulating

methadone, holding jails and prisons accountable when MAT is not initiated or continued, expanding the number of drug courts which offer treatment rather than incarceration, increasing the number of addiction medicine residency positions paid for by the federal government, prohibiting skilled nursing facilities and recovery housing from refusing to administer MAT, and developing mechanisms for patients to secure housing and transportation (Andrilla, Moore, et al., 2019).

Roy and Stein (2019) call for making buprenorphine available without a prescription in emergency settings at all pharmacies across the United States. The authors wrote:

Historically, medications have been made available without a prescription when they are relatively safe and effective and the public can easily comprehend indications for their use. Buprenorphine meets these conditions. Confining treatment to the offices and business hours of the medical community limits the ability of patients to receive needed treatment. It is time to consider novel and potentially controversial solutions. (p. E1)

France as an example of buprenorphine deregulation. Fatseas and Auriacombe (2007) describe how buprenorphine became a successful treatment for OUD throughout France since being approved by the country's government in 1996. From the onset of this approval, buprenorphine could be prescribed by any physician including general practitioners, without any additional training. Prior to this, French patients with OUD were required to visit specialized centers, with only 15% to 30% of the 150,000 to 200,000 patients entering treatment. By 2003, 83,000 patients were being treated with buprenorphine, with 84% of treatment occurring in primary care. In part due to the introduction of widespread buprenorphine availability, opioid overdose deaths declined in France by 79% between 1995 and 1999 (Fatseas & Auriacombe, 2007).

The rapid growth of buprenorphine utilization in France for the treatment of OUD, and the positive patient-centered and healthcare system outcomes, is unseen elsewhere in the world. Of note, France offers universal health coverage (including addiction treatment) which the authors also believe contributed to the large adoption rate of buprenorphine in primary care. This approach of France to quickly expand access to treatment "raises questions about the value of tight regulations imposed by many countries throughout the world" (Auriacombe, Fatséas, Dubernet, Daulouède, & Tignol, 2004, p. S24). According to the European Monitoring Centre for Drugs and Drug Addiction (2019), France has led the European Union in providing access to pharmacologic treatment of OUD. In 2017, almost all French patients seeking access to such treatment were able to access it.

Health Professions Training

There is an overall lack of knowledge and education in the health professions related to substance use disorders (van Boekel et al., 2013). This absence of critical teaching may contribute to gaps in clinical care and stigma. Minimal training and limited exposure to addiction medicine is known to have resulted in a workforce gap (Thomas, 2019). Stigmatizing perceptions related to people with substance use and opioid use disorders are reinforced in medical education and increase during time spent in formal education, revealing the "hidden curriculum" of negative bias towards individuals with OUD (Ashford et al., 2018; Meltzer et al., 2013). Such "hidden curriculum" may even cause harm to trainees with a history of OUD (Lucey et al., 2019).

Resident physicians' stigmatization of patients with substance use disorder (SUD) has been demonstrated to increase during residency training. While specific training may improve overall attitudes towards opioid use disorder from baseline, residents continue to view OUD

more harshly than other substance use disorders such as alcohol use disorder (Avery et al., 2019). For example, in a large Boston-based internal medicine residency program, more than one-third of residents received no formal education around addiction during medical school (Wakeman et al., 2013). Twenty-five percent of residents were not confident in their ability to diagnose a substance use disorder, and over 60% did not feel able to treat addiction. There was no difference in confidence across PGY years.

Fewer than 20% of internal medicine clerkships for medical students include content around medication-assisted treatment, and only 52% of clerkship directors find this content important (Ari et al., 2019). Among 476 internal medicine, family medicine, and psychiatry residency program directors surveyed in a national sample, 77% stated their trainees encountered patients with OUD on a frequent basis (Tesema et al., 2018). However, fewer than 25% reported spending more than 12 hours on curriculum related to addiction, only 36% provided infrastructure for clinical application of outpatient buprenorphine prescribing, and only one in four encouraged or required residents to obtain their x-waiver certification. The most common barrier identified to integrating OUD treatment into training was lack of local expertise and x-waivered faculty. As expected, residency programs with program directors supportive of medications for the treatment of OUD, or who had x-waivers themselves, were more likely to support clinical training for OUD treatment within their residency programs (Tesema et al., 2018).

Nursing students describe encounters of patients with OUD as distressing, awkward, overpowering, and uncomfortable (Lewis & Jarvis, 2019). Some identify lack of experience and education in screening patients for OUD and would avoid the topic altogether, relying on shift reports and medical documentation alone rather than direct interaction with the patient in relation

to opioid misuse. Others feel comfortable with screening but do not feel educated on how to move forward if it is felt a patient has OUD. A component of this discomfort is fear of appearing insulting or accusatory towards patients (Lewis & Jarvis, 2019).

Weiner (2018) notes the lack of formal education about SUDs within the health professions is rapidly changing. Over 85% of medical school curricula now incorporate education of OUD prevention and treatment and over 90% have held continuing education for faculty about how to best navigate the topic for students. Despite this, however, 97% of faculty have shared challenges in teaching or evaluating learning knowledge related to OUD.

The Association of American Medical Colleges (AAMC, 2019) has several initiatives underway to improve teaching of OUD within undergraduate medical education. These initiatives include convening several national workshops and curricula development meetings, highlighting medical school curricula abundant in substance use disorder training, and administering grants for curricular redesign around OUD and stigma reduction. However, among dozens of advances featured by the AAMC, few describe strategies to increase awareness of treatment for OUD and x-waiver trainings (AAMC, 2019). The American Association of Colleges of Osteopathic Medicine [AACOM] is involved in similar efforts and also emphasize instruction in osteopathic manipulative medicine as an alternative to opioid medications for the treatment of chronic pain (American Association of Colleges of Osteopathic Medicine, 2019).

Ratycz, Papadimos, and Vanderbilt (2018) call for increasing access to simulation-based medical education around OUD. Case-based learning over two hours has been shown to increase resident comfort with treating opioid withdrawal (Simmons & Siegel, 2016). Brown University utilizes an interprofessional approach in a 4-hour dedicated timeframe including a patient panel, standardized patient lab, and case study incorporating students from medicine, nursing,

pharmacy, social work, and physical therapy (Monteiro et al., 2016). Among 514 interprofessional students who attended the patient panel featuring individuals in long-term recovery from OUD, 70% reported a more favorable attitude toward this patient population after hearing the patients' experiences (Dumenco et al., 2019). Brown University's medical students also engage in a multiple-year longitudinal curriculum that includes over 10 hours of lecture specifically about OUD and the management of chronic pain (McCance-Katz et al., 2017).

Starting in July 2019, all residency programs credentialed by the Accreditation Council for Graduate Medical Education (ACGME) are required to "provide instruction and experience in pain management if applicable for the specialty, including recognition of the signs of addiction" (ACGME, 2018, p. 23). Programs are expected to develop competencies to reduce incidence of addiction while appropriately treating pain, identifying addiction early, and learning how to navigate systems of care for addiction (Combes, 2019). With passage of the Substance Use Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) Act of 2018, medical students who graduate from medical schools which include necessary educational components around buprenorphine prescribing may automatically receive their x-waiver without undergoing additional training (Shapiro et al., 2019).

The American Association of Colleges of Pharmacy has urged schools of pharmacy to increase education around appropriate opioid prescribing, empower pharmacists to engage in community outreach, and prepare pharmacy students to use life-saving interventions (Crabtree et al., 2017). The Council on Social Work Education (CSWE) has promoted the efforts of social work stakeholders in Massachusetts to develop a competency-based approach to training social work students about OUD (CSWE, 2018). Among these include the ability to assess a patient's risk for substance use disorder, coach patients about non-opioid treatments for chronic pain,

assist patients in navigating available support systems for long-term recovery, and recognize substance use disorder as a chronic disease along with appreciating how stigma creates barriers to care (Governor's Social Work Education Working Group on Substance Misuse, 2017).

Compton and Blacher (2019) provide a review of the opioid epidemic's impact on nursing curricula. The authors note:

The paucity of pain content in nursing curricula is accentuated by a lack of content on substance use disorders. The current state of addiction content in nursing curricula is inconsistent at best... Curricula on substance use-related content are less than optimum, and schools of nursing have been described as not keeping up with the increasing public health concerns related to substance use disorders. (p. 2)

The American Association of Colleges of Nursing has described a goal of all nursing programs to incorporate enhanced curricula to address the opioid epidemic (American Association of Colleges of Nursing, 2018). Curricula for registered nurses and advanced practice nurses regarding substance use disorders including OUD have been described (Finnell et al., 2019).

In 2018, the Physician Assistant Education Association (PAEA) launched an effort for its over 150 member programs designed to promote integration of the x-waiver training into PA program curricula (PAEA, 2018). Prior to launching the initiative, less than 3% of PA programs required the x-waiver training. After one year, 30% of programs require the x-waiver training for their students. An additional 30% were expected to implement the curriculum by May 2020 (Majewski, 2019). Physician Assistant programs are required to teach about the identification and treatment of substance use disorders (Accreditation Review Commission on Education for

the Physician Assistant, 2018). With regard specifically to OUD, Lopes (2019) has stated “all PAs must become familiar with their diagnosis and management” (p.11).

Minimal Guidelines for Hospital-Based Treatment

Clinical and organizational practice guidelines have increased in prevalence over many decades as a way to improve quality, reduce costs, and preserve autonomy in medical decision-making (Weisz et al., 2007). The absence of extensive, meaningful, interprofessional and multidisciplinary guidelines on the hospital-based treatment of OUD is likely a barrier to widespread acceptance and adoption. Saitz (2019) writes:

Simply issuing an edict or guideline promulgating initiation of OUD treatment when it is identified in general hospital patients would seem to be akin to picking low hanging fruit. But it appears not to be the case... It is unacceptable to discharge a patient with insulin-requiring diabetes from an acute care hospital with no prescription for insulin and instead a referral to or phone number of a diabetes treatment program where the patient may be seen some weeks hence. It should be similarly unacceptable to discharge a patient with OUD from an acute care hospital without starting medication known to have efficacy for OUD (assuming the patient has not declined it), and with only a referral to an addiction treatment program (p. 84).

The Institute for Healthcare Improvement calls for the development of an “addiction consult service to engage patients during acute hospitalizations to provide screening for opioid use disorder, initiation of medications for opioid use disorder, brief behavioral interventions, counseling, and referrals to treatment” (Botticelli et al., 2019, p. 7) and also to “integrate addiction care into primary care and other care settings, where appropriate” (p. 8).

Bart et al. (2020) describe an evidence-based clinical decision support tool for OUD. While it is mainly designed for use in primary care, numerous components are applicable to the hospital setting. Elements are provided in Appendix 1. The process begins by utilizing the Tobacco, Alcohol, Prescription Medication, and Other Substance Use (TAPS) Tool for screening. In its validation study, McNeely et al. (2016) found the practitioner-administered tool screened positive for heroin use disorder with 78% sensitivity and 100% specificity and prescription opioid use disorder with 71% sensitivity and 99% specificity. A free online version called “myTAPS” is available at <http://www.drugabuse.gov/taps>. This online form was validated by Adam et al. (2019) who reported the tool was found easy to use by 98% of patients and completed within a median time of four minutes. A print version of the TAPS Tool is provided in Appendix 2.

If a TAPS screen is positive for opioid use disorder, the process described by Bart et al. (2020) continues with brief motivational counseling and determination of a patient’s desire for change. The model provides separate pathways for patients who desire to cease opioid misuse, patients who would like no change in opioid use patterns, and patients ambivalent about change. The TAPS approach promotes shared decision-making and provides a clear context for evaluating, initiating, stabilizing, and maintaining buprenorphine therapy. It also calls for the ability to escalate care to an addiction medicine specialist when warranted. Finally, the model requires designating personnel to perform specific tasks including diagnosing OUD, assessing readiness for change, discussing treatment options, and ensuring follow-through with referrals when indicated, among others.

Other models provide financial incentive for hospitals to engage in treatment related work. For example, in 2018, Pennsylvania dedicated financial resources to hospitals that

incorporated opioid stewardship into their operations (Kilaru et al., 2020). In the Opioid Hospital Quality Improvement Program, hospitals received an incentive payment from the state for implementing the following four areas: ED-initiation buprenorphine, handoff to community partners, referral of pregnant patients for treatment, and inpatient treatment initiation. Hospitals received \$193,000 for implementing all four components. Of 155 Pennsylvania hospitals evaluated in January 2019, 51% participated in all four pathways, 29% participated in fewer than four, and 20% did not participate in any (Kilaru et al., 2020).

Measurement. There is lack of consensus in the medical community about the best measure of success for prevention and treatment of OUD in the hospital setting or upon discharge. Much of the focus on existing measurement tools revolve around responsible prescribing practices. For example, the Healthcare Effectiveness Data and Information Set (HEDIS) measures are used by the Centers for Medicare and Medicaid Services (National Committee for Quality Assurance, 2020b, 2020a). This system collects data on the number of patients prescribed high-dose opioids for greater than 15 days and patients who receive opioid prescriptions from multiple prescribers or fill them at multiple pharmacies. Few measurements evaluate OUD care across the continuum.

Houston Methodist Health System developed 19 metrics to evaluate their work on opioid stewardship (Rizk et al., 2019). These metrics are provided in Table 5. Williams et al. (2018) applied principles from other published substance use disorder metrics to develop a seven-measure “OUD Treatment Cascade.” A summary of the cascade is shown in Figure 21. Samuels et al. (2019) created over one dozen measures specifically for the emergency department across three domains including primary prevention, harm reduction, and treatment. These are provided in Table 6. The Assessment of Recovery Capital has been validated to assess quality of life

measures in substance use disorder as a whole and, thus, may have a role in predicting response to treatment (Groshkova et al., 2013; Sánchez et al., 2020). Unfortunately, there are no known tools to adequately measure quality of life over the course of treatment specifically for patients with OUD (Strada et al., 2017).

Post-acute settings. Ten-percent of patients hospitalized with OUD in 2012 were discharged to skilled nursing facilities or inpatient medical rehabilitation centers (Ronan & Herzig, 2016). Many of these facilities restrict or entirely prohibit access to buprenorphine or methadone (Bond, 2018; Pytell et al., 2019; Spencer, 2019). In these settings, patients with OUD may be protected under the Americans with Disabilities Act because "addiction may be considered a substantially limiting impairment" (United States Commission on Civil Rights, 2019).

Such restrictions prompted the Massachusetts Department of Health to publish guidelines for methadone and buprenorphine administration at long-term care facilities, stating such treatment "shall be continued" (Sheehan, 2016). Buprenorphine can be continued in the post-acute setting just as any other home medication so long as a valid prescription from an x-waived providers exists from the patient's primary prescriber, the post-acute facility's medical director, or from the hospital as a bridge prescription (Pytell et al., 2019; Wakeman & Rich, 2017).

Inpatient addiction treatment. Inpatient addiction treatment centers may require patients to discontinue MAT prior to entering treatment (Cherkis, 2015; Seville et al., 2017). Huhn et al. (2020) evaluated over 230,000 admissions to residential treatment facilities nationally. The authors found MAT was used in 18% of admissions within states that expanded Medicaid and in only 2% of admissions in states that did not.

Sharfstein & Meisel (2019) describe this practice as an “unfortunate reality” of the opioid crisis and one which increases mortality and provides low-value care. The authors outline several potential remedies. Journalists and government websites have been raising awareness of the dangers of such facilities, but patients are unlikely to find these resources in moments of crisis. Accreditation agencies of rehabilitation facilities do not currently have protocols around MAT, however the American Society of Addiction Medicine will soon begin requiring residential treatment centers to offer MAT to receive voluntary certification. State and local governments could also revoke licenses of residential treatment centers that do not offer MAT. Such entities could also enact regulations promoting or requiring the use of MAT within residential treatment centers or to partner with treatment programs that can offer these medications. This has been the case in California and Massachusetts (California Department of Health Care Services, 2019; Massachusetts Department of Public Health, 2016).

Payers

The lack of reimbursement infrastructure for patients with substance use disorders has been recognized by the Alliance for Recovery-Centered Addiction Health Services (2018) who state:

Today’s recovery services are delivered through a system often lacking alignment or integrated economic structures that incentivize long-term recovery... the human and economic cost for this fragmentation and inefficiency is unsustainable. A vacuum exists for both health systems and patients as to what is the ‘gold standard’ for an integrated, comprehensive medical and community response for addiction (p. 5).

The report provides a framework for the development of an addiction recovery medical home in the spirit of patient centered medical homes that have been promoted under the Affordable Care Act. A summary of this model is presented later in this paper.

Medicaid, Medicaid expansion and regulations. Medicaid participation is a predictor for patients not engaging in long-term buprenorphine care (Shcherbakova et al., 2018). Researchers attribute this to psychosocial circumstances that often accompany the lives of patients enrolled in Medicaid, rather than a direct association on buprenorphine therapy itself (Shcherbakova et al., 2018). Importantly, 25% of all patients in the United States with OUD are members of their respective state's Medicaid program (Medicaid and CHIP Payment and Access Commission, 2017).

States which expanded Medicaid had 10% fewer deaths related to opioid overdoses by the end of 2017 compared to states which did not expand Medicaid (Kravitz-Wirtz et al., 2020). Knudsen and Studts (2019) interviewed a nationally representative sample of 1,174 buprenorphine prescribers. Of these, only 52% accepted Medicaid, compared to 72% who accepted commercial insurance. Surprisingly, no association was found between these qualitative results and individual state implementation of Medicaid expansion under the Affordable Care Act.

This is in contrast to the findings of Sharp et al. (2018), who found buprenorphine prescribing increased in all states from 2011 to 2016, but significantly more rapidly in states that expanded Medicaid. Interestingly, methadone prescribing declined in the same period, but declined more rapidly in states that expanded Medicaid. This suggests support of buprenorphine over methadone when improved reimbursement models are constructed. Among states that expanded Medicaid, Wen, Hockenberry, and Druss (2017) found a 70% increase in Medicaid-

covered buprenorphine prescriptions and a 50% increase in expenditures on buprenorphine from 2011 to 2014. This is summarized in Figure 22.

In 2017, the state of Virginia, which did not expand Medicaid, launched the Addiction and Recovery Treatment Services program to increase access to treatment for OUD. The program set the reimbursement rate for OUD treatment to that provided by commercial plans in the state. In the first 12 months, an additional 63% of total Medicaid members sought such treatment (Cunningham et al., 2018). Among pregnant Medicaid members with OUD, 18% sought treatment within the first year compared to 2% the year prior. There was also a 20% increase in the number of Medicaid patients receiving buprenorphine and a 25% reduction in emergency department visits for Medicaid patients with OUD (Cunningham et al., 2018; Lopez, 2018).

Prior authorizations. The prior authorization (prior auth) process is a barrier for the treatment of OUD. Historically, formulary restrictions including the prior auth process have been used to control spending and safeguard against inappropriate use of prescription medications. However, these restrictions are often associated with decreased medication adherence, poor clinical and patient-centered outcomes, and increased total healthcare costs (Park et al., 2017).

As of July 2019, nearly all Medicaid plans provide coverage for buprenorphine, however 80% of states require a prior auth before buprenorphine can be prescribed for the treatment of OUD (Weber & Gupta, 2019). Andrews et al. (2019) examined prior auth regulations for buprenorphine across all 50 states in relation to the availability of buprenorphine in addiction treatment programs that accepted Medicaid. In states where no prior auth was required, 42% of treatment programs offered buprenorphine. In states where annual limits were imposed on the total number of doses dispensed, but no prior auth existed, 26% of treatment programs offered

buprenorphine. In states that required a prior auth and had mandatory annual limitations, 13% of programs offered buprenorphine (Andrews et al., 2019).

Medicaid and commercial insurers may make advances based on policy put forth by Medicare. In 2017, 96% of Medicare Part D plans required a prior auth before a prescription for buprenorphine could be filled (Hartung et al., 2019). In April 2018, CMS announced it would no longer support insurance plans which require a prior auth for buprenorphine more than once annually under Medicare Part D (Centers for Medicare & Medicaid Services, 2018). Subsequently, by 2019, a prior auth was required in less than 1% of Medicare part D plans (Mark et al., 2019).

Mandatory counseling. Many Medicaid programs require patients to participate in psychosocial counseling as part of a buprenorphine maintenance program, despite evidence from a Cochrane review that such psychosocial support may not further improve outcomes including treatment retention and abstinence from opioids during the treatment period (Amato et al., 2011; Miller, 2018). Among over 650 patients randomized to buprenorphine therapy with or without counseling, there was no difference in outcomes among patients who received counseling as reflected by self-reported or urine-tested abstinence (Weiss, 2011). Among over 140 patients engaged in a primary care buprenorphine program and randomized to a 24-week course of physician-led medication management versus medication management with cognitive behavioral counseling, no difference was found in the rate of illicit opioid consumption based on data collected by self-report or urine toxicology (Fiellin et al., 2013). There was no difference in opioid negative drug screens or treatment retention among almost 50 patients with OUD and HIV randomized between 15-minute buprenorphine visits with a physician and 45-minute buprenorphine visits with a physician plus ongoing medication adherence counseling with a

nurse (Tetrault et al., 2012). In a study of over 200 patients randomized to buprenorphine medication management only or buprenorphine with different types of counseling for 16 weeks, and then followed for 52 weeks, counseling at the beginning of treatment did not result in decreased opioid use or improved retention the end of the year (Ling et al., 2013). The role of counseling throughout the buprenorphine care continuum requires further study as it is possible counseling has greater benefit once stability is achieved as part of program rooted in pharmacotherapy. Most comparative effectiveness studies appear to focus on the role of counseling early in treatment and not longitudinally.

Potential reimbursement model. The Addiction Recovery Medical Home (ARMH) proposed by the Alliance for Recovery-Centered Addiction Health Services [ARAHS] (2018) is an alternative payment model for the treatment of SUDs, including OUD. The model has been endorsed by numerous national organizations and includes five overarching elements: payment reform, enhancement of quality metrics, development of integrated care networks, coordination care within interprofessional teams, and long-term recovery plans. The model also defines three distinct phases of recovery: pre-recovery and stabilization, recovery initiation and active treatment, and community-based recovery management. Unlike many alternative payment models, the ARMH calls for retaining a fee-for-service components, but only for acute, pre-recovery care. Most maintenance care under ARMH would be delivered in a capitated, episodic payment model that are connected to population-based severity indexes. Reimbursement would be increased based complexity of the SUD and co-occurring mental health disorders. To encourage participation a "stop-loss" measure would be included for providers to protect against perceived financial loss from higher-risk patients. There is a quality achievement payment for providers who achieve a specific percentage of the quality metrics (proposed as 75% in the

document.) Moreover, providers are eligible to receive a percentage of overall savings achieved throughout the continuum of care (ARAHS, 2018).

The model requires the development of integrated treatment networks which includes behavioral health and primary care interventions in the acute and outpatient settings as well as telemedicine. It also calls on hospitals to intentionally and actively seek patient enrollment during acute hospitalization. To accomplish the work of systematically treating SUDs, ARHM seeks an interprofessional approach to care which includes a peer recovery coach, care coordinator, primary care provider, and behavioral health specialist. Connecticut, Kentucky, North Carolina, Tennessee, Washington D.C., and Texas are currently implementing demonstration pilots of this innovative model (Valentino, 2019).

Outpatient Buprenorphine Capacity-Building

Developing widespread capacity for buprenorphine and OUD care in the community has been challenging, but much can be learned from systemwide implementations. For example, Croff et al. (2019) describe the process used to roll-out buprenorphine therapy to nine treatment centers in Oregon that previously did not incorporate pharmacotherapy into care plans. The authors conducted a qualitative analysis of 39 system leaders at the beginning and end of the six-month implementation process. The first step was moving towards a stakeholder consensus for all nine sites to offer buprenorphine therapy. Centers with strong and supportive medical leadership and prescribers with previous exposure to using pharmacotherapy in treating behavioral illness were noted to have an easier time with implementation. Apprehensive sites had medical leadership who felt buprenorphine was “the new methadone” (p. 334) and that patients with OUD may be disruptive to the rest of the practice. One center described an issue with incrementalism where half of the staff were engaged and the other half did not want to

participate. However, after six months, the culture had shifted and the site leader noted that “staff has definitely accepted buprenorphine as part of the culture here. It’s part of who we are and what we are” (p. 334). Although most site leaders were not concerned about service reimbursement, several were concerned about the cost of buprenorphine for the patient. One leader felt that ‘if the insurance doesn’t pay, 95% of the people or more are not interested in obtaining medicated assisted treatment” (p. 334). In response to these concerns, team leaders were formally trained on the “business case” of offering buprenorphine and responding to concerns from their colleagues.

When centers decided as a group to implement a buprenorphine program, they agreed to use the Plan-Do-Study-Act model of quality improvement. Some centers initially elected to have another site start the medication with local team members maintaining the medication afterwards. Some centers actively sought to build partnerships with local pharmaceutical representatives who could provide medication training to staff and also assist with building a network of additional sites across the state. Teams frequently reviewed metrics of importance, such as induction success rates, which they promoted internally to continue their push for positive change (Croff et al., 2019).

When the initial barriers were overcome and the initial implementation was deemed successful, the final categorical step identified by Croff et al. (2019) was normalizing buprenorphine therapy for the remainder of the system, a process the authors referred to as “routinizing”. The risk of returning to a treatment environment void of buprenorphine appeared secondary to conflicting philosophies (albeit less so over time), staff attrition, patient variables such as adherence with medication protocols, an external factors including payer or regulatory factors. The centers worked together to keep each other on track, met regularly to discuss

common pain points, and were empowered by executive leadership to adapt to needs as they developed. Clinical teams also became accountable for offering treatment as part of routine care. A site leader reported that “with accountability comes sustainability. The staff loves it. The patient feedback is phenomenal” (p. 336).

Diversion Concern

Diversion is a concern among providers eligible to prescribe buprenorphine for the treatment of OUD. However, the extent and root of this concern varies between prescribers with an x-waiver and those without. Kermack et al. (2017) describe that among over 70 New York buprenorphine prescribers, 91% felt that diversion was primarily a result of inadequate access to buprenorphine practices for patients experiencing OUD and opioid withdrawal. One-fifth of prescribers felt diverted buprenorphine worsens the epidemic or can be used to achieve euphoria in relatively opioid naïve patients. Conversely, among 74 physicians without an x-waiver surveyed in 2016, diversion was second only to concern about being overwhelmed with requests for buprenorphine therapy (Huhn & Dunn, 2017). In the same study, among 272 physicians with a waiver, only 10% expressed concern about diversion.

Diverted buprenorphine may reflect an environment with inadequate access to legitimate care. Among a national sample of 175 patients who used diverted buprenorphine, 79% reported use related to withdrawal prevention and 67% reported the desire to maintain abstinence (Cicero, Ellis, & Chilcoat, 2018). One-third of patients reported issues gaining access to a buprenorphine clinic while 81% of patients preferred to access buprenorphine through a legitimate source. Among 128 individuals from Rhode Island who used illicit opioids in 2016, 38% reported using diverted buprenorphine at least once (Carroll et al., 2018). Among these patients, 41% reported using the diverted medication to avoid withdrawal symptoms and 39% reported using to self-

treat OUD. Twelve-percent of patients reported attempting to achieve euphoria from the diverted medication. In an earlier study of 51 Rhode Island patients who used diverted buprenorphine, 74% used the medication to treat withdrawal and 66% used it to treat OUD (Bazazi et al., 2011). Among 602 individuals with histories of intravenous drug use in Baltimore, 72% reported using diverted buprenorphine to palliate withdrawal symptoms and half of these individuals used diverted buprenorphine for this purpose specifically while waiting to enter treatment (Genberg et al., 2015). Some patients are able to continue illicit buprenorphine therapy until they can enter a treatment program, although many describe symptoms of precipitated withdrawal from buprenorphine taken without appropriate medical instruction or supervision (Tofighi et al., 2019).

Barriers Specific to the Emergency Department

In emergency departments, clinical staff often need to complete the x-waiver training on their own time. This is a leading reason that some choose not to pursue the x-waiver (Lowenstein et al., 2019). D’Onofrio et al. (2018) outline several barriers to facilitating treatment of OUD in the emergency department setting including addiction being seen as a moral failing, perceived increased length of ED stay, concern for repeated ED admissions, and worry that patients will “flock” to the department seeking treatment. A summary of concerns regarding ED-based buprenorphine treatment and potential responses and solutions to such concerns are provided in Table 7. There is no evidence that these perceived barriers are a reality (NIDA, 2018). The Surgeon General and Director of the CDC have commented

Given the increasing number of Americans who need access to lifesaving addiction treatment, we believe all emergency medicine training programs should ensure their graduating residents are trained and equipped to treat patients with opioid use disorder.

This includes identification of candidates and initiation of medications for opioid use disorder treatment. (Houry & Adams, 2019, p. 2).

In a mixed-methods single-center study at an academic hospital in Boston with a buprenorphine program, responses varied regarding appropriateness of ED-initiated buprenorphine. Of the 93 ED providers who participated, greater than half agreed buprenorphine should be administered as part of standard ED practice. Providers with greater than five years of experience were more likely to feel that buprenorphine was replacing one addiction with another. While most providers endorsed an overall standard of care limited to referral at the time of the study, many felt this was an ineffective approach with minimally positive outcomes. The majority felt that an ED-based buprenorphine program might be possible with adequate institutional backing, training, support staff, and assurance of follow-up clinic capacity after discharge (Im et al., 2018).

In a survey of 84 ED attending physicians and residents in two academic centers, 29% of respondents felt they could adequately connect patients with outpatient addiction-related care and 27% felt comfortable initiating or prescribing buprenorphine therapy (Lowenstein et al., 2019). Although fewer than one in five of the respondents had completed the x-waiver training, less than 60% of this group felt comfortable initiating buprenorphine and there was no difference in the comfort level for discharge planning in the x-waivered group compared to the non-waivered group. Some providers felt patients would not elect to start treatment or have social limitations. Others expressed concern about absence of easy-to-access electronic health record ordersets (Lowenstein et al., 2019).

Attitudes towards substance use disorder as whole by emergency department physicians may influence the work on a buprenorphine program. In a single-center survey of 50 emergency

department physicians conducted by Mendiola, Galetto, and Fingerhood (2018), addressing substance use disorders had the lowest satisfaction score of all chronic medical illnesses assessed (such as diabetes and COPD). Less than 10% of the surveyed physicians found satisfaction in treating pain for patients with a substance use disorder, with over half responding affirmatively that “patients like this irritate me” (p. 133).

Barriers Specific to Pregnancy Women’s Health

Saunders, Jarlenski, Levy, & Kozhimannil (2018) describe numerous barriers for women of reproductive age to receive access to opioid treatment in addition to stigma. Females of reproductive age with substance use disorders may see a psychiatrist for their behavioral health needs and therefore may not have contraception counseling or early pre-natal screening performed appropriately. Several states require mandatory reporting when a pregnant patient is suspected of having an opioid use disorder. This may result in newborns being removed from their mother. New moms often struggle to balance employment needs and childcare responsibilities with the time needed for treatment. Many of these programs do not allow children to be present (Saunders et al., 2018).

Increased access to buprenorphine prescribers who specifically treat pregnant patients is critical. For example, Louis et al. (2020) found that family medicine trained physicians who also care for pregnant patients, as part of their practice may treat ten times more pregnant patients with buprenorphine for OUD compared to obstetricians. This is likely attributed to residency training on the part of family medicine programs. Unfortunately, few family medicine residency programs appear to promote or offer the x-waiver curriculum. Of the over 600 residency programs who participated in the research, fifteen of the programs trained 25% of the family medicine physicians treating pregnant patients with buprenorphine for OUD (Louis et al., 2020).

There are significant barriers to opioid treatment even in some of the country's most disproportionately affected areas, such as Appalachia (Patrick et al., 2018). It can often be weeks until the first appointment for pregnant patients in this region. Outpatient buprenorphine prescribers are also less likely to treat pregnant patients, perhaps secondary to fear of lawsuits or lack of experience or training. Many of these providers also do not accept Medicaid, which is a primary form of insurance for pregnant patients with low incomes (Patrick et al., 2018). Fear of losing Medicaid coverage shortly after delivery is one reason patients prematurely discontinue buprenorphine therapy in the post-partum period (Ostrach & Leiner, 2019).

Barriers Specific to Jails and Prisons

Brezel, Powell, & Fox (2019) describe several factors limiting MAT from being provided in jails including stigma, perceived ineffectiveness of medications compared to non-agonist therapy, security and safety concerns, and the possibility of incarcerated patients lacking the ability to provide informed consent in part because of the sometimes strongarm nature of jail environments. The authors argue that providing MAT in jails is the ethically and morally appropriate practice especially taking into account beneficence, non-maleficence, patient autonomy, and positive impacts on public health.

In a survey of probation leaders across Illinois, Reichert & Gleicher (2019) found that 64% of the states' departments felt they had at least moderate barriers to providing buprenorphine. Most of these barriers involved inadequate medical and institutional knowledge, cost, and internal regulations prohibiting the use of pharmacotherapy to treat addiction. Over 75% of the leaders surveyed stated their department had received no or little formal training about buprenorphine or its role in the treatment of OUD. While over 70% of leaders endorsed

willingness to setup a system for referring patients for buprenorphine, less than 40% could identify resources in their communities (Reichert & Gleicher, 2019).

Peer Recovery and Coaching

Peer recovery, coaching, and support “is the process of giving and receiving encouragement and assistance to achieve long-term recovery. Peers offer emotional support, share knowledge, teach skills, provide practical assistance, and connect people with resources, opportunities, communities of support, and other people” (SAMHSA, 2012, p. 6). Peer coaching reduces the rate and length of hospitalizations and ED visits, increases treatment retention, develops relationships with clinical staff, improves societal functioning and self-efficacy, reduces costs, decreases recurrence of OUD, reduces risk behavior associated with HIV and hepatitis C transmission, and improves the chances for long-term recovery (Reif et al., 2014; Tracy & Wallace, 2016; SAMHSA, 2012).

Generally, the implementation of peer recovery services requires organizational values, policies, practices, knowledge, attitudes, and supervisory infrastructure that support such a program (Gagne et al., 2018). These organizational characteristics are summarized in Table 8. Jack et al. (2018) describe expectations and boundary-setting among clinicians and coaches. These are provided in Table 9. Coaches strive to abide by professional core competencies. These include an orientation towards recovery, person-centered care, voluntary participation, relationship-focused interactions, and trauma-informed relationships (SAMHSA, 2015). Several organizations offer certifications based on these competencies (Connecticut Center For Recovery Training, 2019; International Association of Professional Recovery Coaches, 2019; International Certification and Reciprocity Consortium, 2019; National Association of Alcoholism Counselors

and Trainers, 2019). Most states also have training programs and pathways to become certified and licensed to provide peer coaching services (Kaufman et al., 2014).

For example, over a two-month period in 2017, peer recovery coaches visited neighborhoods in Chicago considered to be "hot spots" for heroin use (Scott et al., 2018). The coaches worked with 70 individuals using heroin who were not engaged in treatment. Ninety-six percent of patients entered a methadone program by referral of the coach with 69% and 70% still engaged in treatment at 30-days and 60-days, respectively.

Inpatient medicine. The role of peer coaches in the hospital setting to support patients with OUD is relatively new and evolving (Englander, et al., 2019). Patients who receive direct counseling from a peer coach during hospitalization are less likely to leave against medical advice and more likely to enter treatment and maintain abstinence after discharge (Blondell et al., 2008). Among over 80 patients connected to Greenville Health System's Faces and Voices of Recovery (FAVOR) program after an unintentional overdose, 79% continued to follow with coaches after discharge (Carey et al., 2018).

Collins et al. (2019) performed a qualitative study of clinical providers, peer mentors, and patients in an inpatient hospital setting at Oregon Health and Science University. Patients described being able to access peers in the hospital setting as meaningful and the peers themselves as honest and relatable. Coaches were able to legitimize and vouch for the hospital's addiction medicine consultation service. Coaches were described as being uniquely able to translate the care plan for patients using words, frankness, and clarity specific to patients with longstanding substance use disorders. Peers were noted to be skilled at de-escalating crises and were believed to reduce discharges against medical advice. Coaches were described as being "cultural brokers" between the lives patients with substance use disorders have in the community

and life within the walls of hospitals, that latter which may be perceived as chaotic, stigmatizing, and non-welcoming (Collins et al., 2019). A summary of peer coach effects on hospitalization for patients with substance use disorder can be found in Figure 23.

Emergency medicine. McGuire et al. (2020) collected qualitative data from 22 different ED-based peer recovery coaching programs in Indiana, Nevada, and New Jersey. Peers were typically located in the hospital during regular hours (although most often not housed directly in the ED) or were available through referral to an outside agency. There was one example of a telehealth program in Indiana. Administratively, none of the peers in any of the programs reported through ED management. Rather, peers were overseen within another hospital department or an outside agency. Most programs did not provide peers access to the electronic health record. Peers were notified of patients who may benefit by a designated person in the ED who could be a clinician, charge nurse, social worker or unit clerk. In one health system, an EHR improvement was being developed to request a peer referral through a pop-up reminder. Most programs required such a referral before a peer could see a patient at the bedside. All programs facilitated entry into MAT through an ED-initiated protocol or referral to outside agency, and all programs provided at least short-term follow-up after ED discharge to reduce barriers to MAT with many being empowered to solve transportation issues through organization-owned vehicles or public transportation vouchers (McGuire et al., 2020).

The New York City Department of Health and Mental Hygiene launched an ED-based peer recovery program in June 2017 (Welch et al., 2019). The program has multiple aims including naloxone distribution, reduction of social isolation, and referral to MAT. At the time of publication, the Relay program was live in six emergency rooms with plans to expand to 15 by 2020. Peer coaches engage patients with OUD in the ED and for 90-days post discharge on a 24-

48-hour, 30-day, 60-day, and 90-day basis. The coaches target patients who have experienced an overdose. Between June 2017 and December 2018, over 875 patients were enrolled in the program. Forty-seven percent of patients were reached within 24 to 48 hours after discharge, 36% at 30 days, 36% at 60 days, and 33% at 90 days. Sixty percent of patients received naloxone kits for the first time from the coaches and over 25% of patients were referred for substance use disorder treatment (Welch et al., 2019).

In a randomized control trial of over 1,150 patients with drug use disorders in Boston, patients who encountered a peer coach during a routine medical visit at a hospital-based outpatient clinic were more likely to abstain from heroin and cocaine at three and six months (Bernstein et al., 2005). In another randomized control trial evaluating the impact of peer coaching on syringe-sharing and transmission of hepatitis C (HVC) among over 400 people in New York City, Seattle, and Baltimore, a 26% reduction in distributive risk was found which was thought to reduce HCV transmission by 5% to 10% (Latka et al., 2008). Patients engaged in a community peer coaching program for five hours per week were less likely to be hospitalized over a three-year period than those without a coach. When hospitalization occurred among this cohort, fewer patients were re-hospitalized, and those who were spent greater time in the community without the need for acute interventions compared to those without a peer mentor (Min et al., 2007).

In Rhode Island, the AnchorED program was implemented to provide on-call certified peer recovery support to all of the state's ten Eds (Waye et al., 2019). Certification requires an individual be in long-term recovery for two or more years, have 500 hours of work experience, complete a 75-question multiple choice exam, and receive almost 50 hours of training. AnchoredED coaches provide peer support, naloxone education and distribution (after a

prescription is written by an ED prescriber), and facilitate transition to the Anchor Recovery Community Center or similar peer recovery programs in the state. Among almost 1,400 patients seen by the program in the ED from July 2016 to June 2017, more than 85% agreed to post-discharge follow-up with a peer recovery specialist and half agreed to referral to a community-based intervention including MAT (Waye et al., 2019).

Peers and pregnancy. Fallin-Bennett et al. (2020) conducted focus groups of postpartum patients in a buprenorphine clinic with access to peer recovery coaches. Participants felt the presence of coaches facilitated their journey to recovery and increased their chance of success. Patients felt coaches should be authentic and supportive and desired coaches to hold them accountable for their actions. All patients valued peer coaches sharing their experience with substance use disorders. However, responses varied on the importance of such experiences being with the same substance or severity of the patients. The presence of peers was important in building trust with the medical community, and participants described this as being of particular benefit immediately after delivery while still in the hospital (Fallin-Bennett et al., 2020).

Barriers to peer recovery. There may be barriers to implementing peers in the hospital setting. Where hospital clinical staff may be apprehensive of or have strong feelings about substance use disorder, peers are empowered by their lived experience and engage in dialogue with patients based on this experience (Englander et al., 2019). Where hospital staff attempt not to share personal information, much of a peer's involvement is sharing such experience. Hospital staff may find a peer's acceptance of patient choices uncomfortable (Englander et al., 2019).

In a qualitative study of peer coaches in a primary care setting, Jack et al. (2018) found coaches felt their role was not clear at times. For example, patients would call coaches at night or on weekends and ask for help outside the coaches' scope. At other times coaches were asked to

see patients with active suicidality or having a psychotic crisis, which were also outside the coaches' scope. Coaches felt like they were sometimes viewed as holding a "magic sobriety wand" (p. 311). Coaches also felt clinical staff were in conflict with evidence-based practice dictating a specific approach to patient care while ignoring the lived experience of the coach. While initially asked to dress in business casual attire, coaches moved towards dressing in jeans in an effort to be more relatable to patients (Jack et al., 2018). Given the necessity for peers to self-identify as being in long-term recovery, they may in turn perceive stigma from clinical staff similar to that of patients with substance use disorders. One concern is "the use and misuse of recovery language when identifying a peer as a person in recovery can pose a challenge, especially if staff members focus more on the person's recovery and less on his/her collegial role" (SAMHSA, 2012, p. 12).

Harm Reduction

The Harm Reduction Coalition (2019) defines harm reduction as "a set of practical strategies and ideas aimed at reducing negative consequences associated with drug use" (para. 1).

Principles of harm reduction include:

Understanding for better and or worse that licit and illicit drug use is part of our world and chooses to work to minimize its harmful effects rather than simply ignore or condemn them... acknowledging that some ways of using drugs are clearly safer than others... [and] establishing that quality of individual and community life and well-being—not necessarily cessation of all drug use—as the criteria for successful interventions and policies (para. 3).

By definition, harm reduction refers to efforts to reduce the risk of harm among people who continue to use substances; abstinence is not a goal of harm reduction (Lenton & Single,

1998). Kiluk et al. (2019) noted that much of the research related to the treatment of OUD rely on mortality as a primary end-point, or frequency of use as surrogate for the same. The authors argue this is different from studies on alcohol use disorders, many of which include non-abstinence-based end-points focused on quality of life. The authors called for increased research and interventions focusing on societal functioning. Ray et al. (2019) advocate for measures and approaches that sufficiently share if patients “get their life back” (p. 114) as is done in research, policy, and clinical approaches related to mood and anxiety disorders.

Sharma et al. (2017) described potential harm reduction efforts specifically in the hospital setting. Decreasing stigma is a foundational approach to reducing harm in the acute care setting. Strategies include promoting appropriate patient-centered language and involving individuals with lived experience in care delivery and as part of administrative committees. Providing clean syringes at discharge for patients at risk of continued intravenous drug use likely reduces harm yet is controversial and violates laws and regulations in many parts of the United States. Hospitals should develop a standard of care for how to approach a discharge against medical advice to avoid practice variability and poor follow-up. Similar policy development should occur for optimal use and discontinuation of peripherally inserted central venous catheter (PICC) lines. The use of treatment contracts should be closely considered as there is a lack of evidence to support their use and they can “detract from building trust in a clinical relationship when experienced as paternalistic and legalistic and may contribute to stigmatization” (p. 3). Supervised injection sites and areas for observed cigarette smoking is also suggested (Sharma et al., 2017).

Burris et al. (2020) reported the first supervised injection site in the United States was planned to open in Philadelphia. Backed by the city’s mayor, the Safehouse program would

provide a space where individuals with OUD could consume substances in the presence of trained staff capable of reversing possible overdoses. However, the U.S. Attorney filed suit stating that such programs violate the Controlled Substance Act (CSA) which states it is illegal to manage or control a space for unlawfully using a controlled substance. In October 2019, a federal district judge found in favor of the city and stated the program was not in violation of the CSA. This decision is currently under appeal (Burriss et al., 2020). While further litigation is likely, this case is an important step towards adopting an evidence-based practice which exists in numerous other countries (Potier et al., 2014).

Naloxone. One particular harm reduction approach that has far-reaching effects in hospitals and the outpatient setting is the distribution and accessibility of naloxone. Naloxone (Narcan®) is a mu receptor antagonist (NIDA, 2017). The medication binds to the opioid receptor quickly displaces existing opioids while preventing new opioid molecules from binding to the site. Naloxone immediately reverses the effects of opioids and is the primary antidote for an opioid overdose (NIDA, 2017). Naloxone distribution programs lead to decreased mortality. Over 104,000 naloxone doses were administered by EMS nationwide in 2016, compared to 36,933 administrations in 2012 (Cash et al., 2018). In a 30-month period starting in July 2013, EMS administered naloxone to 12,192 patients. Eighty-four percent of patients were alive after one year (Weiner et al., 2017). Moreover, non-medical bystanders provided appropriate training are likely to administer the medication in the event of a witnessed overdose (Clark et al., 2014). Prescribing naloxone for appropriate patients is recommended by the World Health Organization (2014), the U.S. Food and Drug Administration (2019), and the U.S. Department of Health and Human Services (2018b).

Barriers. Despite the proven efficacy of naloxone to reduce mortality from opioid overdoses, it is rarely prescribed and dispensed. Lin et al. (2019) evaluated naloxone-related claims in a large U.S. insurance database from 2013 to 2017. The authors found that less than 2% of patients with an overdose related to opioids were provided naloxone. Of over 44,000 patients with OUD, less than 2% were provided naloxone. Of note, this reflects naloxone dispensed at the pharmacy. It's likely the number of prescriptions is higher compared to the number of patients who pick up the medication from the pharmacy. In one ED-based program, 26% of patients who were given a prescription for naloxone had the prescription filled at the pharmacy and only 18% of patients picked up the prescription once filled (Verdier et al., 2019).

Nonetheless, access to naloxone in this high-risk population is minimal. For example, among over 370 patients using intravenous drugs, less than half received naloxone over a six month period (Allen et al., 2019). In a survey of 84 ED prescribers across two academic settings, less than 40% reported they had prescribed naloxone for patients discharging from the ED in the previous three months (Lowenstein et al., 2019). The CDC (2019a) estimates that 9 million more prescriptions for naloxone could have been written in 2018 for patient at high risk for an opioid overdose. While the total number of naloxone prescriptions doubled from 2017 to 2018, there is still only one naloxone prescription written for every 70 high-risk opioid prescriptions, not including patients using non-prescription opioids.

Inpatient medicine. Ninety-percent of internal medicine residents in a Baltimore-based program expressed a willingness to prescribe naloxone (Wilson et al., 2016). However, only 15% of residents did so despite a perception among 79% of residents that they cared for patients who would have benefited. In an urban academic hospital in New York City, a pilot consultation service was established specifically for naloxone distribution (Wilson et al., 2016). Between

April 2016 and January 2018, 142 patients were engaged in naloxone education based on criteria including OUD, high doses of prescription opioids, opioid use concurrent with benzodiazepines or alcohol, hospitalization for opioid overdose, home medications that include methadone or buprenorphine, recent incarceration, or patient request (Castillo et al., 2018). Sixty-seven percent of those patients were provided education and naloxone kits prior to discharge. However, 20% of patients declined to participate, although of those, 11 already had a naloxone kit.

Among over 70 multidisciplinary stakeholders in an academic health system in California, the most widely cited barriers to prescribing naloxone included time constraints (33%), lack of patient desire (26%), unaffordability (24%), and lack of prescriber familiarity (24%.) However, one in five respondents felt there were no barriers. Over 65% of prescribers reported no formal training in naloxone indication or benefit. The presence of a system-wide guideline facilitated naloxone prescribing, but only 36% of respondents knew the guideline existed (Martino et al., 2020).

Emergency Medicine. An Australian qualitative study of emergency physicians and pharmacists evaluated perspectives of providing take-home naloxone. While 75% of participants felt naloxone was life-saving, the cohort identified several barriers (Holland et al., 2019). Some providers felt naloxone increases risky behavior by encouraging "irresponsible" behavior. Others felt the practice might be wasteful as there was a perception patient who experienced naloxone-induced withdrawal would never want to experience it again and would therefore not administer the naloxone. Identifying which patients would benefit from the treatment was also challenging in addition to finding time to provide appropriate counseling and instruction (Holland et al., 2019).

A systematic review of over 2,200 naloxone-related articles by Gunn et al. (2018) found only five papers that described outcomes from ED-based naloxone distribution programs. The authors report that patients are willing to accept take-home naloxone but adoption by prescribers in the ED has been low. Several implementation considerations are suggested. Staff need to be identified for counseling and patient education. These may include social workers, counselors, trainees, advanced practice providers, physicians, pharmacists, or nurses, among others. Further integration within the electronic health record including order sets and notifications for patients at high-risk of an overdose would be helpful (Gunn et al., 2018). Among over 400 patients who received take-home naloxone in a Boston ED, 16% reported using naloxone to reverse an opioid overdose after discharge. Importantly, the response rate in the retrospective study was only 12% and the authors estimated the number of times naloxone was used to save a life to be higher (Dwyer et al., 2015).

Jails and Prisons. Horton et al. (2017) performed a systematic review of 19 articles pertaining to naloxone distribution programs in the jail and prison setting at time of release. Among those who were incarcerated and engaged in an opioid treatment program after release, a minimum of one-third across all studies evaluated had experienced an overdose at some point and over 70% had witnessed an overdose at least once. Over 70% of former inmates indicated a desire for further training and take-home naloxone. Among prison leadership, it was unclear who would benefit from naloxone and how to practically administer a distribution program. Further research is needed about the implementation and outcomes of jail and prison-based naloxone distribution programs Horton et al. (2017).

Legal Environment and Naloxone Access Laws. One approach to increasing patient access to naloxone in the community has been through state-level Naloxone Access Laws

(NALs). These legislative remedies have several components which vary by state (Network for Public Health Law, 2016). Some include the ability for a patient to receive naloxone without an individual prescription by authorizing pharmacists to prescribe the medication or making it available over-the-counter. Some laws eliminate liability on the part of the prescriber and others create a Good Samaritan clause where bystanders cannot be held liable from administering the medication. All 50 states have enacted some form of a NAL. Lambdin et al. (2018) found NALs incorporating immunity for prescribers, dispensers, and laypeople were all independently associated with increased odds of a naloxone distribution program existing within a given county. These laws have been associated with a 15% decreased in opioid-related mortality (McClellan et al., 2018).

Cost. Hufford and Burke (2018) report that in the 1980s, a gram of heroin cost \$2,220. Today, a gram of heroin costs 80% less. Over a decade ago, naloxone cost \$1 per dose. Today, the nasal spray costs \$150 and the auto-injector costs \$4,500. Naloxone distribution in underserved areas continues to be “scandalously underfunded” secondary to cost (Davis & Carr, 2017). However, naloxone distribution is cost-effective. Townsend et al. (2020) performed a cost-effectiveness analysis and mortality projection when naloxone is distributed to laypeople, police officers and firefighters, and emergency medical personnel - or in any combination of these groups. When naloxone distribution is maximized across these groups, opioid mortality may be reduced by over 20%. All models were shown to be cost-effective, with the greatest cost-effectiveness found when all distribution channels are incorporated. If only a single group could be targeted, distribution of naloxone to laypeople would be more cost-effective than the remaining groups (Townsend et al., 2020).

Further Considerations

While the focus of the preceding literature review has been on treatment and harm reduction, there are additional aspects of the opioid epidemic which must also be addressed.

Opioid Prescribing and Acute versus Chronic Pain

The CDC published its first opioid prescribing guidelines in 2016 (Dowell et al., 2016). The organization defined chronic pain as pain lasting greater than three months. Cancer and end-of-life care was excluded from the recommendations. There are 12 total guidelines divided across three categories: determination of when opioids are appropriate for chronic pain, dosage and duration of care, and addressing potential harms of opioid use. The guidelines are provided in Figure 24. Included in these guidelines is the recommendation to carefully select patients who will be receiving greater than 50 morphine milligram equivalents (MME) per day and to avoid escalating therapy to greater than 90 MME per day. Citing that opioid treatment for acute pain often leads to chronic opioid prescribing, the guidelines call for opioid prescriptions for acute issues be written for no more than seven days. Also, opioid regimens should be tapered after three months if the benefits no longer outweigh the risks (Dowell et al., 2016).

The guidelines were met with significant controversy from the medical community. Wegrzyn et al. (2018) argue the guidelines were based on too narrow of a literature review and the conclusions were not patient-centered, disallowed clinicians from practicing with discretion, and stripped patients of their autonomy. Juurlink (2018) highlights that while there are several limitations to the guidelines, they also provide a framework for discussions around safe opioid prescribing that did not previously exist. A later consensus panel also agreed with the spirit of the guidelines to improve safe prescribing but also called on the healthcare community to “avoid misinterpreting the guideline by insisting on opioid reduction or cessation in pain conditions or

treatment settings where opioid use may still be warranted” (Kroenke et al., 2019, p. 734). In an editorial supporting the CDC guidelines, Ballantyne et al. (2018) concluded:

We do not know the best ways to negotiate the transformation of evidence-based guidelines into practice and policy. While physicians and scientists cannot be held responsible for every unintended consequence of their recommendations, consequences can sometimes be anticipated and addressed as part of the guideline-making process. The CDC will need to reassess and adjust recommendations as experience and new research information becomes available (p. 948.)

In December 2018, the Human Rights Watch issued a report calling on the federal government to revise the guidelines so patients with chronic pain are not forced to taper high doses of opioids (Human Rights Watch, 2018). In March 2019, a group of over 300 practitioners including many who practice in pain management sent a letter to the CDC asking for clarification and review of the prescribing guidelines (Health Professionals for Patients in Pain, 2019). In a separate paper, several of the letter’s authors expressed concern the guidelines were being inappropriately interpreted by insurance companies, regulators, and individual healthcare organizations resulting in pain and suffering among patients with chronic pain (Kertesz & Gordon, 2019).

In April 2019, the director of the CDC issued a statement to the letter’s authors stating forced tapering is inconsistent with the goals of the guidelines (Redfield, 2019). That same month the FDA issued a Drug Safety Communication stating

Rapid discontinuation can result in uncontrolled pain or withdrawal symptoms. In turn, these symptoms can lead patients to seek other sources of opioid pain medicines, which may be confused with drug-seeking for abuse. Patients may attempt to treat their pain or

withdrawal symptoms with illicit opioids, such as heroin, and other substances... Health care professionals should not abruptly discontinue opioids in a patient who is physically dependent. (FDA, 2019a, para. 3)

In June 2019, the authors of the original CDC guidelines issued a statement in the *New England Journal of Medicine* stating that many of the recommendations had been misinterpreted and inappropriately applied in ways that were likely causing harm to patients with chronic pain (Dowell et al., 2019). The authors discussed eliminating forced tapering, removing hard MME limits, and not dismissing patients from clinics. Importantly, patients prescribed chronic opioids who have those prescriptions abruptly stopped are at high-risk for subsequent overdose or suicide (Oliva et al., 2020). Being prescribed opioids chronically for longer periods of time is correlated with increased risk.

There are many non-opioid approaches to analgesia including acetaminophen, aspirin, non-steroidal anti-inflammatory agents, antidepressants, and anti-seizure medications. Numbing agents such as lidocaine patches can be applied topically and regional anesthetics may be used as well (Finnerup, 2019). The National Institute of Health is currently investing \$945 million across dozens of studies to determine additional non-opioid approaches to management of acute and chronic pain (National Institutes of Health, 2019).

Discontinuing chronic opioid therapy is a delicate decision that may result in death secondary to illicit opioid use if not performed appropriately. For example, among 572 patients engaged in long-term opioid therapy in a chronic pain clinic from 2010 to 2015, 60% discontinued opioid therapy during the study period with 77% of discontinuations initiated by the prescriber. Twenty-one percent of patients died during the study period with 5% of total deaths confirmed to be an opioid overdose (J. R. James et al., 2019).

There have been calls to use buprenorphine as a treatment option for patients with prescription opioid dependencies which may not otherwise strictly qualify as an OUD (Chou et al., 2019). Doing so currently would be considered an off-label use and implications of using buprenorphine in this setting without an x-waiver is unclear (Chou et al., 2019). In a pharmaceutical industry-funded review article and consensus statement, Webster et al. (2020) argue buprenorphine should be more widely adopted for chronic analgesia over full-agonist opioids given its better safety profile. The authors conclude “buprenorphine’s classification as a partial mu-opioid receptor agonist should not be clinically translated to mean partial analgesic efficacy” (p. 1).

Prevention such as PDMPs

Modern Prescription Drug Monitoring Programs (PDMPs) date back to 1939 when California started the first continuously functioning program in the country (Green et al., 2012). In 1990, Oklahoma became the first state to require electronic transmission of high-risk prescription data to its PDMP. Every state except Missouri has a PDMP, each state relies on technologically advanced data warehouses (PDMP Training and Technical Assistance Center, 2018). Prescription Drug Monitoring Programs are viewed primarily as a tool to reduce “doctor shopping”, the process by which a patient procures large amounts of legal opioids from several providers for personal use, diverting to another individual for free, or selling for a profit (Green et al., 2012). Bao et al. (2016) evaluated over 25,000 office visits related to pain management in 24 states that had implemented a PDMP between 2001 and 2010. The authors found a reduction in opioid prescribing in addition to pain medication overall. Prescriptions for schedule II opioids were reduced by over 30%.

Gabay (2015) shares several areas of deficiencies in PDMPs including poor data collection, ineffective use of data, lack of data sharing across state lines, and minimal use of information by law enforcement. Most states do not require reporting of cash payments or documenting the party picking up the prescription. Most PDMPs have a lag-time in reporting data to users, although it's unclear if this delay is clinically significant. The absence of interstate collaboration results in prescriptions being easily filled across state lines. This is particularly important for communities located near state borders (Gabay, 2015). Fishman (2011) writes of similar concern that the actual impact of PDMPs cannot be recognized until “technological solutions that offer data reliability, security, uniformity, and compatibility across states line” (p. 845) are implemented. Fink et al. (2018) write of unintended consequences of PDMP programs. In a review of 17 published studies evaluating patient-centered outcomes after implementation, the authors found multiple examples of a statistically significant increase in the amount overdose deaths related to heroin. While PDMPs are related to an overall decrease in the general number of opioids prescribed and administered within state populations, an unanticipated outcome is that this lack of access to legal opioids may push patients to seek heroin. The authors argue efforts to increase utilization of PDMPs must be met with additional resources for the treatment of patients with OUD (Fink et al., 2018).

Telemedicine

There are several barriers to growing telehealth for OUD. The Ryan Haight Act of 2008 requires physicians perform an in-person exam before prescribing a controlled substance (Huskamp et al., 2018). This can be avoided if a patient is in a hospital or clinic appropriately registered with the Drug Enforcement Agency. In addition, the SUPPORT for Patients and Communities Act passed in 2018 specifically allows for the in-person exam to be waived when

prescribing buprenorphine and also allows the patient to be located at any site including their home, but the DEA has not yet released rules on how to implement this legislation (Huskamp et al., 2018).

The Ryan Haight Act also provides an exception for individuals being treated by federal agencies (Rubin, 2019). As such, the Indian Health Service (2018) now permits appropriately licensed practitioners to initiate buprenorphine therapy via telemedicine without first performing a physical exam. Despite potential advances being made at the federal level, there is great variation in telemedicine law at the state level (Pepin et al., 2019). Some states have passed laws allowing for buprenorphine to be prescribe via telemedicine without a physical exam such as Indiana, Ohio, and West Virginia (Yang et al., 2018).

Among commercially insured patients from 2010 to 2017, telemedicine encounters for SUD-related diagnoses grew from 0.62 visits per 1,000 people to 3.05 visits per 1,000 people. However, telehealth for SUDs represented less than 2% of all telehealth visits during this period, was disproportionately found in urban areas, and was most often used to complement in-person SUD treatment (Huskamp et al., 2018). Among over 175 patients in Maryland treated in a buprenorphine-based telemedicine program in a transitional housing unit, 98% continued at one week, 91% at one month, 73% at two months, and 57% at three months (Weintraub et al., 2018). In a retrospective study of a West Virginia opioid treatment program, there was no statistical difference in rates of disease recurrence or retention among 100 patients, however the sample size was likely not large enough per power analysis (Zheng et al., 2017). Nonetheless, a large gap in research exists for the use of telemedicine to address OUD. There are no known powered randomized controlled trials of the overall efficacy of MAT delivered via telehealth or the physical setting of the interaction such as a clinic versus a patient's home. Further research is

also needed into patient and provider satisfaction while engaged in telehealth for OUD (Lin et al., 2019).

Literature Review Limitations

There are limitations to the literature review that should be considered:

- 1) The opioid epidemic is complex. The intention of the previous literature review was to illuminate areas of the opioid epidemic based on questions, feedback, and conversations the author participated in when implementing a single-center solution in the three years preceding this document's development. The review is targeted based on this experience and does not touch upon all of the many facets of the opioid epidemic.
- 2) One such exclusion is the limited review or discussion regarding "prevention" – or ways in which to avoid the increase in incidence and prevalence of opioid use disorder. Perhaps the most common is responsible and appropriate opioid prescribing. Such research, while vital, is beyond the main objectives of this paper, which focuses on overlapping but quite different topics: treatment of opioid use disorder, reduction of stigma towards patients with opioid use disorder, and harm reduction efforts related to intravenous drug use.
- 3) The program described as part of the case study relies in large part on buprenorphine, a medication approved by the Food and Drug Administration to treat opioid use disorder. Another such medication is methadone. However, because of the regulatory environment and access issues related to methadone, the program described does not directly incorporate the medication. This is in contrast to other programs in the literature. Therefore, in light of the programmatic focus on buprenorphine, the literature review

focused primarily on buprenorphine, which is not necessarily intended to dissuade the use of methadone.

- 4) Contributions to the literature regarding the opioid epidemic are rapidly emerging. In fact, of the over 525 references cited in this paper, 39% were published in 2019 or 2020, and 67% between 2017 and 2020. It should be noted that this literature review covered publications made available up to April 1, 2020. The review also did not include content regarding the impact of the Covid-19 pandemic on access to care for patients with OUD.

Chapter 3: Methods

Methods

Study Objective

To further analyze the issue of offering treatment of OUD in the hospital setting and contribute to the growing literature in this area, a single-embedded case study will be performed to share the experience of how a single 220-bed academic hospital in central Texas promoted the importance of treatment and overcame the barriers mentioned above. While elements of programs have been described in the literature, there does not appear to be a case study describing the entire build and implementation process, especially in an institution that does not have an addiction medicine consultation service. Because most hospitals in the nation lack the presence of such a service, sharing how one hospital accomplished the goal of treating OUD and reducing stigma may present a more useful and scalable model for other health systems.

Research Question

What are the successful components and barriers of an in-hospital buprenorphine program?

Study Design

A case study design will be used. Albright, Howard-Pitney, Roberts, and Zicarelli (1998) explained that a case study should be used to intensely analyze a specific program with the mission of revealing in depth experiences. This method is particularly helpful when a program is unique, exists in a different setting than currently described in the literature, or has a unique outcome. Case studies provide an opportunity to share a complete, multifaceted picture of what has taken place.

Data Sources

The primary data source will be in-person key informant interviews of program stakeholders. The purpose of these interviews will be to understand the stakeholders' perspectives on the decision-making process and challenges. The semi-structured interviews will take place approximately 18 months after the program began. Respondents will be purposefully selected to represent program leadership from academia, the hospital network, outpatient clinics, clinicians, and payers. Interview protocols will cover the history and context of the program development, goals, strategies for developing and implementing the program, as well as barriers and facilitators to adoption. To ensure construct validity, secondary data documents such as policies and meeting minutes will be used to triangulate interview findings and provide additional details on the programmatic activities and processes (Yin, 2003). Finally, quantitative program data will be used to describe outcomes, such as the number of patients treated and outpatient engagement.

Data Collection

Interviews will be prioritized for impact to the overall project and interviewees availability. It is anticipated that each interview will take no more than 60 minutes. Each interview will be recorded on two separate devices. Interviews will continue until the saturation of themes has been reached and no new relevant information is revealed. Those interviewed will be 18 years of age or older and have clinical or administrative responsibility related to opioid use disorder. Participants will have direct engagement in the hospital-based opioid treatment program described in the case study and will hold professional degrees including physician, nurse, social worker, and chaplain. The goal of the interviews is to reveal overall understandings of the role of medications for the treatment of OUD in the hospital setting, barriers to providing

such medications during hospitalization, how such barriers may be overcome, and how interprofessional health care contributes to the program's effectiveness. The interview questions are provided in Appendix 3. This study has been approved as exempt by the University of Texas at Austin Institutional Review Board.

Data Analysis

The study will use a generalized inductive approach, which provides a systematic process to analyze the raw qualitative data to develop concepts and themes (Thomas, 2006). Inductive approaches are well suited to understand the program content, context, and procedures (Sofaer, 1999; Sofaer, 2002). Transcripts will be read to develop inductive codes to capture emerging themes (Thomas, 2006). The principal investigator will assign codes in addition to the chair of the dissertation committee. Disputes will be resolved by the remaining three committee members. This process will continue until no new themes emerge. The procedure allows for investigators to efficiently decipher the relevant data to answer specific research inquiries and to identify relationships between themes and similarities and differences across participants (Thomas, 2006). Descriptive statistics will be used to describe the program evaluation metrics.

To ensure confidentiality, the attribution of quotes are aggregated to three categories, which describe the respondent role in the program. Citations regarding specific demographic information of the single site have been de-identified. In the following, the respondent category *prescriber* includes all internal medicine, psychiatric, and palliative care physicians in addition to an advanced practice nurse. The respondent category *clinical team member* includes the team nurse, pharmacist, social worker, and chaplain. The respondent category *leadership* refers to an executive leader.

Chapter 4: Case Study and Early Results

The following descriptive elements of the program are based on a review of 4,608 computer files from program inception and a review of 9,465 emails between November 2017 and December 2019 and key informant interviews. A total of eleven stakeholder interviews were conducted. Interviewee characteristics are provided in Table 10.

Practice Setting and Organizational Stakeholders

The case study takes place in Texas between October 2017 and December 2019. With a population of over 1.25 million people, the County is also among the top ten fastest growing in the United States. The Research University is at the heart of the community. Academic Medical Center (AMC) is a 220-bed hospital in the center of downtown. It is the primary teaching hospital for the Medical School and employs hundreds of trainees as part of graduate medical education. Academic Medical Center is the main safety net facility for adult patients in the region. While it is affiliated with the Medical School from educational and research perspectives, it is owned and operated by one of the largest not-for-profit hospital systems in the nation.

Primary Care Practice is the largest system of Federally Qualified Health Centers in the county. The organization has 27 offices, which includes primary, specialty, and sub-specialty care. In 2019, Primary Care Practice provided over 375,000 appointments to over 100,000 patients. Another important outpatient entity is Behavioral Health Practice, which serves as the Local Mental Health and Intellectual and Developmental Disability Authority. The organization has over 45 offices in the county and served almost 28,000 patients in 2019. Finally, Main Health is a public entity of the county charged with providing access to affordable healthcare for residents. Main Health is a regional payer and responsible for administering the Clinical Access Program (CAP), which will be discussed shortly.

In 2017, Primary Care Practice and Behavioral Health Practice, with funding from Main Health, launched the Opioid Treatment Clinic (OTC). The pilot program is designed to bring primary care and behavioral health under one roof specifically for patients with opioid use disorder. As a central component to its wraparound services, the clinic provides buprenorphine initiation and maintenance therapy in addition to counseling and social services. The program is designed as a “hub and spoke” model (Clark-Madison et al., 2018). In such a model, patients who are clinically complex or not already engaged in buprenorphine therapy enter the system directly at OTC (the “hub”) where buprenorphine-related and social services might be more intense as compared to a satellite clinic where there may be additional focus on primary care in addition to buprenorphine maintenance (the “spoke”). Both hub and spoke sites have prescribers who have completed the x-waiver training and have experience with buprenorphine. In 2017, only the OTC existed. At time of publication, there are two operational spoke sites with another expected to launch in 2020. Notably, creating a spoke site often means integrating buprenorphine therapy into already existing primary care practices and workflow (Clark-Madison et al., 2018).

Texas Opioid Use Disorder Statistics

In 2018, over 1,400 Texans died from opioid poisonings (NIDA, 2020). In 2017, there were over 131 inpatient stays per 100,000 population resulting from opioid poisonings (AHRQ, 2020). Over 90% of people living in Texas who need treatment for illicit drug do not receive it (amfAR, 2020). The CDC has identified Texas as a state with a statistically significant increase in opioid overdose death rates (CDC, 2018a).

The City Public Health Department urged policymakers to be more proactive by providing treatment for patients with OUD (De-identified1, 2018). When the program described here was first conceptualized in 2017, the County reported that 2.3 deaths per 100,000 residents

were attributed to opioids. In 2012, over \$2 million was spent on emergency medical services (EMS) related to OUD (De-identified², 2017). Just under 600 deaths in the County were attributed to opioids between 2006 and 2016 (De-identified³, 2018). More recently, in an 18-month period beginning July 2018, there were 490 opioid poisonings reported to EMS of which 83% required transport to the hospital and 67% required resuscitation in the field with naloxone (De-identified⁴, personal communication, January 9, 2020). This data does not take into account patients with OUD who do not require emergent intervention, or who are not engaged in outpatient treatment. It is also subject to the limitations of death certificate data discussed previously. Only 15 of the over 250 counties in Texas have access to a medical examiner (Price, 2019). While this represents the majority of the Texas population, over 40% of Texans live in counties without a medical examiner (Karacostas, 2017).

County Payer System for Underinsured and Uninsured Patients

According to Dunkelberg (2017), approximately 4.5 million Texans participate in the state's Medicaid program. Over 75% of participants are children who receive coverage through the Children's Health Insurance Program (CHIP). Texas has among the strictest eligibility criteria for Medicaid in the nation and is second only to Alabama in terms of lowest enrollment. Adults in Texas independently qualify only if they have a minor child and earn less than 15% of the federal poverty level (Norris, 2019). Over 750,000 adults in Texas are in the "coverage gap" where they are ineligible for Medicaid and tax credits for Marketplace coverage (Garfield & Orgera, 2020; Keiser Family Foundation, 2019b). As such, "most low-income uninsured adults will not qualify for Medicaid in Texas today" (Dunkelberg, 2017, p. 3).

In the County, Main Health provides care to residents over age 21 who are up to 200% of the federal poverty level. The goal is to ensure affordable health care for those who are

underinsured or uninsured. The program also provides care to those experiencing homelessness and undocumented immigrants. Funding for CAP is provided through local property tax revenues in addition to certain state and federal programs. Main Health does not own clinics or hospitals but rather works closely with hospitals such as Academic Medical Center and clinics such as Primary Care Practice to provide care delivery.

Central to this case study is the absence of Medicaid expansion in Texas under the Affordable Care Act. As discussed previously, such expansion has been associated with increased access to treatment for opioid use disorder. As the primary safety-net hospital in the county, Academic Medical Center sees a large proportion of underinsured and uninsured patients with OUD who participate in the Clinical Access Program and require hospitalization.

Concept Development

In 2017, this author was engaged in discussions about changing his full-time clinical focus from hospital medicine to palliative care. A significant component to the practice of effective palliative medicine is an understanding of chronic pain, which often appropriately revolves around ongoing opioid analgesia. While researching the use of opioids for acute and chronic pain, it became apparent that some patients engaged in opioid therapy may develop an opioid use disorder.

Around the same time, the American Academy of Physician Assistants hosted an online-based *ask the expert* session on the topic of addiction medicine, which the author joined. One participant asked for insight about the connection between opioid analgesia used in the clinical setting and the development of opioid use disorder. The expert suggested participation in the buprenorphine x-waiver program, not necessarily to prescribe buprenorphine for OUD but

because the x-waiver curriculum also included information about current epidemiology and pathophysiology of opioid addiction.

In October 2017, the author (a physician assistant) began the 24-hour x-waiver curriculum. Concurrently, the Society of Hospital Medicine began promoting a webinar about the hospital-based treatment of OUD using buprenorphine. The webinar was part of a larger program called Support Hospital Opioid Use Treatment (SHOUT) at the University of California San Francisco. The SHOUT group had received funding to assist California hospitals in developing policies and clinical capacity for initiating buprenorphine during hospitalization. Participation in the webinar combined with engagement in the x-waiver training sparked the initial interest in learning more about how such a program might have an impact at Academic Medical Center. Moreover, a \$5,000 grant sponsored by the National Institute on Drug Abuse through the National Institute of Health was being offered by the Physician Assistant Foundation to support implementation of PA-led behavioral health projects.

These early events raised important questions about the current state of opioid use disorder treatment at Academic Medical Center and began an exploration into why Academic Medical Center should initiate buprenorphine therapy for patients.

Recognition of the Opportunity to Treat OUD

Document reviews and interviews revealed that early recognition of the opportunity to treat OUD in the hospital was rooted in appreciating hospitalization as a reachable moment for patients with OUD, treating OUD may positively impact metrics that evaluate hospital performance, and supporting patients with OUD being an appropriate action for patients, clinicians, and the institution.

Reachable moment

A formative component of the team was recognizing that hospitalization was a reachable moment for addressing substance use disorders. Although some patients presented to the hospital specifically for the treatment of withdrawal, others presented for sequelae of intravenous drug use. Some patients who presented to the hospital may have not otherwise sought care for OUD in the community. Hospitalization may evoke a desire for change among some patients with OUD.

It's sort of a come-to-the-mountain-top experience. You've got their attention; what teachers call a teachable moment. They're thinking, "Oh my God, what am I doing with my life?" You've got the opportunity to kind of open that door. If you had something, you could kind of step through that door with them right then. You really might make some headway. -Leadership

The patients we reach aren't necessarily coming to the hospital because of their opioid use disorder. They're coming to the hospital because they have skin and soft tissue infections or other complications of their use and they know that their opioid use has caused them bodily harm.

That's one of the diagnosing principles of a use disorder... The patients that come to the ED and come to the hospital are suffering from the consequences of their use. -Prescriber

If they're here in the hospital and it's bad enough to where they have to be admitted and have a serious heart infection or huge abscess, I think that's when maybe contemplation of change happens, it's kind of a good moment. -Clinical Team Member

Common Hospital Metrics

It was recognized that objective measures used to evaluate hospital performance may be negatively impacted by unaddressed and untreated substance use disorders in the hospital setting. These measures include discharges against medical advice (AMA), in-hospital mortality, and

readmissions. Such metrics may be improved for patients with OUD when buprenorphine is offered as the standard of care for hospitalized patients.

[Not offering buprenorphine therapy] is a missed opportunity for the hospital system as well. Maybe this time they're just being admitted for a cellulitis but maybe next time it's a six-week admission for endocarditis. -Clinical Team Member

The patients that possibly would have been dismissed or left AMA within their first day or two because they would have not gotten sufficient pain control now stay. They would have had a lot of disastrous outcomes. They have gotten good care. They've been able to stay in the hospital and they've had a resource to stop using and be connected with [the outpatient clinic]. -Clinical Team Member

I think clinicians that treat a lot of patients could find themselves treating the same patients over and over. And that's always frustrating. -Leadership

People come in with a horrible vegetative valve and they need IV antibiotics for six weeks and they leave AMA because they need that narcotic. To me, addiction and opioid use disorder, is a life limiting illness. -Prescriber

Support of Patients with OUD

According to some interviewees, offering treatment of OUD during acute hospitalization supported patients with OUD in an environment that may have otherwise been divisive and degrading for this patient population.

Throughout the hospital, it seems that since now there is something we can do, we view them more as patients and not as problems. We don't say that we can't offer them anything and they just need to help themselves. -Prescriber

Opioid use disorder is isolating and dehumanizing. Part of my work is bringing back the humanity and reminding patients they are human, that they matter, that they have emotions, that they have experiences and all of those are valid and important. -Clinical Team Member

Social and Institutional Responsibility

One interviewee expressed that the medical community contributed to the opioid epidemic and therefore, the medical community needed to be part of the solution.

I'd say at least eight out of ten began their opioid use disorder journey with prescribed drugs from medical professionals. It's not high school kids going out, getting drunk, getting high and then deciding to try heroin. Eight out of ten for me have been started on Vicodin or Oxy for a sprained ankle or something. It was something prescribed. And I feel like we have a responsibility to help because this is partly our problem. -Prescriber

Early Discovery – First Thirty Days

The initial part of the discovery process was dedicated to evaluating if offering buprenorphine therapy for hospitalized patients at AMC was necessary and feasible. This involved early stakeholder engagement in the inpatient and outpatient setting, requests for internal data, and building an understanding of systems-based practice for patients with OUD in the county.

Initial Stakeholder Meeting

An initial meeting of inpatient and outpatient stakeholders was held in November 2017. Attendees included the author, the chief of psychiatry, the lead of the behavior health social work program, the chief quality officer, the chief medical officer, the head of the hospital-based retail pharmacy, and clinical and administrative leadership from the OTC. At the time of this meeting, the OTC had 11 patients enrolled in outpatient treatment.

Problem statement. The group agreed on the following problem statement:

During the past 10 months, 275 patients at AMC were evaluated by the behavioral health social workers and documented to carry a diagnosis of opioid use disorders. Some of these patients would have benefited from induction of suboxone therapy while in the inpatient setting.

Intervention statement. The group also agreed on an intervention statement:

Pilot an interprofessional and multidisciplinary buprenorphine induction program with the goal of initiating treatment and facilitating community follow-up for 50 patients in a twelve-month period.

Mission statement. Finally, the group agreed on an overall mission statement:

To be an interprofessional and multidisciplinary group that works to screen appropriate patients for buprenorphine induction, assists in the starting of this treatment while patients are hospitalized, facilitates linkage with an outpatient maintenance clinic, and provides institutional education in an effort to reduce stigma and raise awareness about opioid use disorders.

Inclusion and exclusion criteria. Inclusion and exclusion criteria for patient participation were agreed upon. These somewhat restrictive criteria were based on unfamiliarity with buprenorphine at that time as well as to mirror the criteria of the OTC. However, the group planned to reassess the criteria at regular intervals as the inpatient group gained comfort with what was perceived to be a potentially complex process and medication. The initial criteria are provided in Figure 26.

Initial goals. A set of milestones were agreed on by the group and are provided in Figure 27.

Executive Support

Several respondents felt that obtaining executive support as part of the initial buildout was critical. In this context, executive support meant backing of the program and its volunteers within the hospital's hierarchy at the managerial level and also among senior leadership.

While the volunteer spirit is amazing, I think things like that can lose momentum without some institutional willpower and support behind it. -Prescriber

My department has been supportive of me doing the work as long as I am able to do it. My current supervisor is also very supportive and really wants me to go above and beyond as I'm able, which is really good. You want to feel like you can devote your time to something and not be bogged down by the day to day things. Because this is important too, and I think it deserves attention. - Clinical Team Member

It was important to find key stakeholders in different parts of the hospital, most importantly in the C suite. And not just identifying them, but developing good relationships with them and making sure they fully understand the scope of what we were trying to accomplish. -Prescriber

One interviewee felt that equally important was maintaining the support of executives and leadership as the program grew and ensuring all stakeholders were recognized for their departments' contributions.

I think some of my managers have hoped that maybe [my department] would get more recognition for this at times for their contributions... The line of communication was very open to begin with, but maybe wasn't maintained as well as administration would have liked. -Clinical Team Member

Interprofessionalism

The interprofessional aspects of the team were paramount from inception, according to those interviewed. Learning the viewpoints of the various engaged disciplines based on individual professional experience helped develop and legitimize the program while also working to obtain buy-in. Consequently, patient care benefited by interprofessional care delivery.

You cannot have a program without it being interdisciplinary. It would just be horrible. It wouldn't be a successful program. It so enriches the way that you practice. You're a much, much better provider. So I just think you cannot do it without that aspect. -Prescriber

Having an interprofessional team where we are engaging social workers, case managers, the chaplain, pharmacy - multiple provider groups. We're able to disseminate a larger message of what this practice change could look like in the hospital. And be able to continue pushing that forward, that message. I think that's absolutely necessary... It's huge. If you really want to disseminate an idea, you really have to hit the hospital from multiple angles. We have trusted individuals from each profession that then have colleagues that look at that person for information. People trust those who are their peers... There have been many meetings where I feel like an idea is thrown out and that idea maybe wasn't necessarily the right thing for the team to do, but because the idea was thrown out there, it ends up as if it was a lump of coal at the beginning then pressure of everyone talking about it turns it into a diamond; mainly because we have a think-tank of multiple perspectives that have weighed in on that. -Prescriber

You really need to have a team of people that can pull up a chair and talk with that patient at some length and you need to have a bunch of people that are really on the same page. So if the patient really gets the feeling that they're surrounded by a whole team that you know, all works together and really cares about them, that they're sort of embedded in a therapeutic community. I don't see it really working any other way than as a very interprofessional endeavor. -Leadership

I think each of us has brought a new perspective to the table. Those sort of conversations into our core group has been really helpful and really enlightening ... people coming from different backgrounds. That has been crucial to making this program a success. -Clinical Team Member

Professionally it's been amazing. I've never worked with an interdisciplinary group in this manner that is so dedicated and it's so diverse in terms of we have psych, we have PAs, we have nurses, pharmacists, social workers, chaplains, you know, MDs, palliative, I mean we, we pretty much touched, you know, just about everything. -Clinical Team Member

Outpatient Collaboration

A clear need in the very early stages of planning the program was establishing relationships in the outpatient settings with clinicians and prescribers who could take over buprenorphine maintenance care after discharge. A clinical executive from Primary Care Practice was asked if any prescribers in the organization had an x-waiver, to which the executive responded “*what is an x-waiver?*” This response may have reflected the lack of buprenorphine-related knowledge in the medical community at that time.

A message was also sent to the Chief Medical Officer of Main Health who responded with an introduction to the program administrators of the “MAT pilot”. Unbeknown to those in the hospital setting, the Opioid Treatment Clinic (OTC) pilot project had been started and a mutually beneficial relationship could potentially be struck. The hospital needed an outpatient clinical partner where CAP was accepted as a form of payment, and the OTC, which was designed for patients with CAP funding, needed referral sources to justify their pilot.

Care coordination. Facilitating relationships early-on with the OTC helped ensure that patients would have access to care after discharge and played a vital role in the program’s success.

I think you just have to be really flexible, especially with all the different insurances and all the different patients. I think being very committed to navigating the health care insurance and MAT treatment. Patients really trust what we're saying. When I say I work with the [OTC to arrange follow-up], they really do believe that whoever they meet on the other side is going to be worth their while. It's going to be a positive experience, not like a judgmental negative kind. -Clinical Team Member

It's really important to start conversations with an outpatient treatment facility early on. Because really, we may be doing patients a disservice if we start them on buprenorphine in the hospital without having a place for them to go to continue their prescriptions. -Prescriber

We set them up with outpatient services, so we don't just take care of them in the hospital. We try to get them to the next step where they can have continued sobriety. -Clinical Team Member

I think what will become inevitable is that the use of buprenorphine in medical hospitals will be routine and standard of care within the next five to ten years. We're just trying to push it forward faster in our hospital system because we have a place to send patients once they leave so they can continue their care. -Prescriber

While working to ensure outpatient follow-up was seen as important, some respondents commented that the program still had efficacy even if a patient did not follow-up at the clinic after discharge.

Whether they make it to [the outpatient clinic] is neither really here nor there. It's important, but the fact is that they have a resource that is there to help, to be on their side, and to make a difference when they're mentally prepared to try to stop and they're not going at it alone. -Clinical Team Member

Even when patients aren't interested in Suboxone, if you meet them in a nonjudgmental patient-centered fashion, you're planting a seed to try to help them move forward towards sobriety. And so every single case, whether they get on Suboxone or not, whether they start methadone or not, whether they get any treatment at all or not, is just an opportunity to help that patient move forward towards sobriety, better health, etc. etc. -Prescriber

I know there have been at least two patients that we've seen who have said at the time "I don't want to do it" and left, but who came back and eventually have been initiated onto buprenorphine successfully. I think we plant seeds, not everybody's ready for sobriety at the same time. - Prescriber

Avoiding Redundancy

The clinical group recognized certain aspects of care that would normally occur in the outpatient setting would now occur in the hospital setting. For example, laboratory studies done as part of an initial visit to an outpatient clinic would likely now be done in the hospital. To strengthen the collaboration with the outpatient clinic and to reduce waste and increase value, the team decided to build the hospital-based intake process to be in parallel as much as possible with the outpatient clinic. In particular, this meant ensuring appropriate labs were done before buprenorphine initiation in the hospital, and that the outpatient clinic would receive pertinent information such as substance use history and treatment history. Agreed upon lab studies are shown in Figure 28, and the hospital-based treatment initiation history form is available in Figure 29.

Inpatient Needs Evaluation

Through data analysis conducted at the time of program inception, it was discovered that from October 2015 through September 2017, over 2,240 patients admitted to AMC carried a

diagnosis of a substance use disorder, and over 100 patients had an opioid use disorder and were deemed candidates for methadone or buprenorphine treatment. From October 2016 through September 2017, over 270 admitted patients carried a diagnosis of opioid dependency. Those data was based on consultations performed by a team of behavioral health social workers who provided care at that time under Delivery System Reform Incentive Payment (DSRIP) funding.

The data at that time had limitations since the behavioral health social workers only evaluated certain patients based on strict criteria including positive urine drug screens and direct consultation requests, and the social workers did not include patients on the trauma service. It was considered highly likely that the true number of patients with OUD who were appropriate for MAT was higher. Shortly after the data were shared in November 2017, the behavioral health social work program was discontinued, thus leaving a potential gap in care for patients with substance use disorders.

After reviewing the data and briefly discussing the general concept of offering buprenorphine therapy in the hospital with the Chief of the Psychiatry Service, the authored draft an email to the Chief Medical Officer (CMO) who was asked to be an executive sponsor. In this role, the CMO would support the effort from a senior leadership perspective. This request was granted.

Inpatient / Outpatient Pharmacy Needs and Bridge Prescriptions

From an inpatient perspective, part of the early discover process was determining which formulations of buprenorphine were available in the hospital system's formulary and if the inpatient pharmacy regularly stocked the medication. Buprenorphine sublingual films and buccal tabs were found to be on the formulary and stocked in the hospital.

Ideally, the outpatient appointment would be arranged for the day immediately following hospital discharge. Yet it was clear this would not always be possible since many treatment programs saw new patients only on certain days of the week and rarely on weekends. An important part of this hospital-based buprenorphine program was the ability for the patient to continue receiving buprenorphine treatment from the time of hospital discharge until the time of outpatient follow-up appointment. Therefore, it was determined early in discovery that patients would need to be provided with a “bridge prescription” of buprenorphine.

From an outpatient perspective, assurances were needed that patients would be able to obtain the medication from retail pharmacies. This included brief phone calls to random local retail pharmacies to confirm they stocked the medication. The hospital also had a retail pharmacy located in the main lobby. For patients with CAP, the preference was to send prescriptions to the hospital-based retail pharmacy since the pharmacy’s staff is intimately familiar with the CAP program. Therefore, any issues with discharge prescriptions would be quickly forwarded to the prescribing inpatient teams.

Charity medication. A review of the CAP formulary showed that buprenorphine was available for outpatient prescribing. However, further analysis revealed that in order for buprenorphine to be dispensed for patients with CAP, the medication would need to be picked up at a single central pharmacy near the OTC. Also, it would need to be prescribed by a provider credentialed by the Primary Care Practice system. These two factors made it impossible to prescribe bridge therapy for patients with CAP at the time of hospital discharge for pickup at outside retail pharmacies.

The only alternative would be to request Academic Medical Center pay for the discharge medication as part of the inpatient treatment pilot. At the time, the hospital-based retail pharmacy

had a 340B designation for discounted pharmaceuticals. This meant an 8mg sublingual film cost \$7.93 each. A funding request was made assuming a maximum daily dose of 24mg for up to 10 days, or a maximum of \$237.90 per patient. It was noted that the OTC appointment would be made prior to discharge so only the exact amount of medication needed would be prescribed and dispensed, and that most patients would likely not require 24mg daily. The business case was that bridge buprenorphine would likely cost far less than a readmission for OUD-related reasons. The request was reviewed and approved by the Director of Case Management and the Chief Medical Officer.

Building the Inpatient Team

The importance of providing interprofessional care was noted early on by the stakeholder group. An email was sent to the nurse managers of the five acute care areas asking if any bedside nurses were interested in joining the volunteer group, in particular among those with interest in public health or opioid use disorder. The director of case management was contacted for recommendations of a bedside social worker. The pharmacy department also employed a pharmacist who learned about the work and expressed interest in participating. With little recruitment efforts needed, the initial clinical launch team included the chief of psychiatry, internal medicine resident, acute care nurse, intensive care unit nurse, intensive care unit social worker, pharmacist, palliative care advanced practice nurse, and the author (an internal medicine PA). This team became known internally as the “Core Team”.

Volunteerism and team-building. A large part of obtaining long-term and ongoing buy-in was instilling and building on a sense of volunteerism driven by passion and team-building. When staff and clinicians saw the dedication of the volunteer team, such observations furthered encouraged curiosity and encouraged adoption as reflected in the following comments.

I think one of the biggest things that helps with buy-in is seeing the drive of the people that are on the team. I think it's obviously a volunteer driven program at the moment, but I also think that really speaks volumes to the type of program that it is. It creates a lot of potential for other people to gauge their own interests. Then people start to see the benefits of this therapy, especially among nursing staff and the other staff on the floor. We're actually being accepted and offering treatment that can potentially change our patients' quality of life. Seeing all of that I think creates a lot of buy-in in other avenues. That in and of itself has created buy-in in the hospital infrastructure because looking at things like readmissions and other actual tangible outcomes, which are showing improvement, creates financial buy in. -Prescriber

[Team members] have come in on their days off for some of these meetings. People have taken time out of their lunch breaks. People have made time in their workday. -Clinical Team Member

The majority of this work is really passion-oriented and there are a lot of people in our profession with personal experience with substance use or with loved ones who have endured a substance use disorder. So I think that tapping - it's not necessarily tapping into or taking advantage of that experience - but there are certain people that have a heart for patients that are undergoing troubles with substance use. You'd be surprised at how many people volunteer because of that passion. -Prescriber

Although volunteerism was a cornerstone of the program, it was also seen as a potential weakness. Volunteers who are otherwise busy members of clinical care teams may have limited time to spend on extra clinical work.

I think with any program that is made up 100% of full-time workers who are volunteering for this job, it's difficult to always ensure someone from the team is available and able to help patients that need help. -Prescriber

Having a more standardized approach and having more experienced providers would be helpful. I think we rely on our one or two providers who are very experienced and we've learned a ton from them. We've made progress in that area. But as we expand our pool of providers, we get less experienced people. And that's good - the benefits of that outweigh the downsides. But I think it's an issue. -Physician

Having enough providers was a barrier at one point. We were getting a lot of consults and [our providers] were oftentimes busy with their own services. -Clinical Team Member

We're all doing this volunteer and so I think that hinders our ability to respond as quickly as we could. - Clinical Team Member

Consultation service. The group agreed that the ideal approach to kickstarting buprenorphine initiation in the hospital was to have a group of dedicated providers who had developed subject matter expertise and could be relied upon to start the medication for interested patients. As primary teams recognized a patient may have a diagnosis of OUD, the volunteer team would be consulted. At that point, the volunteer team would provide education to bedside providers, initiate buprenorphine, write discharge bridge buprenorphine prescriptions and ensure linkage to outpatient treatment. In hindsight, this general model of the program may have contributed to its success early on, but it may also have represented a barrier to hospital-wide adoption of buprenorphine therapy, especially among prescribers.

I think just knowing that you can call [the program] inherently shifts the culture towards a culture of more understanding and more meeting patients where they are and offering them help in their time of need. We've been incredibly nimble on the front lines in terms of adapting our workflow to make sure patients are being seen every time we get a consult. -Prescriber

Just ping [the program] and then we'll take it from there and work with the primary team on if the patient needs us or not. That's been an integral part of making it successful and easy to accept consults and keeps us fast on our feet so we can go see people quickly when they're struggling with withdrawal. I think the takeaway for other hospitals systems is you actually don't need that many people. It's helpful to have some anchoring members who have some comfort in it, some expertise. -Prescriber

There are important disadvantages to highlight in using this model. The consultation model makes it challenging if not impossible to have 24/7 coverage, which is particularly important if a patient is actively withdrawing from opioids during the evening hours. Also, having a consultation service may work against the goal of clinicians learning more about buprenorphine on their own.

If you're so used to just calling someone to get your answer or calling the social worker or calling [the program] or whoever, then you don't have much motivation to learn yourself unless you really care about the patients also. But if you think someone else is handling it, then why would you do extra work? -Clinical Team Member

We're not always here every single day of the week. So that's been kind of a gap in service. We're not available 24/7. We have gotten consults in the middle of the night, there's not necessarily someone to just jump in and see somebody. -Prescriber

Sometimes I feel like it's a little bit like "Oh, just call [the program]. They will take care of it". Sometimes it feels like we've done too good of a job. And so on those patients who can be quite challenging, people just sometimes feel like they want somebody else to take care of it. - Prescriber

One way I've tried to approach it is when I was the [hospital triage physician]. It was busy and I got a consult from a plastics surgery provider who said "This patient uses heroin, can you consult?" It took me a while to explain "It's busy. I'm the only person in-house because it's 8:00 PM. I need you to do a basic history, get a sense of what they want and do they want Suboxone and I'm happy to order and walk through that." But they were just kind of like "well, it's just heroin, can't you just see them?" In some ways, I get it. You want to be able to do the consulting and higher-level work. But, if you call renal, you shouldn't just say the creatinine is 1.5 - fix it. Then again, I recognize renal gets those consults all of the time. -Prescriber

I think I still struggle with how we make the transition from this robust B-Team to now transitioning to having primary providers take over the care of it. -Prescriber

There are some valid concerns that unless you work with this patient population and unless you've been trained in motivational interviewing and being a receptive listener, you probably aren't going to connect as well with these patients. And there are some people that just have that innately and there's some people that need to be taught. I do think it is a teachable skill, but just letting people cut loose with these patients and treat opioid use disorder on their own. I have a lot of questions regarding how effective teams will be, but I also think that it's a very important step forward that all providers should feel like they have the tools to speak to patients in this way. - Prescriber

Alternatives to a consultative model were offered. One model would have been to serve as consultative experts over the phone, but for primary teams to be charged with placing the orders, counseling patients, and only utilizing the program for additional input when necessary. Another model offered was encouraging certain disciplines to be more hands-on and other disciplines would receive a higher degree of interventions from the team. For example, internal medicine practitioners might be encouraged to counsel patients and initiate buprenorphine on their own

with support of the team, while general surgery practitioners might call and ask for the intervention to be completed fully by the team instead. There was also recognition that for the most part, the majority of the team's work could be accomplished by the vast majority of practitioners in the hospital with professional development. Ultimately, interviewees recalled selecting the consultation service model for ease of early adoption.

If you had a model where it was even just a phone consult: "Oh, okay, well what does the patient say?... Well, this is what you should do..." and have the primary team write the orders and follow up and then call us with issues. That ultimately probably might've been a more effective way to reach that goal [of widespread education], but I also think it would've taken longer. We certainly wouldn't be where we are right now. But, in the meantime, would we have lost support for the program initially and lost the benefits of cultural change and stigma reduction that we have from having had the B-Team? I think those would be the tensions, the things that you would have to weigh, but it's definitely an interesting model to think about. -Prescriber

Step two is really getting all providers to do this and providing a little bit of a higher-level consultant, a consultative expertise rather than doing all the evaluations. But I think that's been step two, step three all along. -Prescriber

*I think general surgery is always going to have challenges with trying to do this themselves. This is seen more as a chronic medical disease and typically they're not starting patients on new blood pressure medications, where an internal medicine team may start new medications for chronic diseases. I think this will always remain a chronic disease that's outside some specialties' comfort zone of managing. I think it's going to be hard to remove the consult service from teams like that. But for internal medicine, we've become a barrier to managing these patient on their own. -
Clinical Team Member*

When you first start, everyone's like "who are you", "we don't need you", and you're begging for business. Now we're at the stage where people are like "we love you". People say "We can't live without you and we can't do what you do." But, it's like, actually 90% of what I do, you can actually do. -Prescriber

Our grand vision is to be a very hands-off team. Our hope is that our residents in the hospital and attending providers in the hospital are okay taking the reins on starting buprenorphine for every patient that could potentially benefit from it. -Prescriber

Ideally, we would hand this off to everyone to where we're the backup so to speak. We want to empower the rest of the medical staff to start these inductions on their own and start having these conversations with the patients on their own. And to use as a resource. - Clinical Team Member

Seed Funding

After the initial meeting, an application was submitted for the NIDA Mentored Outreach Award in Mental Health, which was subsequently presented to the team. This provided \$5,000 to be used towards educational material development and printing, refreshments for meetings, and a stipend for clinical mentorship. It also provided an opportunity to legitimize the effort by stating it had received a grant which was connected to the National Institutes of Health. The proposal agreed upon by the stakeholder group and used to apply for the award is provided in Appendix 4.

Team name

Once it was decided that the overall model would establish a consultation service, the stakeholder group suggested forming a team name. It was felt that giving the team a formal name would help with branding of the effort and normalization of hospital-based buprenorphine therapy. Initially, the group agreed on the name Opioid Agonist Support Team (OAST). At a subsequent meeting, it was suggested to add “the” to the beginning of the phrase so it would

become catchier with the acronym TOAST. However, one content expert emailed to “please consider renaming the group. ‘TOAST’ in reference to OUD patients suggests something negative (i.e. You're toast. -- you're dead).”

After discussion, the group agreed to rename the program “the suboxone squad”. However, this name was quickly recognized by external reviewers as being potentially stigmatizing given the war on drugs and “militarizing” of drug-related policy. The group decided to rename the program “the suboxone team”, which also raised potential issues as this would be referring to a pharmaceutical brand name. Finally, the group decided on calling the program “the buprenorphine team” or “B-Team” for short. It was felt this name was clear and direct without the risk of stigmatization. The team also felt that naming it the “B-Team” would offer creative branding opportunities since some people may think of “being on the A-Team”.

People Experiencing Homelessness

During early discussion about coordinating outpatient care, one stakeholder expressed in an email:

There may need to be some provisions made for individuals that are homeless because I don't know that sending them from the hospital with extra doses of medication will be the best idea, since they have no way to store it, it could get stolen or sold – just a thought.

After much deliberation, the stakeholder group decided that bridge medication would not be in sufficient enough quantities to warrant concern, and the benefit of unintentionally diverted buprenorphine outweighed the risk.

Incubator Session

About a month after the initial stakeholder meeting, the proposal was presented to the Medical School Incubator. The Incubator was a monthly program where academic medical leadership gather to provide feedback about quality and process improvement programs and scholarly products. The brief presentation delivered is provided in Appendix 5. The group offered several suggestions to improve the initial proposal as summarized in the presentation.

Patient Selection

One of the main topics of conversation was deciding on who would screen admitted patients for opioid use disorder, and which tool they would use to do so. There were several suggestions of who could screen patients including the admitting resident, bedside nurse, social worker, or pharmacy students. At that time, screening was perceived to be a potentially time intensive process. However, no validated OUD screening tool for hospital-based use was identified, and the group focused on a self-reporting process by the patient as part of the admission or history; or an overt admitting diagnosis was recognized by the primary team as stemming from intravenous drug use such as skin and soft tissue infections.

Electronic Communication

How hospital-based care teams would communicate with the group of buprenorphine prescribers was also discussed. Pagers were in the process of being phased out of the institution at the time of discovery. The team felt that it was important to communicate that patient information should not be shared over standardized text messages. However, the hospital system was also in the process of extensively building out and increasing utilization of TigerText, a secure texting platform. The software was accessible on personal or hospital-owned smart phones by all care teams in the hospital including physicians, trainees, nurses, social workers,

and pharmacists. In addition, the software featured a “broadcast” option that allowed the creation of a group that could be texted. The team decided that an effective way to be notified of a new patient who may benefit from buprenorphine therapy would be by creating a broadcast group that would message the entire team when a message was sent by any individual in the institution. Order sets were created to facilitate easy ordering and the communication software provided for quick and direct exchanges.

Luckily, we have TigerText. I don't know if it will be as easy for some other systems to develop a way for team members to communicate or how to consult their B team program. This platform was easy for us. - Clinical Team Member

Because we have TigerText and because we opened up the process - a typical medical provider consult comes only from doctors for the most part. We still get the blessing of the doctor part of the team, but anybody on the care team can bring a patient to our attention. Since TigerText is such an easy and commonly used technology, we'll get consults from a chaplain, social worker, nurse, trauma counselor - whoever just happened to notice. They get us immediately on board. We reached out to the primary team and pretty quickly, in real time, we're able to see people rapidly. I think it's because TigerText breaks down barriers and communication. -Prescriber

Revenue Cycle

Billing was also addressed during the discovery period. During initial conversations, the primary prescribers who would be the individuals ordering buprenorphine in the hospital included an internal medicine PA, palliative care advanced practice nurse, and the hospital's Chief of Psychiatry services. The team felt strongly that buprenorphine should be the standard of care for patients with OUD. The example was often used that a patient with severe diabetes would always be provided extensive education during hospitalization and a discharge

prescription for insulin. Since buprenorphine was a similar evidence-based medication to treat OUD, the team felt that it should be offered as a routine part of care by those caring directly for patients. Under these circumstances, separate billing for buprenorphine-specific services would not be required since the services would be provided by the primary team as part of the overall hospitalization. However, in the absence of primary teams counseling patients and ordering buprenorphine, the psychiatrist and palliative care advanced practice nurse would be seeing patients specifically and only for OUD. From a billing perspective, this would be done in a consulting role. In addition, both practitioners were professionally evaluated at least in part by relative value units (RVUs), further supporting the need to bill for professional services when prescribers were acting in this consultant role. As a result, the author volunteered his clinical time as part of the non-RVU-based internal medicine service, whereas the team psychiatrist and advanced practice nurse billed for their time in a traditional fee-for-service model.

I think it's important to keep billing mind unless you have doctors that are just straight salary and their RVUs don't matter. I think it benefits them. Instead of it being just completely, sort of, pro bono, it adds an incentive where you're seeing these patients and it's counting for all the work that you do in general. When they pay attention to your numbers and being able to count these "as your part of your numbers", the work that you do and the way you benefit the hospital, it's helpful. Whether it's billing or some other way probably wouldn't make that much of a difference.

- Prescriber

I've never heard anybody voicing a concern that this program is not paying for itself. I don't think it's the kind of thing you'd necessarily expect it to pay for itself. I think it's one of those things that falls in the category of it's just the right thing to do. If you could help people get off a habituating drug, particularly when there's so many people that have his issue, then I think it's just the right thing to do. I guess in a purely for-profit situation, there could theoretically be some concerns

about it. I would think in a for-profit institution that had to answer its shareholders there might be less enthusiasm for a program like this than there is at our safety net hospital. But, you know, fortunately I've never had to test that. -Leadership

The biggest medication factor I think was making sure that we could provide the medication upon discharge. And I think that is going to be a frequent barrier of other programs. Luckily our hospital has the affiliation with our own outpatient pharmacy and we received the approval to provide a short supply of medication to these patients upon discharge. But again, I think if other sites don't have that, there's a lot of Patient Assistance Program 30-day free cards. - Clinical Team Member

Importance of Outpatient Follow-Up

The importance of having established relationships with outpatient clinics who are able to assume care for patients who are initiated on buprenorphine during hospitalization became apparent during the discovery process. One of the team members, influenced by the internal discussions of potentially starting to offer buprenorphine, was asked to see a patient as part of the regular daily workflow. The prescriber felt the patient was a good candidate for buprenorphine and the patient agreed. Following protocols from the literature, although not yet approved by hospital administration or the stakeholder group, the prescriber-initiated buprenorphine for the patient who responded well to treatment.

However, the relationship with the OTC was not yet formalized, and the process for transitioning to outpatient care was unconfirmed. When the time came for hospital discharge a few days later, the process for establishing care at the outpatient clinic was unclear, and no prescriber in the hospital had an x-waiver yet. This forced the outpatient clinic to alter the clinic

schedule to ensure same-day follow-up for the patient. The OTC director subsequently messaged:

Please do not perform any further inpatient inductions with the expectation of a discharge to [our clinic] until we have a clear and functional process in place. It puts the patient at risk for significant adverse outcomes. Was there any communication with the outpatient service prior to induction? I'm concerned.

This illuminated the importance of outpatient relationships for patients who desire buprenorphine maintenance therapy and emphasized the importance of close communication with the OTC. After this occurred, the project team reinforced its commitment to ongoing exchanges with the OTC.

Reason for Admission

As the team discussed the possibility of starting buprenorphine in the hospital internally, the larger stakeholder group began mentioning the idea of the hospital-based work to some of their constituents in the outpatient setting. This resulted in the author receiving emails over the course of the planning process from interested healthcare professionals in the community. Some of those emails asked about admitting a patient or client to the hospital specifically for the treatment of OUD. It needed to be communicated on several occasions that buprenorphine initiations were only being offered to patients who were admitted for a medical diagnosis other than opioid withdrawal. It was stressed that the program would not supplement the unfortunate dearth of clinics in the community that could offer medically assisted withdrawal to uninsured patients, and to do so would be against federal regulations. Rather, initiation of long-term maintenance therapy would be made available only for patients who presented to the hospital with OUD as a secondary diagnosis.

Learning from Others

There was a recognized knowledge gap among the clinical workgroup early. While the chief of psychiatry had utilized buprenorphine previously, none of the group members had used the medication as part of a hospital-based treatment approach or algorithm. The group divided the work for a literature search of hospital-based OUD treatment work. Ten papers were discovered (referenced previously), and the corresponding authors of the studies were emailed asking for time on the phone to discuss their process for beginning similar work at their institution. Four authors responded and participated in brief meetings. The interview guide for these short meetings is available in Figure 30. Brief memos collected from these meetings were incorporated into workflow development for the team.

Length of Stay Requirement

As the process for starting buprenorphine was discussed, one of the criteria developed based on initial research was that patients with an anticipated length of stay less than 72 hours would not be started on the medication. In these early stages of process development, it was felt that longer time spent in the hospital would yield more effective initiations. As one outpatient subject matter expert wrote “48h is not long enough for inductions in many cases. Safer to use 72h window.” However, the group also recognized that some patients with OUD may only be admitted to the hospital for short periods of time – much less than 72 hours. The chief medical officer was asked if patients could be kept in the hospital for one additional day beyond what their medical diagnoses may dictate otherwise. This request was denied, and therefore, part of the initial criteria became that patients’ anticipated stay on the hospitalist service be at least 72 hours.

Developing the Process

Service Line

Deciding which service lines would have access to the program was a key decision. Since the group was made of volunteers, it was felt that limiting the scope to specific areas of the hospital would be ideal. Therefore, for patients to receive buprenorphine therapy, it was originally decided that patients had to be admitted to the internal medicine. This meant buprenorphine was not available from the volunteer consult service for patients being cared for by the emergency department or general surgery service, among others.

Initiation Algorithm

There was significant discussion about the creation and implementation of an institution-specific buprenorphine initiation algorithm. As part of the process of developing the algorithm, the team discovered that the Clinical Opioid Withdrawal Scale (COWS) assessment would need to be a paper form outside of the electronic health record. All paper forms were required to be approved by a hospital network “forms committee”, which ultimately took several months for final authorization. A barcode was then created to ensure proper scanning into the electronic health record after patient discharge. The algorithm is provided in Appendix 6, and the final COWS form is available in Appendix 7.

Nursing role. The initial planning stages called for nursing staff to perform the COWS assessment every hour. This plan received substantial negative feedback from nursing leadership. There was typically one nurse for every four to five patients on the acute care floors. This ratio meant that following an algorithm that called for assessment every hour would not be possible. It was also hospital policy that patients requiring nursing assessments more frequently than every four hours had to be transferred to the intensive care unit. Transferring patients to the ICU for

buprenorphine initiation would be costly, prohibitive to general hospital workflows, and not clinically indicated otherwise. After careful discussion with nursing leadership, including the Director of Acute Care Nursing, it was agreed that nurses would be permitted to do the COWS assessment every two hours for three to four COWS cycles on the first day of initiation.

Nursing policy. During the initial discussions, bedside nurses raised concerns about policy that would allow them to administer buprenorphine based on the algorithm. In the absence of specific policy, some nurses felt they were putting themselves at increased liability. This was further vetted by nursing leadership who responded in an email communication:

Having policies in place is a generally good idea when an organization wants something to do be done a certain way every single time (e.g. removal of a central line) however, polices that are written about medication administration or treatment of specific conditions generally aren't able to take into consideration the nuances that individual patients have with their specific treatment needs. Policies don't lend themselves to this nuance and any time you're practicing outside the policy, you put yourself at risk.

It's possible that we could write a guideline that is specific to treatment of patient experiencing opioid withdrawal but, even then, I would like to know about any specific gaps that have been identified which would likely help determine what would needed; either a guideline for use only at [Academic Medical Center] which is written to allow for some discretion in treatment, some formalized education on treatment of opioid withdrawal, or some updates to the orders that provide more thorough instruction on how to administer Suboxone, side effects to monitor for, and when to notify the clinician.

In subsequent meetings it was decided that buprenorphine-specific policies were not required and such policy would hinder ongoing progress. Rather, nursing education occurred as part of the

annual nursing fair or just-in-time training at the time of a buprenorphine initiation would be sufficient

Discussion with outpatient clinic. During the vetting process, the OTC suggested it would be helpful to have a screening and approval process in place before buprenorphine initiation. The clinic was concerned about potential scenarios where the hospital-based team might initiate a patient on the medication and request follow-up, but the clinic may come to the conclusion that the patient was not actually appropriate. This would create several issues if the patient was already engaged in treatment through the hospital but now had nowhere to follow-up as an outpatient. This had already occurred once in the development process as mentioned earlier. Clinic leadership messaged via email:

Initial screening will allow us to identify clients that may require a pre-induction conversation between prescribers. I doubt that will be necessary for most clients, but there are certain conditions that typically illicit concern, and further inquiry. In an effort to be mindful and intentional of people's time, the initial screening will provide an opportunity to request more information/communication, only when applicable.

Additionally, it is very helpful for scheduling purposes, to be aware of upcoming appointments that need to be prioritized, for a smooth transition of care. As we discussed previously, a conversation between physicians, post-induction, would be optimal, but we have had successful transfers without that, in the case that scheduling does not permit.

Therefore, it was initially agreed that all patients would be reviewed with the outpatient clinical medical director before inpatient initiation and before discharge. However, after careful consideration of how this process would be practically implemented during busy clinical days, it was decided to move forward with these conversations being optional.

Processing mapping exercise. To further visualize and agree upon the process of buprenorphine initiation by each team member's and profession's role, a process mapping exercise was conducted. This was led by an individual with experience in facilitating group discussion. Process mapping occurred over approximately two hours and also served as a team-building exercise. The initial process map is shown in Appendix 8. A brief summary of the team is provided in Figure 31.

Electronic Health Record Order Sets

The creation of ordersets required hospital approval at regional and national levels. The team felt strongly that that prescribers would be more likely to initiate buprenorphine if an automated order process existed in the electronic health record. Since a traditional orderset could not be established in a timely manner, the team built one themselves and saved it in a folder under the nursing director. This folder was then made available to any staff member with access to the electronic health record. This workaround allowed for an alternative method of accessing a group of automated orders. The orders follow the algorithm. These are available in Figures 32 – 35. As two interviewees stated:

We also had to develop a standardized way to approach patients without a [nationally-approved] orderset. So we made our own with a bunch of favorite ordersets. -Clinical Team Member

Getting the orderset built into the computer system, into the EHR, I think would have been helpful from the beginning. It may require a little bit less education of staff. If they could just easily access everything, directly on the computer. That's about 99% of where we, from a nursing perspective, do our work. -Clinical Team Member

Education

General Education

Providing widespread education was discussed as being key to any institutional change, including introduction of a new medication and reducing stigma of specific patient population. This was accomplished through patient stories, word of mouth, department meetings, and one-on-one "just in time" trainings. The local recovery community was also engaged for advice on how to message OUD, its treatment, and harm reduction to hospital-based practitioners.

We did a lot of word of mouth and organized a lot of small education groups within different aspects of the hospital with administration, the social work team, the pharmacy team, and the new residents every year. We slowly built awareness. And then as patients came in we showed and educated. -Clinical Team Member

I think at the end of the day that was really helpful to be in person instead of rather than just sending out an email to overcome those misconceptions and stigma. So we got out of there and performed our presentation in front of so many groups and tried to answer questions. -Clinical Team Member

The educational efforts included going to different departments and telling them what we were doing, working with administration, having some successes, and reaching out to the community - particularly engaging people in the recovery treatment community was really helpful. -Prescriber

I did the primary assessment for a patient down in the [observation unit] who ended up being a candidate for buprenorphine and the nurse practitioners down in the unit, I remember that they said some things that were a little, I guess made my hairs stand a little bit, like talking about how "I don't know if there's anything we can do for this guy." "He's been here X amount of times and yeah, he's an addict and I don't know if he's ready for help." I remember spending a lot of time talking with those providers and kinda telling them more about what buprenorphine is and they

had never heard of the drug. They had heard of the B-Team, but that was the only reason why they had heard of it. And so talking them through the pharmacodynamics of the medicine and that it's safe, it seems like that really opened the door for them to think differently about these patients. And the patient ended up being started on buprenorphine later that day. -Prescriber

One of our greatest successes is that we weren't complacent with getting a couple patients here and there. We kind of kept pushing the envelope and encouraging the entire hospital to be involved and educated on opioid use disorder as well as the stigma around it. -Clinical Team Member

However, striking a balance between clinical education and stigma reduction ultimately proved important. There may already be a perception by some providers that treating OUD with buprenorphine is complicated or high-risk. Providing extensive and in-depth repeated education may inadvertently bolster this belief by unintentionally reinforcing that such a high degree of education is needed for buprenorphine initiation, harm reduction, or stigma elimination.

There was some level of complexity that was developed early on within our program that in some ways helped from an education standpoint, but also created a little bit of a barrier by increasing the complexity of what it requires to start buprenorphine in some cases. Over time, part of it is just our staff: medicine, nursing, pharmacy in general are more familiar with buprenorphine. And so even despite any complexities of initiation or titration and that sort of thing it no longer is as, as big of an issue. But I think early on the creation of certain protocols though necessary and in some ways useful also could be seen as a hindrance of this and may be more complicated than it seems. -Prescriber

I think the educational tools for providers, nurses, staff, the development of the B-Team intranet website with all of those tools easily available to all employees was important. The messaging on the floors, all of the different educational tools I think were important to the rollout and success.

Similarly, lectures with residents, faculty, nursing staff, pharmacy staff, things like that. I think were critically important. As with many, many projects, the first time you engage in a positive outcome it's easy to build on that. But getting to that first positive outcome is the big challenge. And so starting small, starting with identifying a single patient and initiating buprenorphine earlier rather than later. And then developing sort of strategies as you learn about sort of things that need to need to be developed along the way is probably a good approach that doesn't stifle or slow down the process too much. You could take six months developing all the educational tools, literature, lectures, series, all of that. Or you could start initiating buprenorphine on patients that are in the hospital and continue to develop those tools over time with orientation towards your specific patient population. -Prescriber

As part of the funding provided by the National Institute on Drug Abuse, the team was able to contract with an academic entity specialized in health communication. This team of researchers with extensive experience in graphic design and health communication worked with the team to create flyers for institution-wide education. These flyers were distributed at department meetings, internal presentations, and lectures. They were also attached to the walls of nursing break rooms and staff bathrooms. The flyer is shown in Appendix 9. It is important to develop a plan for educating the institution about buprenorphine itself. For nursing staff, comparing the overall algorithm to that of alcohol withdrawal was helpful. Ensuring there was a support system for physicians and nurses to ask questions or receive clarifications was also helpful. References were developed to support clinical workflows, and a clear differentiation was made between buprenorphine and methadone.

The cows is so similar to the CIWA scale as far as how you do it. So just by saying, "it's just like a CIWA" helped to make sure nurses, nursing managers, the CNO of the hospital more comfortable. -Prescriber

Another barrier as a provider would be not feeling comfortable with all the little wrinkles that come up. But, with two experienced clinicians, I felt like I had someone I could go to. -Prescriber

*I think a big thing too is people are scared of buprenorphine because they think it's methadone. -
Clinical Team Member*

Internal website. The team built an internal website to serve as a central digital hub for information related to buprenorphine therapy and hospital-specific protocols and policies.

Screenshots are available in Appendix 10.

The B-team internet site - that has been integral. -Prescriber

Stigma Reduction

Stigma against patients with OUD was appreciated as a barrier to treatment during hospitalization. Clinicians at the bedside and administrators may have initially stigmatized substance use disorders to the extent that treating OUD during hospitalization was seen as unimportant or ineffective.

I think our biggest impact was changing attitudes about these patients. A big part of stigma reduction has been role modeling. Being enthusiastic about treating these patients and treating them with respect. I think that has been really, really important in changing behavior and attitudes. -Prescriber

*I think there's a whole lot of people out there, even my wonderful colleagues and colleagues across the world who still believe addiction is just a matter of willpower and you know. They still put a bad person as opposed to a bad disease framework around it. And I think that's a problem. -
Prescriber*

We had a big barrier in the hospital in terms of providers and staff stigmatizing patients and not wanting to deal with. These patients were thought of as being difficult and as bringing issues onto

themselves through their behavior and substance use issues. I think that carried over to not just providers but also to administration thinking these aren't desirable patients, and we don't want to deal with these patients. -Prescriber

Stigma may limit a provider's willingness to work with patients who have OUD as there may be a certain degree of perceived skill or knowledge needed to do so appropriately or effectively.

When I think back to the first couple of people I was nervous. I was scared. I was afraid I wouldn't be able to convey that I was nonjudgmental of their opiate use disorder. That I understood that they were caught in this terrible addiction. That I understood and wanted to help them. I think sometimes patients feel judged and that leads to them leaving. And I think I was afraid that it felt like the pressure was on to prove that I really did care and I really did want to help. And then once they agreed, then it's really important to get a history. And that history is very different from when did you last get your tetanus shot? This is intense history. It gets into what kind of stressors in their life have they that led to them wanting to hide in addiction, hide in opiates. It's very intense. I mean it's rare that a patient doesn't cry, for example, during a consultation. It's an intense emotional journey that you agree to take on with your patient and then help them get through it. The actual administration of the drug and evaluating it and tweaking the dose and all of that - that's the easy part. I think the more difficult part is making the connection and proving to the patient that you really do get what's going on with them and that you care about them and that you're going to be there for them. -Prescriber

Institutional education about appropriate language may have improved stigma by expanding knowledge and improving attitudes among clinical providers. Further, educating clinicians about buprenorphine may have subsequently opened the door to having difficult conversations about stigma and substance use disorders that otherwise would not have occurred.

We really hit the ground running with holding talks or education sessions. We participated in the nursing education fair. We worked in groups with all the new residents coming in and talking about stigma surrounding the disease... Talking about addiction and letting people know that addiction can happen to anyone. It doesn't have to be a homeless patient that comes in. It can be me. It can be your mom. It can be your brother. It can be your sister. The more we talk about it the better we do reducing stigma. -Clinical Team Member

We've reduced stigma throughout the hospital and I would say we've reduced stigma throughout the hospital system by setting an example. Like many providers, I didn't think there was a lot we could do in the hospital setting for these patients. And once we started to have these initial conversations, I realized that there was an evidence-based treatment that was accessible to me as a clinician in the hospital. Word of mouth has spread and staff now realize that they are not just limited to managing withdrawal and promoting abstinence. - Clinical Team Member

I still sometimes hear "Oh, he's just a drug abuser" or "Oh, he's an addict." But the degree at which I hear that is much lower as compared to before. I feel like because my co-residents now know that there's something, we can offer these patients, that they feel able to provide assistance as opposed to feeling like the patient is just an addict, just a junkie, doing it to themselves and there's nothing we can do. -Prescriber

I think we've done a lot of education about using the right terminology, not being judgmental, and really coming at patients from an aspect of caring and wanting to help. I think a lot of these patients have preconceived notions of how hospitals will treat them based on how they have been treated in the past. They're going to be on guard and they're going to be looking at how that provider is talking to them. They're going to judge us too. And if they judge us wrong, they might say no thank you or they might leave AMA. -Clinical Team Member

Nurse Education

As discussed previously, nursing staff was recognized as key participants requiring training regarding buprenorphine initiation. Nurses were responsible for performing the COWS assessment and administering the medication per order in the electronic health record.

The hospital hosted a twice annual “nursing fair” to accomplish widespread instruction on new or updated topics relevant to nursing care. Attendance was required of all bedside nurses throughout the institution. The team requested a booth at the fair, which was approved by the director of nursing education. Brief education, less than five minutes, was required by all acute care nurses about buprenorphine initiation and the COWS assessment. The education was optional for critical care and emergency department nurses.

The core team also arranged for brief three-to-five minute presentations at nursing huddles which took place at the beginning of each shift. These short information sessions took place on a rotating schedule during the first few weeks of the program’s launch. At each of the information sessions and trainings, the nurse information sheet was shared and is available in Appendix 11. A significant amount of time was invested early on in educating nurses about the COWS assessment and buprenorphine protocol. However, once a critical mass of nurses received this education, those with experience were able to train others on their unit.

Every time I see a new patient, I always ask the nurse, "do you know what a COWS is?" "Have you checked out the B team page?" More often than not they're like, "Oh yeah, I totally read all that." Or "Oh yeah, I'm good." But that was obviously a lot of work on the front end to have a lot of information out there and available to help people feel comfortable with this sort of change of how they were caring for patients in the hospital. -Prescriber

The biggest barrier was working with individual nurses who hadn't used the protocol before.

Walking them through [the protocol] was a barrier. -Prescriber

I think we reached enough staff in the beginning by doing the nurse education fair and really showing them the nursing COWS assessment, showing them where to access it on the intranet. Because we reached so many nurses in the beginning, every floor in our hospital has at least a handful of nurses that are familiar with the program. When we have a newer nurse or someone that may not be familiar with the program, generally there's someone there that is like, "Oh, I've done that. I've done that three or four times already. Like it's easy. Let me show you." - Clinical Team Member

Nurse empowerment. Nursing staff were empowered to advocate for patients with OUD and promote treatment and harm reduction principles. This was seen as a cornerstone of program success. By treating withdrawal in the hospital setting, some patients may have become more adherent with the plan of care. Further, bedside nurses may be the first member of the care team to recognize a patient has OUD.

I think a lot of it is just keeping nursing engaged. They have the power to reach out to us or to reach out to their primary medical team. It sometimes is missed in the H&P that this patient may have opioid use disorder. The patient doesn't want to divulge it at that time for whatever reason. - Clinical Team Member

The nurse's usually the first one who sees opioid withdrawal and says "Uh oh. For the first time in two days of being in the hospital, [the patient] just said they use heroin." -Psych

We really empowered nurses. I think that could be something that other sites easily missed, but nurses were the source of a lot of our referrals. So I think getting nursing staff engaged is really important. - Clinical Team Member

I think the nurses are uniformly enthusiastic. It makes their job so much easier and it's super helpful. Caring for patients on buprenorphine is so much easier. -Prescriber

Attending and Resident Education

Internal medicine residents were engaged and trained as part of the educational process. This included attending noon conferences and presenting OUD-based morning report cases. Lectures were adapted from slide decks available from the Support Hospital Opioid Use Treatment (SHOUT) program. These trainings were led by the internal medicine resident on the Core Team. Attending physician and resident education may have also led to increased overall participation from clinical staff. In particular as an academic center, teaching evidence-based treatment of OUD to trainees was considered relevant, and those residents may have influenced their supervising attendings in some cases.

The other area where it's been incredibly rich is that we're a teaching hospital. These cases are very focused and are rich in both kind of clinical teaching of how to use buprenorphine, but also in how to interview patients without judgment and to really engage in full patient-centered care. I think that has been really fantastic. -Prescriber

It's important to get resident and student involvement so that treating opioid use disorders really becomes part of the learning environment. People will carry that with them for the rest of their careers. -Prescriber

Especially as a teaching institution, a really great way to do it is to train all the residents because then there's pressure from below. And that way you get some of the grumpy older providers who are never going to change to do it. -Prescriber

I was in training not so long ago and I feel like I can still somewhat relate to what it's like to be a resident in training. There was no formalized training on addiction or substance use disorders, nor was it a core focus of training. It was a very rampant issue in the community. We all volunteered some of our additional time outside of residency to work in these clinics or work on

needle exchange vans. But it was never structured in any way. When it comes to substance use disorders, there's a little bit of a disconnect because the way that it works for us is that they consult the B team and the B team assumes the responsibility for that care and provides the appropriate recommendations for treatment. I think it would be great and highly beneficial for the residents to be an active part of that process. They can learn a lot more about their patients and the stressors and the life situations that have brought to brought them to where they are. That can provide a lot of insight and build a lot of empathy which can then drive their interest in enhancing this care. Thankfully we have something wonderful that has shown great outcomes that we can utilize and is available to us. So I think it gives them a potential to have an active role, feel like they're participating and making a difference potentially for these patients, especially the ones that they see repeatedly for conditions that are associated with their substance use disorders. -Prescriber

Pharmacist Education

The pharmacy department hosted a one-hour in-service training about buprenorphine led by the Core Team's pharmacist. The slides were provided by the Support Hospital Opioid Use Treatment (SHOUT) program. In addition, the team pharmacist authored a memorandum for the pharmacy department about the new program and utilization of buprenorphine based on the Situation Background Assessment Recommendations (SBAR) method. The pharmacist education document is provided in Appendix 12 and the SBAR is provided in Appendix 13.

Institutional Education

In addition to building awareness of indications for buprenorphine and its clinical applications, the team recognized the need to start fundamentally shifting culture away from a detoxification-only mentality to a treatment and harm reduction mentality. By speaking about buprenorphine, the team felt it would be possible to open doors for additional productive

conversations about the treatment of patients with OUD. Therefore, several non-clinical presentations were arranged as follows.

Medical executive committee. The Medical Executive Committee (MEC) was charged with creating clinically-oriented policy across the hospital. The monthly meetings were comprised of division chiefs across all service lines in addition to key hospital administrators such as the president, chief medical officer, and chief nursing officer. Presentation slides are provided in Appendix 14.

All-hands meeting. The “All Hands” meeting was a quarterly event at the medical school in a large auditorium with representatives and leaders from numerous departments and divisions across the institution. The meeting was primarily an opportunity for the dean to share important news and developments from around the school. In addition, there were usually two to three five-minute presentations from groups with innovative initiatives or programs. The core team was asked to present at one of the meetings. The brief address is provided in Appendix 15.

Process Improvement Council. Interprofessionalism was incorporated as a cornerstone of the program from the beginning. The Process Improvement Council was a quarterly meeting of interprofessional stakeholders from the acute care areas of the hospital. Nursing is well represented at this meeting in addition to attending physicians and residents. The presentation given at this meeting is provided in Appendix 16.

X-waiver training. The team advocated for an x-waiver training for the regional prescriber community around the time of the program’s launch. The training was offered free of charge through the federally funded Provider Clinical Support Systems. The institution offered space and PCSS arranged for a trainer, processed registrations, and provided handouts and

continuing medical education. Several local organizations such as the local medical society agreed to promote the event.

A substantial amount of work went into delineating the difference between ordering buprenorphine as part of hospitalization and prescribing buprenorphine for the treatment of OUD at discharge so that a patient could pick up the medication from a retail pharmacy. It was a common misunderstanding by clinicians, pharmacists, and administrators that any provider incorporating buprenorphine into their care plan needed to have an x-waiver, whereas only those prescribing buprenorphine at the time of discharge to be filled at a retail pharmacy needed to have the x-waiver.

We had to overcome the misconception that you cannot start Suboxone in the hospital setting without an x-waiver. Working with the pharmacist and the medical staff to overcome that was important. In the outpatient setting, there's been all sorts of confusion with the [hospital-based retail pharmacy] around who has an X waiver and things like that. They were very hesitant at first, but I think talking to them again really helped a lot. One thing that's been a real barrier as you know, is mid-levels have had a lot of trouble prescribing. I know that's been hard for a least two to set up. So those sorts of regulatory barriers have definitely been a challenge. - Clinical Team Member

Open Forum

Early on in the program's development and initiation, the team hosted a one-hour "open forum" for community stakeholders to engage and ask questions. This dialogue provided an opportunity for decision-makers who did not have a daily operational role in hospital or community-based OUD treatment to offer feedback and build a better understanding of the program's mission and goal. Approximately 30 leaders from the community attended the event.

Local Area Opioid Workgroup

At the county level, a group met frequently to discuss initiatives, policies, and programs in the region to benefit patients with OUD. The team was asked to present at this meeting, which was attended by individuals whose daily role was to provide care for this patient population.

Building Momentum

Witnessing Efficacy

Buy-in and momentum was built as care teams in the hospital began to observe the efficacy of buprenorphine therapy during hospitalization.

Seeing the efficacy of treatment had a huge impact on people. It's like "Oh, this isn't hopeless. I've always thought this is hopeless, but this isn't hopeless. There is treatment for this and it actually works." And I think when people see it work, it makes a big impact. -Prescriber

Sharing Impact

The initial program launch was scheduled for July 2018. However, in June of the same year, an opportunity presented to initiate buprenorphine for a patient with OUD who was admitted for endocarditis. The patient expressed a desire to leave the hospital against medical advice secondary to uncontrolled opioid withdrawal. After discussion with the patient and chief medical officer, the patient was started on buprenorphine therapy. By the next morning, the patient was feeling well and was cooperative and adherent with the plan of care. He completed six weeks of hospitalization without any further issues and attended his follow-up appointment at the OTC. The outpatient case manager wrote shortly after:

I wanted to share with you all that during the assessment, he became quite emotional, started crying to the point where he could not talk (not just tearful), and expressed a lot of gratitude for everything you all have provided there, for him. He acknowledged that he

was so relieved to not have been kicked out after having been caught using in the hospital, but more importantly, it really seemed to be about his feelings, and almost disbelief, that “they actually really care about me.” It was kind of heartbreaking, but very awesome that you all have made such an impact.

This message was shared widely with the internal stakeholder group in addition to the narrative provided in Appendix 15. In particular, among nurses and social workers, the story of a successful buprenorphine initiation and the positive impact of that initiation on a patient’s hospital course was shared across the institution. As more bedside staff learned of the story, demand for buprenorphine consultations slowly increased.

Continual Improvement

The group met on a regular and continual basis in an effort to quickly assess the program’s roll-out and need for improvement. These meetings were performed in the spirit of the Institute for Healthcare Improvement’s Plan-Do-Study-Act (PDSA) model of continuous improvement (Institute for Healthcare Improvement, 2020). In the beginning, the group had a standing weekly meeting to evaluate progress from items identified the week before. A single area for change or improvement was discussed and then quickly implemented. Several enhancements were made to the program based on this model. For example, the process by which the team received consultation requests was transformed over the course of the first several weeks of the program. Initially, only the primary care team (resident or attending physician) could request buprenorphine initiation. However, the program soon recognized that nurses and social workers were often recognizing OUD more quickly than the primary teams. Through the improvement meetings, a new process was created where nurses or social workers requested the services of the team. After the first two months, meetings were changed to twice

monthly and eventually once monthly with an additional but optional second meeting monthly if needed.

Another change was altering the exclusion criteria for patient participation. Ultimately, any patient who would benefit from buprenorphine therapy was seen by the team. The only criteria were that patients must have been age 18 or older and have met diagnostic criteria for OUD. Interestingly, as the inpatient team eliminated inclusion criteria over time, the OTC did the same in parallel.

I recall sitting in on several meetings at [the OTC] speaking with their staff and getting a bit discouraged at the limited eligibility criteria that they had for their program... And that they really would want patients that we refer to them to fall in that eligibility criteria and had originally included things stable housing and no comorbid physical or addiction illnesses... but at the beginning they just wanted to make sure that they had capacity to accept all these patients and understandably so because really without having another outpatient clinic to send these patients to our program wouldn't be feasible. -Prescriber

Community Engagement

Part of the team's overall promotional strategy was to contribute to the national conversation about opioid treatment through non-peer reviewed publication such as blog posts. This would serve two purposes: to share the work with others who may be interested in starting something similar in their hospital and to take those publications and share them internally as a way to encourage institutional adoption. For example, by having an article published by a professional medical society, legitimacy could be added to the local effort. In addition, the team engaged with local media to generate stories in the local press about the importance of hospital-based substance use disorder treatment and transitions from the hospital to the community at discharge.

Resulting challenges. Information about the program spread in the community within two groups: clinical providers and patients. The primary local newspaper ran a story about the program on the front of the Sunday edition. This generated interest from patients who were left with the impression that they could present to the emergency department and receive buprenorphine therapy. Within 24 hours, hospital executives received messages of concern that “several patients” had visited the ED for this purpose and had to be sent away since the program did not have any services in the emergency department. Upon further review and discussion with ED leadership who were on duty during that time period, it appeared that three patients had asked for treatment based on the article during the 24-hour period. Administration was initially left with the impression that many patients had “flocked” to the ED for this service, but this was resolved when objective information was shared. While buprenorphine was not available in the emergency department, social workers were empowered with resources to make available for interested patients.

One concern of administration from the inception of the program was that as more people in the community learned about the program, there would be increased interest in patients with OUD receiving care specifically at the single hospital. Prior to the program’s launch, administrators believed that patients with OUD were somewhat distributed across the city’s hospitals. However, by offering a program tailored for this patient population at a single hospital, it was felt that patients may preferentially choose that hospital for their OUD-related care. The resulting disproportionate increase in OUD care at Academic Medical Center would potentially pose two issues: Reimbursement for medical services related to OUD for patients who were underinsured and uninsured was complex and presumably expensive for the institution as a result, and the perception that patient’s with OUD were disruptive and challenging and therefore

would attract more cases of OUD, which may be detrimental to the care experience for neighboring patients and employee satisfaction.

As the program continued to grow, the hospital was indeed sometimes sought out specifically for its OUD-related program. Patients asked to be transported by ambulance to the hospital for treatment of medical complications of OUD. It was common for patients to mention access to buprenorphine and reduced stigma as primary reasons for this. However, some patients also asked to be transferred to the hospital after already being admitted to another facility within the same hospital network, or at another local hospital in a separate system altogether. Because interfacility transfers require physician approval, the team sometimes received phone calls from other facilities asking for patients to be transferred because the originating facility did not have the “capability” of offering buprenorphine therapy, and therefore a transfer was felt to be appropriate for reasons related to a “higher level of care.” Counseling and recommendations were provided to these outside physicians. In particular, it was repeatedly messaged that no special capability or training was required to initiate buprenorphine therapy in the hospital and that the team was happy to provide support from a distance.

In addition, frequent communication with administration was necessary to ensure satisfaction that patients would not be transferred to the hospital specifically and solely for buprenorphine initiation. However, there were three instances where patients with endocarditis who required six weeks of intravenous antibiotics left another hospital against medical advice, arrived at Academic Medical Center’s emergency department, and were subsequently admitted to complete long-term therapy. Had the program not been in existence, this likely would not have occurred. In addition, two of these cases were likely facilitated unofficially by paramedics who

had strong relationships with patients and who knew about the program. However, as a result of these transfers, patients were able to access holistic hospital-based treatment.

Lastly, the team began receiving phone calls and emails from community-based providers asking if patients could be admitted to the hospital for medically assisted withdrawal. Over a period of several months, inquiries from paramedics and other community providers were met with careful and intentional counseling and education about the role of the program and the absolute need for patients to be admitted for a medical diagnosis other than OUD itself. Much of this education centered around the laws and regulations of opioid treatment programs, and the importance of recognizing the hospital would not have such a designation.

The patients were already coming to the hospital anyway. Before starting the program, we were still seeing patients who use heroin or use other drugs and they were probably just going in and going out. - Clinical Team Member

I think there's good word of mouth in the community about our program. That hasn't led to an increase seeing patients with OUD. If anything, I think we're more effectively able to treat the patients we were already seeing... We've definitely run into barriers with administration being fearful of the program causing increases in our patient population seeking treatment. It was important to overcome that stigma and help them realize that we were only treating patients who were already admitted to the hospital. -PharmD

It never occurred to me "wait a minute, we're going to be attracting opioid abusers here that we wouldn't otherwise get" I just assumed we were getting them already. We already had them. - Prescriber

It just hasn't happened. I think we can make predictions about what phenomenon may or may not happen, but the data tells a clearer story. -Clinical Team Member

However, there was recognition that “flocking” might be a possibility at other institutions. This would be mitigated by buprenorphine initiation being standard of care at all hospitals in a region.

People go to the hospital where they know they can get the care that they need. Frequently that's the hospital closest to them. For example, if you have substandard cardiac care at one hospital versus another hospital then patients might prefer the hospital with better cardiac care. I would argue the same for OUD. -Prescriber

There might be a challenge for the one hospital that does it initially. Once the word gets out that there's a group of people at our hospital that care about me as an addicted person, will care about my friends, will take good care of me without judgment and help me - there is a risk of patients flooding to our doors wanting help and that's wonderful on one hand, but that's not the main mission of our hospital. It's not the mission of administration. So it needs to be offered everywhere. And it's just not yet. -Prescriber

Early Results and Outcomes

In the first twelve months of the program, 122 adult hospitalized patients were referred to the team. Of those, 50 patients were eligible to receive buprenorphine therapy and all were initiated on the medication. There were several reasons the other 72 patients did not receive buprenorphine therapy. These included disinterest by the patient, short length of stay, prior engagement in methadone treatment, not meeting diagnostic criteria of OUD, or severe comorbid illness (Figure 36). Of the 50 patients initiated on therapy, 45 were referred to the outpatient clinic. Five patients were discharged to a skilled nursing facility, correctional facility, or left the hospital against medical advice (Figure 37). Of the 45 patients who were referred to the outpatient clinic, 60% attended the one-week appointment, and 14% were still engaged in care at 6 months (Figure 38). Patients who engage in outpatient treatment tend to stay in outpatient

treatment. Of the 27 patients who made their 1-week appointment, 63% made their one-month appointment. Of those 17 patients, 35% made their three-month appointment, and of those six, half made their six-month appointment (Figure 39). There was an average of 5.75 buprenorphine orders per month in the year prior to the starting the program, and an average of 28.75 orders per month in the year following the program's launch (Figure 40).

Perceived Patient Response

As a result of the program, patients may feel supported and respected in the hospital setting, which may be different from experiences they have had in other institutions.

I think patients are really happy to have someone respect where they're at and understand that this is not easy. Being in the hospital is not easy. They're scared of the unknown. But, I think they feel really welcomed. They feel trusting of people who are understanding of what they're going through and able to direct them in a path. It's probably going to set them up for success more than other interactions with providers or hospitals that they've had before. I think patients seem really future-oriented. - Clinical Team Member

I was just blown away with how surprised a patient was that a program like ours exists and his feelings of gratitude were just immense. The fact that he even said that people on the streets, people using drugs now know about our program because it's made such an impact on his life and the lives of other friends that he had had. I just find that for lack of better words, I'm left in awe, that just the simplicity of offering patients' treatment in the hospital setting could have such a profound ripple effect as that. And could give people hope in a disease process that otherwise is mainly full of despair and anxiety and a lack of self-confidence. -Prescriber

Just having someone come in who treats them with respect and wants to hear about their experiences in an authentic, real way. A non-voyeuristic way. Just wanting to listen and hear. That alone is a real huge seismic shift for many of our patients. And then being offered treatment

is great. I think some of the patients that have given the most positive responses have been those who buprenorphine is not going to work. But just the fact that we're there and want to talk to them about their substance abuse and want to listen to them and want to hear them. It makes a difference. -Prescriber

I think most of the patients we talk to about [buprenorphine] are kind of exuberant that we actually have a program addressing it. That there's someone on their side. That we want to do what we can to take care of them. That they have options. That they don't have to worry about going into withdrawal in the hospital. That there is a possibility of a way that seems manageable or at least semi manageable to stop using. I've really just gotten a lot of really positive feedback from patients. -Clinical Team Member

Patients who have been involved in the program are nothing short of thankful for even being given the opportunity and for not being treated how they have been treated in the past at other hospitals. They aren't judged. They are spoken to in a manner that we understand this addiction and that we want to help them. We're not here to judge them. We want to offer them the opportunity to take the next step. -Clinical Team Member

I've seen a culture shift among physicians, leadership, and on the floor among nursing staff - they feel supported. They feel like they're some expertise about how to answer some of these tough questions. -Clinical Team Member

Perceived Impact on Organizational Culture

Overall, initiating buprenorphine as part of acute hospitalization appeared to have resulted in a perceived improvement of organizational culture around OUD treatment and stigma of substance use disorders. This was accomplished by sharing patient stories, recognizing OUD

is a medical disease with physiologic characteristics, and a realization for many healthcare workers that there are systems of care and treatments available to help patients with OUD.

Find cases you know, people that came in that were really having a hard time, ones that are willing to tell their testimonial, just have some vignettes that would talk about somebody's life that you turned around in their own words. I wasn't really a believer that docs and nurses needed that. But, I'm seeing it really does seem to influence people. They need sometimes see an actual human face on a program like this. -Leadership

Our cultural change really depended upon telling patient stories, mainly because people don't really connect with numbers, but the stories just tend to resonate... That was a huge tool that we used to leverage that cultural change. That opened the doors for us to enter different service lines and also just get the support of our nurses and doctors in the hospital... Time and time again, we hear these incredible stories and honestly that's where the power is in this program. -Prescriber

A huge success has been the change in how all the other hospital workers see the B team, how they see people with opiate use disorder. People are realizing it's the drug, not the person. The drug causes the behavior. -Prescriber

I feel like the nursing staff has been so receptive. At first we needed some of that stigma reduction and education. There was a lot of hesitancy. And I think a lot of providers and nurses now feel like we have a tool now to help these patients. They don't feel so helpless at the bedside. Before where there were very minimal resources. Now we have a whole team of people that can help them and teach them and can help them treat the underlying disease. -Clinical Team Member

It's clear that our hospital treats folks with opioid use disorder differently and better than others. -Prescriber

I've had tons of positive comments [from staff]. "Thank God you're here." "I'm so glad you're taking care of him or her." "She's so different today than yesterday." "I can't believe what a difference." He's being so agreeable to wound care." "I'm so glad that he's not in pain anymore." I mean, really positive comments. -Prescriber

I've spoken with at least 10 nurses that have told me how much their patient changed in the course of just a few hours after getting inducted on Suboxone and how they went from this kind of aggressive "I'm going to leave AMA" taking up all of the nurses time, calling the provider, trying to convince the patients to stay. I think the nurses have also started to recognize that they're doing something good for this patient. They're not just improving their shift or work experience, but they're really helping this person if they stay the entire course of their medical treatment. - Clinical Team Member

I think there's more of an understanding that this disease isn't just someone's moral failing and that it's not just their decision to continue to use, that there's a lot more at play socially and biochemically. This medicine helps patients stabilize their brains so that they can get the help they need and make the changes in life that they want to make. -Prescriber

B-Team perceptions of OUD. Team members expressed that participation on the team influenced their perceptions of patients with opioid and substance use disorders. Judgmental and stigmatizing attitudes improved, as did appreciation for appropriate and thorough history-taking.

I used to say "Oh, of course I'm open minded and nonjudgmental about treating patients with substance use and opiate use disorder." But, you know, looking back on it now, I think I was judgmental. -Prescriber

Just taking a substance use history, I had never been taught to do that long list of questions and really dive deep into people's use and where it came from and what they've been through. I

thought I was doing a good job by asking "have you ever been sober and what's the longest you've been sober?" Most providers don't even do that. -Prescriber

I definitely stigmatized this population in the past and now I am ashamed of how I would approach these patients. I just didn't think there was a lot that could be done and I just didn't have a lot of faith in I guess recovery. Which now just feels so bitter and terrible coming out of my mouth. - Clinical Team Member

It really has impacted me in terms of giving more humanity to patients; seeing them as people and not patients... it's really impacted me in the way that I practice medicine. Just remembering there's a story behind every person and how they ended up where they are. And just a lot of times the most important thing you can do is just ask, tell, ask. -Prescriber

Personally I would say that it has allowed me to engage with my patients in conversations that I sometimes shy away from due to due to various reasons whether it's time constraints or some other pressure related constraints but knowing that this is a treatment strategy that I'm actively trying to engage in pushes me to sort of say that I have a professional role to engage in some of these conversations, I think just from a purely personal standpoint is helpful. This is very gratifying. -Prescriber

Implementation Themes and Messages

Overall, three main themes were revealed in analysis. Early and ongoing engagement with a diverse group of internal and external interprofessional and multidisciplinary clinicians and administrators was key to success. A thoughtful and careful approach was needed to educate all members of the care team about the role and efficacy of buprenorphine for the treatment of OUD and how the medication can be initiated from a workflow perspective. Educating staff about buprenorphine contributed to shifting culture, raising awareness, and promoting important

conversations about systems-based practice for hospitalized patients with OUD and reducing stigma. Finally, an initial approach to buprenorphine care delivery needs to be adopted, such as a consultation service, with special attention to the pros and cons of that process and the ability to engage in frequent evaluation and adaptation.

In addition, several consistent messages were shared with stakeholders and were evident in the documentation reviewed for this paper. This content was the foundation of much of the communication about buprenorphine and the program, and was shared widely with stakeholders. These messages include information about the clinical efficacy of buprenorphine, regulatory environment, and systems-based practice. Opportunities to engage in discussions about buprenorphine were actively sought, which may have led to additional conversation about appropriate care and management of OUD. The salient points are provided in Figure 41.

What's Next?

Several interviewees commented that they felt other hospitals in the country should have a similar program, and that treating opioid use disorder during hospitalization should be the standard of care. Action should be taken to increase health equity for access to substance use disorder treatment programs. Further education is needed to continue instilling empathy among hospital-based clinicians and staff.

The program alleviates human misery and human suffering and treats our patients. It's very patient centric. And I think wherever you are, doesn't matter what hospital you're at. There's so much opiate problems in the United States and so much of it is orders of magnitude more potent than it used to be. Being able to tell that story really resonates with people and it would be compelling in any hospital. -Prescriber

I think this is something that should be in every hospital in the United States, every hospital in the world. I truly believe that. Positive evidence-based treatment should be offered to all hospitalized patients who have a comorbidity of OUD or come in primarily with an overdose. -Prescriber

The medicine part is easy. The complex social needs, provider alignment, and making sure the meds are filled with pharmacy. That gets complicated quickly. Dealing with poverty, trauma, and poor coping behaviors. That's real hard. -Prescriber

Other hospitals absolutely need to start this. It is standard of care and if you don't have a program like this in place, you are under treating your patients. You're not doing a good job taking care of your patients. -Prescriber

There's definitely opportunity in fore fronting conversations around the intersection of health equity and quality improvement as it specifically relates to substance use disorders or opioid use disorders. How to think about strategically developing a program with an equity framework. I think that's something that we're engaging in now and it has been some part of the conversation I think in the past, but could be more robust in many ways of trying to understand public policy, institutional racism, structural racism, the history of health system development over the course of the last several decades really, and how that specifically effected the epidemic of opioid use disorders and also other substance use disorders that the development of certain stigmas over time. -Prescriber

I think people are scared and timid of all the things our patients have been through. They don't know how to convey that they care about them. They may feel it's not what they signed up for something. People just aren't comfortable with what we do all the time. - Clinical Team Member

Chapter 5: Discussion and Lessons Learned

Treating opioid use disorder during hospitalization with buprenorphine among other interventions has been well described in the literature (Englander, Dobbertin, et al., 2019; Liebschutz et al., 2014; Suzuki J et al., 2015; Trowbridge et al., 2017). The case study presented is unique to the literature as the program described is managed by a team of volunteers already present within the walls of the hospital. As described, the development of a volunteer-based program to treat hospitalized patients with OUD with buprenorphine while reducing stigma of OUD is feasible, even with limited resources including the absence of an addiction medicine consultation service and absence of Medicaid expansion. The following facilitators and barriers were identified for the creation and implementation of the program. These descriptions may be beneficial for other institutions.

First, recognition across stakeholder groups that hospitalization is a reachable moment for patients to begin their journey to recovery is important. Where many hospitals may view substance use disorders as a diagnosis strictly managed in the outpatient setting, this program intentionally addresses in-hospital OUD treatment in parallel to medical treatment with positive outcomes. Such work is likely to improve hospital-based metrics such as mortality, readmissions, patient experience, and staff satisfaction. Interprofessionalism is paramount to a successful program of addressing opioid use disorder in the hospital setting. No one discipline is capable of understanding and impacting the many facets and issues surrounding opioid use disorder. Volunteerism may facilitate and accelerate this work early on through mutual interest, dedication, and teamwork. However, over time, relying on volunteers to conduct clinical work in addition to their regular daily responsibilities presents challenges. In addition, depending on the number of volunteers, it is likely that coverage gaps will exist in particular during overnight hours and weekends.

Similarly, establishing a consultation service model likely facilitates adoption of OUD treatment and harm reduction, but presents challenges later on. A consultation service seems to raise a large amount of awareness while only providing minimal to moderate education for non-team members. While this may achieve the goal of increasing buprenorphine utilization and appears to reduce stigma, it is unlikely that many non-team members will learn enough to manage buprenorphine on their own. The ease of relying on a consultation service may limit complete clinical adoption at the level of individual practitioners.

Having an accessible outpatient clinical partner facilitates stakeholder engagement as does executive support. There may be times when administrators become cautious of the work particularly around patients presenting to the emergency department specifically seeking treatment of OUD. However, potential issues can be mitigated with increased frequency and depth of program communications and updates.

An in-hospital retail pharmacy may facilitate launch of a program since patients can obtain buprenorphine bridge prescriptions before leaving the hospital and because the inpatient team has familiarity with the pharmacists. However, a barrier may be that not all insurance is accepted at the pharmacy. In this instance, the hospital may choose to pay for the bridge prescription to facilitate patient follow-up.

Overall, the largest barrier is lack of education around OUD treatment and harm reduction among hospital clinicians, staff, and administrations in addition to stigma. Also, even in the early days of a program, volunteers may have a learning curve around clinical and systems-based practice. Some volunteers may recognize their own stigmatizing bias early on, which can improve with increased education and work at the bedside. Access to a network of content and addiction medicine experts in the early phases of such a program is critical.

Further discussion is provided by the themes outlined previously.

Theme 1: Early and ongoing engagement with a diverse group of internal and external interprofessional and multidisciplinary clinicians and administrators is key to success.

Outpatient Clinical Partnerships

Meeting the goal of assisting patients to start or continue their journey to recovery required strong, intentional, and meaningful connection to an outpatient clinic. The Opioid Treatment Clinic provided an opportunity for patients to seamlessly establish OUD-related care including buprenorphine after discharge. The relationship with the OTC, which was not owned by or formally affiliated with Academic Medical Center, exemplifies the significant relationships that should exist between hospitals and community clinics in addressing substance use disorders. From a revenue cycle perspective, such relationships are also mutually beneficial as the hospital could serve as an important referral source to community clinics. Further, in the case of buprenorphine, much of the treatment cost may occur earlier in the continuum of care when the burden of counseling, medication management, and laboratory testing is higher. These services are often provided in the hospital as a regular part of medical admissions related to OUD. Thus, forging hospital-community relationships may reduce total cost associated with buprenorphine care for patients who interact with the hospital system.

Interprofessional and Multidisciplinary Care Delivery

Assembling a team of stakeholders with varying perspectives and trainings was pivotal to success. The team included nurses, physicians, social workers, pharmacists, chaplains, and a physician assistant representing internal medicine, psychiatry, and palliative medicine. This engagement provided for transparency, maximal knowledge transfer, and critical collaboration. For example, the initial roll-out plan was planned to be physician-focused, but as time

progressed, the team more fully recognized the role of nurses and social workers in recognizing OUD, often long before physicians. As such, nurses and social workers ultimately became the primary champions and drivers of patient referrals to the inpatient program.

Executive and Leadership Support

Ongoing support from executive and department leadership was pivotal in success of the program. The Chief Medical Officer and Chief Nursing Officer promoted institutional change and provided support around issues such as provisioning buprenorphine bridge prescriptions at no cost to patients and facilitating widespread physician and nursing education. Department leaders also supported individual team members and assisted with gathering feedback and highlighting patient success stories.

Continuous Improvement

Establishing a plan for regular program analysis and adjustments as necessary was critical. The team initially met weekly for the first two months and then began to spread the intervals over time, ultimately agreeing to meet once monthly. The vast majority of process improvements for the team originated in these meetings.

Theme 2: A thoughtful and careful approach is needed to educate all members of the care team about the role and efficacy of buprenorphine for the treatment of OUD and how the medication can be initiated from a workflow perspective.

Sub-theme 2A: Stigma of opioid use disorder in the hospital setting is pervasive. Educating staff about buprenorphine contribute to shifting culture, raising awareness, and promoting important conversations about systems-based practice for hospitalized patients with OUD.

Caution with High-Volume Education

There appears to be risk in providing “excessive” education and creating excessive structure around buprenorphine therapy. The use of buprenorphine for the treatment of OUD is perceived by some to be complicated, likely in part because of the eight-hour x-waiver training. The course perpetuates an idea that buprenorphine is a risky or potentially dangerous medication. Providing extensive clinical support educational campaigns, lectures, and just-in-time training may reinforce these inaccurate notions.

Opioid Use Disorder Specific

The program represented a specific intervention for a targeted patient population. It was not an addiction medicine consult service. However, in the absence of such a service, the team was seen as a possible conduit for addiction related care and resources for primary care teams. It was not uncommon early on for the team to be consulted for perceived diagnoses of OUD, which turned out to be other substance use disorders. The team occasionally received questions specifically asking if buprenorphine could be used for substance use disorders other than OUD.

Appropriate Admissions and Transfers

There was concern among administrators that a disproportionate number of patients would “flock” to the emergency department seeking buprenorphine therapy. This did not occur. When an article appeared about the program in a local Sunday newspaper, a few patients visited the ED in the following 48 hours seeking treatment. Those patients were referred to the OTC. Otherwise, there were no examples where patients presented to the ED specifically seeking buprenorphine treatment. However, there were examples where patients with medical sequelae of OUD such as endocarditis left another hospital against medical advice and arrived at Academic Medical Center. This was facilitated by emergency services personnel in two cases.

These transfer cases occurred infrequently, but they likely represent a major gap of in-hospital opioid treatment services elsewhere in the region. After careful and intentional education to the community that patients cannot be admitted solely for medically assisted withdrawal with buprenorphine, those patient presentations and inappropriate transfers ceased. In addition, education with community practitioners was needed to solidify that Academic Medical Center was not a traditional opioid treatment program and patients had to be admitted for medical care. However, these scenarios represent a foundational issue. Buprenorphine for the treatment of OUD should be the standard of care for any hospitalized patient who might benefit, thus eliminating the desire or perceived need to transfer care.

Institutional and Practitioner Naivety

Institutional and practitioner naivety around OUD and buprenorphine existed. This is likely a combination of widespread stigma of patients with OUD in society and healthcare, in addition to a historical dearth of OUD-related curricula in health professions. As such, numerous assumptions were made early in the development of the program, and programmatic decisions occurred because of those assumptions. For example, initially there were extensive enrollment criteria for inpatient buprenorphine initiation. Those were mostly eliminated later and a patient need only be over age 18 and have a diagnosis of OUD to receive treatment. The team had also worked out a robust handoff arrangement with the outpatient clinic based on the presumption that buprenorphine and patients with OUD were complex. As the program grew, less communication existed between the hospital and the clinic at the time of discharge to the point where appointments were confirmed, and the clinic obtained the remaining information from clinical documentation. Ultimately, improved clinical processes and workflows reflected a deeper understanding of and appreciation for buprenorphine therapy. In another example,

patients were initially required to have an anticipated length of stay of 72 hours because it was thought that period of time would be needed to accomplish a meaningful buprenorphine-based intervention. In reality, such interventions can be accomplished in less than 24 hours and are often done same-day in the outpatient setting. Finally, nursing staff asking for specific hospital-approved policy around buprenorphine therapy also expressed early discomfort with the medication, which was resolved with bedside experience and without the need for new written policies. Even among all the team members, buprenorphine was initially thought to be more complex than it ultimately proved to be. Further, stigmatizing language was used in the original internal promotional materials. These have since been revamped based on lessons learned as shown in Appendix 17.

Theme 3: An initial approach to buprenorphine care delivery needs to be adopted (such as a consultation service) with special attention to the pros and cons of that process and the ability to engage in frequent evaluation and adaptation.

Meeting as a team early and regularly in the process contributed to success. Developing a process map and determining group consensus around a problem statement, intervention statement, mission statement, and list of milestones was helpful.

Consultation Service Model

The team felt that a consultation service was the most appropriate and effective way to introduce buprenorphine in the hospital setting, especially considering the high degree of stigmatization of patients with OUD. The consultation team was responsible for protocol development, bedside education, buprenorphine initiation, linkage to treatment, and institutional stigma reduction. However, the team was staffed by a group of enthusiastic volunteers which represented a significant weakness in the program structure from a clinical perspective. Patients

admitted during overnight hours or on the weekends may have had a delay in receiving buprenorphine therapy since the B-Team was perceived as the only individuals capable of starting the medication. Also, while a consultation model appears to have been highly effective at building awareness and general knowledge, it has not yet influenced non-team attending physicians or residents to initiate buprenorphine on their own.

Using the TigerText secure texting platform played a critical role in quickly and easily communicating protected health information among team members and those requesting consultations. Unfortunately, the true power of leveraging information technology was limited based on institutional regulations and policies around modifications to the electronic medical record. While the team was able to build an electronic order set, this was done in a non-traditional way that made it harder for non-team members to access.

Limitations

While this study represents one method of initiating buprenorphine therapy for hospitalized patients without the presence of an addiction medicine consultation service, there are aspects that limit its external validity. The hospital focused on in this paper is the central academic medical center in an urban hub. Although addiction medicine specialists were not available, several other resources were readily available to help launch the program including a robust consult liaison psychiatry program. In addition, although most of the team were volunteers doing this work in addition to their normal clinical duties, the team psychiatrist was able to bill professional fees for services rendered. At certain times, no volunteer members were available and the team psychiatrist was able to still visit with patients. Institutions without an in-house psychiatry consult liaison service may find larger gaps in coverage. Moreover, part way through the development of this program, the author was provided administrative time to lead

further clinical integration of the program. In addition, being in an urban environment increased the likelihood of buprenorphine prescribers being available to refer patients to at discharge. In this case, a robust publicly funded outpatient pilot program to support patients engaged in buprenorphine therapy was developed in parallel. In other regions, in particular rural areas, absence of buprenorphine prescribers in the community may reduce feasibility of in-hospital buprenorphine initiation. Nonetheless, as demonstrated here, hospitals may play a role in advocating for change in their communities. Finally, for patients with insufficient insurance, the hospital system agreed to pay for bridge buprenorphine prescriptions until outpatient follow-up.

Internal validity is limited by the subjects interviewed and document review conducted. Only those with direct and intimate knowledge of the program's launch were interviewed. With the exception of the executive leader, those individuals self-selected to be part of the team; thus, there may be inherent selection bias towards this type of clinical work in the interview responses. In addition, not all team members who participated in the launch of the program were interviewed, although saturation was reached across the themes identified. Further, the documents reviewed included only those saved by the author, which likely does not represent all documents or messages generated since the inception of the program.

The Future

The team will soon be training internal medicine residents about the clinical aspects of buprenorphine specific to hospitalization in addition to motivational interviewing and counseling. Following this, residents will be expected to initiate buprenorphine and counsel patients on their own, with the team following closely for additional support and bridge prescriptions. The team is also planning a renewed focus on naloxone distribution including a standing order for the rescue medication. Patients will be able to receive naloxone at the time

bridge buprenorphine is picked up. In addition, peer recovery will be integrated into the inpatient wards.

Importantly, the work detailed in this paper represents a targeted intervention for a specific diagnosis. The program is not an addiction medicine consultation service. The team does not counsel patients, conduct clinical education, or provide resources for substance use disorders other than opioid use disorder. However, the initial work around opioid use disorder has illuminated the many gaps in care for patients with substance use disorders as a whole. As a result, there are ongoing conversations within the Medical School, Academic Medical Center, and Clinical Access Program about expanding addiction-related services in the hospital and the community. Expanding capacity to provide meaningful care for hospitalized patients with any substance use disorder is critical, and would further solidify hospitalization as an important touchpoint and reachable moment.

Conclusion

Hospital systems have a critical role in managing and treating opioid use disorder. Despite starkly elevated and increasing opioid poisoning mortality and morbidity related to intravenous drug use over the last decade, few U.S. hospitals engage in treating opioid use disorder and integrating harm reduction strategies. Such evidence-based and cost-effective interventions may reduce mortality and readmissions, and improve patient experience and provider satisfaction. A dedicated group of interprofessional hospital-based healthcare professionals working in a consultative model is one feasible method of increasing access to life-saving treatment and harm reduction for patients with opioid use disorder. Such interventions should be the standard of care in every hospital across the United States.

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Tables

Table 1

Opportunities and Resources for Hospitalists, Hospital Leaders, and Hospitalist Organizations for Addressing Substance Use Disorders

Action Opportunities	Hospitalists	Hospitalist Leaders	Hospitalist Organizations
Clinical Management	Initiate medications for SUD (eg, methadone or buprenorphine for OUD; naltrexone for AUD) Prescribe naloxone at hospital discharge Offer harm reduction resources (eg, clean syringes, fentanyl test strips) Practice trauma-informed care	Review hospital guidelines and policies (eg, methadone, active drug use) Implement inpatient SUD screening and treatment workflows Develop pathways to post hospital community addictions treatment (eg, office-based buprenorphine, methadone clinics, syringe access services) Hire an SUD navigator and/or peer mentor	Publish and promote guidelines or position statements supporting addiction care, including medication for OUD in hospital settings
Training and Certification	Obtain a buprenorphine waiver Participate in addiction medicine mentoring or training programs	Provide incentives and/or pay for hospitalists to complete buprenorphine waiver training Develop a staff education campaign on evidence-based addiction treatment, trauma-informed care, harm reduction, and avoiding stigma	Support addiction medicine training at hospitalist society meetings Lobby medical specialties to include addiction medicine competencies in board certification and maintenance of certification requirements
Stakeholder Engagement	Engage hospital- and community-based peer mentors, social workers, counselors, case managers Advocate for evidence-based treatment if stigma impedes care (eg, cardiac valve repair if medically indicated) Model and advocate for the use of nonstigmatizing language when discussing SUD	Identify and support SUD clinical champions Develop addiction medicine consult services Integrate peer mentors with lived experience into hospital care Create treatment pathways with community SUD partners Organize a taskforce to coordinate diverse SUD efforts across the hospital	Partner with addiction medicine societies and harm reduction groups Advocate with governmental leaders to reduce barriers that restrict treatment access such as the buprenorphine waiver
Resources	National treatment guidelines ¹⁴ Point-of-care clinical tools ^{15,16} Free mentoring and online buprenorphine waiver trainings ¹⁵ UCSF Telephone Warmline: clinician-to-clinician real-time case support 9 AM to 8 PM EST ¹⁷ Harm reduction in hospital reference ¹⁸ Changing the Language of Addiction brief ¹⁹ ECHO: remote telementoring that includes didactics and case discussions ²⁰	California Bridge: acute care resources on buprenorphine and methadone, including webinars, dosing guidelines, patient materials ¹⁶ IMPACT toolkit ²¹ Recommendations for integrating peers into hospital care ²² State and federal funding opportunities (eg, 2019 State Opioid Response grants)	Example position papers include: American College of Emergency Physicians Position Statement on Buprenorphine in the Emergency Department ²³ Society of Hospital Medicine Consensus Statement on safe opioid prescribing ²⁴

Abbreviations: AUD, alcohol use disorder; ECHO, extensions for community healthcare outcomes; IMPACT: inpatient addiction medicine consult service; OUD, opioid use disorder; SUD, substance use disorder; UCSF, University of California, San Francisco.

From "A Call to Action: Hospitalists' Role in Addressing Substance Use Disorder" by H.

Englander, et al. 2019, *Journal of Hospital Medicine*, P. E2. Copyright 2018 by Wiley. Reprinted with permission.

Table 2*Complete List of Stereotypes, Prejudice, and Discrimination Themes*

Stereotypes (N = 35)	Prejudice (N = 16)	Discrimination (N = 15)
1. Dangerous	Blatant	Opportunity Restriction
Unpredictable	1. Fear	1. Don't provide job opportunity
Uncontrollable	Wary	Drug test
Impulsive	Paranoid	Wait for him/her to mess up
Crazy	2. Anger	2. Don't help or give support
Have strange behaviors	Hate	Don't give chances
2. Criminal	Resentment	3. Deny Services
Cheats/Liars	3. Disgust	Deny apartment to rent
Sneaky	Subtle	Dehumanization
Will do anything for a fix	4. Indifferent	4. Dehumanize
3. Sinner	5. Curious	5. Avoid
Promiscuous	Confused	Dismiss
Don't have standards/limits	6. Pity	Ignore
4. Dirty	Sad	6. Reject
Don't take care of themselves	7. Helpless	Cut off from social network
5. Hopeless	Insecure	7. Watch closely
Helpless	Worried	Act suspicious
Homeless	8. Embarrassed	
Poor		
6. Worthless		
Ignorant		
Lazy		
Weak		
Not able to function normally		
7. No job potential		
Uneducated		
Loser		
Can't keep job		
8. Self-Destructive		
Can't go back		
9. To blame		
Will relapse		
10. In denial		
Blame others		
Selfish		

*Overall themes in each category are indicated in BOLD with individual codes falling into that theme listed underneath.

From "Exploring the public stigma of substance use disorder through community-based participatory research" by K Nieweglowski, et al. 2018, *Addiction Research & Theory*, P. 326.

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Table 3

Rank Scored Phrases of People with Substance Use Disorders

Negative word/phrase (Mean) (Min.) (Max.)	Positive word/phrase (Mean) (Min.) (Max.)
<i>People in recovery (n = 15)</i>	
1. Crackhead (3.5) (1.0) (6.0)	1. Person in long-term recovery (2.50) (1.0) (5.0)
2. Junkie (4.17) (1.0) (10.0)	2. Person in recovery (2.67) (2.0) (4.0)
3. Addicts (4.83) (2.0) (8.0)	3. Person / people (3.83) (1.0) (10.0)
4. Abuser (5.0) (3.0) (9.0)	4. Recovered / recovering person (4.67) (3.0) (7.0)
5. Alcoholics (5.17) (1.0) (9.0)	5. Sober (5.50) (2.0) (10.0)
6. Criminals (5.50) (2.0) (9.0)	6. Person with a substance use disorder (5.50) (3.0) (9.0)
7. Felon (5.50) (2.0) (10.0)	7. Person with an alcohol use disorder (6.00) (4.0) (8.0)
8. Sinners (6.50) (1.0) (10.0)	8. Recurrence of use (7.0) (6.0) (8.0)
9. Drunk (7.0) (4.0) (10.0)	9. Former drug user (8.0) (6.0) (10.0)
10. Boozer (7.83) (6.0) (10.0)	10. Drug user Substance user (9.33) (8.0) (10.0)
<i>Family members (n = 15)</i>	
1. Junkie (2.73) (1.0) (10.0)	1. Long-term recovery (2.55) (1.0) (5.0)
2. Dope fiend (3.73) (2.0) (10.0)	2. Person with a substance use disorder (3.55) (1.0) (8.0)
3. Addict (4.18) (1.0) (7.0)	3. Honest (4.36) (1.0) (9.0)
4. Drug abusers (4.82) (2.0) (7.0)	4. Impacted loved one (4.36) (1.0) (10.0)
5. Alcoholic (5.18) (1.0) (8.0)	5. Positive/negative urinalysis (5.64) (1.0) (10.0)
6. Dirty/clean (5.73) (3.0) (8.0)	6. Substance free (5.82) (2.0) (9.0)
7. Drunk (6.19) (2.0) (10.0)	7. Drug-free person (6.5) (3.0) (9.0)
8. Codependent/enabler (7.0) (1.0) (10.0)	8. Sober (6.64) (2.0) (10.0)
9. Relapse (7.64) (1.0) (10.0)	9. Period of abstinence (7.45) (4.0) (10.0)
10. Rock bottom (7.82) (2.0) (10.0)	10. Law-abiding citizen (7.91) (3.0) (10.0)
<i>Professionals (n = 15)</i>	
1. Junkie (1.38) (1.0) (3.0)	1. Person/human being (2.25) (1.0) (10.0)
2. Dope fiend (4.0) (2.0) (9.0)	2. Person in recovery (2.50) (1.0) (6.0)
3. Addict (4.25) (1.0) (7.0)	3. Recurrence of symptoms (4.38) (2.0) (6.0)
4. Substance abuser (5.25) (4.0) (7.0)	4. Person with a substance use disorder (4.63) (2.0) (7.0)
5. Pothead stoner (5.50) (3.0) (10.0)	5. Multiple pathways of recovery (4.75) (3.0) (7.0)
6. Alcoholic (5.75) (3.0) (8.0)	6. Person who uses drugs (6.25) (4.0) (9.0)
7. Criminal (6.63) (3.0) (10.0)	7. Free from addiction (6.63) (2.0) (10.0)
8. Drug injector (7.0) (2.0) (9.0)	8. Abstinence (7.25) (4.0) (10.0)
9. Relapse (7.50) (2.0) (10.0)	9. Returning citizen (8.13) (4.0) (10.0)
10. Recovering addict/alcoholic (7.75) (1.0) (10.0)	10. Survivors (8.25) (5.0) (10.0)
Notes: Negative Group: 1 = most stigmatizing, 10 = least Positive Group: 1 = most positive (least stigmatizing), 10 = least	

From “Expanding language choices to reduce stigma: A Delphi study of positive and negative terms in substance use and recovery” by R. Ashford, et al., 2019, *Health Education*. Copyright 2019 by Emerald Publishing Limited. Reprinted with permission.

Table 4*Factors Associated with Leaving AMA and 30-Day Readmissions in People Who Use Opioids*

	AMA discharges	30 Day readmissions
	AOR (95% CI)	AOR (95% CI)
Opioids only	REF	REF
Opioids + Stimulant ^a	1.83 (1.73, 1.96)	1.30 (1.23, 1.37)
Opioids + Alcohol	1.31 (1.23, 1.39)	1.68 (1.58, 1.79)
Opioids + Sedative	1.55 (1.42, 1.69)	1.27 (1.18, 1.37)
Opioids + Stimulant + Alcohol	2.41 (2.24, 2.60)	2.56 (2.36, 2.79)
Opioids + Alcohol + Sedative	2.22 (1.98, 2.50)	2.57 (2.28, 2.90)
Opioids + Stimulant + Sedative	2.61 (2.19, 3.10)	1.87 (1.68, 2.09)
Opioids + Stimulant + Alcohol + Sedative	3.84 (3.34, 4.40)	4.00 (3.55, 4.52)
Age (years)	0.99 (0.98, 0.99)	1.01 (1.01, 1.012)
Urban	1.42 (1.14, 1.77)	1.16 (1.01, 1.34)
Female	0.69 (0.66, 0.73)	0.95 (0.92, 0.98)
Infection	1.77 (1.66, 1.89)	2.40 (2.32, 2.48)
Overdose	1.01 (0.95, 1.08)	0.96 (0.92, 1.01)
Psychiatric diagnosis	0.99 (0.94, 1.04)	2.21 (2.12, 2.31)
Elixhauser sum of comorbidities	0.96 (0.94, 0.98)	1.07 (1.06, 1.09)
Insurance type		
Private insurance	REF	REF
Medicaid	1.73 (1.56, 1.92)	1.34 (1.28, 1.41)
Medicare	1.51 (1.38, 1.66)	1.49 (1.41, 1.57)
Self-pay	1.57 (1.38, 1.80)	1.01 (0.93, 1.08)
No charge	1.32 (1.09, 1.58)	0.99 (0.89, 1.10)
Other	1.14 (0.995, 1.30)	0.99 (0.91, 1.08)

^a Amphetamine and/or cocaine use.

From “Hospitalization Outcomes of People Who Use Drugs,” by E. Merchant, et al. 2020, *Journal of Substance Abuse Treatment*, 112, p. 26. Copyright 2020 by Elsevier. Reproduced with permission.

Table 5

Potential Measurements of In-Hospital Opioid Stewardship Programs

Table 2. Scores and Ranks for Final Quality Indicators^a

Indicator (Survey Domain)	Mean Value (Rank)	Lower Bound of 95% CI (Rank)	Upper Bound of 95% CI (Rank)	25th Percentile Value (Rank)	Median Value (Rank)	75th Percentile Value (Rank)	Sum of Ranks ^b	Final Rank ^c
Proportion of hospitalized patients who received naloxone (patient outcomes) ^{9,20,27}	8.15 (1)	7.73 (1)	8.57 (1)	8 (1)	9 (1.5)	9 (7)	12.5	1
Proportion of patients who have multiple p.r.n. opioid orders with duplicate p.r.n. indication (pain management) ^{21,30,40,41}	7.97 (2)	7.51 (2)	8.43 (2)	7 (7)	9 (1.5)	9 (7)	21.5	2
Proportion of hospitalized patients who are opioid naïve and have long acting or extended release opioid orders (methadone, patches, extended release formulations) (pain management) ^{6,7,8,31,42}	7.70 (3)	7.26 (3)	8.14 (5)	7 (7)	8 (7.5)	9 (7)	32.5	3
Average dose of MME administered per day (pain management) ^{6,7,8,20,33}	7.64 (4.5)	7.00 (7)	8.27 (4)	7 (7)	8 (7.5)	9 (7)	37	4
Proportion of opioid discharge prescriptions that exceed 7 days of treatment (discharge) ⁹	7.64 (4.5)	6.97 (10)	8.30 (3)	7 (7)	8 (7.5)	9 (7)	39	5
Proportion of hospitalized patients on opioid therapy who have a POSS ≥3 (patient outcomes) ²⁹	7.55 (7.5)	7.01 (5)	8.08 (8)	7 (7)	8 (7.5)	9 (7)	42	6
Proportion of hospitalized patients with concurrent administrations of high doses of opioids and at least one medication from the following classes: benzodiazepines, barbiturates, sedative hypnotics, GABA analogs, or muscle relaxants (pain management) ^{4,6,7,11,25,34,37}	7.58 (6)	7.14 (4)	8.01 (11)	7 (7)	8 (7.5)	9 (7)	42.5	7
Proportion of patients with opioid doses ≥ 90 MME/day (pain management) ^{6,7,9}	7.55 (7.5)	6.98 (8)	8.11 (6)	7 (7)	8 (7.5)	9 (7)	43	8
Proportion of discharged patients with opioid discharge prescriptions of ≥ 50 MME/day (discharge) ⁸	7.52 (9)	6.98 (9)	8.05 (9)	7 (7)	8 (7.5)	9 (7)	48.5	9
Proportion of hospitalized patients who have documentation of patient defined pain goals (patient assessment) ^{10,12,24,38}	7.48 (10)	7.01 (6)	7.96 (12)	7 (7)	8 (7.5)	9 (7)	49.5	10

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Table 2. Scores and Ranks for Final Quality Indicators^a

Indicator (Survey Domain)	Mean Value (Rank)	Lower Bound of 95% CI (Rank)	Upper Bound of 95% CI (Rank)	25th Percentile Value (Rank)	Median Value (Rank)	75th Percentile Value (Rank)	Sum of Ranks ^b	Final Rank ^c
Proportion of hospitalized patients with opioid orders who have a standardized documentation of the pain management plan (eg use of approved order sets) (pain management) ^{24,27}	7.45 (11)	6.89 (11)	8.02 (10)	6 (14.5)	8 (7.5)	9 (7)	61	11
Proportion of patients with opioid discharge prescriptions given in the ED that exceed 3–5 days (discharge) ^{22,21}	7.42 (12)	6.75 (14)	8.09 (7)	6 (14.5)	8 (7.5)	9 (7)	62	12
Proportion of hospital days with 1 or more severe pain rating score (patient outcomes) ^a	7.27 (13.5)	6.77 (13)	7.78 (13)	7 (7)	7 (15.5)	8 (16.5)	78.5	13
Proportion of patients with opioid doses ≥ 50 MME/day (pain management) ^{2,7}	7.27 (13.5)	6.84 (12)	7.71 (15)	7 (7)	7 (15.5)	8 (16.5)	79.5	14
Proportion of patients discharged on opioids who receive discharge education on opioid purpose, adverse effects, monitoring, secure storage/disposal, and alternatives (discharge) ^{20,20,24,27}	7.18 (15)	6.64 (15)	7.72 (14)	6 (14.5)	7 (15.5)	8 (16.5)	90.5	15
Proportion of patients discharged from the ED with opioid discharge prescriptions (discharge) ²²	6.52 (17)	5.72 (18)	7.31 (17)	5 (18)	7 (15.5)	9 (7)	92.5	16
Proportion of hospitalized patients who have documentation of patient defined function goals (patient assessment) ^{15,21}	6.97 (16)	6.31 (16)	7.63 (16)	6 (14.5)	7 (15.5)	8 (16.5)	94.5	17
Proportion of patients discharged from the hospital with opioid discharge prescriptions (discharge) ^{21,24}	6.36 (19)	5.59 (19)	7.14 (18)	5 (18)	7 (15.5)	8 (16.5)	106	18
Proportion of hospitalized patients receiving i.v. opioid pushes (pain management) ^{21,24,28}	6.42 (18)	5.73 (17)	7.12 (19)	5 (18)	6 (19)	8 (16.5)	107.5	19

^a CI = confidence interval, MME = morphine milligram equivalent, POSS = Pasero opioid-induced sedation scale, GABA = gamma-aminobutyric acid, ED = emergency department.
^b The pooled rank score was calculated by adding the ranks of the mean, median, lower bound of 95% CI, upper bound of 95% CI, 25th percentile, and 75th percentile.
^c The final priority ranking of quality indicators was based on the pooled score rank.
^d Thresholds for 'high doses' will be defined for each drug by the research team.
^e Quality indicator added by panelists during expert panel meeting.

From “Quality indicators to measure the effect of opioid stewardship interventions in hospital and emergency department settings,” by E. Rizk, et al., 2019, *American Journal of Health System Pharmacy*, 76, p. 230-231. Copyright 2019 by American Society of Health-System Pharmacists / Oxford University Press. Reprinted with permission.

Table 6

Quality Measurement Framework for Emergency Department Treatment of Opioid Use Disorder

OUD Domain	Structural Measures	Process Measures	Outcome Measures	
			ED	Population
Primary prevention	Availability of nonopioid pain management	Patient education about opioid safe storage and disposal on discharge	Adverse events after ED discharge after receiving new opioids	Patients with unintended prolonged opioid use
	PDMP-EMR integration	Trial of nonopioid analgesics before opioid initiation when indicated	ED revisitation for analgesia-associated adverse medication events	New OUD per-capita incidence
	"Safe prescribing" ED policies	Median days opioids prescribed Median MME/day per ED visit Frequency of benzodiazepine and opioid coprescribing		OUD prevalence Opioid overdose incidence
Harm reduction	ED naloxone distribution policy	Proportion ED OUD patients: a) Provision of overdose prevention and response patient education	Risk-adjusted in-hospital mortality for overdose	Risk-adjusted repeated nonfatal overdose
	Community syringe access program	b) Discharged with/prescribed naloxone c) Referred to a syringe access program d) Referred to community resources	Risk-adjusted 30-day repeated ED visit for nonfatal opioid overdose	Risk-adjusted repeated fatal overdose Risk-adjusted out-of-hospital overdose mortality HCV and HIV incidence and prevalence
	Buprenorphine-waivered providers (ED and community)	Structured screening and diagnostic questionnaires		Repeated ED visit rates for opioid overdose, opioid withdrawal, or complications of injection drug use
	addiction medicine specialist consultation access	Urine toxicology testing	Opioid withdrawal scale at ED discharge	Proportion patients engaged in formal addiction treatment at 30 days
Treatment	Availability of outpatient providers of medication for OUD	Proportion ED OUD patients:		Proportion patients maintaining receipt of medication for OUD at 30 days
	Community opioid treatment programs and providers	a) With initiated medication for OUD	Risk-adjusted in-hospital mortality for overdose	Risk-adjusted repeated nonfatal overdose
	Hospital or community bridge clinics	b) Prescribed medication for OUD c) Linked to outpatient OUD treatment d) Counseled by health promotion advocates, counselors, or social workers		Risk-adjusted repeated fatal overdose Risk-adjusted out-of-hospital overdose mortality

From “A Quality Framework for Emergency Department Treatment of Opioid Use Disorder,” by E. Samuels, et al., 2018, *Annals of Emergency Medicine*, 73, p. 240. Copyright 2018 by American College of Emergency Physicians / Elsevier. Reprinted with permission.

Table 7

Concerns, Realities, and Solutions Regarding Opioid Use Disorder and Buprenorphine

Treatment in the Emergency Department

Concern	Reality	Solution
Addiction is a moral failing; patients keep coming back to the ED time and time again.	Addiction is a chronic and relapsing disease that can be effectively treated with opioid-agonist therapies. Emergency physicians often see a skewed sample of patients not in treatment.	Provide patient-specific feedback to ED providers on success stories regarding engagement in treatment.
Providing buprenorphine to patients will lead to diversion.	There is less diversion of buprenorphine than of other opioids. Buprenorphine bought off the street is often used to reduce withdrawal symptoms. Every buprenorphine pill taken is one less opportunity for overdose, complication of injection drug use, or death.	Offer limited supplies, preferably 2–7 days' worth of treatment, until an appointment with a community provider or program can be arranged.
Initiating buprenorphine treatment is complicated, and the ED is already crowded and chaotic.	Buprenorphine is safer and more predictable than many medications used in routine ED practice. Treatment can be accomplished in less time than an urgent care visit.	Integrate protocols electronically into the ED workflow from triage to discharge that engage all providers in order to facilitate a simplified and streamlined process. Identify a cadre of champions available to support new prescribers.
Initiating buprenorphine will increase length of stay.	Initiating buprenorphine will reduce length of stay and reduce the potential for violent behaviors and injury to staff. Buprenorphine markedly reduces withdrawal symptoms in 20–30 minutes.	Streamline protocols and educate staff to achieve times of 60–90 minutes from presentation to discharge, in keeping with urgent care criteria.
There is a lack of referral sites for patients who have initiated buprenorphine treatment.	Most communities have treatment resources of which the ED staff are unaware.	Partner and develop relationships with community resources and local health departments to permit efficient referral and feedback. Hire an ED staff member such as a health promotion advocate, which is helpful and cost-effective. ³
Patients will return repeatedly for redosing.	Repeated visits for redosing have not been demonstrated at sites that consistently offer buprenorphine.	Develop treatment plans that are similar to those for other chronic diseases, such as sickle cell disease. Treat withdrawal with buprenorphine and referral.
Patients will flock to the ED for treatment.	Patients with OUD are already in the ED. Sites with ED-initiated buprenorphine do not report an uptake of patients seeking treatment.	Initiate treatment protocols at triage to promote rapid assessment, treatment, and referral.
Many patients don't want treatment anyway.	Some patients, often after an overdose, are not ready for treatment after a brief psychosocial intervention, but discussion may lead to a change in motivation in the future. The ED visit is often a missed opportunity to engage patients who may be contemplating a positive change but need guidance and support.	Introduce harm-reduction strategies such as overdose prevention and naloxone distribution. Establish rapport to facilitate improved outcomes.
Obtaining a waiver to prescribe buprenorphine is too burdensome.	The training required to obtain a waiver can be done all online or as half-day courses coupled with half-day online services. Most training is free and similar to other required learning and counts toward CME requirements for specialty certification, recertification, and licensing in many states.	Identify resources online and at institutions using the SAMHSA and ASAM websites. Offer faculty development days or group learning events.

* ASAM denotes the American Society of Addiction Medicine, CME continuing medical education, and SAMHSA the Substance Abuse and Mental Health Services Administration.

From “Emergency Departments — A 24/7/365 Option for Combating the Opioid Crisis,” by G.

D’Onofrio, R. McCormack, and K. Hawk, 2018, *New England Journal of Medicine*, 379, p.

2489. Copyright 2018 by Massachusetts Medical Society. Reproduced with permission.

Table 8

Organizational Characteristics Indicating Readiness to Hire Peer Workers

Characteristics
<p>Organizational values</p> <ul style="list-style-type: none"> • A recovery-oriented mission • Defined peer roles that are permanent with secure funding • Clear job descriptions for peer workers • Equitable wages and benefits packages for peer workers
<p>Policies and practices</p> <ul style="list-style-type: none"> • Policies and practices align with recovery-oriented values • Clear confidentiality policies and practices • Clear policies regarding relationships and personal boundaries • Inclusive hiring policies and practice • Policies that ensure regular communication among staff members • Policies that ensure routine performance evaluations that reflect the peer worker's role
<p>Staff knowledge and attitudes</p> <ul style="list-style-type: none"> • Staff believe that recovery is possible • Staff is knowledgeable about the benefits of peer support • Staff continue to develop their knowledge and understanding of peer support • Staff address their own prejudices about people with behavioral health conditions
<p>Supervision and support</p> <ul style="list-style-type: none"> • Organization ensures the provision of regular supervision • Supervision is recovery-oriented and trauma-informed • Supervisors know how to use reasonable accommodations for colleagues with disabilities

From "Peer Workers in the Behavioral and Integrated Health Workforce: Opportunities and Future Directions" by C. Gagne, et al. 2018, *American Journal of Preventative Medicine*, 54, P. S258. CC BY NC ND.

Table 9

Sample Program Expectations for Providers and Coaches

Coach-provider Interaction	For providers	For coaches
Introducing the coach role to the patient	<ul style="list-style-type: none"> • Before the coach is introduced, communicate with the coach to update them on and engage them in the development of treatment goals. • Invite the coach to attend an appointment to meet the patient and demonstrate the importance of the coach’s role encouraging coaches to take the lead in introducing their role. • Consider reinforcing boundary setting (times the coach is available, types of services the coach provides) by coaches during the initial visit. • If the patient will meet the coach at a separate time, ask the coach how their role should be described to the patient before this meeting. 	<ul style="list-style-type: none"> • Ask the provider what they have communicated to patients about the coach role. • In collaboration with the rest of the care team, develop a written description of the coach role that the provider can share with patients. • Many patients are reluctant to ask for help because they don’t know what services coaches offer or they assume they must be interested in recovery to work with a coach. Provide a clear description to patients about the range of services and supports you can provide.
Confidentiality	<ul style="list-style-type: none"> • A provider statement to the patient supporting patient-coach confidentiality is a strong signal of respect to both patient and coach. • Work with your institution to establish a peer mentor program and clear supervision structure for coaches that offers support and guidance around difficult decisions about disclosure. 	<ul style="list-style-type: none"> • Work with your providers to develop a list of “red flag” information that should be communicated to providers. • Discuss difficult issues around disclosure with a peer mentor and your supervisor.
Shared decision-making	<ul style="list-style-type: none"> • Agenda setting before or early in a shared appointment should include both patient and coach priorities. • During shared appointments, use teach-back with patients and coaches to get an assessment of the collective understanding of a treatment plan. • Involve coaches in multidisciplinary discussions of the management of complex patients in recovery. 	<ul style="list-style-type: none"> • Work with patients to develop a list of topics to discuss with a provider during an upcoming appointment. • During appointments, encourage patients to ask questions of providers when there may be misunderstanding from either the provider or patient. • If conflict is developing with a provider, work with a peer mentor or supervisor to develop ways of refocusing discussions on patient care.
Integration with care team	<ul style="list-style-type: none"> • Invite coaches to develop brief teaching sessions for providers about addiction and recovery. • Develop clear guidelines for the coach’s notes in the electronic health record. • Elicit feedback from coaches as a way of reflecting on behaviors or language that may be perceived as judgmental. • Develop clear protocols for how RCs should handle psychiatric emergencies. 	<ul style="list-style-type: none"> • Ask a supervisor how you should document your interactions with patients in the her. • Engage with provider-led community-based research efforts. • Ask for feedback from providers and peers.

From “Addressing substance use disorder in primary care: The role, integration, and impact of recovery coaches” by H. Jack, et al. 2018, *Substance Abuse*, 39, P. 312. Copyright 2018 by Taylor & Francis. Reprinted with permission.

Table 10*Characteristics of Interviewees*

ID	Discipline	Age	Ethnicity	Years in Healthcare	Highest Degree
Physician1	Internal Medicine	33	White	11	MD
Physician2	Internal Medicine	31	Asian	7	MD
Physician3	Internal Medicine	39	Asian	11	MD
Physician4	Internal Medicine / Palliative Care	52	White	30	MD
Resident1	Internal Medicine	32	White	7	MD, MBA
Psych1	Psychiatry	42	White	11	MD
SW1	Social Work	26	White	3	LCSW
APN1	Palliative Care	63	White	39	MA
RN1	Nursing	33	White	5	BSN
Chaplain1	Chaplain	33	White	3	MA
Executive1	Administration	67	White	40	MD

Figures

Figure 1*Timeline of Opioid Epidemic*

1850s: Opioids used for medicinal purposes

Early 1900s: New forms analgesia reduced reliance on opioids

1930s to 1960s: International conflicts resulted increased utilization of opioids to treat acute and pain

1986: Case series in the journal *Pain* published reporting opioids are safe

1990s: Purdue Pharma uses the 1986 *Pain* article as the foundation for marketing OxyContin.

Opioid prescriptions rise by over 300%. Concurrently, overdose deaths related to this medication begin to rise.

1995: American Pain Society launches "Pain is the Fifth Vital Sign" campaign

1998: American Pain Society and American Academy of Pain Medicine release statement that pain is undertreated

2000: The Department of Veteran Affairs and the Joint Commission begin promoting the Pain is the Fifth Vital Sign campaign

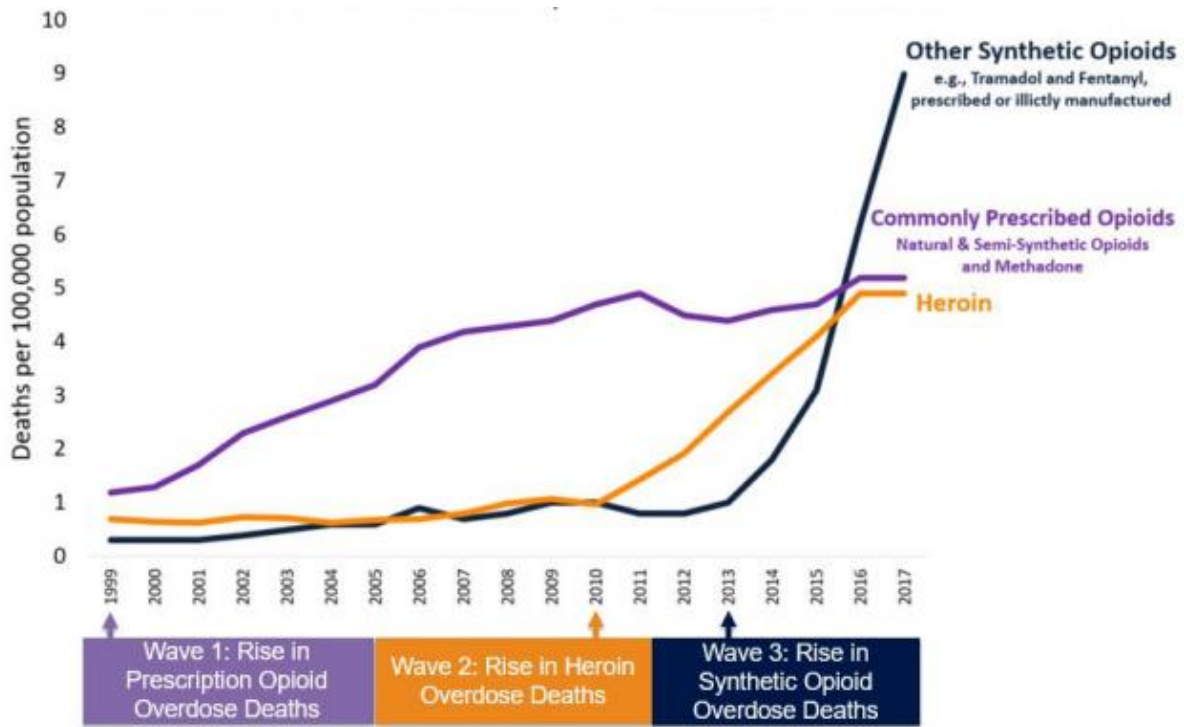
2010: To deter abuse of oxycontin, its formulation changes which results in patients pursuing heroin.

2013: Fentanyl starts to be introduced into the heroin supply chain.

2015: Overdose deaths from heroin surpass that of opioid pills for the first time.

Figure 2

Three Waves of the Rise in Opioid Overdose Deaths



From “Understanding the Epidemic,” by Centers for Disease Control and Prevention, 2018

(<https://www.cdc.gov/drugoverdose/epidemic/index.html>). In the public domain.

Figure 3*Criteria for Opioid Use Disorder*

The Diagnostic and Statistical Manual of Mental Disorders, 5th Edition describes opioid use disorder as a problematic pattern of opioid use leading to problems or distress, with at least two of the following occurring within a 12-month period:

1. Taking larger amounts or taking drugs over a longer period than intended.
2. Persistent desire or unsuccessful efforts to cut down or control opioid use.
3. Spending a great deal of time obtaining or using the opioid or recovering from its effects.
4. Craving, or a strong desire or urge to use opioids
5. Problems fulfilling obligations at work, school or home.
6. Continued opioid use despite having recurring social or interpersonal problems.
7. Giving up or reducing activities because of opioid use.
8. Using opioids in physically hazardous situations.
9. Continued opioid use despite ongoing physical or psychological problem likely to have been caused or worsened by opioids.
10. Tolerance (i.e., need for increased amounts or diminished effect with continued use of the same amount)
11. Experiencing withdrawal (opioid withdrawal syndrome) or taking opioids (or a closely related substance) to relieve or avoid withdrawal symptoms.

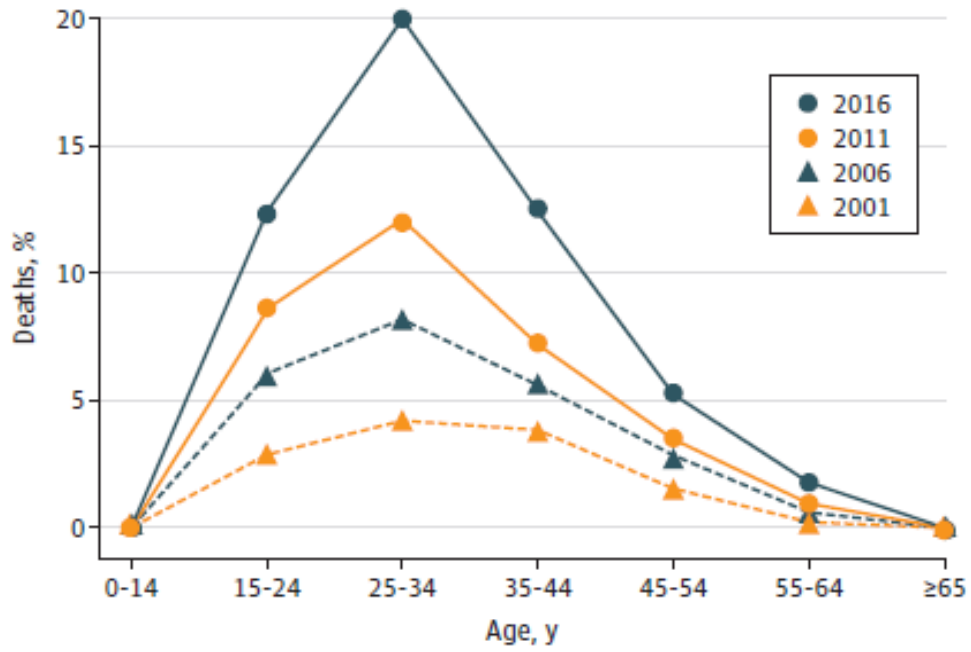
From “Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition,” by American

Psychiatric Association, 2013. Copyright 2013 American Psychiatric Association. **Reprinted**

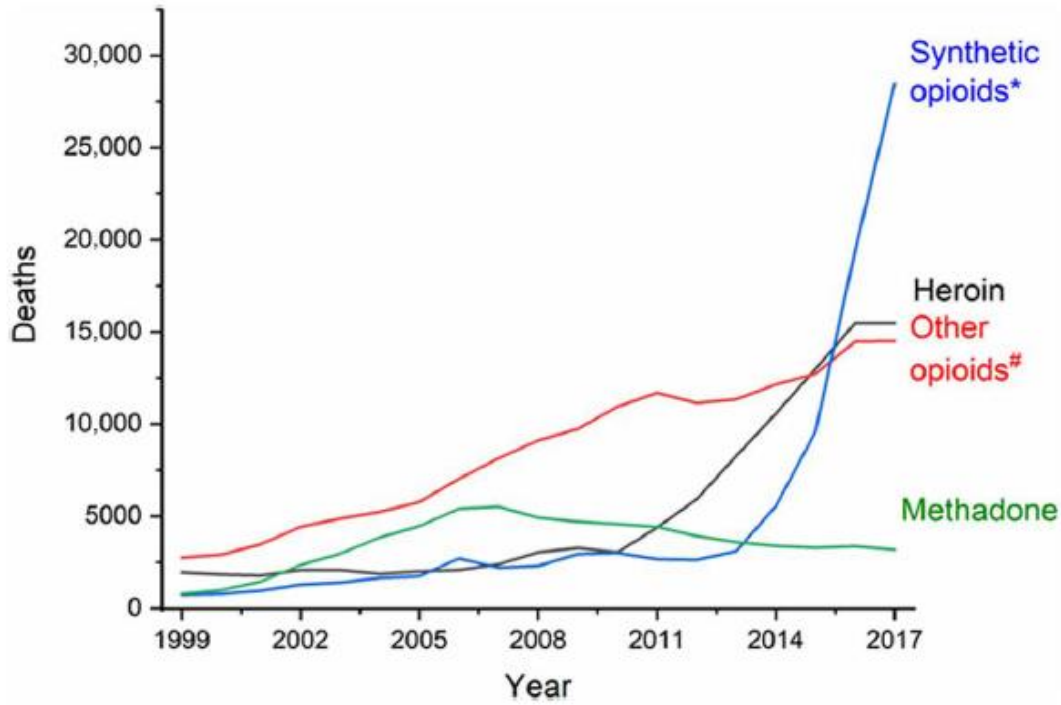
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Figure 4

Proportion of Deaths Related to Opioid Use by Age Group in 2001, 2006, 2011, and 2016



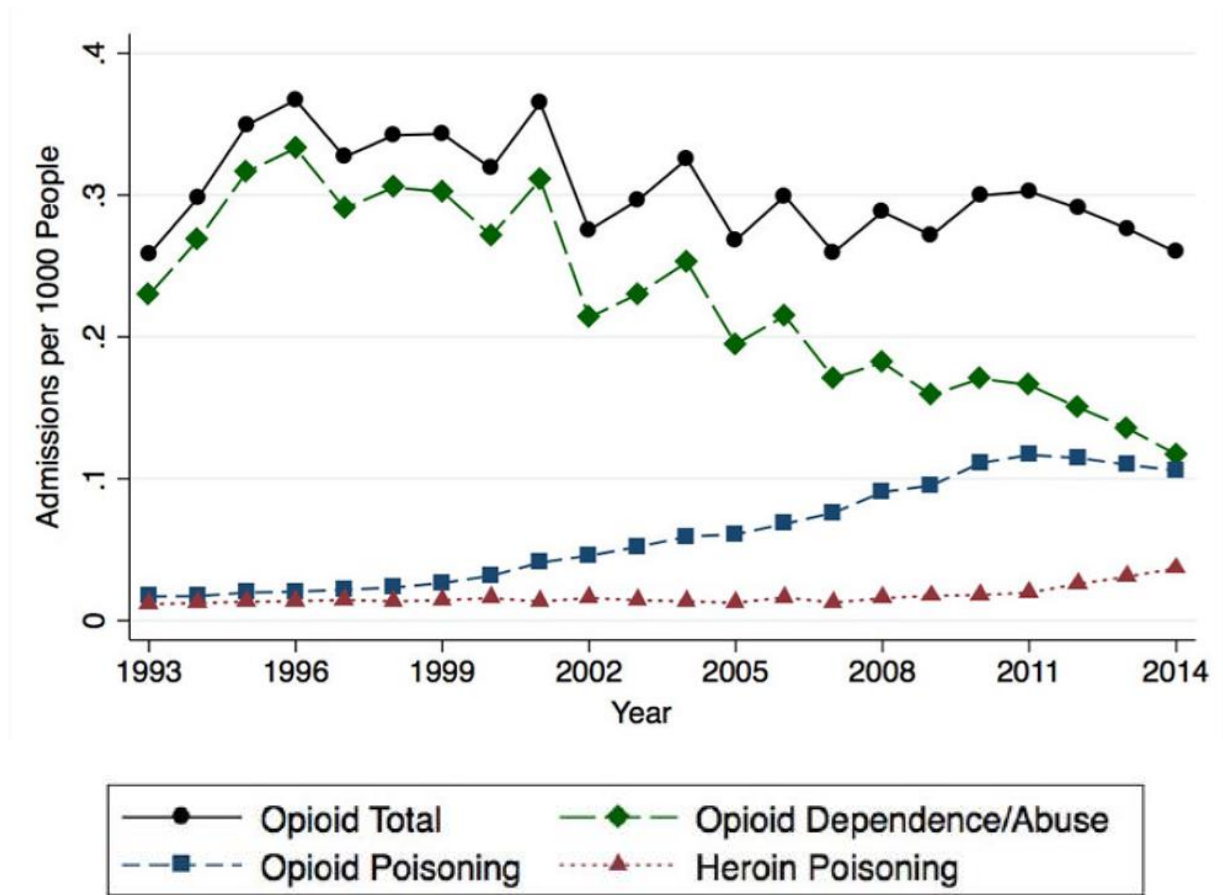
From "The Burden of Opioid-Related Mortality in the United States" by T. Gomes, M. Tadrous, M. Mamdani, et al. 2018, *JAMA Network Open*, 1, P. 3. CC BY.

Figure 5*Opioid Overdose Deaths in the United States*

From "Current status of opioid addiction treatment and related preclinical research" by M. Kreek, B. Reed, and E. Butelman, 2019, *Science Advances*, 5, P. 3. CC BY NC.

Figure 6

Hospitalizations by Type of Opioid-Related Diagnosis, 1993-2014

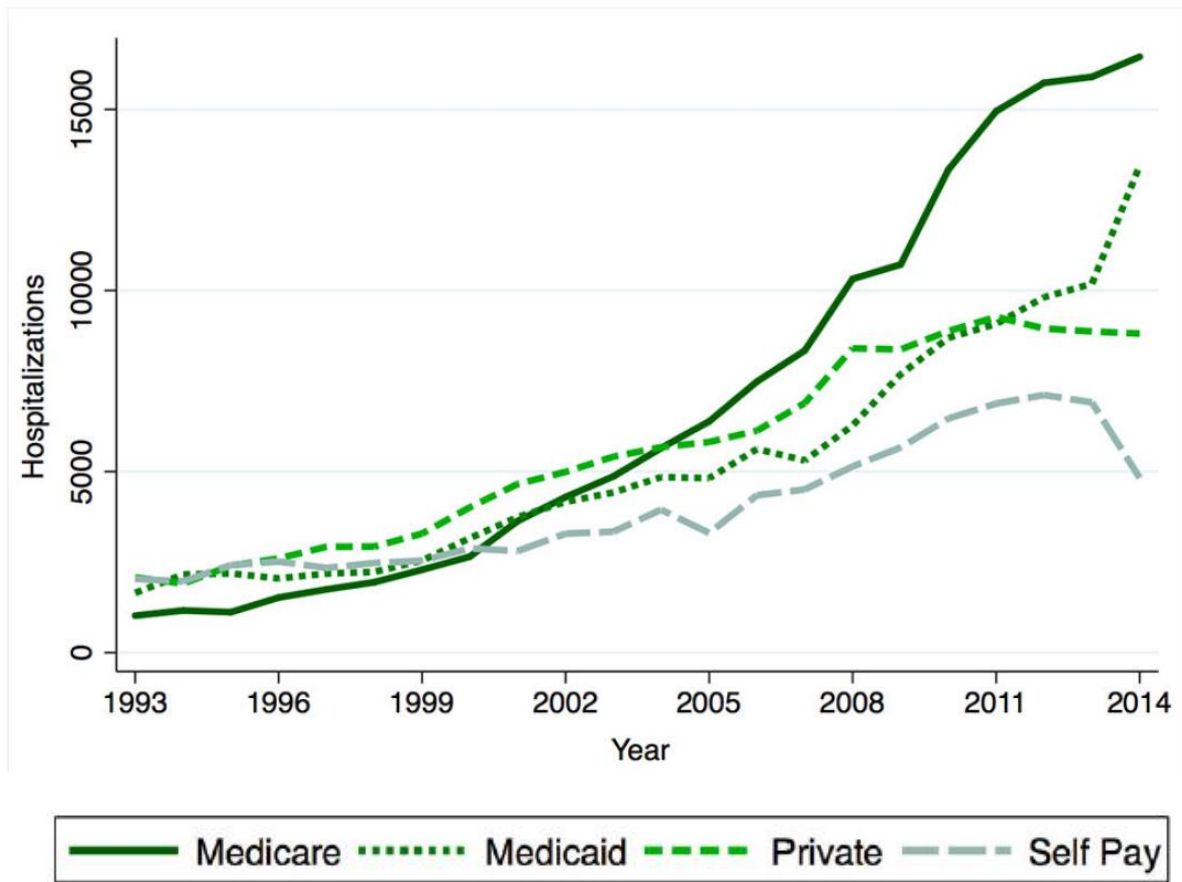


From “Mortality Quadrupled Among Opioid-Driven Hospitalizations, Notably Within Lower-Income And Disabled White Populations,” by Z. Song, 2017, *Health Affairs*, 36, p. 2057.

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Figure 7

Hospitalizations for Opioid Poisoning by Payer

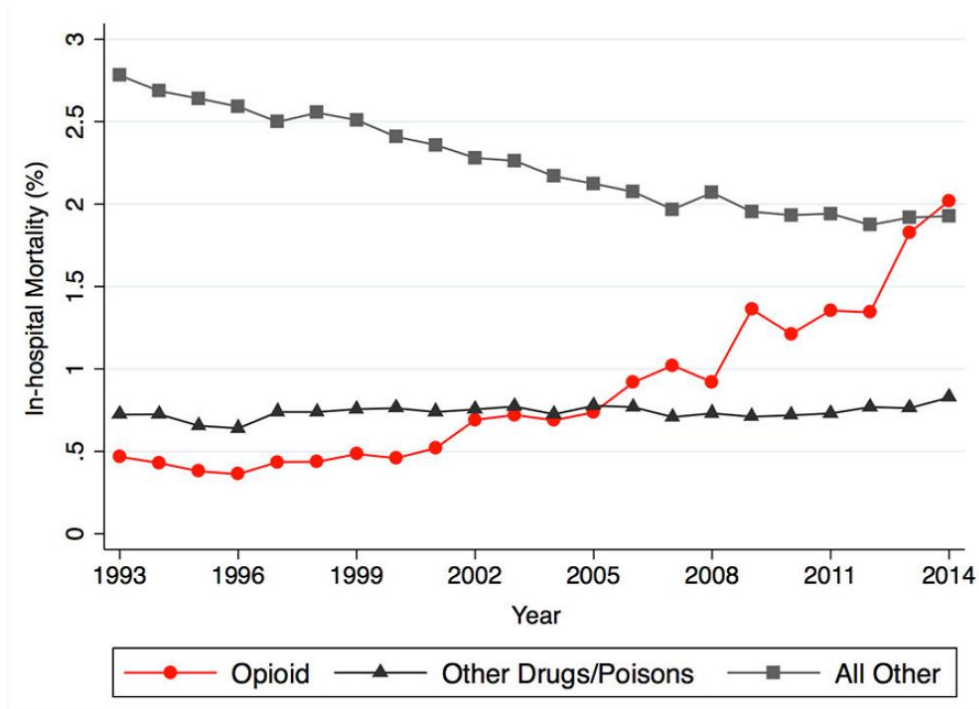


From “Mortality Quadrupled Among Opioid-Driven Hospitalizations, Notably Within Lower-Income And Disabled White Populations,” by Z. Song, 2017, *Health Affairs*, 36, p. 2057.

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Figure 8

In-Hospital Mortality for Opioid vs Other Primary Diagnoses

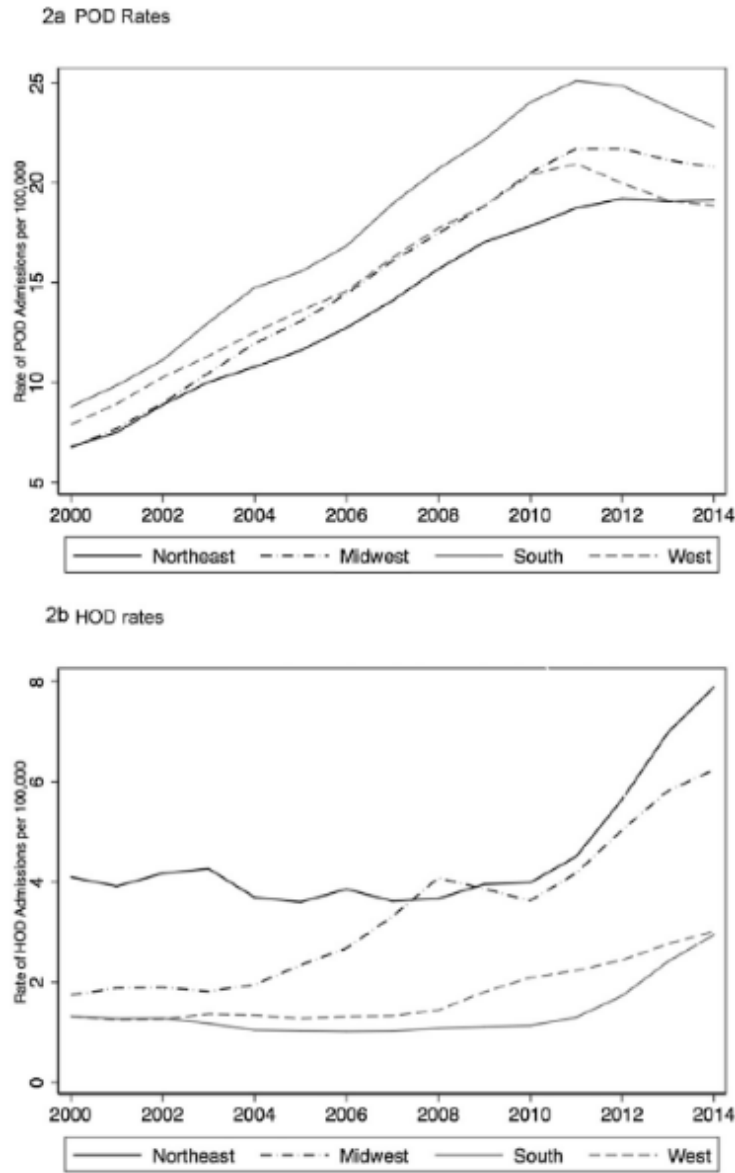


From “Mortality Quadrupled Among Opioid-Driven Hospitalizations, Notably Within Lower-Income And Disabled White Populations,” by Z. Song, 2017, *Health Affairs*, 36, p. 2057.

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Figure 9

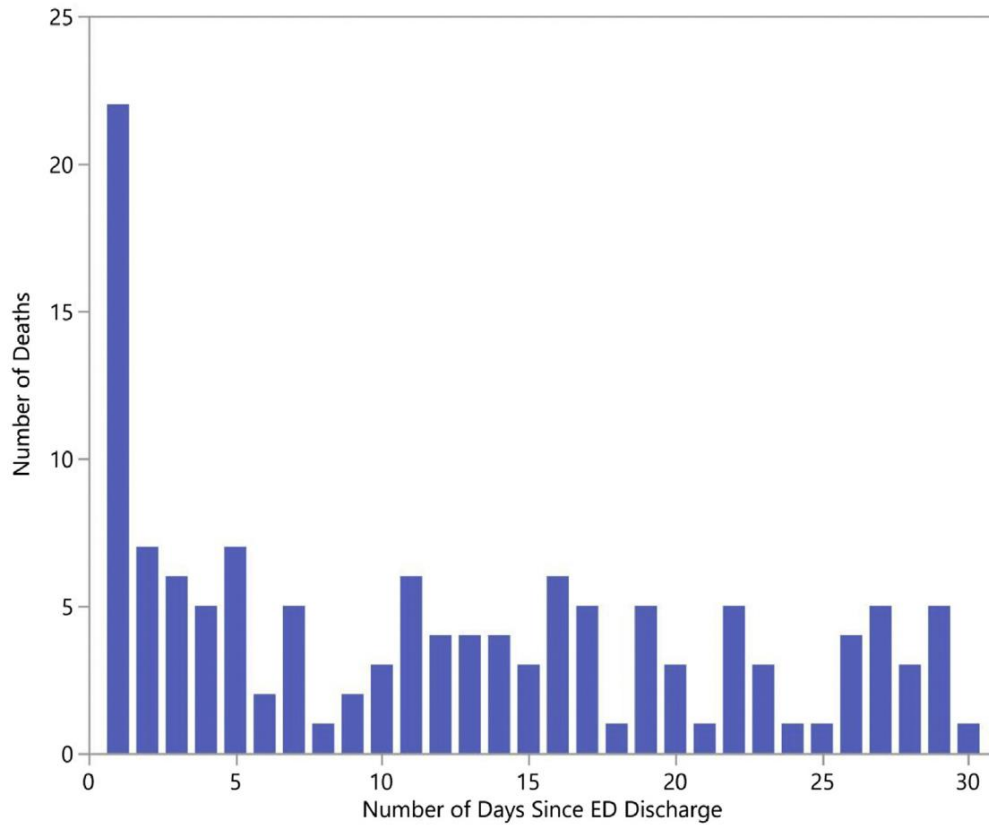
National Differences in Hospitalizations Related to Prescription Opioid Poisoning (POD) vs Heroin Poisoning (HOD)



From "US regional and demographic differences in prescription opioid and heroin-related overdose hospitalizations" by G. Unick and D. Ciccarone, 2017, *International Journal of Drug Policy*, 46, P. 115. Copyright 2017 by Elsevier. Reprinted with permission.

Figure 10

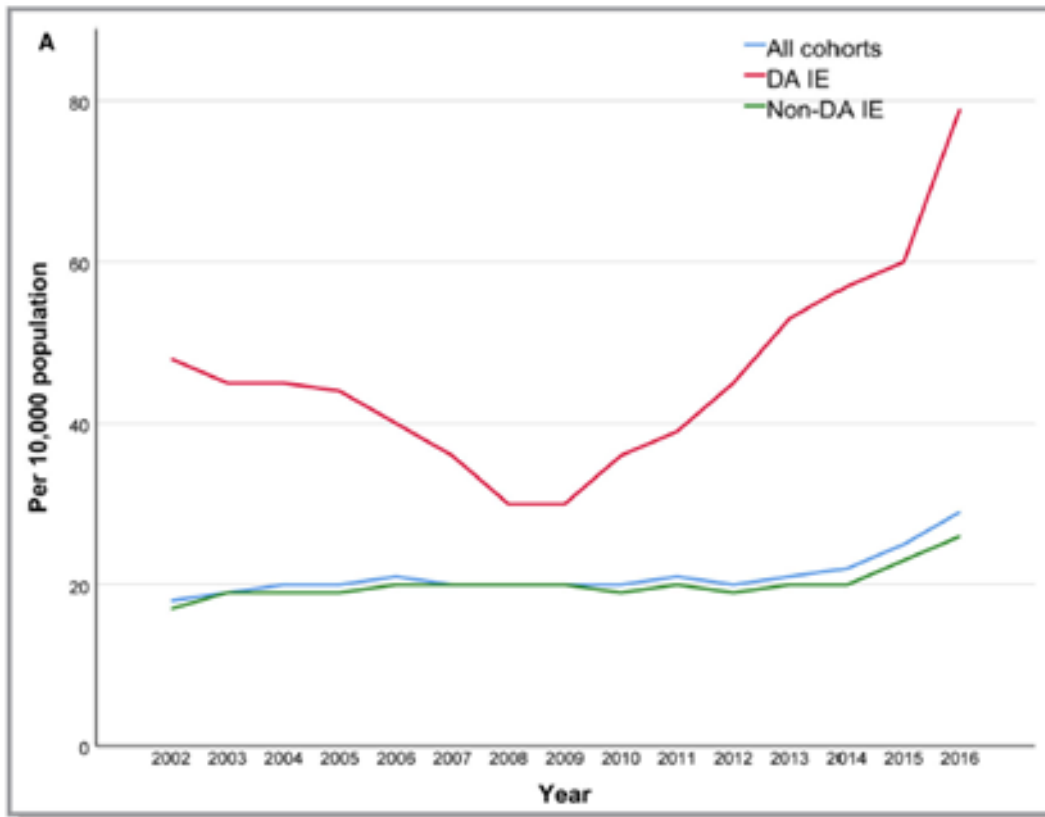
Deaths After ED Treatment for Non-Fatal Opioid Overdose by Number of Days After Discharge



From "One-Year Mortality of Patients After Emergency Department Treatment for Nonfatal Opioid Overdose" by S. Weiner, O. Baker, D. Bernson, and J Schuur, 2019, *Annals of Emergency Medicine*, 75, P. 17. Copyright 2019 by Elsevier. Reprinted with permission.

Figure 11

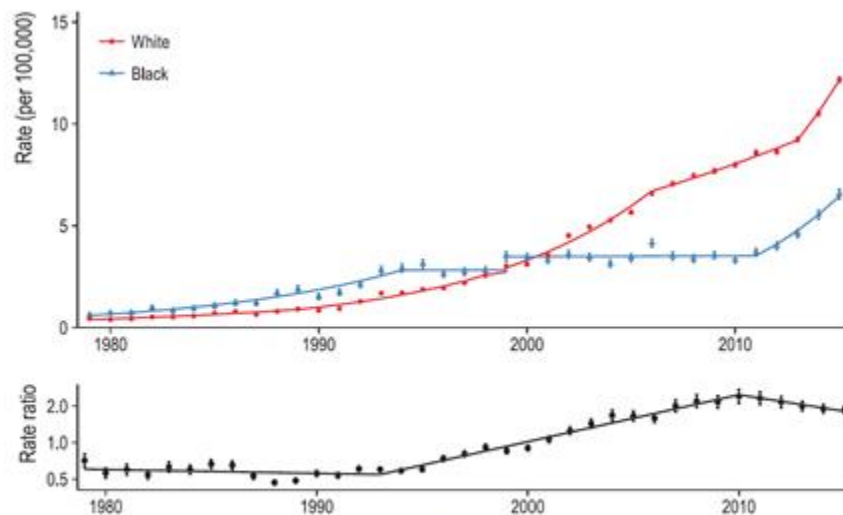
Incidence of Drug Associated Infective Endocarditis (DA IE) Compared to Non-DA IE, 2002-2016



From "Geographic Trends, Patient Characteristics, and Outcomes of Infective Endocarditis Associated With Drug Abuse in the United States From 2002 to 2016" by A. Kadri, et al., 2019, *Journal of the American Heart Association*, 8, P. 7. CC BY NC ND.

Figure 12

Trends in Black and White Opioid Mortality in the United States, 1979-2015



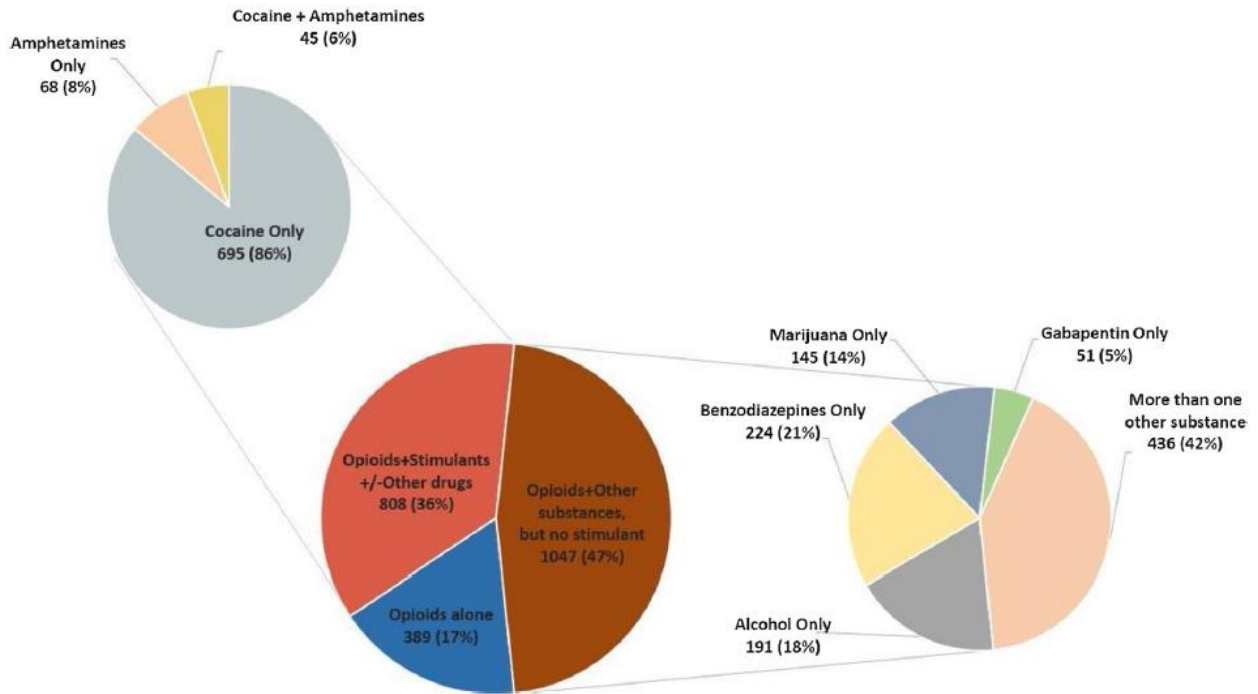
A, Age-standardized opioid mortality rate for the white (red) and black (blue) US resident populations, 1979–2015. B, Rate ratio (white/black) of opioid mortality rates. Dots are estimated rate. Vertical bars represent 95% confidence interval. Solid lines are joinpoint model fits.

From "Trends in Black and White Opioid Mortality in the United States, 1979–2015:" M.

Alexander, M. Kiang, and M. Barbieri, 2018, *Epidemiology*, 29, p. 711 CC BY NC ND

Figure 13

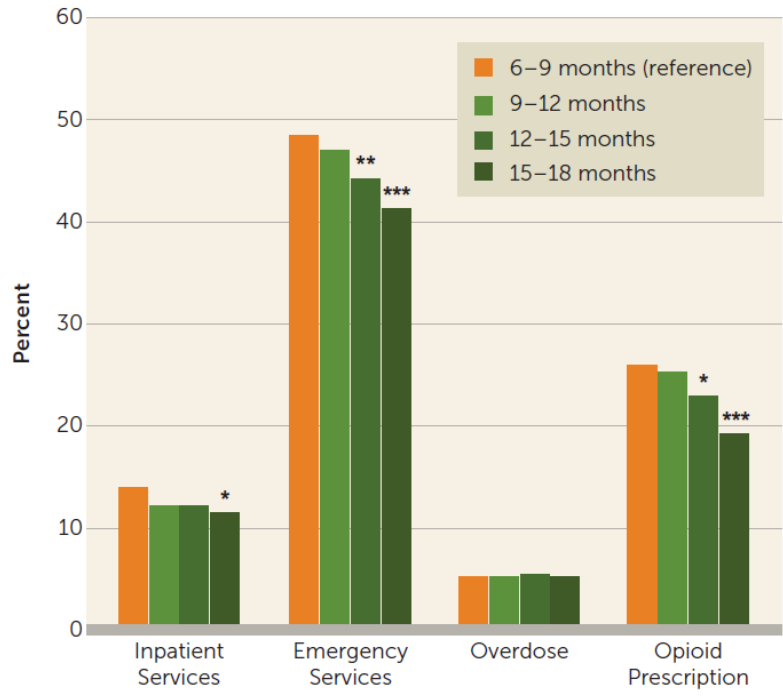
Opioid-Related Overdose Deaths with Accompanying Toxicology



From " Sociodemographic Factors and Social Determinants Associated with Toxicology Confirmed Polysubstance Opioid-Related Deaths," J. Barocas, et al., 2019, *Drug and Alcohol Dependence*, 200, p. 60. Copyright 2019 Elsevier / Drug and Alcohol Dependence. Reprinted with permission.

Figure 14

Impact of Discontinuing Long-Term Buprenorphine Treatment for Opioid Use Disorder

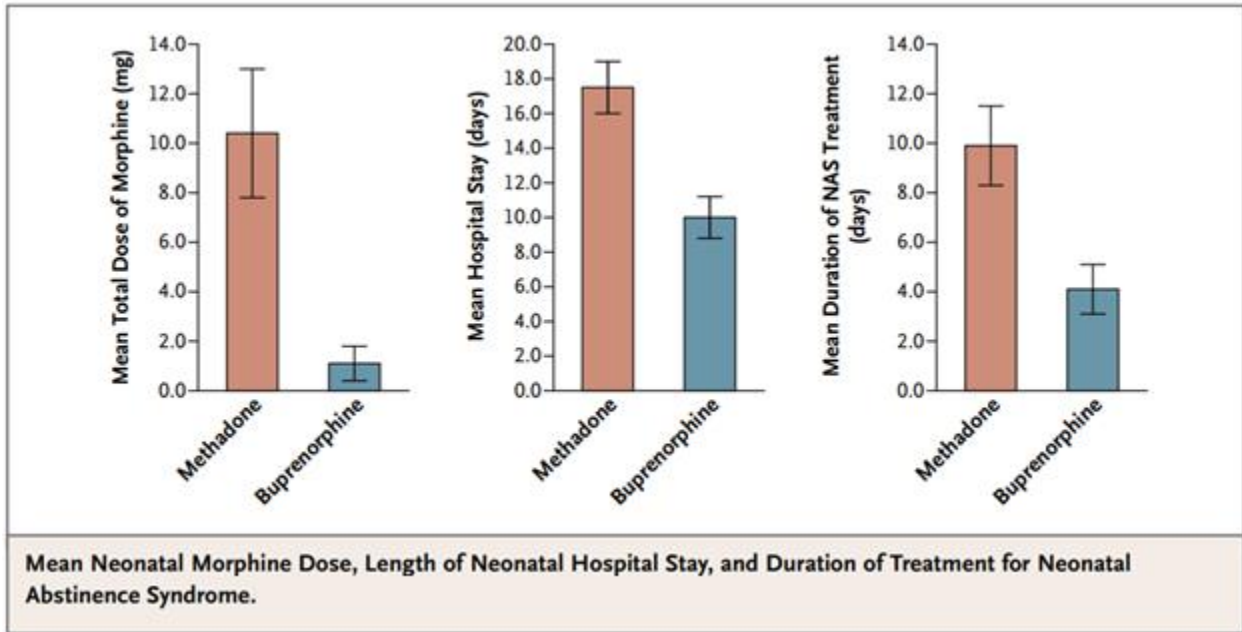


^a All comparisons are with the reference group (the 6- to 9-month cohort).
 *p<0.05. **p<0.01. ***p<0.001.

From " Acute Care, Prescription Opioid Use, and Overdose Following Discontinuation of Long-Term Buprenorphine Treatment for Opioid Use Disorder" by R. Williams, et al., 2019, *American Journal of Psychiatry*, P. 5. Copyright 2019 American Psychiatric Association. Reprinted with permission.

Figure 15

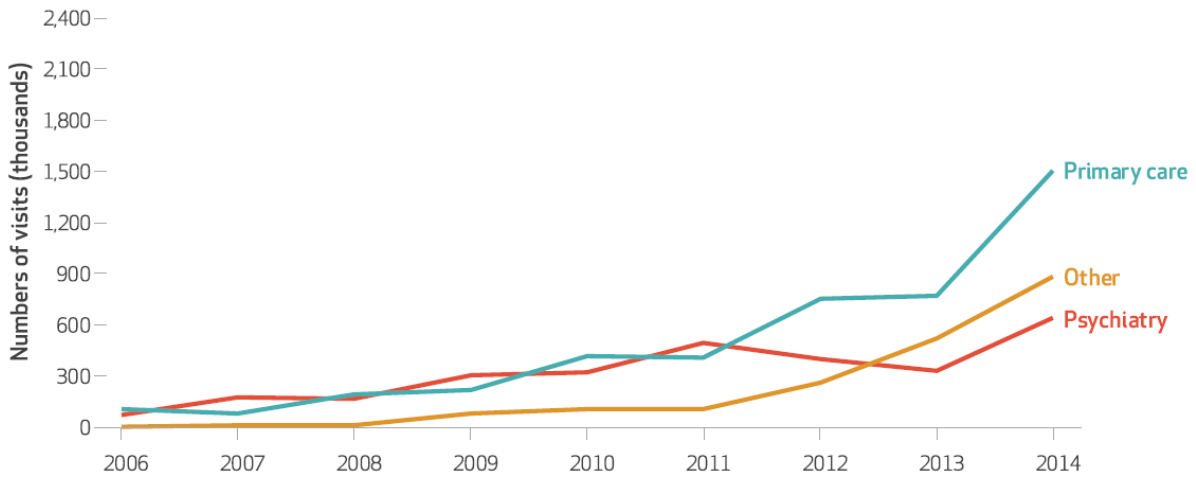
Impact on Neonatal Abstinence Syndrome with Exposure to Methadone Compared to Buprenorphine



From “Neonatal Abstinence Syndrome after Methadone or Buprenorphine Exposure,” by H. Jones et al., 2010, *New England Journal of Medicine*, 363, p. 2326. Copyright 2010 by Massachusetts Medical Society. Reprinted with permission.

Figure 16

Trends in Buprenorphine Prescribing by Physician Specialty, 2006-2014

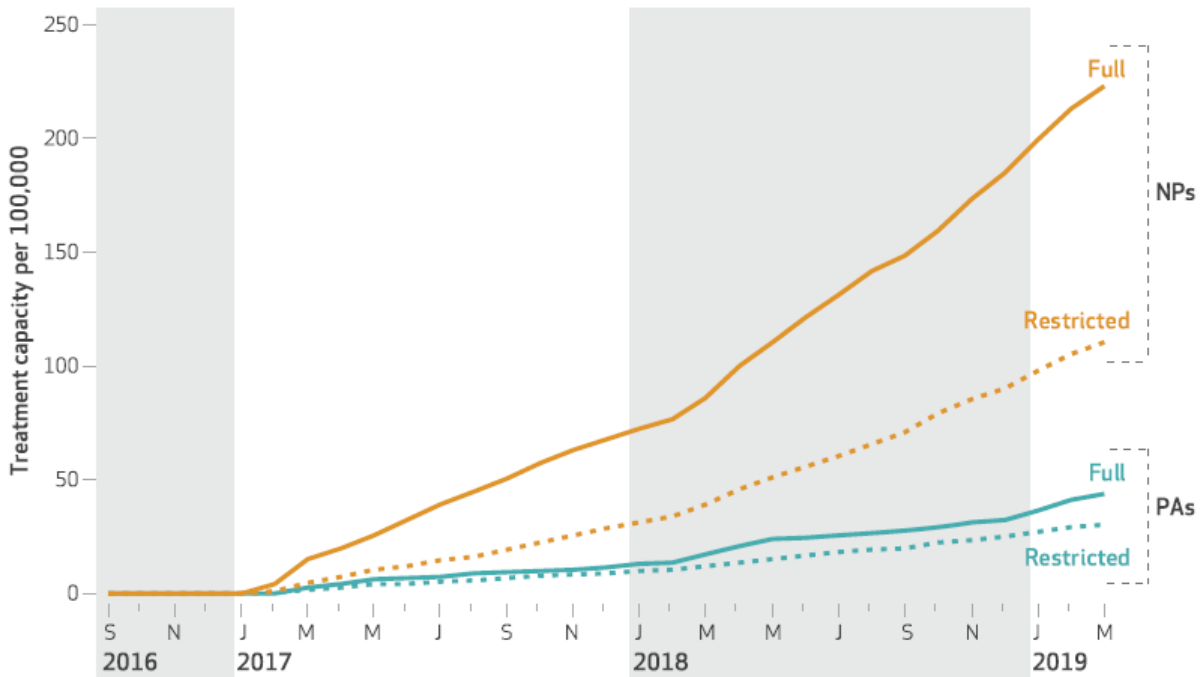


SOURCE Authors' analysis of data for 2006-14 from the National Ambulatory Medical Care Survey. **NOTE** "Psychiatry" and "other" are explained in the notes to exhibit 1.

From "Trends In Buprenorphine Prescribing By Physician Specialty," by H. Wen, T. Borders, and J. Cummings, 2019, *Health Affairs*, 38, p. 27. Copyright 2019 by Project HOPE/Health Affairs. Reprinted with permission.

Figure 17

Growth in Buprenorphine Treatment Capacity per 100,000 People in Rural Counties for Nurse Practitioners and Physician Assistants, by Scope of Practice Regulations, 2016-2019



From “In Rural Areas, Buprenorphine Waiver Adoption Since 2017 Driven By Nurse Practitioners And Physician Assistants,” by M. Barnett, D. Lee, and R. Frank, 2019, *Health Affairs*, 38, p. 2054. Copyright 2019 by Project HOPE/Health Affairs.

Figure 18

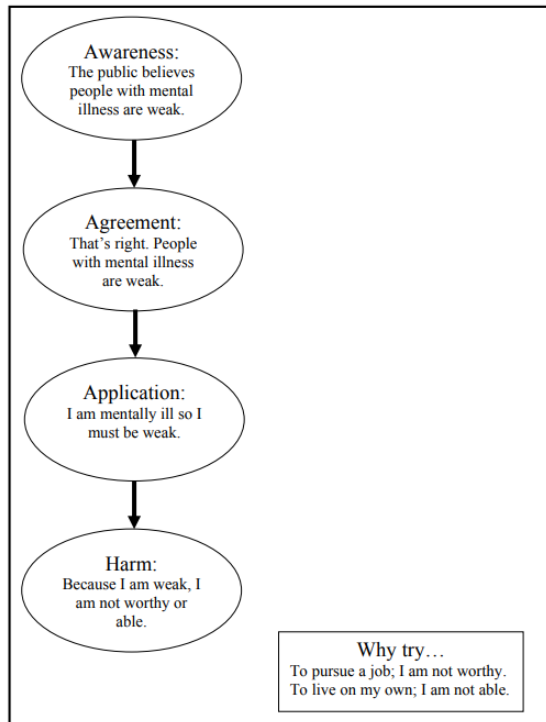
Challenges in Increasing Buprenorphine Access



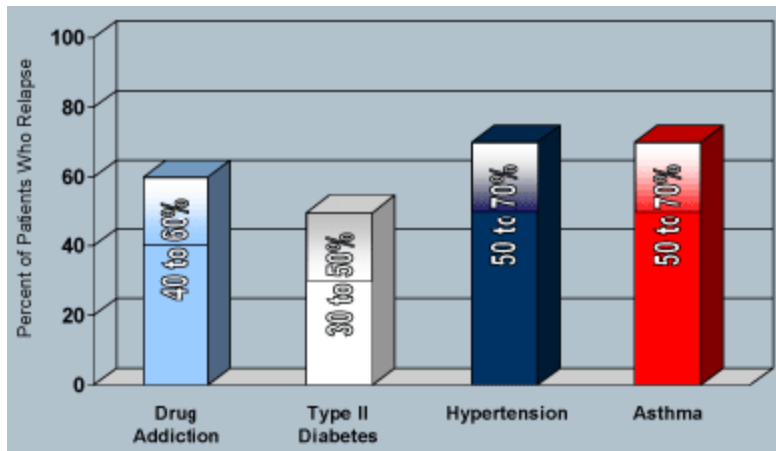
Clinicians' Perceptions/Properties of Bup Treatment	Contextual Factors
<p>Perceived Benefits Versus Risks:</p> <ul style="list-style-type: none"> ✓ Perceived effectiveness of Bup. ✓ Perceived risks (e.g., patient in office all day not responding to Bup). ✓ Desirability/complexity of population. ✓ Burdensome waiver requirements. ✓ Financial viability (e.g., uncertain coverage, Rx time consuming). <p>Compatibility with Clinician's Values, Beliefs and Current Needs:</p> <ul style="list-style-type: none"> ✓ Stigma/negative attitudes towards opiate addiction and its treatability. ✓ Treatment orientation/negative attitude towards Bup and psychopharmacologic treatment of addictions. ✓ Consistency of Bup Rx with professional role identity (e.g., not trained in addictions/don't perceive substance abuse as a medical problem), practice, and economic goals. ✓ Perceived need for Rx in caseload/area. <p>Simplicity:</p> <ul style="list-style-type: none"> ✓ Challenges evaluating patients and providing induction dosing. ✓ Challenges providing psychosocial Rx. ✓ Lack of clear national guidelines increasing Rx protocol confusion. ✓ Office logistics complicated/not amenable (Bup on site, multiple visits, patient variability, time/space to observe). <p>Observability:</p> <ul style="list-style-type: none"> ✓ Training programs often don't include observation (real or video). ✓ Colleagues/mentors using Bup. ✓ On-site technical assistance (TA)/training opportunities. <p>Trialability:</p> <ul style="list-style-type: none"> ✓ Required training/waiver a barrier. ✓ Complexity of Bup dosing a barrier. ✓ On-site availability of medication. 	<p>Regulatory Oversight/Implementation:</p> <ul style="list-style-type: none"> ✓ Required training for non-qualifying physicians. ✓ Availability/accessibility/effectiveness of training. ✓ Administrative burden of DATA waiver process. ✓ 30 patient limit. <p>Financing Issues/Incentives:</p> <ul style="list-style-type: none"> ✓ Treatment coverage and formulary restrictions. ✓ Clinician reimbursement levels and mechanisms. ✓ Time and resources to observe, try, adapt and adopt. <p>Organization, Management, Services Delivery Issues:</p> <ul style="list-style-type: none"> ✓ Health plan/systems of care support (e.g., training staff, developing treatment programs, guidelines, integrated Rx models, and policies to facilitate Bup Rx). ✓ Organizational and practice infrastructure for treatment referral/coordination between primary care, mental health, and substance abuse treatment sectors. ✓ Availability of mental health/substance abuse psychosocial Rx. ✓ Role of pharmacies and the pharmaceutical industry. <p>Communications/Media:</p> <ul style="list-style-type: none"> ✓ Public, professional, media communications surrounding Bup. ✓ Informal communications from peers/opinion leaders. ✓ Demand for Bup from patients/other professionals. <p>Leadership Issues:</p> <ul style="list-style-type: none"> ✓ Professional organizations advocating/implementing Bup. ✓ Advocating/making Bup a standard of care. ✓ Advocates to facilitate insurance coverage, effective Rx models. ✓ Local experts/leaders to train, mentor, provide clinical advice.

**This work is largely adapted from the work of Berwick (10); Rogers (17); Ryan & Gross (18). Beal & Bohlen (19).*

From “Challenges in Increasing Access to Buprenorphine Treatment for Opiate Addiction,” by J. West et al. 2004, *American Journal on Addictions*, 13, p. S14. Copyright 2004 by John Wiley and Sons. Reprinted with permission.

Figure 19*Stage Model of Self-Stigma*

From “On the Self-Stigma of Mental Illness: Stages, Disclosure, and Strategies for Change,” by P. Corrigan and D. Rao, 2012, *Canadian Journal of Psychiatry*, 57, p. 466. Copyright 2012 by Canadian Journal of Psychiatry. Reprinted with permission.

Figure 20*Recurrence Rates of Chronic Diseases*

From “Drug Abuse and Addiction: One of America's Most Challenging Public Health Problems,” by National Institute on Drug Abuse, 2005

(<https://archives.drugabuse.gov/publications/drug-abuse-addiction-one-americas-most-challenging-public-health-problems/addiction-chronic-disease>). In the public domain.

Figure 21

Opioid Use Disorder Treatment Cascade

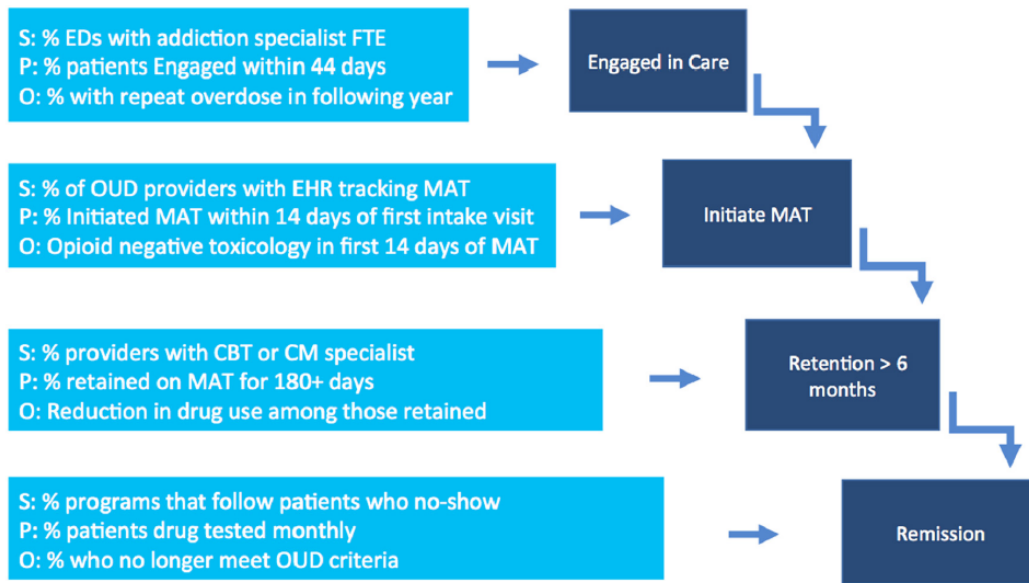


Fig. 2. Candidate quality measure concepts for an OUD treatment cascade at structural, process, and outcome levels for patients treated for overdose.

S = structure; P = process; O = outcome;

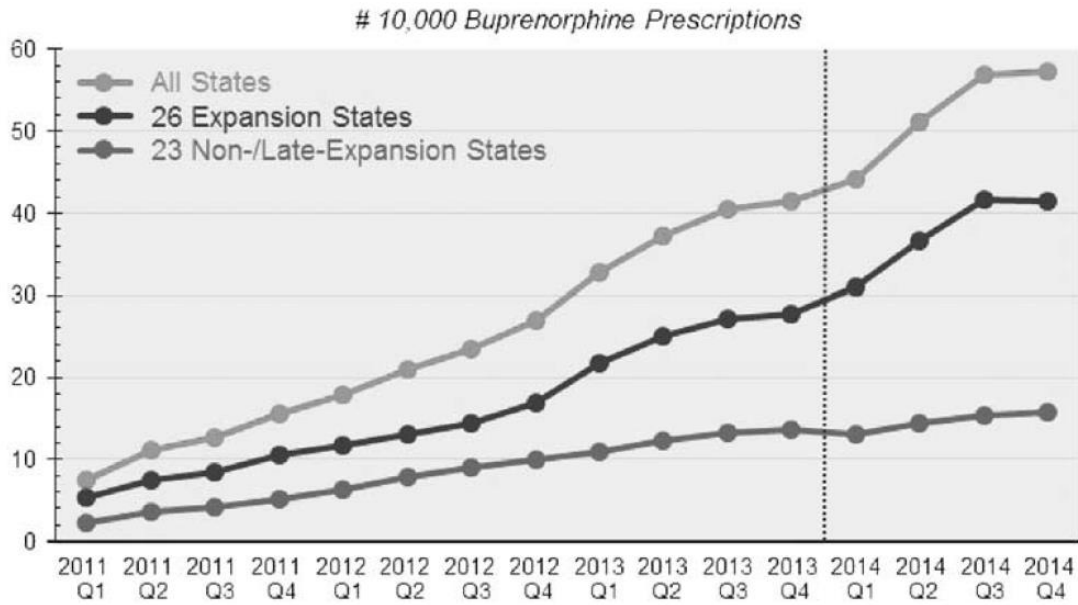
From “Developing an opioid use disorder treatment cascade: A review of quality measures,” by

A. Williams, et al., 2018, *Journal of Substance Abuse Treatment*, 91, p. 65. Copyright 2018 by

Elsevier. Reprinted with permission.

Figure 22

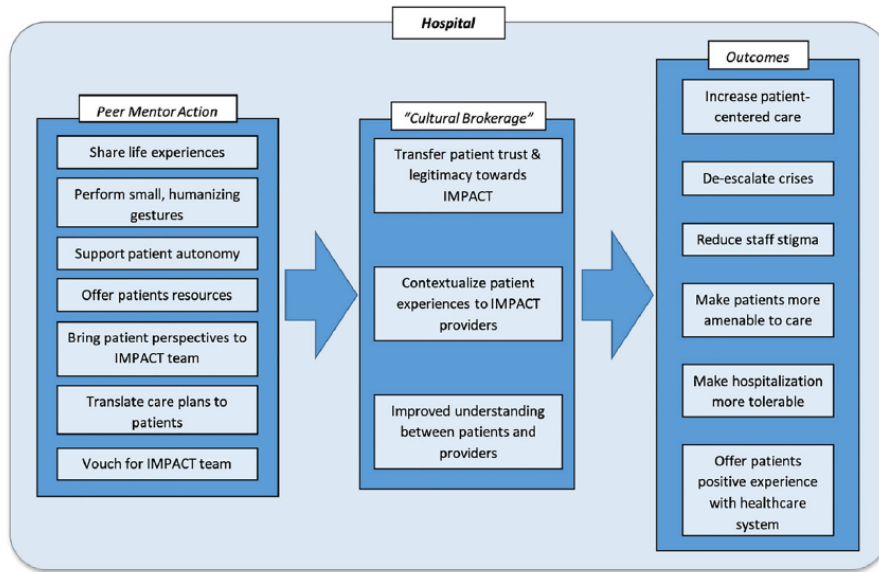
Trends in Medicaid Prescriptions for Buprenorphine by Medication Expansion Status



From “Impact of Medicaid Expansion on Medicaid-covered Utilization of Buprenorphine for Opioid Use Disorder Treatment” by H. Wen, J. Hockenberry, and B. Druss., 2017, *Medical Care*, 55, P. 338. Copyright 2017 by Wolters Kluwer Health and Medical Care. Reprinted with permission.

Figure 23

Benefits of Peer Mentorship in the Hospital



From “If It Wasn’t for Him, I Wouldn’t Have Talked to Them”: Qualitative Study of Addiction Peer Mentorship in the Hospital” by D. Collins, 2019, Journal of General Internal Medicine.

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Figure 24*CDC Recommendation for Prescribing Opioids for Chronic Pain Outside of Active Cancer, Palliative, and End-Of-Life Care*

<p>Determining When to Initiate or Continue Opioids for Chronic Pain</p> <ol style="list-style-type: none"> 1. Nonpharmacologic therapy and nonopioid pharmacologic therapy are preferred for chronic pain. Clinicians should consider opioid therapy only if expected benefits for both pain and function are anticipated to outweigh risks to the patient. If opioids are used, they should be combined with nonpharmacologic therapy and nonopioid pharmacologic therapy, as appropriate. 2. Before starting opioid therapy for chronic pain, clinicians should establish treatment goals with all patients, including realistic goals for pain and function, and should consider how therapy will be discontinued if benefits do not outweigh risks. Clinicians should continue opioid therapy only if there is clinically meaningful improvement in pain and function that outweighs risks to patient safety. 3. Before starting and periodically during opioid therapy, clinicians should discuss with patients known risks and realistic benefits of opioid therapy and patient and clinician responsibilities for managing therapy. <p>Opioid Selection, Dosage, Duration, Follow-Up, and Discontinuation</p> <ol style="list-style-type: none"> 4. When starting opioid therapy for chronic pain, clinicians should prescribe immediate-release opioids instead of extended-release/long-acting (ER/LA) opioids. 5. When opioids are started, clinicians should prescribe the lowest effective dosage. Clinicians should use caution when prescribing opioids at any dosage, should carefully reassess evidence of individual benefits and risks when increasing dosage to ≥ 50 morphine milligram equivalents (MME)/day, and should avoid increasing dosage to ≥ 90 MME/day or carefully justify a decision to titrate dosage to ≥ 90 MME/day. 6. Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than seven days will rarely be needed. 	<ol style="list-style-type: none"> 7. Clinicians should evaluate benefits and harms with patients within 1 to 4 weeks of starting opioid therapy for chronic pain or of dose escalation. Clinicians should evaluate benefits and harms of continued therapy with patients every 3 months or more frequently. If benefits do not outweigh harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower dosages or to taper and discontinue opioids. <p>Assessing Risk and Addressing Harms of Opioid Use</p> <ol style="list-style-type: none"> 8. Before starting and periodically during continuation of opioid therapy, clinicians should evaluate risk factors for opioid-related harms. Clinicians should incorporate into the management plan strategies to mitigate risk, including considering offering naloxone when factors that increase risk for opioid overdose, such as history of overdose, history of substance use disorder, higher opioid dosages (≥ 50 MME/day), or concurrent benzodiazepine use, are present. 9. Clinicians should review the patient's history of controlled substance prescriptions using state prescription drug monitoring program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. Clinicians should review PDMP data when starting opioid therapy for chronic pain and periodically during opioid therapy for chronic pain, ranging from every prescription to every 3 months. 10. When prescribing opioids for chronic pain, clinicians should use urine drug testing before starting opioid therapy and consider urine drug testing at least annually to assess for prescribed medications as well as other controlled prescription drugs and illicit drugs. 11. Clinicians should avoid prescribing opioid pain medication and benzodiazepines concurrently whenever possible. 12. Clinicians should offer or arrange evidence-based treatment (usually medication-assisted treatment with buprenorphine or methadone in combination with behavioral therapies) for patients with opioid use disorder.
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*All recommendations are category A (apply to all patients outside of active cancer treatment, palliative care, and end-of-life care) except recommendation 10 (designated category B, with individual decision making required); see full guideline for evidence ratings.

From “CDC Guideline for Prescribing Opioids for Chronic Pain — United States, 2016,” by D.

Dowell, T. Haegerich, and R. Chou, 2016

(<https://www.cdc.gov/mmwr/volumes/65/rr/rr6501e1.htm>). In the public domain.

Figure 25*Questions Received from Stakeholders During Planning Stages of Hospital Based**Buprenorphine Program*

1. Who will lead the project?
2. Does a similar program exist already within the hospital system or within other hospital systems at local, regional, state, or national levels?
3. How does offering buprenorphine as part of hospitalization fit with the department or organizations vision, mission, and / or goals for a specific time period?
4. What are the milestones for rolling out the program? How will success be measured?
5. Are trainees involved?
6. Will the hospital be performing buprenorphine initiation and maintenance therapy?
7. Is buprenorphine on the hospital formulary?
8. What is the capacity for outpatient buprenorphine treatment in the region? Who are those stakeholders? Are they willing to collaborate with the hospital?
9. Do patients have reliable transportation to attend their initial follow-up appointment? If not, what resources are available to ensure this.
10. Do local retail pharmacies stock buprenorphine?
11. If a patient cannot afford to pay for bridge buprenorphine, is the hospital willing to pay for that?
12. What infrastructure is needed to support this project and is that infrastructure reliably in place?
13. Which members of the interprofessional team might participate?
14. Is it possible to bill for these services?

15. From nursing order perspective, what are the notification parameters?
16. Who will provide coverage after hours?
17. Under what circumstances might a patient be transferred to the ICU?
18. What is available on the formulary?
19. How will orders be entered / saved into the electronic health record?
20. What are the relationships like with local retail pharmacies?
21. For nurses:
 - a. What is the “B-Team”
 - b. Who is the “B-Team”
 - c. A brief overview of the Medication itself.
 - d. How and when do I consult the “B-Team” (more consults the better, worse case scenario is they don’t qualify).
 - e. Accessing our Intranet page
 - f. Administering the medication
 - g. Introduction to COWS form and nursing responsibilities with charting, reassessments, etc. (follow the medication order instructions).
 - h. A possible patient scenario that runs through COWS form to familiarize nurses
 - i. Educating nurses that each patient will be different based on whether they are in acute withdrawal or have multiple days clean and are only experiencing “cravings”
 - j. What to do if there is a question in off hours or weekends (not sure if we have an answer to this yet).
 - k. Informing nurses that packets of information will be placed at nurses station.

Figure 26*Inclusion and Exclusion Criteria for Hospital-Based Buprenorphine at Conception***Initial Inclusion criteria for enrollment with OAST**

- Inpatient status on the internal medicine or family medicine service.
- Over age 18 with stable housing.
- Anticipated length of stay at least 48 hours from the time of referral.
- Enrollment in the Travis County Medical Assistance Program or be eligible for enrollment.
- Have a Community Care Clinic primary care provider.

Initial Exclusion criteria for enrollment with OAST

- Incarceration at the time of referral.
- Severe benzodiazepine disorder.
- Severe alcohol use disorder.
- Severe medical or psychiatric problems.
- Chronic pain being treated with opioids.
- Current enrollment in a buprenorphine or methadone treatment program.
- Administration of methadone during the current hospitalization.

Figure 27*Working Milestones for Hospital-Based Buprenorphine at Conception*

- Develop and distribute digital and print awareness campaign for distribution to all Internal Medicine and Family Medicine attending and resident physicians, in addition to acute care registered nurses.
- A minimum of 10 Internal Medicine and Family Medicine attending or resident physicians to complete x-waiver training within four months.
- Complete 100 patient screens for the diagnosis of opioid use dependency, conducting 10 within the first month and increasing by 20% monthly thereafter.
- Provide buprenorphine counseling to 75% of affirmatively screened patients.
- Administer buprenorphine induction therapy to 50% of eligible patients.
- Greater than 50% of patients who have been provided induction attend their first maintenance therapy follow-up appointment.
- Greater than 30% of patients who have been provided induction in the hospital continue to follow-up with maintenance therapy after six months.

Figure 28

Laboratory studies obtained as part of B-Team program

Order the MAT Baseline Lab Panel consisting of the following tests:

- a. CBC with differential
- b. BMP
- c. Hepatic panel
- d. Lipid profile
- e. Urinalysis
- f. Pregnancy test for women of childbearing potential
- g. Toxicology test for drugs of abuse
- h. Blood alcohol test
- i. HIV 4th Generation Screening test
- j. Hepatitis B virus serology (HBsAg, anti-HBc antibody, anti-HBs antibody)
- k. Hepatitis C virus (HCV) antibody screen
- l. RPR with Reflex FTA (syphilis screening)

Figure 29*History Obtained from Patients as Part of B-Team Program***Basic info**

- Confirm phone #
- Employment
- Support system
- Living situation (and do others use illicit substances)
- Transportation
- Children
- Goal for treatment

Substance use history

- Age first use, how often, amount, route, last use
- Specifically ask about heroin, oxycodone, oxycontin, benzos
- Needle sharing?
- ETOH use history
- Fhx related to substances

Substance Treatment history

- Detox, residential, 12-step
- Behavioral health counseling
- Methadone
 - When, where, how long, dosing history
 - Reason for cessation
- Suboxone
 - When, where, how long, dosing history
 - Reason for cessation
- Attempts made to become sober and most recent attempt
- Longest period of sobriety and trigger for relapse

Mental health history

- Depression, anxiety, bipolar, schizophrenia, OCD, PTSD, ADHD
- Psychiatrist (who / how often)
- SI/HI currently or hx
- Psych hospitalizations

Criminal

- Arrest, incarceration

Clinical

- PCP – who and when last seen
- PmHx
- Med Hx
- HIV and TB
- Pain hx

Figure 30*Brief Interview Guide*

1. Can you describe the general structure of your program?
 - a. Teaching vs non-teaching services? Consult service structure?
 - b. What is the workflow?
2. How do you screen patients for appropriateness for inpatient suboxone induction?
3. What specific education did you do (and to which audiences) when you began performing inpatient suboxone inductions?
4. Do you use the Clinical Opiate Withdrawal Scale (COWS)? Who performs the assessment? How frequently? How is it documented?
5. What best practices have you developed for transitioning to community maintenance therapy?
6. There is some concern from our compliance department that performing inpatient suboxone induction will require extra privacy control as per 42 CFR. Has this been an issue for you?
 - a. Have you experienced any patients presenting to the ER specifically for suboxone induction therapy? What has been done to prevent this from happening?
7. You've done a great job publishing your findings. What advice might you have for us? What data should we collect? How should it be stored? Who maintains your research database?
8. If you could redesign your program based on what you've learned, what would you do differently?

Figure 31

B-Team Summary

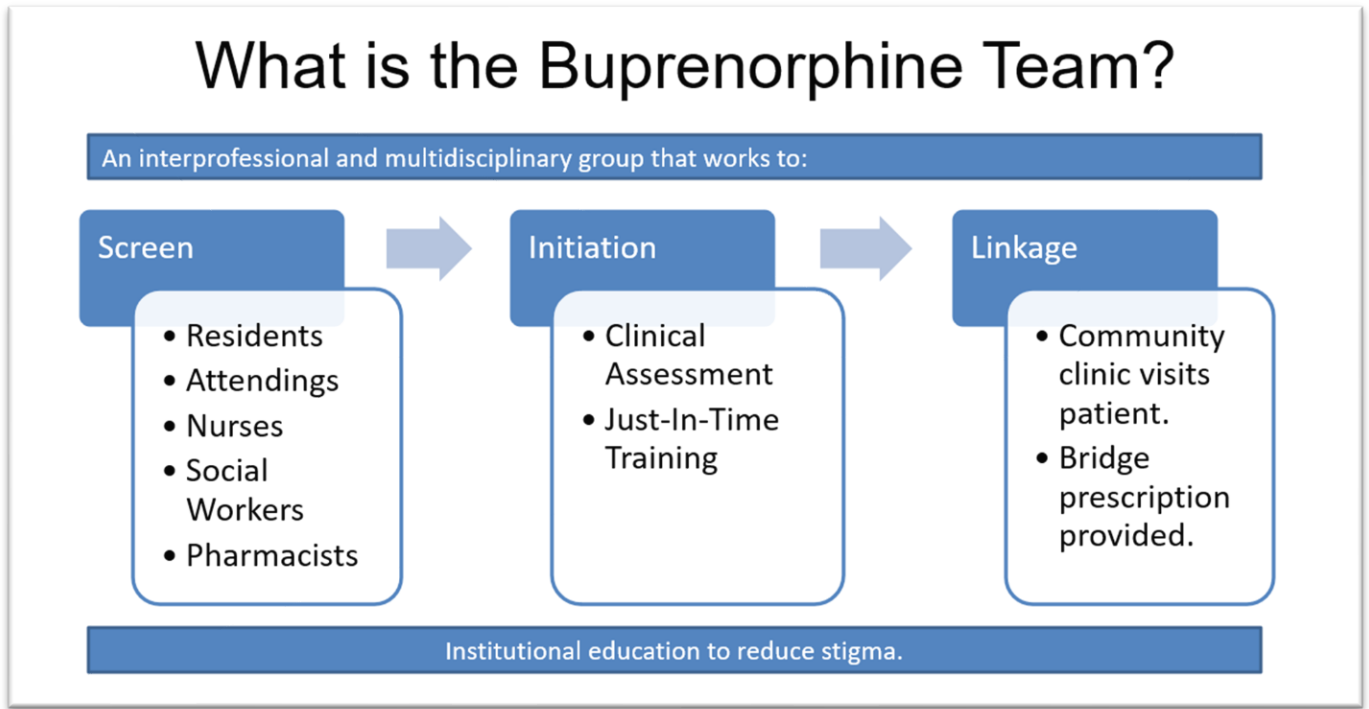


Figure 32

Buprenorphine Order – Main Screen with adjunctive medications

<p>■ Cravings Treatment</p>	<p>promethazine 25 mg PO (oral) q6hr PRN Nausea or Vomiting, Form: Tab ☆</p>
<p>■ Active Withdrawal</p>	<p>traZODone 25 mg PO (oral) at bedtime PRN Insomnia, Form: Tab ☆</p>
<p>■ Maintenance Dosing</p>	<p>melatonin 9 mg PO (oral) at bedtime, Form: Tab ☆</p>
<p>LFT Blood, AM collect, qMonday ☆</p>	<p>cloNIDine 0.1 mg PO (oral) q6h, Form: Tab ☆</p>
<p>hydrOXYzine 25 mg PO (oral) tid PRN Anxiety, Form: Tab ☆</p>	<p>cloNIDine 0.1 mg PO (oral) q6h, Form: Tab ☆</p>
<p>ondansetron 4 mg PO (oral) q6hr PRN Nausea or Vomiting, Form: DIS Tablet ☆</p>	<p>gabapentin 100 mg PO (oral) tid, Form: Cap ☆</p>
<p>ibuprofen 600 mg PO (oral) q6hr PRN Pain, Form: Tab ☆</p>	
<p>melatonin 9 mg PO (oral) at bedtime PRN Insomnia, Form: Tab ☆</p>	
<p>loperamide 2 mg PO (oral) q6hr PRN Diarrhea, Form: Cap ☆</p>	
<p>acetaminophen 500 mg PO (oral) q6h, Form: Tab ☆</p>	

Figure 33*Buprenorphine Order – For Cravings*

Treatment Instructions Once, Reassess opioid craving symptoms two hours after initial Suboxone dose	☆
Notify Provider For worsening opioid withdrawal symptoms or cravings.	☆
Suboxone 2 mg-0.5 mg sublingual film 1 Each SubLINGUAL Once	☆
Suboxone 2 mg-0.5 mg sublingual film 1 Each SubLINGUAL q2hr PRN Other (see order comment) For 4 dose(s)	☆

Figure 34

Buprenorphine Order – For withdrawal

<p>Treatment Instructions q4hr for 6 Times</p>	☆
<p>Notify Provider Reassess COWS assessment 2 hours after 2nd buprenorphine dose. Notify Primary Team if COWS assessment remains greater than or equal to 8 after 8 mg of buprenorphine given.</p>	☆
<p>Suboxone 4 mg-1 mg sublingual film 1 Each SubLINGUAL q2hr PRN Other (see order comment) For 3 dose(s) PRN COWS greater than or equal to 8</p>	☆

Figure 35*Buprenorphine Order – For maintenance*

Suboxone 8 mg-2 mg sublingual film 1 Each SubLINGUAL qDay	☆
Suboxone 2 mg-0.5 mg sublingual film 1 Each SubLINGUAL qDay	☆
Suboxone 4 mg-1 mg sublingual film 1 Each SubLINGUAL qDay	☆

Figure 36

B-Team One Year Outcomes – Total Referrals

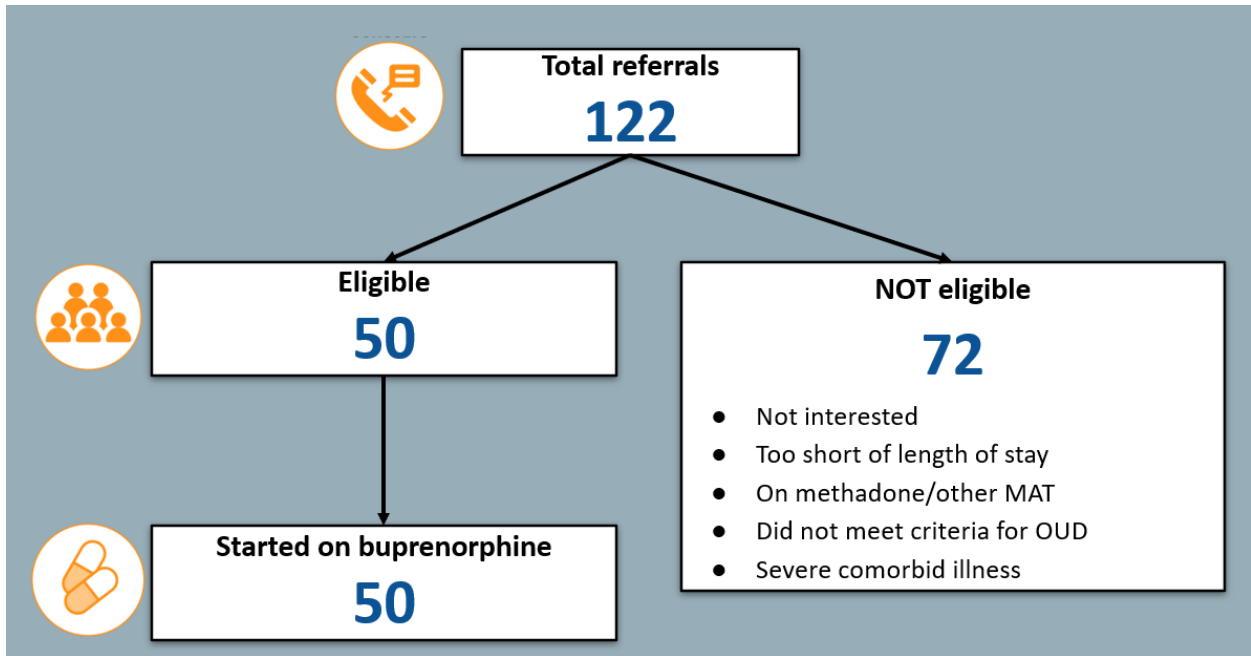


Figure 37

B-Team One Year Outcomes – Patients Not Referred

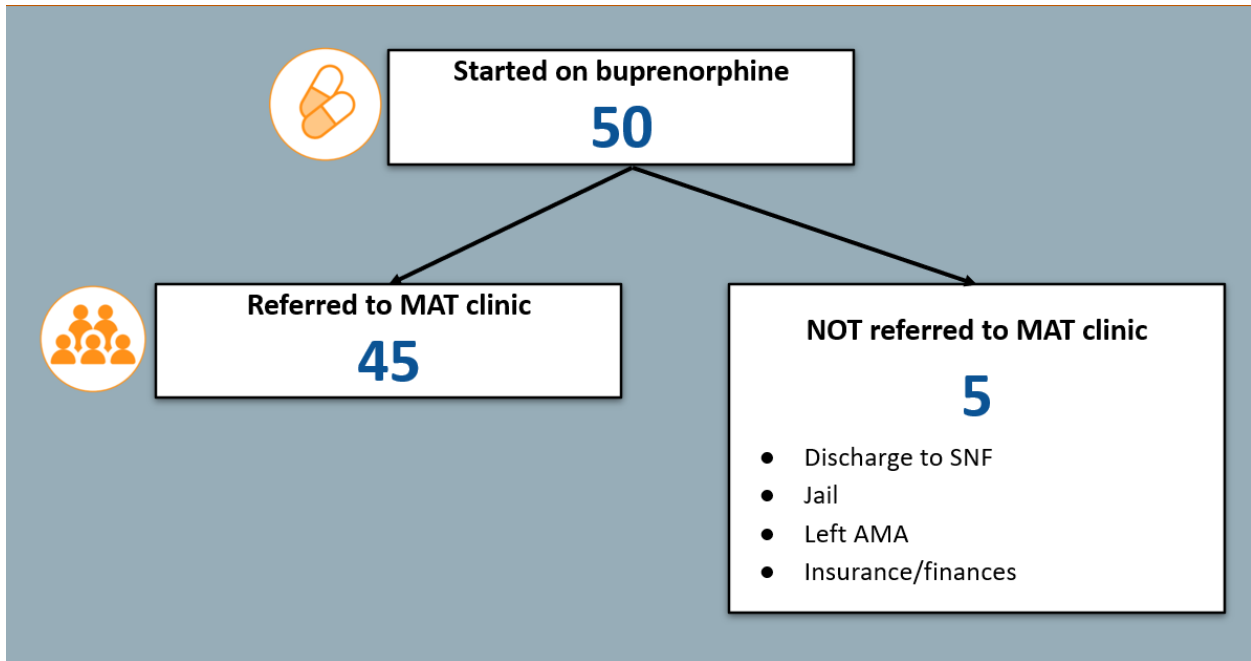


Figure 38

B-Team One Year Outcomes – Treatment Retention

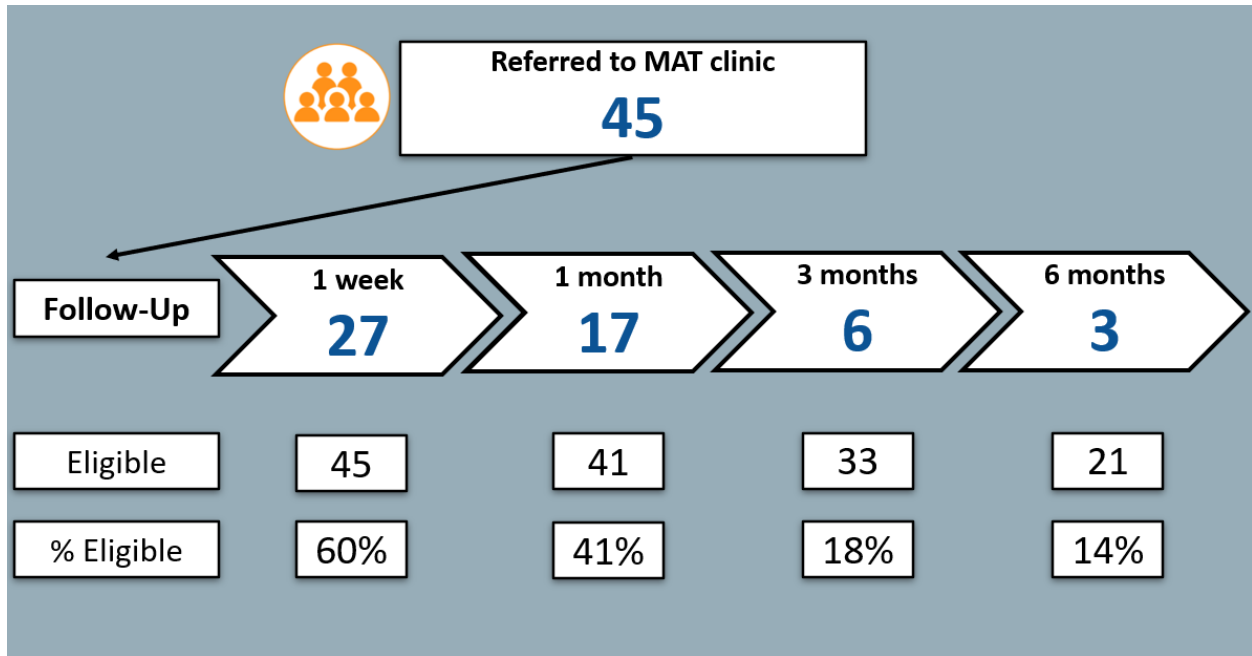


Figure 39

B-Team One Year Outcomes – Treatment Retention

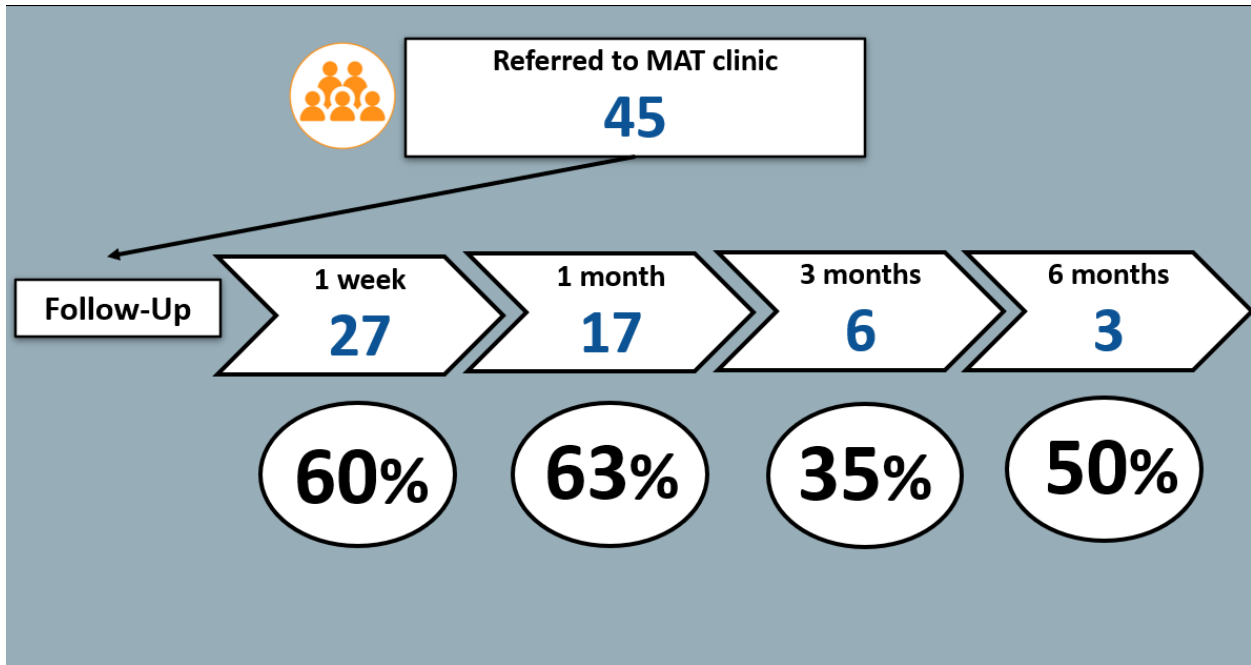


Figure 41*Consistent Messages Used When Discussing In-Hospital Buprenorphine*

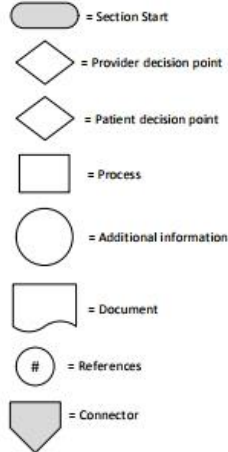
- Buprenorphine is life-saving, evidence-based, and cost-effective.
- Patients are not admitted solely for buprenorphine initiation or continuation of maintenance therapy.
- Offering buprenorphine as part of acute hospitalization is the standard of care.
- The program does not advertise this externally.
- An x-waiver is not needed for inpatient ordering of buprenorphine. It is only needed for outpatient prescribing at discharge.
- The hospital is a place where patients come for acute care needs. Opioid use disorder is a life-limiting and potentially life-threatening medical disease. Therefore, the hospital can and should be a place where patients can go to, in part, initiate their journey to recovery. However, the hospital should not be a place where patients receive long-term care for OUD or other chronic medical diseases.
- Buprenorphine is technically an opioid, but is the only one classified as a partial agonist. This is a key part of its efficacy in addition to its high affinity for and slow disassociation from the mu receptor.

Appendix

Appendix 1

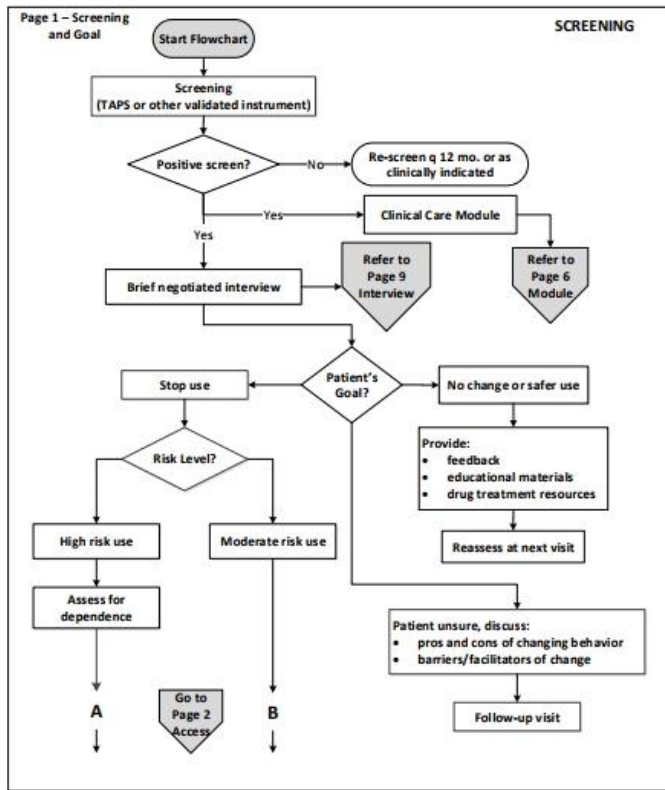
Figure 1 in Multiple Parts Denoted as Pages 1 – 9

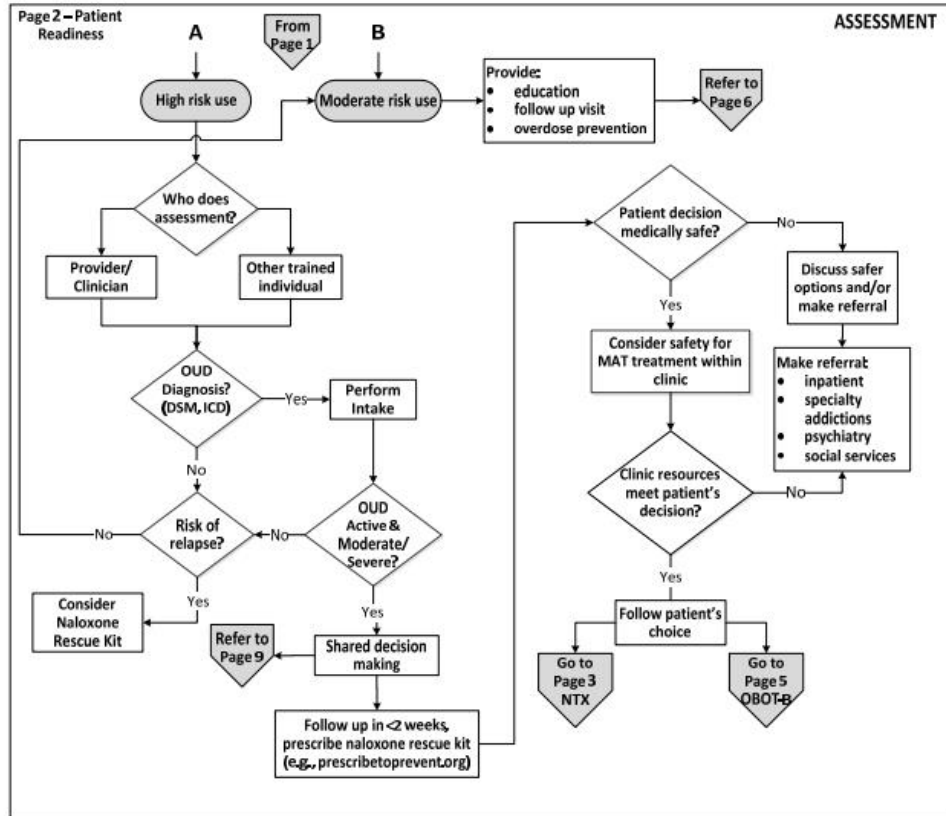
Clinical Decision Support for Opioid Use Disorders (Short Version)

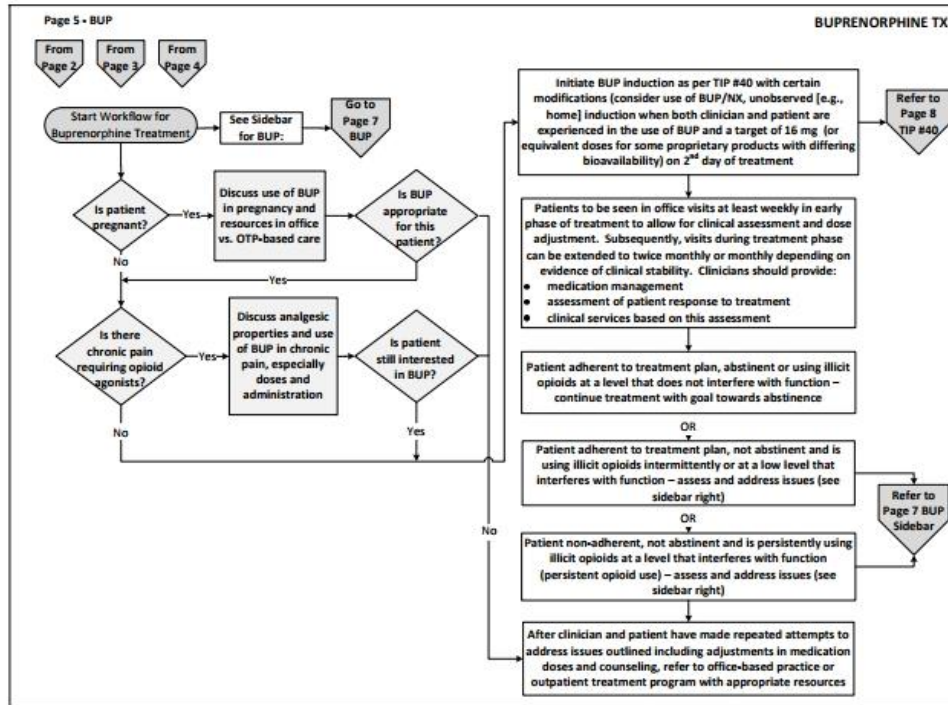


Abbreviations:

DSM = APA Diagnostic and Statistical Manual of Mental Disorders
 OUD = Opioid Use Disorder
 NX = Naloxone
 NTX = Naltrexone
 BUP = Buprenorphine
 OBOT-B = Office-Based Opioid Treatment with Buprenorphine
 MOUD = Medications for Opioid Use Disorder







Page 6 - Clinical Care Module

From Page 1

From Page 2

Clinical Care Module - clinical actions that are independent of the treatment decision

- review screening results for tobacco, alcohol, other drug use
- assess lifetime/current IDU, counseling on safer injection
- ask about drug treatment history
- screening for infectious diseases: HIV, HBV, HCV, STIs, TB
- screening for common health and mental health problems: chronic pain, depression, anxiety
- screening for pregnancy
- review of prescribed medications with potentially harmful interactions: sedatives, opioids
- check prescription drug monitoring program
- obtain/Review urine toxicology results
- overdose education, provision of naloxone kit
- vaccination for HAV, HBV, tetanus, influenza, pneumococcal pneumonia (as indicated)

Page 7 - Sidebars SIDEBARS FOR NTX & BUP

From
Page 3

Naltrexone Sidebar:

Assure:

- adequate resources (e.g., insurance coverage for medication, visits, counseling, urine and blood testing)
- ability to safely store medication
- baseline liver tests obtained
- no contraindication to use of NTX
- confidentiality

Consider:

- comorbid substance use/disorders
- benzodiazepine use disorder
- untreated psychiatric comorbidity
- visit frequency
- history of adherence and of diversion
- comorbid chronic pain

Assess and address:

- medication adherence
- triggers
- comorbid substance use
- psychosocial counseling needs

From
Page 5

From
Page 7

Buprenorphine Sidebar:

Assure:

- adequate resources (e.g., insurance coverage for medication, visits, counseling, urine and blood testing)
- ability to safely store medication
- baseline liver tests obtained
- no contraindication to use of BUP
- confidentiality

Consider:

- comorbid substance use/disorders
- benzodiazepine use disorder
- untreated psychiatric comorbidity
- visit frequency
- history of adherence and of diversion
- comorbid chronic pain

Assess and address:

- medication adherence
- dose to assure cross tolerance and narcotic blockade
- triggers
- comorbid substance use
- psychosocial counseling needs

From " Developing a clinical decision support for opioid use disorders: a NIDA center for the clinical trials network working group report – supplement and figures," G. Bart, et al., 2020, *Addiction Science & Clinical Practice*, 15, p. 1-2,5-7 CC0 1.0

*Only pages pertaining to buprenorphine therapy have been included.

Appendix 2

NIDA Clinical Trials Network
The Tobacco, Alcohol, Prescription medications, and other Substance
(TAPS) Tool

TAPS Tool Part 1

Web Version: 2.0; 4.00; 09-19-17

General Instructions:

The TAPS Tool Part 1 is a 4-item screening for tobacco use, alcohol use, prescription medication misuse, and illicit substance use in the past year. Question 2 should be answered only by males and Question 3 only be females. Each of the four multiple-choice items has five possible responses to choose from. Check the box to select your answer.

Segment:

Visit number:

1. In the PAST 12 MONTHS, how often have you used any tobacco product (for example, cigarettes, e-cigarettes, cigars, pipes, or smokeless tobacco)?

<input type="checkbox"/> Daily or Almost Daily	<input type="checkbox"/> Weekly	<input type="checkbox"/> Monthly
<input type="checkbox"/> Less Than Monthly	<input type="checkbox"/> Never	

2. In the PAST 12 MONTHS, how often have you had 5 or more drinks containing alcohol in one day? One standard drink is about 1 small glass of wine (5 oz), 1 beer (12 oz), or 1 single shot of liquor. (Note: This question should only be answered by males).

<input type="checkbox"/> Daily or Almost Daily	<input type="checkbox"/> Weekly	<input type="checkbox"/> Monthly
<input type="checkbox"/> Less Than Monthly	<input type="checkbox"/> Never	

3. In the PAST 12 MONTHS, how often have you had 4 or more drinks containing alcohol in one day? One standard drink is about 1 small glass of wine (5 oz), 1 beer (12 oz), or 1 single shot of liquor. (Note: This question should only be answered by females).

<input type="checkbox"/> Daily or Almost Daily	<input type="checkbox"/> Weekly	<input type="checkbox"/> Monthly
<input type="checkbox"/> Less Than Monthly	<input type="checkbox"/> Never	

4. In the PAST 12 MONTHS, how often have you used any drugs including marijuana, cocaine or crack, heroin, methamphetamine (crystal meth), hallucinogens, ecstasy/MDMA?

<input type="checkbox"/> Daily or Almost Daily	<input type="checkbox"/> Weekly	<input type="checkbox"/> Monthly
<input type="checkbox"/> Less Than Monthly	<input type="checkbox"/> Never	

5. In the PAST 12 MONTHS, how often have you used any prescription medications just for the feeling, more than prescribed or that were not prescribed for you? Prescription medications that may be used this way include: Opiate pain relievers (for example, OxyContin, Vicodin, Percocet, Methadone) Medications for anxiety or sleeping (for example, Xanax, Ativan, Klonopin) Medications for ADHD (for example, Adderall or Ritalin)

<input type="checkbox"/> Daily or Almost Daily	<input type="checkbox"/> Weekly	<input type="checkbox"/> Monthly
<input type="checkbox"/> Less Than Monthly	<input type="checkbox"/> Never	

NIDA Clinical Trials Network
The Tobacco, Alcohol, Prescription medications, and other Substance
(TAPS) Tool

TAPS Tool Part 2

Web Version: 2.0; 4.00; 09-19-17

General Instructions:

The TAPS Tool Part 2 is a brief assessment for tobacco, alcohol, and illicit substance use and prescription medication misuse in the PAST 3 MONTHS ONLY. Each of the following questions and subquestions has two possible answer choices- either yes or no. Check the box to select your answer.

1. In the PAST 3 MONTHS, did you smoke a cigarette containing tobacco? Yes No

If "Yes", answer the following questions:

- a. In the PAST 3 MONTHS, did you usually smoke more than 10 cigarettes each day? Yes No
- b. In the PAST 3 MONTHS, did you usually smoke within 30 minutes after waking? Yes No

2. In the PAST 3 MONTHS, did you have a drink containing alcohol? Yes No

If "Yes", answer the following questions:

- a. In the PAST 3 MONTHS, did you have 4 or more drinks containing alcohol in a day?* (Note: This question should only be answered by females). Yes No
- b. In the PAST 3 MONTHS, did you have 5 or more drinks containing alcohol in a day?* (Note: This question should only be answered by males). Yes No

*One standard drink is about 1 small glass of wine (5 oz), 1 beer (12 oz), or 1 single shot of liquor.

c. In the PAST 3 MONTHS, have you tried and failed to control, cut down or stop drinking? Yes No

d. In the PAST 3 MONTHS, has anyone expressed concern about your drinking? Yes No

3. In the PAST 3 MONTHS, did you use marijuana (hash, weed)? Yes No

If "Yes", answer the following questions:

- a. In the PAST 3 MONTHS, have you had a strong desire or urge to use marijuana at least once a week or more often? Yes No
- b. In the PAST 3 MONTHS, has anyone expressed concern about your use of marijuana? Yes No

4. In the PAST 3 MONTHS, did you use cocaine, crack, or methamphetamine (crystal meth)? Yes No

If "Yes", answer the following questions:

- a. In the PAST 3 MONTHS, did you use cocaine, crack, or methamphetamine (crystal meth) at least once a week or more often? Yes No
- b. In the PAST 3 MONTHS, has anyone expressed concern about your use of cocaine, crack, or methamphetamine (crystal meth)? Yes No

5. In the PAST 3 MONTHS, did you use heroin? Yes No

If "Yes", answer the following questions:

- a. In the PAST 3 MONTHS, have you tried and failed to control, cut down or stop using heroin? Yes No

- b. In the PAST 3 MONTHS, has anyone expressed concern about your use of heroin? Yes No
6. In the PAST 3 MONTHS, did you use a prescription opiate pain reliever (for example, Percocet, Vicodin) not as prescribed or that was not prescribed for you? Yes No
- If "Yes", answer the following questions:
- a. In the PAST 3 MONTHS, have you tried and failed to control, cut down or stop using an opiate pain reliever? Yes No
- b. In the PAST 3 MONTHS, has anyone expressed concern about your use of an opiate pain reliever? Yes No
7. In the PAST 3 MONTHS, did you use a medication for anxiety or sleep (for example, Xanax, Ativan, or Klonopin) not as prescribed or that was not prescribed for you? Yes No
- If "Yes", answer the following questions:
- a. In the PAST 3 MONTHS, have you had a strong desire or urge to use medications for anxiety or sleep at least once a week or more often? Yes No
- b. In the PAST 3 MONTHS, has anyone expressed concern about your use of medication for anxiety or sleep? Yes No
8. In the PAST 3 MONTHS, did you use a medication for ADHD (for example, Adderall, Ritalin) not as prescribed or that was not prescribed for you? Yes No
- If "Yes", answer the following questions:
- a. In the PAST 3 MONTHS, did you use a medication for ADHD (for example, Adderall, Ritalin) at least once a week or more often? Yes No
- b. In the PAST 3 MONTHS, has anyone expressed concern about your use of a medication for ADHD (for example, Adderall or Ritalin)? Yes No
9. In the PAST 3 MONTHS, did you use any other illegal or recreational drug (for example, ecstasy/molly, GHB, poppers, LSD, mushrooms, special K, bath salts, synthetic marijuana ('spice'), whip-its, etc.)? Yes No
- If "Yes", answer the following questions:
- In the PAST 3 MONTHS, what were the other drug(s) you used?
- Comments:

From "The Tobacco, Alcohol, Prescription medications, and other Substance (TAPS) Tool," by National Institute on Drug Abuse, 2017 ([https://cde.drugabuse.gov/sites/nida_cde/files/TAPS Tool Parts I and II V2.pdf](https://cde.drugabuse.gov/sites/nida_cde/files/TAPS_Tool_Parts_I_and_II_V2.pdf)). In the public domain.

Appendix 3**Qualitative Interview Guide****Demographics**

1. What is your age?
2. What is your ethnicity?
3. How many years have you worked in the healthcare industry?
4. What is the highest degree or level of school you have completed?

Treatment of Opioid Use Disorder

5. How do you define opioid use disorder?
 - a. How common is opioid use disorder?
6. Describe your experiences working with or supporting programs for patients who have opioid use disorder.

Questions for Care Team Members of The Program

1. Describe the work of the program.
2. In what ways has the program succeeded? In what ways has it been not as strong?
3. Think back to when you began seeing patients for the program.
 - a. What barriers existed to starting buprenorphine during hospitalization?
 - b. How did you overcome these barriers?
 - c. What barriers exist now?
4. What resources would have helped the program the most in the beginning?
 - a. What resources would be helpful now?

5. Were your peers supportive of the program? Why or why not? Has this changed over time?
6. Was your supervisor supportive of you participating on the team? Why or why not? Has this changed over time?
7. Describe how you feel hospital staff has responded overall to the program?
 - a. Prescribers
 - b. Nurses
 - c. Social workers
 - d. Pharmacists
 - e. Other clinical staff
 - f. Staff at community partners?
8. Describe how you feel patients have responded overall to the program?
9. The program has existed so far only within inpatient medicine. What other areas of the hospital might benefit from such a service?
 - a. What barriers do you perceive in starting such a program in those settings?
10. How has being part of the program impacted you personally?
11. How has being part of the program impacted your job satisfaction?
12. What factors might influence an individual's desire to support the hospital-based treatment of opioid use disorder?
13. What have been the "lessons learned" from the program that may be helpful for other institutions interested in starting a similar program?
14. For members of the program who prescribe buprenorphine
 - a. Overall, how prepared did you feel after completing the x-waiver training course?

- b. Reflect on when you started seeing patients during hospitalization. What modifications, if any, to the x-waiver curriculum would have helped you be more prepared for seeing patients specifically in the hospital setting? Why?
- c. The x-waiver is only required to prescribe buprenorphine at the time of discharge. However, if on the formulary, federal law allows buprenorphine to be ordered by any prescriber as part of acute hospitalization. If you were going to design a one-hour lecture for your colleagues on key points of starting buprenorphine during hospitalization, what topics would you include?

Questions for administrators

7. Describe what you know about the Buprenorphine Team
 - a. What is its purpose
 - b. How does it work
 - c. What are its benefits?
 - d. What are its drawbacks?
 - e. What has been your interaction with the program?
8. Should buprenorphine therapy be offered to patients in inpatient medical wards as part of acute hospitalization? Why or why not?
9. What are the barriers to starting a patient on buprenorphine therapy during hospitalization?
 - a. Probe: Describe how the following may or may not be barriers to starting a hospital-based buprenorphine program (list individually as needed):
 - i. Patient preference towards buprenorphine.

- ii. Pharmacologic treatment of opioid use disorder does not work as well as 12-step or narcotics anonymous.
 - iii. Geographic location of hospital.
 - iv. Financial concerns related to inpatient cost of medication.
 - v. Financial concerns related to ongoing cost of outpatient medication.
 - vi. Availability of outpatient providers who can prescribe buprenorphine.
 - vii. There are other none-restricted medications that can treat symptoms of withdrawal.
 - viii. Not enough prescribers in the hospital with an x-waiver.
 - ix. Nursing staff does not have the time to perform the assessments necessary to implement the protocol.
 - x. Nursing staff does not have the education needed to perform the assessments necessary to implement the protocol.
 - xi. Too few other hospitals in the area performing this work may result in a large influx of patients seeking treatment.
- b. How can these barriers be overcome?
- i. Probe: Are there educational opportunities that may change these barriers?

Questions for all

1. Some have expressed that offering buprenorphine treatment in a hospital will increase the number of patients who present seeking treatment. What are your perceptions about this?
2. Should buprenorphine therapy be offered in other parts of the hospital outside of inpatient medicine? Why or why not?

- a. Probe: Should buprenorphine therapy be offered to patients in the emergency department setting? Why or why not?
 - b. Probe: Should buprenorphine therapy be offered to patients as part of inpatient obstetrics? Why or why not?
 - c. Probe: What other practice areas within the hospital may benefit from the initiation of buprenorphine therapy.
3. Define peer recovery coaching.
- a. Should peer recovery coaches be incorporated into the hospital-based treatment of opioid use disorder? Why or why not?
4. Should the management of buprenorphine therapy be the responsibility of a specific medical discipline?
- a. Specific provider type? (e.g., pharmacist, NP, physician, etc.)
 - b. Specific specialty? (addiction/psych, medicine, etc.)
 - c. How might the service provided by the program change in the presence of a formal addiction medicine consultation service?
5. Describe the current role of interprofessional health care in treating opioid use disorder in hospitals?
- a. How could this be improved?
 - b. In what way might interprofessionalism contribute to effectiveness of the hospital-based treatment of opioid use disorder?
 - c. In what ways do the following disciplines and roles contribute to hospital-based treatment of opioid use disorder: physician, nurse, physician assistant, social worker, chaplain, pharmacist, psychiatrist, palliative care specialist.

6. Are you concerned about diversion of buprenorphine provided at time of discharge? Why or why not?
7. Were there any legal or regulatory concerns that you or your colleagues had at any point about the work of the program?
 - a. How were those concerns resolved?
8. The long-term vision for the program is that all prescribers in the hospital (attending physicians, residents, physician assistants, and advanced practice nurses) are capable of identifying patients with opioid use disorder, starting buprenorphine on their own, and coordinating outpatient care related to opioid use disorder in concert with other members of the team. If successful, a group like the program might not be necessary. What steps need to be taken for this vision to be fulfilled?
9. Do you have any additional comments that may be helpful in understanding how to successfully start a buprenorphine program for hospitalized patients?
 - a. Do you have any additional comments that may be helpful in understanding the role that interprofessional care may play in the delivery of this care?

Appendix 4

**Note: This document reflects early knowledge and contains language stigmatizing of patients with opioid use disorder which has since been changed.*

The Buprenorphine Team

Inpatient Buprenorphine Induction



Prepared by Richard Bottner, PA-C

Original: November 10, 2017

Updated: April 5, 2018

opioid use disorders is one of the four main strategies deployed by the Department of Health and Human Services to combat the opioid epidemic. MAT programs reduce the risk of drug relapse, improves societal functioning such as employment, reduces the transmission of various infections, and decreases criminal activity. Many of these programs rely on prescribing methadone, a highly-regulated medication that can only be dispensed by Addiction Medicine specialists in specifically licensed clinics. These regulations limit access to methadone.

In 2002, the FDA approved buprenorphine for the use of treating opioid dependency disorders. Importantly, the Drug Addiction Act of 2000 (DATA 2000) and subsequent legislation, allows for physicians, physician assistants, and advanced practice nurses to prescribe buprenorphine, regardless of medical specialty or practice setting (United States Substance Abuse and Mental Health Services Administration, 2016).

In August 2017, the [Opioid Treatment Clinic] was launched. Referrals to this program have been generated from primary care providers, family drug court, mental health clinics, and the local methadone clinic. To date, referrals have not been intentionally or systematically generated from the hospital inpatient setting.

Hospitals as Induction Settings

The hospital setting provides a unique opportunity to deliver education and offer patients treatment with buprenorphine. Hospitalization related to opioid misuse has increase more than 150% from 1993 to 2012. Patients with opioid use disorders cost the healthcare system a minimum of eight times more than non-opioid abusers. Patients with substance use disorders are more likely to be readmitted within 30 days of discharge, and the majority of patients with previous substance abuse before hospitalization will return to that behavior after discharge if treatment has not been initiated. Buprenorphine induction in the hospital setting leads to

increased completion of inpatient medical therapies and ultimate transition to outpatient substance abuse treatment. Given that patients may be hospitalized for several days or weeks at a time, and may be at various stages of dependency during this time, the inpatient setting is an important time to offer treatment to this captive audience.

Unfortunately, there are few programs which offer buprenorphine induction in the inpatient setting. A thorough literature review has revealed only four examples. In one program, 72% of patients attended their first outpatient appointment with 16% remaining at the sixth month. In another program, 50% of patients followed-up for their initial appointment with 40% still enrolled at three months. Another example found 62% attending the initial assessment with 17% still engaged at three months. In the last study, 47% of patients had initiated outpatient treatment within two months of discharge.

Several barriers to MAT induction in the inpatient setting have been reported. Hassamal et al. (2017) divide these obstacles into three domains including patients, practitioners, and organizations. Many patients have misconceptions about MAT. Some may consider initiating this sort of treatment as exchanging one bad habit for another. Clinicians, especially inpatient providers, often lack experience with substance abuse disorders, and have less comfort when dealing with opioid dependency beyond acute withdrawal symptoms. A stigma exists both around patients with opioid dependency as well as its primary treatments such as methadone and buprenorphine. In fact, less than 10% of 102 patients with a diagnosis of infective endocarditis secondary to injection drug use who were evaluated at a large academic tertiary care center in Boston were referred to MAT, despite its availability for this population.

Case for Dell Seton Medical Center

[Academic Medical Center] is in a unique position to offer buprenorphine induction therapy. In [the County], 2.3 deaths per 100,000 residents are attributed to opioids. Approximately \$2.4 million was spent in 2012 in field EMS services related to opioid abuse. From October 2015 through September 2017, over 2,240 admitted patients at [Academic Medical Center] carried a diagnosis of substance use disorder. Over 100 patients were deemed candidates for methadone or buprenorphine treatment. From October 2016 through September 2017, over 270 admitted patients carried a diagnosis of opioid use dependency. This data is based on consultations by the Behavior Health Social Work team. As this group only evaluates certain patients based on strict criteria (including positive urine drug screens and direct consultation requests), it is highly likely that the true number of patients with these diagnoses and who are appropriate for MAT is significantly higher.

The Buprenorphine Team

Buprenorphine is offered through The Buprenorphine Team (TBT.) This interprofessional and multidisciplinary group works to screen appropriate patients for buprenorphine induction, initiate this treatment while patients are hospitalized, facilitate linkage with an outpatient maintenance clinic, and provide institutional education in an effort to reduce stigma and raise awareness.

As [REDACTED] primary teaching hospital, TBT partners with the [Medical School] in addition to the County colleagues previously mentioned to develop an educational campaign for hospital-based clinicians, resident physicians, bedside nurses, and social work staff. The goal of training is stigma reduction, buprenorphine awareness, and resources for outpatient MAT linkage. TBT also offers resources for interested clinicians to participate in the x-waiver program to serve as primary buprenorphine prescribers.

Initial Funding

Buprenorphine is not currently covered by [CAP] insurance. Hospital administrators have endorsed utilizing internal safety-net funds earmarked for outpatient prescriptions to pay for the bridge dosing of outpatient buprenorphine until the patient can follow-up with the [Opioid Treatment Clinic]. The 8mg sublingual film has an estimated 340B pricing of \$7.93 per film. Assuming each patient requires the maximum dose (24mg / 24 hours) and each patient's initial follow-up appointment requires the maximum timeframe for scheduling (10 days), the maximum estimated cost per patient is \$237.90. However, it is expected that the majority of patients will follow-up within seven days or less. The follow-up appointment date will be secured prior to discharge, and only the exact amount of buprenorphine needed to cover the interval between discharge and follow-up will be prescribed. Some patients may only require 8mg or 16mg per 24-hour period. Importantly, it is expected that [CAP] will begin including buprenorphine on its formulary in the future and long-term use of hospital funds to support this program is not expected. The specific timeline for formulary inclusion of buprenorphine therapy is unknown.

In addition, TBT has received a \$5,000 grant from the National Institute on Drug Abuse sponsored by the National Institutes of Health and offered in partnership with the American Academy of PAs. Funding will be used for educational printed materials, video production, x-waiver training, and stigma reduction efforts.

TST Objectives

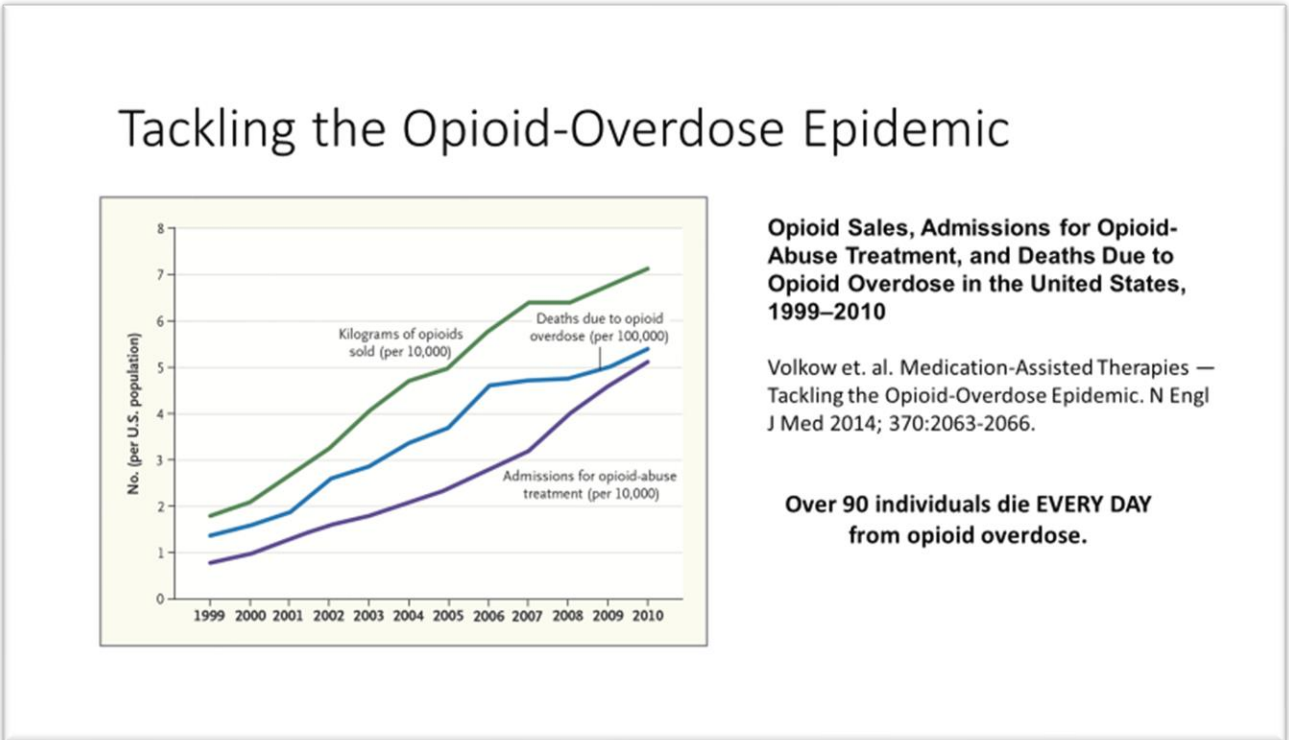
- To raise awareness and provide education about opioid use dependency and treatments among Internal Medicine and Family Medicine attending and resident physicians, in addition to acute care registered nurses.
- To offer x-waiver training for Internal Medicine and Family Medicine attending and resident physicians.
- To evaluate and screen patients for the diagnosis of opioid use dependency.
- To administer buprenorphine induction for qualified, consented patients.

- To facilitate effective transitions of care from the inpatient setting where induction has occurred, to the outpatient setting for maintenance therapy.
- Greater than 30% of patients who have been provided induction in the hospital continue to follow-up with maintenance therapy after six months.

Appendix 5

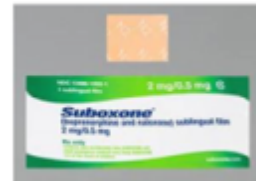
Presentation to Incubator

**Note: This document reflects early knowledge and contains language stigmatizing of patients with opioid use disorder which has been changed.*



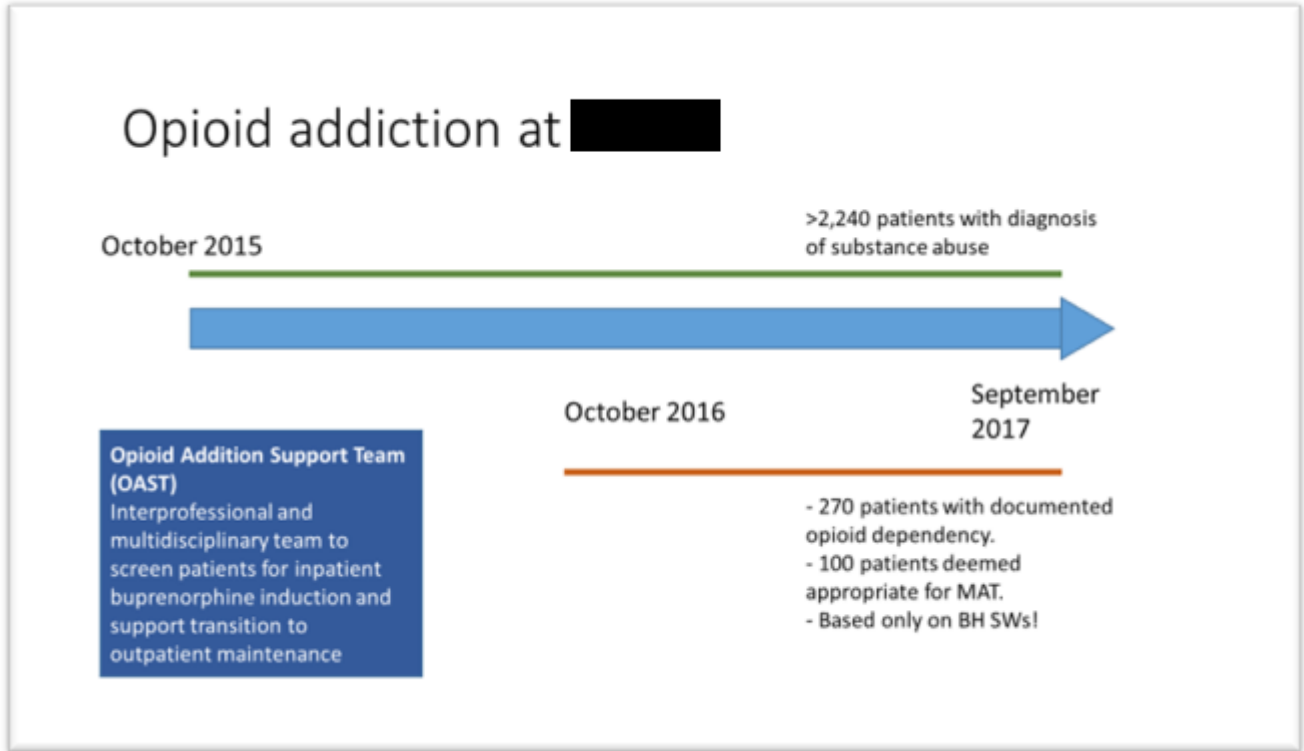
What is Medication-assisted therapy (MAT)?

- Using controlled opioids + counseling + social support to treat opioid addiction
 - Methadone—addiction specialists only
- DATA 2000: Approval to use buprenorphine
 - Can prescribe regardless of specialty
 - Adverse effect profile better compared to Methadone
 - Challenging to overdose / experience euphoria.
- [REDACTED] with [REDACTED] and [REDACTED] started a buprenorphine therapy program in August 2017.



Inpatient buprenorphine therapy

- Patients with opioid dependency are more likely to be readmitted within 30 days, all-cause.
- Patients are more likely to complete inpatient therapies.
- Patients are more likely to attend outpatient substance abuse treatment.
- Four examples of inpatient programs
 - 50-70% attended first visit
 - 16-47% still engaged at 3-6 months post discharge
- Barriers
 - Patient → not ready, concern of “opioid swapping”
 - Practitioners → lack experience, especially outside of acute withdrawal / stigma
 - Organization → financial support, staff, liability



Proposal

- Bridge dosing from inpatient to outpatient not covered at [REDACTED] by MAP.
 - Hospital has agreed to pay
 - \$7.93/8mg film
 - ~\$240 max 10 day supply
- X-waiver –serve as primary buprenorphine prescribers only for bridge dosing.
- Reach faculty, residents, nurses, social work, all clinicians.

Goals

10 physicians with
x-waiver in 4
months

100 patients
screened

Buprenorphine
counseling to 75%
of eligible patients

Buprenorphine
therapy to 50% of
eligible patients

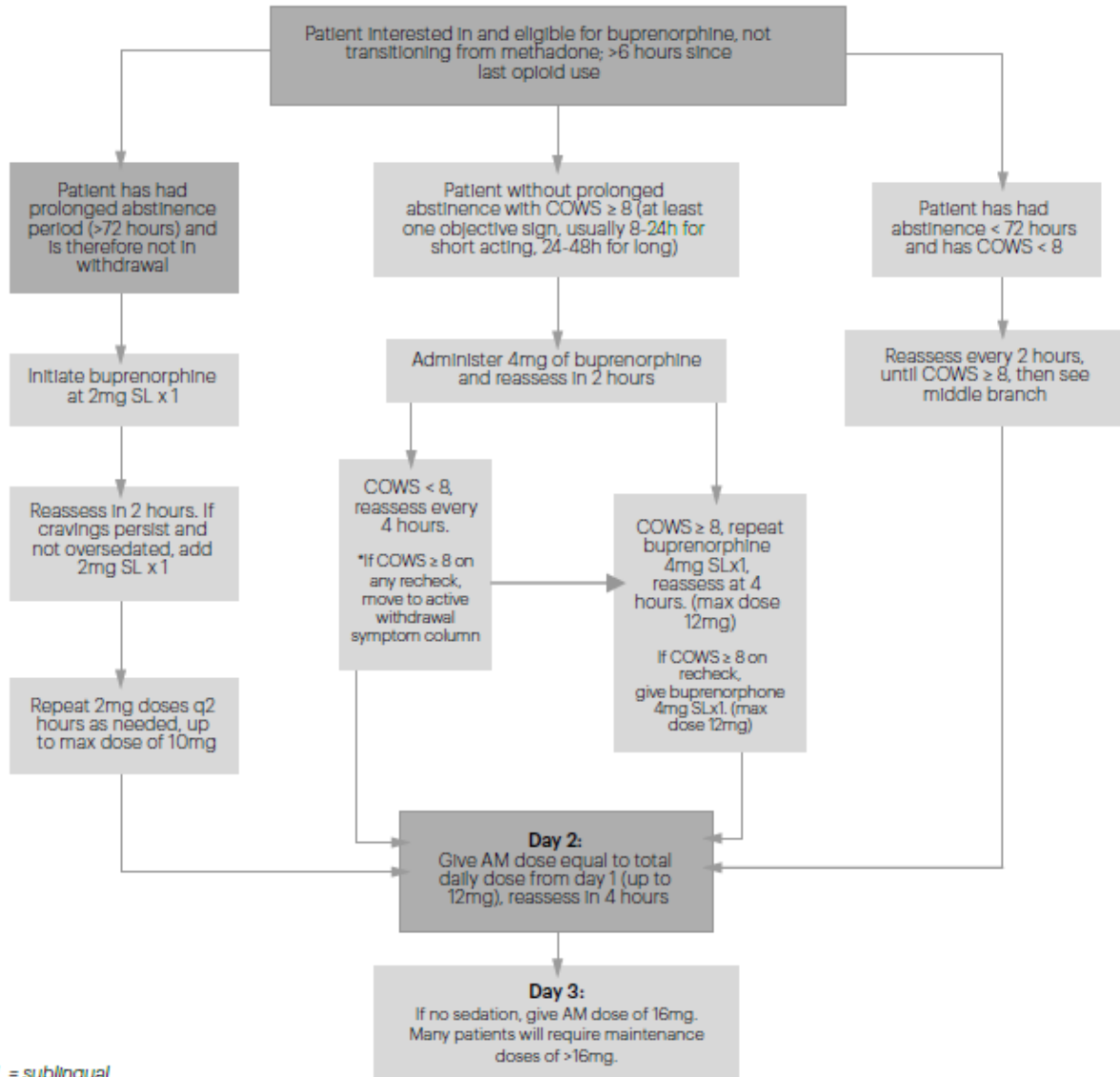
50% of induction
patients attend
first outpatient
visit

30% outpatients
still in program at
6 months

Appendix 6

Treatment Algorithm

Buprenorphine Induction Algorithm



*SL = sublingual
 **Day 1 max dose may surpass 12mg by provider order, up to max dose of 16mg.

The COWS form is available on the intranet under: Clinical > Clinical Practice > Buprenorphine Team > Inductions.

- Document COWS score and evaluate for sedation at each check.
- With each check, consider increasing dose if cravings or withdrawal are present. Decrease if sedation or RR < 8 is present. The goal is for patient to have no sedation, but also no cravings or withdrawal on their final dose.
- Most patients should be discharged on >16mg and may ultimately need to be titrated to higher doses in the outpatient setting.

For questions or concerns, please TigerText the Buprenorphine Team.

Appendix 7

COWS Assessment

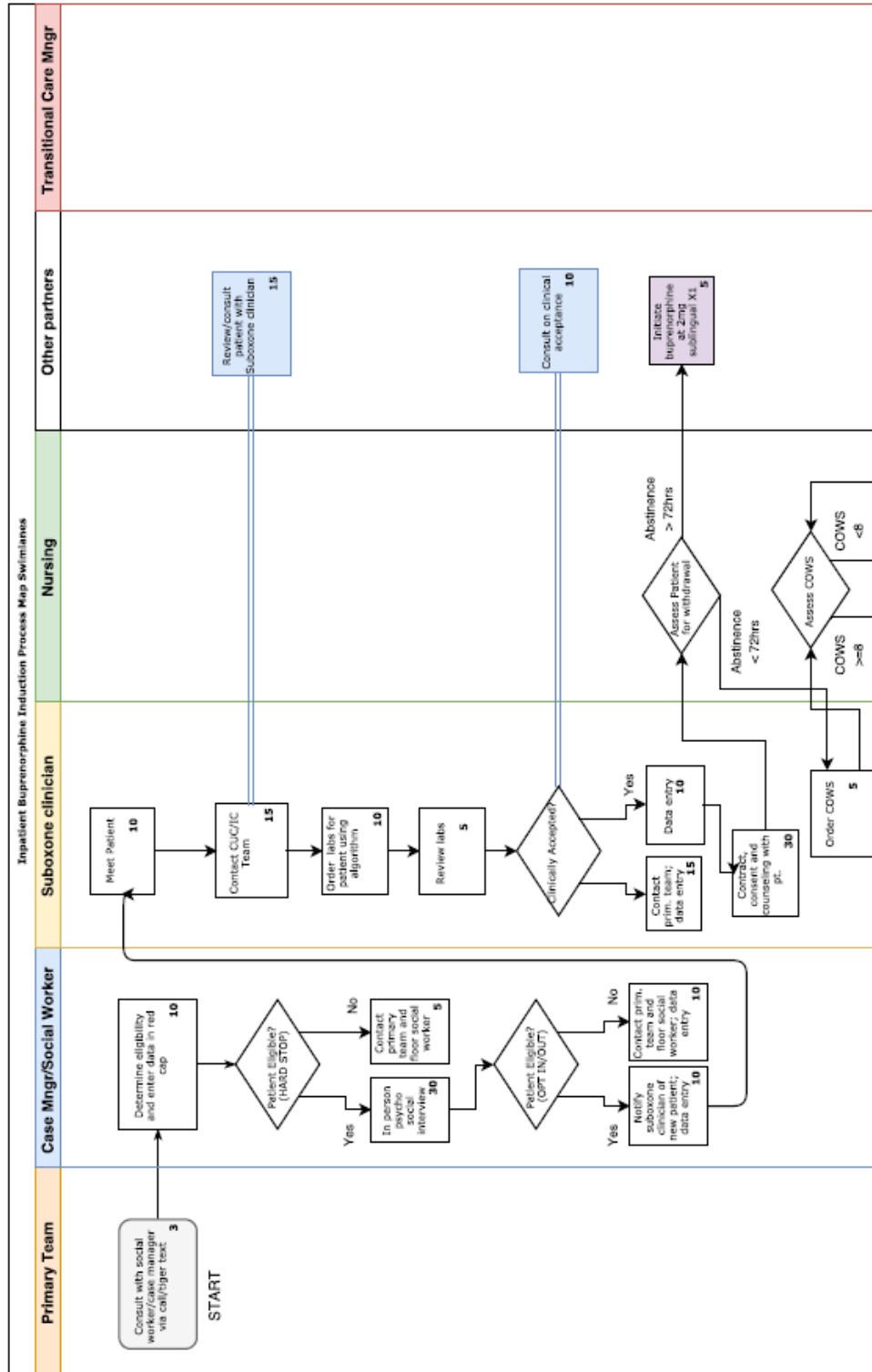
CLINICAL OPIOID WITHDRAWAL SCORE (COWS)		Score
Date and Time of Assessment:	Total Dose of Induction Buprenorphine Administered Before this COWS Assessment: _____ mg	
Resting Pulse Rate: <i>Record beats per minute after patient is sitting or lying down for one minute.</i> 0 = pulse rate 80 or below 1 = pulse rate 81-100		2 = pulse rate 101-120 3 = pulse rate greater than 120
Sweating: <i>Over past 30 mins not accounted for by room temperature or activity.</i> 0 = no chills or flushing 1 = subjective chills or flushing		2 = flushed or observable moistness on face 3 = beads of sweat on brow or face 4 = sweat streaming off face
Restlessness: <i>Observation during assessment</i> 0 = able to sit still 1 = reports difficulty sitting still, but able to do so		2 = frequent shifting or extraneous movement of legs/arms 3 = unable to sit still
Pupil Size: 0 = pupils pinned or normal size for light 1 = pupils possibly larger than normal for light		2 = pupils moderately dilated 3 = only rim of iris visible
Bone or Joint Aches: 0 = not present 1 = mild discomfort		2 = severe diffuse aching of joints and muscles reported 3 = patient rubbing joints or muscles and unable to sit still due to discomfort
Runny Nose or Tearing: <i>Not accounted for by cold or allergy.</i> 0 = not present 1 = mild/diffuse discomfort		2 = nose running or tearing 3 = nose constantly running or tears streaming down cheeks
GI Upset: <i>Over the course of the previous 30 minutes.</i> 0 = no GI symptoms 1 = stomach cramps 2 = nausea or loose stool		3 = vomiting / diarrhea 4 = multiple episodes of diarrhea / vomiting
Tremor: <i>Observation of outstretched hands.</i> 0 = no tremor 1 = tremor can be felt but not observed		2 = slight tremor observable 3 = gross tremor or muscle twitching
Yawning: <i>Observation during assessment.</i> 0 = no yawning 1 = yawning once or twice during assessment		2 = yawning 3+ times during assessment 3 = yawning several times a minute
Anxiety or Irritability: 0 = none 1 = patient reports increasing irritability or anxiousness		2 = patient obviously irritable or anxious 4 = patient so irritable or anxious that participation in the assessment is difficult
Gooseflesh Skin: 0 = skin is smooth		3 = piloerection of skin can be felt or hairs standing up on arms 5 = prominent piloerection
RN Signature: _____ RN Name Printed: _____ Time: _____ AM / PM		Total: 5 – 12 = mild 13 – 24 = moderate 25 – 36 = moderately severe > 36 = severe withdrawal

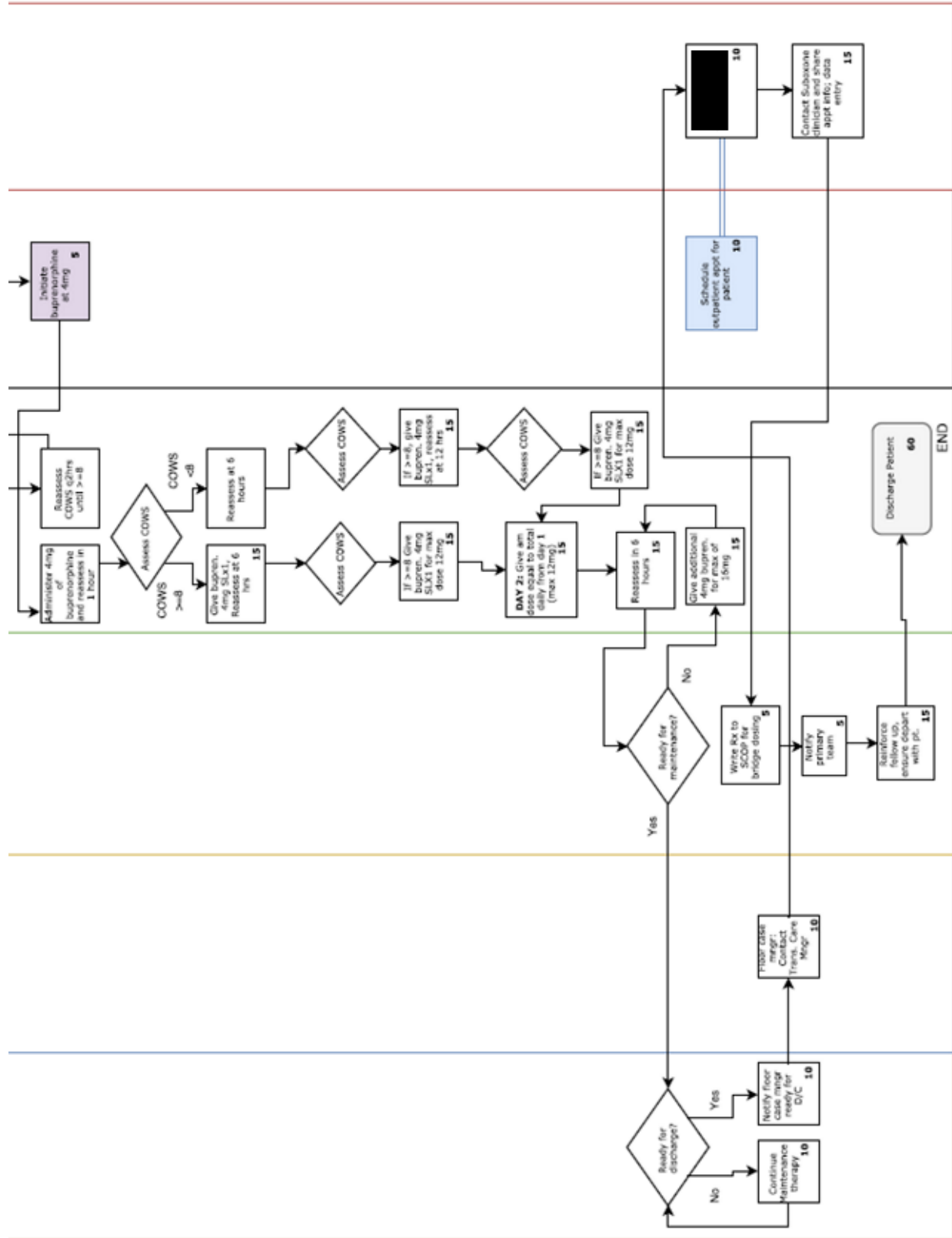


Appendix 8

Initial Process Map

Inpatient Buprenorphine Induction Process Map





Appendix 9

Original Promotional Flyer

**Note: This document reflects early knowledge and contains language stigmatizing of patients with opioid use disorder which has been changed.*

Inpatient Buprenorphine Induction for Opioid Use Disorder

After screening, TigerText the Buprenorphine team.

Program Overview

The Buprenorphine Team offers patients with Opioid Use Disorder (OUD) the opportunity to be started on buprenorphine Medication Assisted Treatment (MAT) while in the hospital. MAT is proven to decrease a patient's dependency on opioids while increasing self-efficacy and overall quality of life during and after treatment. Primary teams are encouraged to TigerText the Buprenorphine Team about any patient who may be a candidate for MAT.

Why use the B-Team?

OUD is a chronic, lifelong medical condition that can be treated with buprenorphine, the safest MAT available. Offering MAT during hospitalization facilitates increased completion of inpatient medical therapies, and ultimate transition to outpatient substance abuse treatment. This program may provide definitive therapy for some of our most vulnerable patients, helping them to achieve meaningful societal contributions such as employment and long-term housing, reducing infections associated with OUD, and decreasing the risk of drug relapse.

Between October 2015 and September 2017, over 100 patients were deemed candidates for methadone or buprenorphine treatment.

From October 2016 through September 2017, over 270 admitted patients at ██████ carried a diagnosis of opioid use dependency.

How do I know when to refer my patient to the B-Team?

Any member of the care team can refer patients to the B-Team — the primary team as a whole is the point of contact with the B-team.

Look for the following signs:

Patient is physiologically dependent on opioids (heroin or illicit pill use), or expresses addictive behavior related to opioids and interest in cessation.

72

Patient has inpatient status, and an expected length of stay of at least 72 hours.

The B-Team is an interdisciplinary group that includes physicians, advanced practice providers, nurses, social workers, case managers, and pharmacists. **To refer a patient, TigerText the "Buprenorphine Team".**

How does the program work?

- A patient admitted to [redacted] reports use of opioids and expresses fear or signs of withdrawing from opiates while in the hospital.
- A member of the primary team TigerTexts the "Buprenorphine Team".
- The B-Team screens the patient for criteria needed to start MAT. If eligible orders are placed, and the nurse follows protocol to administer buprenorphine.
- The patient will stay on buprenorphine while in the hospital, and will receive a prescription upon discharge to last through their first outpatient appointment.
- Lastly, the patient will receive maintenance buprenorphine therapy as an outpatient.



Common Misconceptions about MAT

- ✗ **MAT is replacing one opioid with another**
- Although buprenorphine does activate opioid receptors to some extent, it provides a safer and standardized dose. It is also proven to reduce mortality, decrease opioid dependency, and establish a stable foundation to improve a patient's quality of life.
- ✗ **MAT has high potential for diversion/ misuse**
- The potential for diversion is significantly lower than that of methadone. Buprenorphine in the outpatient setting is typically mixed with naloxone, and administered buccally or sublingually. This makes it very challenging to achieve euphoria if misuse is attempted.

Guidelines and Talking Points



Establish rapport with patients to discuss drug use and opioid dependency in a comfortable, judgment-free setting.



Ask open-ended questions that invite patients to tell their story and consider potential options alongside professional guidance.



Use positive, patient-centered language to foster mutual trust and reduce stigma around opioid use disorder and MAT.

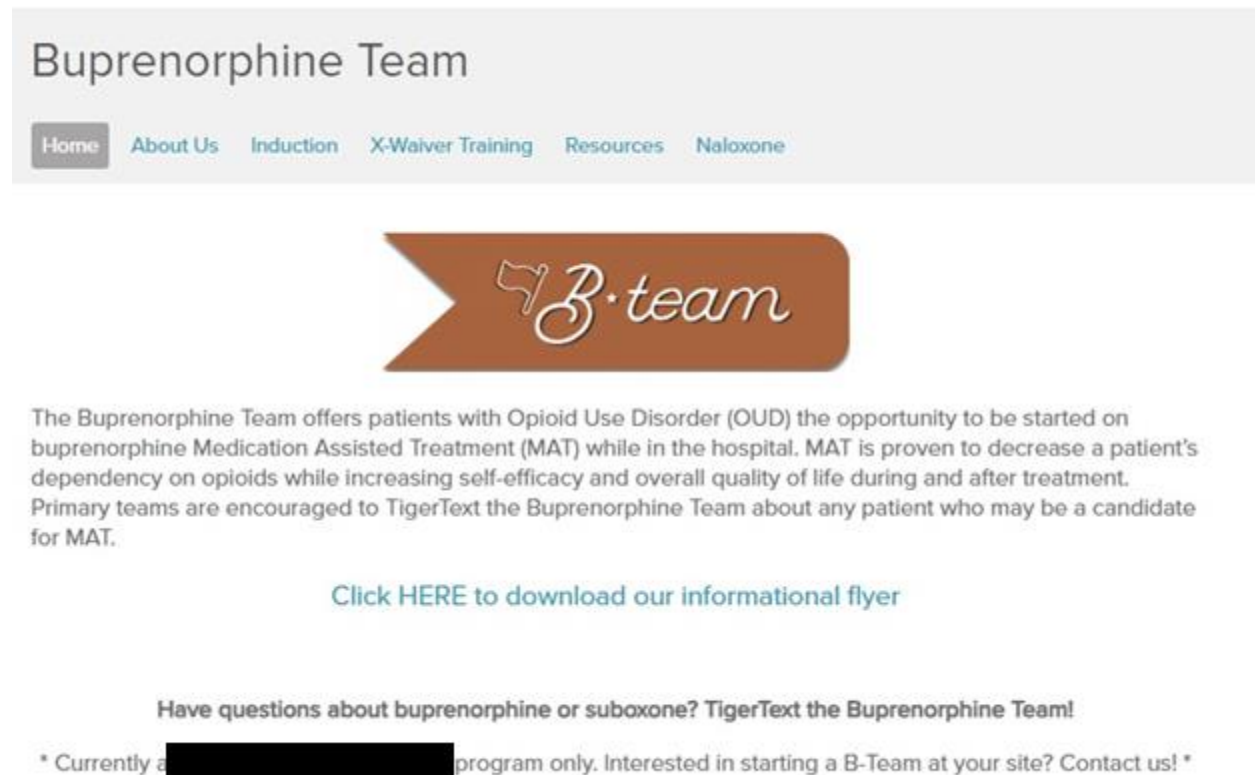


To place a B-Team consult, TigerText the "Buprenorphine Team". For specific questions related to the B-Team Program, please contact Rich Bottner via TigerText: [redacted]

Appendix 10


Internal Website

**Note: This document reflects early knowledge and contains language stigmatizing of patients with opioid use disorder which has been changed.*



Buprenorphine Team

[Home](#) [About Us](#) [Induction](#) [X-Waiver Training](#) [Resources](#) [Naloxone](#)



The Buprenorphine Team offers patients with Opioid Use Disorder (OUD) the opportunity to be started on buprenorphine Medication Assisted Treatment (MAT) while in the hospital. MAT is proven to decrease a patient's dependency on opioids while increasing self-efficacy and overall quality of life during and after treatment. Primary teams are encouraged to TigerText the Buprenorphine Team about any patient who may be a candidate for MAT.

[Click HERE to download our informational flyer](#)

Have questions about buprenorphine or suboxone? TigerText the Buprenorphine Team!

* Currently a [redacted] program only. Interested in starting a B-Team at your site? Contact us! *

[← Buprenorphine Team](#)

About Us

[Home](#) [About Us](#) [Induction](#) [X-Waiver Training](#) [Resources](#) [Naloxone](#)

The United States continues to face a public health crisis of epic proportion. Over 500,000 individuals have died from opioid overdoses since 2000. Medication-Assisted treatment (MAT), such as with buprenorphine, offers patients a comprehensive and effective approach to cessation. The B-Team is one of the nation's first programs to train and partner with primary teams in the inpatient setting to offer buprenorphine inductions on medical or surgical wards.

B-Team Mission Statement

To be an interprofessional group that screens appropriate patients for buprenorphine induction, assists with initiating treatment in hospitalized patients, facilitates linkage with an outpatient maintenance clinic, and provides institutional education in an effort to reduce stigma and raise awareness about opioid use disorders.

Why offer buprenorphine in the inpatient setting?

- › More likely to complete inpatient therapies
- › Improve societal functional including stable housing, meaningful employment, and fulfillment of family obligations
- › Increase abstinence from opioids after discharge
- › Reduce injection and illicit drug use in the community and in the hospital
- › Decrease bacterial bloodborne infections, including their sequelae such as endocarditis.
- › Reduce 30-day readmission rates for patients with Opioid Use Disorder
- › Decrease overall cost to the patient and healthcare system
- › Reduce HIV and viral hepatitis transmission rates

[< Buprenorphine Team](#)

Induction

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[B-Team Patient Education](#)

[B-Team Induction Algorithm](#)

[Nurse Quick Reference Guide](#)

[COWS Assessment](#)

[Pharmacist Quick Reference Guide](#)

[Precipitated Withdrawal](#)

[Lab Testing](#)

[Intake Form](#)

[Patient Responsibility Document](#)

[B-Team Resource Packet](#)

[\[REDACTED\] Program Summary](#)

[MAT Prescribers Accepting Insurance](#)

[← Buprenorphine Team](#)

Resources

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Online Media

Read our original *Society of Hospital Medicine* and follow-up blog posts!

[Overdose Deaths Set a Record Last Year. *New York Times*, November 2018](#)

[Addiction Treatment Gap Is Driving A Black Market For Suboxone, *NPR*, October 2018](#)

[A Medication-Assisted Therapy to Treat Opioid Abuse, *Austin Chronicle*, August 2018](#)

[This E.R. Treats Opioid Addiction on Demand. That's Very Rare., *New York Times*, August 2018](#)

[Moving Addiction Care to the Mainstream — Improving the Quality of Buprenorphine Treatment, *NEJM*, July 2018](#)

[Primary Care and the Opioid-Overdose Crisis — Buprenorphine Myths and Realities, *NEJM*, July 2018](#)

[How America's Doctors Can Help Beat The Opioid Epidemic, *Vox*, June 2018](#)

[When an Iowa Family Doctor Takes On the Opioid Epidemic, *New York Times*, June 2018](#)

[Opioid Addiction Drugs Severely Underutilized, *CNN*, June 2018](#)

[There's A Highly Successful Treatment for Opioid Addiction. But Stigma Is Holding It Back, *Vox*, November 2017](#)

[How The U.S. Has Been Working To Disrupt The Opium Trade In Afghanistan, *NPR*, November 2017](#)

[Hospitalist Involvement Needed To Treat Opioid Epidemic, *ACP Hospitalist*, October 2017](#)

[The Family That Built an Empire of Pain, *The New Yorker*, October 2017](#)

[How Do Former Opioid Addicts Safely Get Pain Relief After Surgery? *NPR*, April 2017](#)

References

[American Society of Addiction Medicine MAT National Practice Guidelines](#)

[Suboxone Medication Package Insert](#)

[Substance Abuse and Mental Health Services Administration MAT – Tip 63](#)

[← Buprenorphine Team](#)

Naloxone

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[Naloxone](#)

[Naloxone Risk Assessment](#)

[Suggested Order Sentences Operation-Naloxone](#)

[Let's Talk About Naloxone](#)

Appendix 11

Nurse Education Flyer

**Note: This document reflects early knowledge and contains language stigmatizing of patients with opioid use disorder which has been changed.*

Buprenorphine/Naloxone (Suboxone) Nursing Quick Reference Sheet

After screening, TigerText the Buprenorphine team.

The Buprenorphine Team (B-Team) offers patients with opioid use disorder (OUD) the opportunity to be started on buprenorphine/naloxone medication-assisted treatment (MAT) while hospitalized. MAT is proven to decrease a patient's dependency on opioids while increasing self-efficacy and overall quality of life during and after treatment. Primary teams are encouraged to TigerText the Buprenorphine Team about any patient who may be a candidate for MAT. The B-Team partners with outpatient clinics for continuity of care after the patient is discharged.

Indication	Medication Assisted Treatment for Opioid Use Disorder, opioid withdrawal, pain.
Mechanism	Buprenorphine - partial opioid agonist; naloxone - opioid antagonist (Prevents IV abuse. Not absorbed significantly orally.
Adverse Effects	Mild risk for over-sedation, potential to induce withdrawal, hepatic injury (rare)
Monitoring	Clinical Opiate Withdrawal Scale (COWS) or 'opioid cravings'; LFTs (performed prior to start of induction), urine drug screens (frequency/need determined by medical provider)
Documentation	Must document COWS score (similar to CIWA) or 'opioid cravings' in MAR comment each time a dose is administered. COWS assessment, when indicated, must be documented on the paper COWS form. COWS assessment versus 'opioid craving' will be determined by medical provider based on whether patient is still in acute withdrawal (based on timing of last opioid use.) The nurse will be notified of which assessment tool to use.
Administration	<p>Buprenorphine/naloxone is administered sublingually. Place one film under the tongue, close to the base on the left or right side.</p> <p>If an additional film is necessary (based on COWS or 'opioid cravings'), place an additional film sublingually on the opposite side from the first film. Place the film in a manner to minimize overlapping as much as possible.</p> <p>The film must be kept under the tongue until the film is completely dissolved. Moistening the mouth with water prior to administration may help absorption. Patients should not eat or drink immediately after administration (-10 minutes).</p>
Additional Tips	<p>If the patient has acute need for pain medication and is receiving buprenorphine/naloxone, they will require higher doses of opioids as there will be competition at the opioid receptor. Ideally, the patient should NOT receive any opioids while on buprenorphine/naloxone unless absolutely necessary. Alternative analgesics (ibuprofen, acetaminophen, gabapentin, etc.) should be used whenever possible.</p> <p>Buprenorphine/naloxone will not compete with benzodiazepine receptors. Although, the combination may cause increased sedation. If there is any concern for illicit drug use while taking buprenorphine/naloxone, please contact the primary medical team or the B-team.</p>

The B-Team is an interdisciplinary group that includes physicians, advanced practice providers, nurses, social workers, case managers, and pharmacists. To refer a patient, TigerText the "Buprenorphine Team". For questions about the B-Team Program, please contact Rich Bottner via TigerText or [REDACTED]

Appendix 12

Pharmacist Education Flyer

**Note: This document reflects early knowledge and contains language stigmatizing of patients with opioid use disorder which has been changed.*

Buprenorphine/Naloxone (Suboxone) Pharmacist Quick Reference Sheet

B-Team Program	The Buprenorphine Team (B-Team) offers patients with opioid use disorder (OUD) the opportunity to be started on buprenorphine/naloxone medication assisted treatment (MAT) while hospitalized. MAT is proven to decrease a patient's dependency on opioids while increasing self-efficacy and overall quality of life during and after treatment. Primary teams are encouraged to TigerText the Buprenorphine Team about any patient who may be a candidate for MAT. The B-Team will partner with Dove Springs Clinic for continuity of care after the patient is discharged.
Indication	Medication Assisted Treatment for Opioid Use Disorder, opioid withdrawal, pain
Mechanism	Buprenorphine – high affinity, partial opioid agonist; Naloxone – opioid antagonist (prevents IV abuse, not significantly absorbed orally)
Dose	See algorithm. Based on presence of withdrawal symptoms and timing of last use of opioids, patients will be placed on protocol driven by either COWS (Clinical Opiate Withdrawal Scale) or cravings.
Dose adjustments	Renal: None. Hepatic: moderate impairment – use caution; severe impairment – avoid use
Adverse effects	Mild risk for over-sedation, potential to induce withdrawal, hepatic injury (rare)
Drug interactions	CYP 3A4 substrate – caution with inducers and inhibitors; additive effects with co-administration of other CNS/respiratory depressing agents
Ordering prescribers	Ideally, B-Team providers will order inpatient, but any provider can order under current regulations. Outpatient prescriptions must be prescribed by prescribers who have received an x-waiver certification from the DEA.
Administration	Buprenorphine/naloxone is administered sublingually. Place one film under the tongue, close to the base of tongue on the left or right side. If an additional film is necessary (based on COWS or 'opioid cravings'), place an additional film sublingually on the opposite side from the first film. Place the film in a manner to minimize overlapping as much as possible. The film must be kept under the tongue until completely dissolved. Moistening the mouth with water prior to administration may help absorption. Patients should not eat or drink immediately after administration (~10 minutes).
Monitoring	COWS or 'opioid cravings,' LFTs (performed prior to start of induction), urine drug screens (frequency/need determined by MD)
Documentation	RN to document COWS in MAR comment and on paper COWS form
Floor PharmD action	1) Ensure SCOP has adequate supply for outpatient prescription until follow-up appointment; 2) counseling

After screening, TigerText the Buprenorphine team.

The B-Team is an interdisciplinary group that includes physicians, advanced practice providers, nurses, social workers, case managers, and pharmacists. To refer a patient, TigerText the "Buprenorphine Team". For questions about the B-Team Program, please contact Rich Bottner via TigerText or [REDACTED]

Appendix 13*Situation Background Assessment Recommendation Document for Pharmacy Department*

The Buprenorphine Team (B Team) is excited for the program launch tomorrow! Please see the SBAR below for additional information. I've also attached a Pharmacist Quick Reference, RN Quick Reference, COWS form, Induction Flow Chart, and a recent NEJM publication regarding buprenorphine utility in opioid use disorder.

Situation: Up to 29% of hospitalized patients meet criteria for substance abuse disorder and only ~65% of these patients are identified by the care team. Although other chronic illnesses unrelated to the admitting diagnosis are often treated in the inpatient setting, opioid use disorder (OUD) is frequently not addressed and patient undergo medically supervised withdrawal (detox) while hospitalized. Medically supervised withdrawal has low retention rates for long term abstinence.

Background: Medication-assisted treatment (MAT) with therapies such as methadone and buprenorphine are proven to reduce mortality due to OUD. Methadone and buprenorphine prescribing is limited to providers who have completed additional training and have been granted an X-waiver. Until recently, there were no active X-waiver providers practicing at [Academic Medical Center].

Within the last year, an interdisciplinary group called the Buprenorphine Team (B Team) has developed protocols, created educational information, and conducted several outreach programs to initiate eligible patients on buprenorphine-naloxone in the inpatient setting with bridging to an outpatient opioid treatment program.

Assessment: As the opioid epidemic continues to grow, we are encountering more patients with OUD in the inpatient setting. At [Academic Medical Center], an interdisciplinary group called

the B Team will now be a resource to assist primary teams with buprenorphine-naloxone inductions.

Plan: Starting September 11th, the B Team will be accepting consults from primary teams regarding patients who have OUD and are interested in initiating therapy with buprenorphine-naloxone. The B-Team has partnered with [Opioid Treatment Clinic] to link patients to comprehensive OUD treatment once discharged.


Additional clinical pearls:

- One of the biggest risks with buprenorphine-naloxone is the potential for precipitated withdrawal. This is due to buprenorphine's high binding affinity at the mu opioid receptor which will "knock off" any other opioid at the receptor site. If a patient is not already in withdrawal, buprenorphine can induce withdrawal.
- If precipitated withdrawal does occur, additional doses of buprenorphine are typically required.
- Ideally, other opioids should not be used in combination with buprenorphine. As mentioned above, buprenorphine will dominate the receptor site due to its high affinity. If patients do experience acute pain, the daily dose of buprenorphine can be divided into TID dosing. Alternatively, opioids can be used in addition to buprenorphine, however, higher doses will likely be required.
- At [Academic Medical Center], our B-Team X-waiver prescribers include [REDACTED] and [REDACTED]. However, there may be additional X-waiver provider not associated with the B-Team program.


Appendix 14*Medical Executive Committee Slides*

**Note: This document reflects early knowledge and contains language stigmatizing of patients with opioid use disorder which has since been changed.*


What is Medication Assisted Treatment?

- Comprehensive approach to opioid abuse cessation including counseling and social support.
 - Reduce the risk of drug relapse, improves societal functioning, reduces the transmission of various infections, and decreases criminal activity.
 - Most think about methadone - highly-regulated medication that can only be dispensed by Addiction Medicine specialists in specifically licensed clinics.
 - But there are others...
- 


Buprenorphine

- Partial agonist, high affinity, slow disassociation
 - Ceiling effect
 - Less likely to cause adverse effects, including respiratory depression
- 


Buprenorphine

- Drug Addiction Act of 2000 (DATA 2000) and subsequent legislation, allows for physicians, physician assistants, and advanced practice nurses to prescribe buprenorphine, regardless of medical specialty or practice setting.
 - To prescribe, must complete “x-waiver” training.
 - 8 hours for physicians
 - 24 hours for PAs and APNs
 - Currently low adoption – 162 physicians, 67 NP, 16 PA
- 


Why Initiate Treatment In The Hospital?

- Patients with opioid use disorders cost the healthcare system a minimum of eight times more than non-opioid abusers.
 - More likely to be readmitted within 30 days of discharge.
 - Majority of patients with previous substance abuse will return to that behavior after discharge if treatment has not been initiated.
 - Buprenorphine induction in the hospital setting leads to increased completion of inpatient medical therapies and ultimate transition to outpatient substance abuse treatment.
- 


Buprenorphine Team Mission

- *To be an interprofessional and multidisciplinary group that works to screen appropriate patients for buprenorphine induction, assists in the starting of this treatment while patients are hospitalized, facilitates linkage with an outpatient maintenance clinic, and provides institutional education in an effort to reduce stigma and raise awareness about opioid use disorders.*
- 

Our Opportunity

- From October 2015 through September 2017, over 2,240 admitted patients at [REDACTED] carried a diagnosis of substance use disorder.
 - Over 100 patients were deemed candidates for methadone or buprenorphine treatment.
 - From October 2016 through September 2017, over 270 admitted patients carried a diagnosis of opioid use dependency.
 - Data only reflects behavioral health social workers.
- 

Summary of Process

- Associate recognizes need (or positive UDS) → primary team → TigerText "Buprenorphine Team" → psychosocial evaluation → clinical evaluation → [REDACTED] confirmation → induction → maintenance → [REDACTED] prescription → discharge → linkage
- 




Cutting Edge

- "For people with an opioid use disorder, medications present the most effective strategy... Given randomized clinical trial outcomes and observational analyses examining mortality, medication treatments, particularly, those using opioid agonists (eg, buprenorphine and methadone), should be a bedrock on which treatment is built... However, clinical strategies allowing physicians or nurse practitioners to work in teams to engage patients with the use of medications are not being implemented with the necessary urgency. A continuing national failure to ensure the accessibility of such treatment disgraces us in a time of tragedy."

Samet JH, Kertesz SG. Suggested Paths to Fixing the Opioid Crisis. *JAMA Network Open*. 2018;1(2):e180218. doi:10.1001/jamanetworkopen.2018.0218



Launching July 16 2018!

- Over 50 individuals part of the Buprenorphine Team
 - Physicians, Nurses, PAs, Pharmacists, Social Workers, Case Managers, Administrators
 - 
 - What you can do
 - Clinical and Stigma Reduction Education – NIH Grant
 - Refer patients – all inpatient service lines
 - Promote our intranet site: 
 - Questions?
- 

Appendix 15

All Hands Address

Note: Patient name below is an alias.

Good afternoon. My name is [omitted] and I am a [omitted] with the department of internal medicine. I am also a [omitted]. I've been a PA for five years but it wasn't until about 12 months ago, that I began realize substance use disorders, more specifically in this case opioid use disorders are a chronic relapsing medical condition.

Since 2000, we've lost over 50,000 patients to opioid overdoses. In the time it takes for me to speak with you today, we will lose another. Despite vast evidence that Medication-Assisted Treatment with agents like methadone and buprenorphine works, we are not using them. For the last year, I have had the privilege of leading an interprofessional team of passionate physicians, residents, nurses, social workers, and pharmacists to offer these life-saving medications to patients suffering from opioid use disorder in the hospital setting.

This is the story of our very first patient. Alvin is a 42-year-old man from [omitted] who was never really given a chance. His parents both had severe alcohol use disorder. At age 12, his parents encouraged him to skip school to sell marijuana in order to fund their drinking. As his parents began using various illicit drugs, Alvin turned to crack cocaine. A year later, he was arrested with enough drugs in his possession to justify a criminal charge for dealing.

Alvin spent the next 20 years in and out of prison. He had never been in a physical altercation, but now he needed to learn how to fight for survival. He had never been an artist, but now he taught himself to draw to pass time in solitary confinement.

I met Alvin when he was admitted to complete six weeks of IV antibiotics for his third bout of endocarditis. The previous two episodes were incompletely treated because he left hospital AMA – against medical advice, by his own wishes because, by his own admission, he sought to use street drugs because we were not adequately addressing his opioid use disorder.

One of the worst outcomes of a hospitalization is an AMA discharge. Imagine a patient with a life-threatening condition who is incompletely treated, not to mention the healthcare resources spent, some might argue wastefully. Alvin may have been two weeks into treating this infection for the third time, but his underlying disease was not.

At one point, just a few days into hospitalization, he snuck out of the hospital and used heroin from the street. There was discussion among staff about discharging him again against medical advice. That is likely what would have happened even a week earlier in our hospital and what happens every day at almost every hospital in America. Instead, the nurse called our team. When I arrived at the room, Alvin was pacing back and forth. Extremely nervous. Screaming at nurses. Cursing. Tearful. Agitated. He kept repeating, "I need a fix. I'm just going to leave. I can't stay here any longer."

I pulled up a chair and spoke with Alvin. Not like a patient but as a human. He would tell me later that was the first time in over 20 years that anyone in the medical system had done that. So together with the rest of our team, we initiated buprenorphine or Suboxone therapy.

Alvin made an incredibly positive turnaround in just a few short days. He was upbeat. Thinking about his future. For those who have been to [Academic Medical Center] you know in the patient rooms we those long couches by the window. Everytime you walked by the room he'd be looking out the window and jamming out loud to Led Zeppelin. He began opening up. Speaking about his troubled past. Wanting to do better for himself and his fiancé.

Alvin completed his entire inpatient medical treatment. Prior to discharge, he drew our hospital staff a picture of life before and after buprenorphine therapy.

On the bottom left, Alvin sits on a street corner in despair. Moving counter-clockwise, he drew the different masks of addiction because as he would say "every time you use you feel like a different person, and none of them are good." A similar sentiment shared with dice, and a stopwatch representing all the time that has ticked away because of oxycodone and heroin. But at the top left, beaming with radiance through the darkness of addiction, a possible solution.

For Alvin, that's buprenorphine. Based on his comorbidities, I am confident that if he had left without completing medical therapy, he would have died.

There are 2.5 million people in the United States with Opioid Use Disorder. Many will be admitted to the hospital at some point during their disease. Just as hospital-based clinicians actively treat chronic illness such as diabetes and heart disease, so to must we actively take steps to offer evidence-based therapies for this population; one that has been stigmatized and underserved for far too long.

If I sound passionate about this it's because I am. A year ago I admit I was part of the problem but now The Buprenorphine Team as were called at the hospital is part of the solution. And the medication that we use, suboxone, can be offered by any prescriber in any practice setting so I invite you to be part of the solution too.


Despite a plethora of reasons to offer MAT on medical and surgical wards, there are a scant number of programs in the nation's 5,500 hospitals. And the only formal program that we know of in the entire state of Texas is at [omitted], leveraging the resources and expertise that we have at [omitted]. We hope to serve as a best practices model for how hospitals in Texas and throughout the country can rethink the treatment of opioid use disorders. Thank you for your time.



Appendix 16*Presentation to Process Improvement Council*

**Note: This document reflects early knowledge and contains language stigmatizing of patients with opioid use disorder which has been changed.*

Outline

1. What is buprenorphine and MAT?
 2. Why start buprenorphine in the hospital?
 3. How does the B-Team work?
 4. Activity, Call to Action
- 

What is Buprenorphine (Suboxone)?

- Partial agonist, high affinity, slow disassociation
- Ceiling effect
- Less likely to cause adverse effects, including respiratory depression
- X-waiver to prescribe as outpatient
 - 8 hours for physicians
 - 24 hours for PAs and APNs

Buprenorphine

Full agonists



“Dimmer effect”

Benefits Of Medication Assisted Treatment For Recovery

helping *reduce* cravings and withdrawal symptoms



Reduction In Drug-Related Overdose Deaths

Reduction In Disease And Violent Crimes

Improved Treatment Outcomes



Hospitalist involvement needed to treat opioid epidemic

Despite rising admissions related to opioid use disorder, few hospitalists are obtaining the expertise to prescribe medications for addiction. Experts say they should.

by Mollie Durkin



In increasing numbers, people with opioid use disorder are being admitted to the hospital with overdoses, infections, or respiratory depression.

The data basically show that we're seeing it more and more in our emergency rooms and on the inpatient floors," said hospitalist Pooja Jagisetty, MD, MSc, a research investigator at the Ann Arbor Veterans Affairs Center for Clinical Management and Research. "As physicians treating this patient population, I think we're often left wondering what we're supposed to do in this situation, outside of just stabilizing the patient and treating their acute needs."

Addiction consultation services – linking hospitalized patients to outpatient addiction treatment

Paul Trowbridge^{1,2,3,4}, Zoe M. Weinstein⁴, Todd Kerensky⁴, Payel Roy⁴, Danny Regan⁴, Jeffrey H. Samet^{4,5}, Alexander Y. Walley⁴

¹Department of Medicine, Section of General Internal Medicine, Clinical Addiction Research and Education Unit, Boston University School of Medicine (BUSM), Boston, MA, USA

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³Department of Community Health Sciences, Boston University School of Public Health, 801 Massachusetts Avenue, Boston, MA, USA

Initiating Buprenorphine Treatment for Hospitalized Patients With Opioid Dependence: A Case Series

Joji Suzuki, MD,^{1,2} Jeffrey DeVido, MD,^{3,4} Inder Kalra, MD,⁵ Leena Mittal, MD,¹ Sejal Shah, MD,^{1,2} Jennifer Zinser, Bsc,¹ Roger D. Weiss, MD^{2,6}

¹Department of Psychiatry, Brigham and Women's Hospital, Boston, Massachusetts

²Harvard Medical School, Boston, Massachusetts

³Department of Psychiatry, University of California, San Francisco, California

⁴School of Medicine, University of California, San Francisco, California

⁵Department of Psychiatry, Albert Einstein Healthcare Network, Philadelphia, Pennsylvania

⁶Division of Alcohol and Drug Abuse, McLean Hospital, Belmont, Massachusetts

ACP Internet Weekly | OPICIDS | JUNE 19, 2018

Mortality in year after overdose lower with methadone or buprenorphine treatment

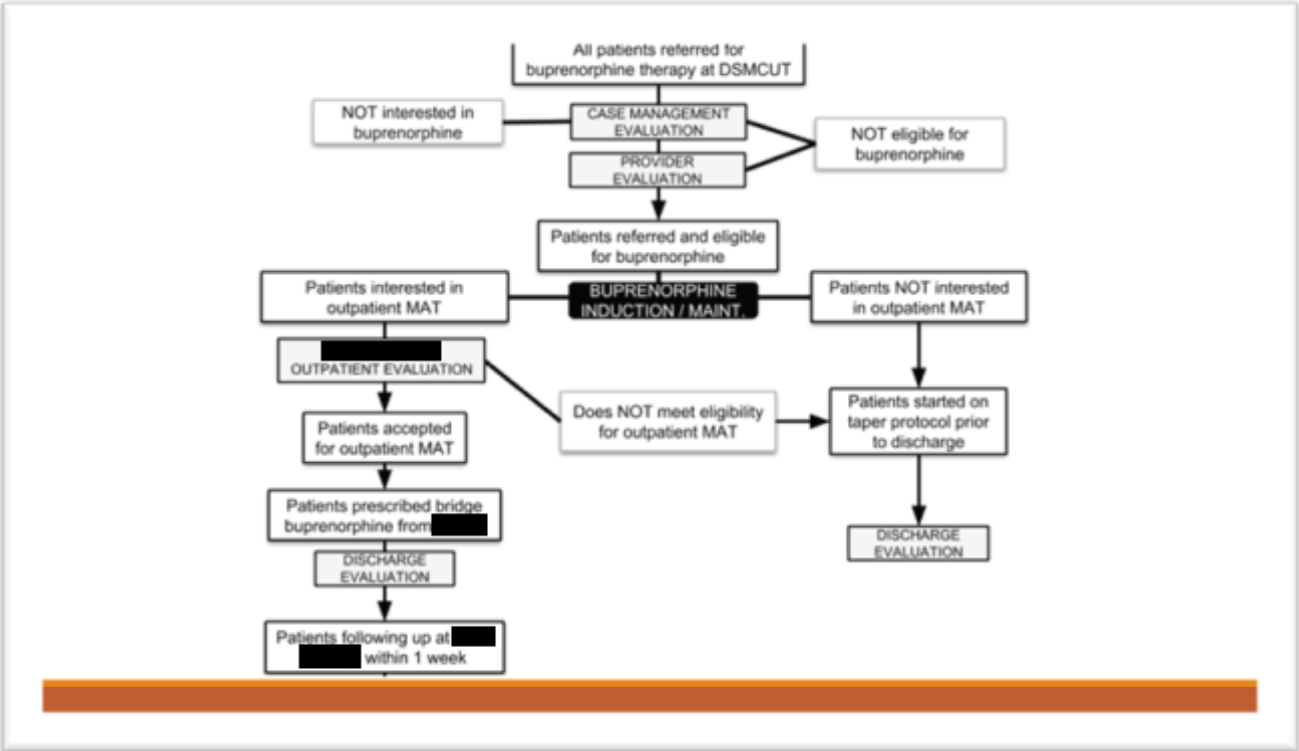
Compared with no medications for opioid use disorder, methadone and buprenorphine were each associated with decreased all-cause and opioid-related mortality.



What is the Buprenorphine Team?

An interprofessional and multidisciplinary group that works to:

1. **Screen** appropriate patients for buprenorphine induction,
2. Assists in the **starting of this treatment** while patients are hospitalized,
3. Facilitates **linkage with an outpatient** MAT clinic, and
4. Provides institutional education in an effort to **reduce stigma** and raise awareness about opioid use disorders.




Activity: Barriers to Care

- 25-year-old white woman with PMH of opioid use disorder involving intravenous heroin for 6 years, chronic hep C, and multiple hospital admissions for complications of endocarditis and sepsis, **admitted for altered mental status and sepsis.**
- TTE + tricuspid valve vegetations as well as severe tricuspid and aortic valve regurgitation. MRI brain + multiple acute infarctions of the frontal, parietal, and occipital lobes secondary to septic emboli.

Overcoming Barriers to Initiating Medication-assisted Treatment for Heroin Use Disorder in a General Medical Hospital: A Case Report and Narrative Literature Review



Case continued...

- The cardiology service recommended surgical repair of the cardiac valves due to the patient's high risk of recurrent infections. However, the cardiothoracic surgeons were reluctant to perform this surgery due to the patient's active opioid use and nonadherence to medical treatments.
 - The patient's earlier hospital courses had been marked by suspected smuggling of contraband into the hospital, misuse of narcotics through her peripherally inserted central catheter (PICC) line, and frequent discharges from the hospital against medical advice.
- 

The primary team decides to start the patient on buprenorphine.

What are the barriers that we face at [redacted] in starting this medication?

TABLE 1. Barriers to Initiating Buprenorphine

<i>Organizational Barriers</i>	<i>Practitioner Barriers</i>	<i>Patient Barriers</i>
<p><i>Financial</i></p> <ul style="list-style-type: none"> (1) Lack of insurance and drug coverage for buprenorphine²¹ (2) Lack of payment for clinical and administrative resources^{17,20} <p><i>Administrative</i></p> <ul style="list-style-type: none"> (1) Lack of support staff, lack of institutional support, and frequent laboratory testing^{17,24,27} (2) Inadequate referral networks, and need to keep buprenorphine notes separately from other medical records^{33,37} <p><i>Government</i></p> <ul style="list-style-type: none"> (1) Limitation on the number of patients to whom a provider can prescribe buprenorphine³⁴ 	<p><i>Information</i></p> <ul style="list-style-type: none"> (1) Lack of knowledge and training about buprenorphine^{12,17} (2) Lack of access to an expert consultant^{17,29} <p><i>Beliefs</i></p> <ul style="list-style-type: none"> (1) Stigma that opioid patients are manipulative, demanding, and disruptive²⁸ (2) Concerns that patients will misuse their buprenorphine²⁴ (3) A belief that patients receiving buprenorphine require more office time for visits²⁴ (4) Concerns about attracting opioid-dependent patients to their practice²⁴ (5) Concern about drug enforcement agency audits²⁴ 	<p><i>Information</i></p> <ul style="list-style-type: none"> (1) Lack of education, knowledge, and interest about buprenorphine maintenance treatment^{12,17,18} <p><i>Beliefs</i></p> <ul style="list-style-type: none"> (1) Stigma and negative attitudes associated with opioid maintenance treatment^{18,28} (2) Lack of confidence in the effectiveness of buprenorphine maintenance treatment due to past negative experience¹⁹ (3) High treatment cost of buprenorphine^{17,20,21} <p><i>Patient characteristics</i></p> <ul style="list-style-type: none"> (1) Cocaine use and younger age²² (2) History of complicated inductions such as precipitated withdrawal²³ (3) Low motivation for change¹⁷ (4) Nonadherence with buprenorphine¹⁷

The Impact

"I wanted to share with you all that during the assessment, he became quite emotional, started crying to the point where he could not talk (not just tearful), and expressed a lot of gratitude for everything you all have provided there, for him. He acknowledged that he was so relieved to not have been kicked out after having been caught using in the hospital, but more importantly, it really seemed to be about his feelings, and almost disbelief, that 'they actually really care about me.' It was kind of heartbreaking, but very awesome that you all have made such an impact." -Sarah, LPC from [REDACTED]

Call To Action: Referrals!

TigerText the "Buprenorphine Team" if your patient...

1. Is dependent on opioids (heroin or illicit pill use), or expresses addictive behavior and interest in cessation
2. Has a length of stay \geq 72 hours

After screening, TigerText the *Buprenorphine team*.



Appendix 17

Improved and Destigmatized Program Collateral

B-TEAM



Inpatient Buprenorphine Initiation for Opioid Use Disorder

PROGRAM OVERVIEW

The Buprenorphine Team (B-Team) offers patients with Opioid Use Disorder (OUD) the opportunity to start buprenorphine treatment while in the hospital. Buprenorphine has been FDA approved to treat OUD since 2000 and is proven to decrease a patient's physical dependency on opioids while increasing self-efficacy and overall quality of life during and after treatment. Primary teams are encouraged to notify the Buprenorphine Team about any patient who may have a diagnosis of OUD.

WHY USE THE B-TEAM?

Opioid Use Disorder is a chronic, lifelong medical condition that can be effectively treated with buprenorphine. Buprenorphine is safe and cost-effective. Importantly, starting buprenorphine for interested patients during hospitalization facilitates increased completion of inpatient medical therapies and the ultimate transition to outpatient substance use disorder treatment. This program may provide definitive therapy for some of our most vulnerable patients and helps them to achieve meaningful societal contributions, such as employment, long-term housing, reducing infections associated with OUD, and decreasing subsequent drug use.

Our team can also help patients who are not interested in buprenorphine therapy, including counseling, resource navigation, and naloxone.

HOW DO I KNOW WHEN TO REFER MY PATIENT TO THE B-TEAM?

Any member of the care team can refer patients to the B-Team — the primary team as a whole is the point of contact with the B-team.

Look for the following signs:

- Patient is physiologically dependent on opioids (heroin or illicit pill use), or expresses interest in cessation of illicit opioids.
- Using opioids other than as prescribed and feeling sick when opioids are abruptly stopped are both signs of possible opioid use disorder.

The B-Team is an interdisciplinary group that includes prescribers, nurses, social workers, case managers, pharmacists, chaplains, and a peer support specialist. To refer a patient, TigerText the "Buprenorphine Team".

HOW DOES THE PROGRAM WORK?

A patient admitted to the hospital reports use of opioids and expresses fear or signs of withdrawing from opioids while in the hospital.

1. **Request a Consultation:** Any member of the primary team TigerTexts the "Buprenorphine Team"
2. **Patient Assessment:** The B-Team screens the patient for opioid use disorder and counsels on buprenorphine treatment. If the patient is interested, orders are placed for buprenorphine, and the nurse follows protocol to initiate the medication.
3. **Treatment Plan:** The patient will continue to receive buprenorphine while in the hospital, and will receive a prescription upon discharge to last through their first outpatient appointment. The patient will also be provided with care coordination and peer recovery support.
4. **Discharge and Outpatient Care:** The patient will receive ongoing buprenorphine therapy and will continue to have access to peer recovery support services as an outpatient.

COMMON MISCONCEPTIONS ABOUT MAT

• *MAT is replacing one opioid with another*

Although buprenorphine does activate opioid receptors to some extent, it provides a safer and standardized dose. It is also proven to reduce mortality in half while decreasing drug use, decrease hepatitis C and HIV transmission, and establish a stable foundation to improve a patient's quality of life.

• *MAT has high potential for diversion/misuse*

The potential for diversion is significantly lower than that of treatments for opioid use disorder. Buprenorphine in the outpatient setting is typically combined with naloxone, and administered buccally or sublingually. This makes it very challenging to achieve euphoria if misuse is attempted.

GUIDELINES AND TALKING POINTS

- Establish rapport with patients to discuss drug use in a comfortable, judgment-free setting.
- Ask open-ended questions that invite patients to tell their story and consider potential options alongside professional guidance.
- Use positive, patient-centered language to foster mutual trust and reduce stigma around opioid use disorder and MAT

CHANGING THE LANGUAGE OF ADDICTION**Say This**

- person with a substance use disorder
- person with an opioid use disorder
- person in recovery
- negative/positive result(s)
- addiction, substance use disorder
- drug or medication misuse

Not That

- addict, abuser, user, junkie, druggie
- oxy-addict, meth-head
- ex-addict
- clean/dirty (drug test)
- addictions, addictive disorders
- drug abuse

To place a B-Team consult, TigerText the "Buprenorphine Team".

Buprenorphine-Naloxone (Suboxone) Pharmacy Quick Reference Sheet

B-TEAM

The Buprenorphine Team (B-Team) offers patients with Opioid Use Disorder (OUD) the opportunity to be started on buprenorphine while in the hospital. Buprenorphine has been FDA approved to treat OUD since 2000 and is proven to decrease a patient's physical dependency on opioids while increasing self-efficacy and overall quality of life during and after treatment. Primary teams are encouraged to notify the B-Team about any patient who may have a diagnosis of OUD. The B-Team partners with outpatient clinics for continuity of care after the patient is discharged.

Indication	<ul style="list-style-type: none"> Moderate to severe OUD and opioid withdrawal (can also be used off-label for pain).
Mechanism	<ul style="list-style-type: none"> Buprenorphine - partial opioid agonist, binds to opioid receptors and reduces cravings. Naloxone - opioid antagonist, displaces opioids at receptor sites and prevents IV abuse.
Adverse Effects	<ul style="list-style-type: none"> Mild risk for over sedation. Potential to induce withdrawal. Hepatic injury (rare).
Documentation	<ul style="list-style-type: none"> When required, the COWS score (similar to CIWA) or opioid cravings should be documented in the MAR comment and on a paper form each time a dose is administered. NOT all patients will have a COWS or opioid cravings documentation required. This determination is made by the B-Team provider and will be discussed with the primary nurse to determine if this assessment is needed or if the patient can be started on scheduled dosing.
Administration	<ul style="list-style-type: none"> Buprenorphine-naloxone is administered sublingually and is poorly absorbed by the oral route. Place one film or tablet under the tongue, close to the base on the left or right side. If an additional dose is needed (based on COWS score), place film or tablet on the opposite side from the first dose. Place the film or tablet in a manner to minimize overlapping as much as possible. Film and tablets should not be chewed, cut, or swallowed. Films and tablets must be kept under the tongue until completely dissolved. Moistening the mouth with water prior to administration can help with absorption. Patients should not eat or drink immediately after administration (~10 minutes).
Monitoring	<ul style="list-style-type: none"> COWS is assessed with each dose of buprenorphine-naloxone and reassessed based on level of withdrawal by previous COWS score. Monitor sedation using validated scales per hospital policy. LFTs (performed prior to start of induction), urine drug screens (frequency/need determined by MD)).
Additional Tips	<ul style="list-style-type: none"> If the patient has an acute need for pain medication and is receiving buprenorphine-naloxone, alternative analgesics (ibuprofen, acetaminophen, gabapentin, etc) should be used whenever possible Ideally, the patient should not receive any opioids while on buprenorphine-naloxone unless absolutely necessary. Buprenorphine-naloxone will not compete with benzodiazepine receptors. Although, the combination may cause increased sedation If there is any concern of illicit drug use while taking buprenorphine-naloxone, please contact the primary medical team or the B-Team.

The B-Team is an interdisciplinary group that includes physicians, advanced practice providers, nurses, social workers, case managers, and pharmacists. For questions about the B-Team or for guidance on starting buprenorphine-naloxone **TigerText The Buprenorphine Team**.

Buprenorphine/Naloxone (Suboxone) Nursing Quick Reference Sheet

B-TEAM

The Buprenorphine Team (B-Team) offers patients with Opioid Use Disorder (OUD) the opportunity to be started on buprenorphine while in the hospital. Buprenorphine has been FDA approved to treat OUD since 2000 and is proven to decrease a patient's physical dependency on opioids while increasing self-efficacy and overall quality of life during and after treatment. Primary teams are encouraged to notify the B-Team about any patient who may have a diagnosis of OUD. The B-Team partners with outpatient clinics for continuity of care after the patient is discharged.

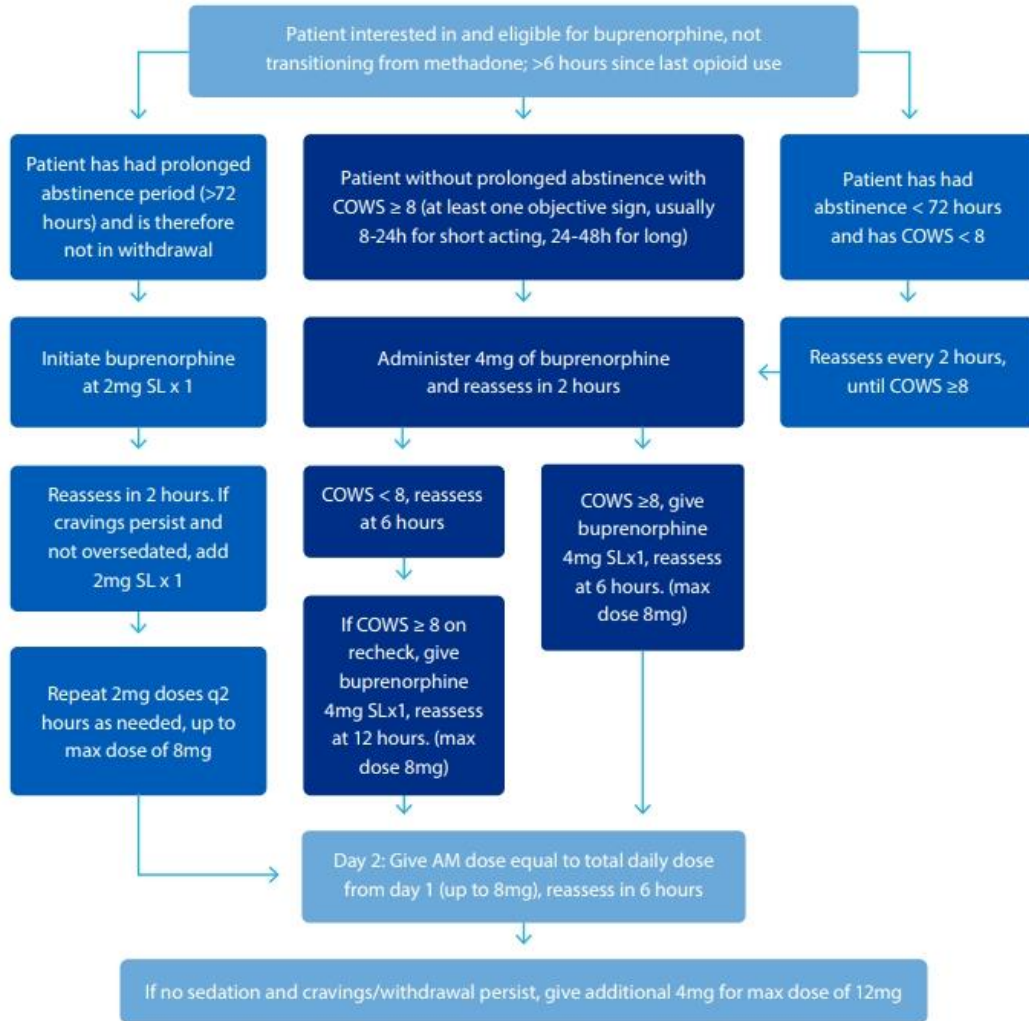
Indication	<ul style="list-style-type: none"> Moderate to severe OUD and opioid withdrawal (can also be used off-label for pain).
Mechanism	<ul style="list-style-type: none"> Buprenorphine – high affinity, partial opioid agonist, binds to opioid receptors and reduces cravings. Naloxone – opioid antagonist, displaces opioids at receptor sites and prevents IV abuse.
Dose	<ul style="list-style-type: none"> Per algorithm. Starting dose is based on presence of withdrawal symptoms and timing of last use of opioids. Subsequent dosing is based on assessment of withdrawal symptoms using Clinical Opiate Withdrawal Scale (COWS). Dosing for tablet versus film are not interchangeable.
Dose Adjustments	<ul style="list-style-type: none"> Renal: None. Hepatic (moderate impairment): Use caution. Hepatic (severe impairment): Avoid use.
Adverse Effects	<ul style="list-style-type: none"> Mild risk for oversedation. Potential to induce withdrawal. Hepatic injury (rare).
Drug Interactions	<ul style="list-style-type: none"> CYP 3A4 substrate – caution with inducers and inhibitors; additive effects with co-administration of other CNS/respiratory depressing agents. Recent use of opioid agonists, including heroin, increases the risk of withdrawal upon initiation of buprenorphine.
Ordering Prescribers	<ul style="list-style-type: none"> Inpatient: the B-Team provider will typically order, though any provider can order under current regulations. Outpatient: prescriptions must be prescribed by prescribers who have received an X-waiver certification from the DEA.
Administration	<ul style="list-style-type: none"> Buprenorphine-naloxone is administered sublingually and is poorly absorbed by the oral route. Place one film or tablet under the tongue, close to the base on the left or right side. If an additional dose is needed (based on COWS score), place film or tablet on the opposite side from the first dose. Place the film or tablet in a manner to minimize overlapping as much as possible. Film and tablets should not be chewed, cut, or swallowed. Films and tablets must be kept under the tongue until completely dissolved. Moistening the mouth with water prior to administration can help with absorption. Patients should not eat or drink immediately after administration (~10 minutes).
Monitoring	<ul style="list-style-type: none"> COWS is assessed with each dose of buprenorphine-naloxone and reassessed based on level of withdrawal by previous COWS score. Monitor sedation using validated scales per hospital policy. LFTs (performed prior to start of induction), urine drug screens (frequency/need determined by MD).
Floor PharmD Action	<ul style="list-style-type: none"> Patient counseling. Just-In-Time education as needed for members of the primary care team. Ensure patient has adequate medication supply between discharge and follow-up outpatient appointment.
Additional Tips	<ul style="list-style-type: none"> If the patient has an acute need for pain medication and is receiving buprenorphine-naloxone, alternative analgesics (ibuprofen, acetaminophen, gabapentin, etc) should be used whenever possible. Ideally, the patient should not receive any opioids while on buprenorphine-naloxone unless absolutely necessary. Buprenorphine-naloxone will not compete with benzodiazepine receptors. Although, the combination may cause increased sedation. If there is any concern for illicit drug use while taking buprenorphine-naloxone, please contact the primary medical team or the B-Team.

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Inpatient Management of Opioid Use Disorder: Buprenorphine/Naloxone

B-TEAM

BUPRENORPHINE INDUCTION ALGORITHM



*SL = sublingual

**Day 1 max dose may surpass 8mg by provider order, up to max dose of 16mg.

• Document COWS score and evaluate for sedation at each check.

• With each check, consider increasing dose if cravings or withdrawal are present. Decrease if sedation or RR < 8 is present. The goal is for patient to have no sedation, but also no cravings or withdrawal on their final dose.

• Many patients will ultimately be on 16-24mg, however they may not reach this dose while hospitalized and can finish the induction outpatient.

This project is funded by Texas Health & Human Services Texas Targeted Opioid Response.