Barriers and Opportunities to Opioid Use Disorder Medication Access in the Primary Care Setting

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Introduction

Opioid use disorder (OUD) remains a significant public health challenge throughout the United States, and effective treatment is crucial to reducing opioid-related mortality. Medications to treat OUD (MOUD), such as buprenorphine and naltrexone have demonstrated efficacy but are underutilized, especially in non-substance use disorder settings like primary care. To address this gap, our project has aimed to assess current barriers to primary care providers prescribing MOUD and identify opportunities to help improve access to these medications.

My interests in this area of medicine were informed throughout my observations in a period in which prescription opioids and synthetic non-prescription opioids have impacted so many lives, especially growing up in a rural community. I was thoroughly intrigued by the intersection between culture, politics, personal beliefs and medicine but also grappled with my own biases of addiction and the people afflicted. I sought answers to many of the questions and cognitive dissonance I was experiencing. It was in two books, Dreamland by Sam Quinones and The Weight of Air by David Poses that I found a vision and a mission.

My vision is one in which everyone with OUD can comfortably discuss their challenges without fear of persecution and have access to the tools they need to live their best lives without compromise. Throughout my readings of David Poses, who wonderfully wrote about his own mental health and addiction struggles as well as society's failure to address these issues for many others, I continuously thought of the strong, long-term relationship needed for this type of care. A type of care that I believe is well-suited for primary care physicians who not only know their patient's medical history

but also their environment as well as their social and community contexts in which they live. Moreover, primary care is the entry point for healthcare for so many people. As someone who wants to work on the front lines of medicine, I believe it is essential that part of that front line is addiction medicine if we want to make an impact on this front.

Literature Review

The drug class focused on in this project are the opioids. As a drug class, opioids include natural opiates, semi-synthetic opioids and fully synthetic opioids. Natural opiates include drugs like opium poppy, morphine, and codeine. Semi-synthetic opioids include heroin, hydromorphone, hydrocodone, and oxycodone (Oxycontin). Oxycodone is historically known as the main driver of the first wave of the opioid crisis with overprescribing accelerated by the onset of pain being considered as the “fifth vital sign,” an idea pushed by the American Pain Society in the 1990s [1]. In the 2010s, when prescription opioids like oxycodone became less available, people who were then dependent on opioids were left to use illicit opioids, most commonly heroin. Fully synthetic opioids include but are not limited to fentanyl, levorphanol, methadone, buprenorphine and tramadol. Used for its potency being 100x more potent than morphine [2, 3], fentanyl began emerging as an adulterant of many other drugs in the mid-2010s [4] and quickly became the number one cause of drug-involved overdose deaths nationally according to the National Center for Health Statistics.

Disordered use of these and other drugs is described in the 5th edition of the diagnostic and statistical manual of mental disorders (DSM-5) as a pattern of substance use leading to clinically significant impairment meeting at least 2 of 11 described criteria [5]. Specific diagnoses are for specific drugs, as in Alcohol Use Disorder, or relating to

this project, specific drug classes, as in Opioid Use Disorder (OUD). Addiction to opioids is largely due to their strong reinforcing abilities with uses including analgesia, anxiolysis and euphoria. However, the constant threat of withdrawal symptoms including pain, diarrhea, nausea and vomiting, anxiety and insomnia often drive continued use.

Once the diagnosis is made, treatment is guided by the American Society of Addiction Medicine's (ASAM) national practice guidelines with the gold standard including behavioral treatment facilitated by psychotherapy in addition to pharmacotherapy, often referred to as medication assisted therapy or MAT [6]. Pharmacotherapy options include buprenorphine, methadone or naltrexone. Naltrexone stands alone in pharmacotherapy options for OUD as an opioid antagonist blocking euphoric effects of these substances. Additionally, naltrexone can be prescribed in any clinical setting with no federal or state regulations. Buprenorphine is a partial opioid receptor agonist while methadone acts as a full agonist. Both medications prevent withdrawal symptoms and cravings for as long as 48 hours depending on the dosage. Significantly, in accordance with federal law [7], physicians, physician assistants, and nurse practitioners can provide buprenorphine but not methadone with regular outpatient prescriptions. While due to its partial agonism buprenorphine can precipitate withdrawal, when patients are properly treated, it has similarly efficacy as methadone in reducing mortality and decreasing rates of remission [8]. Despite the efficacy of these drugs, significant gaps in their access remain [9, 10], especially in rural America [11]. This includes findings that nearly 90% of people with opioid use disorder do not receive MOUD [9]. This is comparable to the lack of treatment in overall drug use disorder treatment described by the National Epidemiological Survey on Alcohol and Related

Conditions (NESARC) which showed only 13.5% of 12-month drug use disorders receive treatment.

The epidemiologic survey, Monitoring the Future funded by the National Institute of Drug Abuse (NIDA) shows that while opioid use has steadied over the years, overdose deaths continue to increase [12]. Due to the increasing toll of opioid-related deaths and the efficacy of MOUD, there have been numerous attempts to increase their access. In January 2023, congress passed the Consolidated Appropriations Act which nullified the X-waiver [13], legislation which was implemented in 2000 authorizing outpatient use of buprenorphine for treating OUD but required specific training for physicians to prescribe an essential medication for OUD. In February 2024, Substance Abuse and Mental Health Services Administration (SAMHSA) extended a COVID-era rule allowing buprenorphine prescriptions via telehealth without an initial in-person exam which became effective April 2, 2024. Efforts to utilize primary care physicians in a post-X-waiver world showed that while the X-waiver nullification was a great advancement, there remained significant systemic barriers to widespread access [14, 15]. Despite these efforts, investigations of the remaining barriers have shown both patient and provider barriers to be quite consistent [16]. Fear of stigma, logistical and structural challenges and gaps in provider knowledge remain the greatest challenges to improving access to MOUD. Specifically, perceived lack of training and experience, perceived lack of psychiatric co-management and low patient interest or responsiveness are commonly referenced barriers.

It is our belief that reducing these challenges and gaps in the primary care setting will improve access to life-saving medications. However, downsides to this strategy do

exist. First, primary care providers can offer limited counseling to pair with pharmacotherapy in the primary care setting considering the gold standard of OUD treatment is MAT therapy. While PCPs can offer pharmacologic intervention, attaining gold standard treatment will continue to require a multidisciplinary approach including specialists. Secondly, despite their connection to patients offering an ideal access point for people with OUD, provider work overload is a significant consideration [17]. It's important to disclose that while these limitations are noted, we continue to believe in building partnerships to fill these gaps will be successful in improving access to MOUD.

Despite the barriers and downsides to these strategies, we know they can work [14, 18]. Although, their role in enhancing access may require further integration into addiction services for retention [19], partnership building will push us forward. There are many questions about how this happens that remain. What role do physicians, physician assistants and nurse practitioners want to have? How much of a role do providers already have? For those who want more involvement, what do they need to prescribe MOUD or establish partnerships to improve care? Do they need help with the process of flowing people into MAT clinics? Do they want education in the form of workshops? These questions need answers to generate change. By understanding these obstacles and provider needs in a post-X-waiver environment, we can develop targeted interventions to improve OUD treatment delivery and enhance patient outcomes. Addressing these points will help promote evidence-based care and reduce the burden of OUD in our communities.

Methods

To identify barriers and opportunities in prescribing MOUD in the primary care setting, we conducted an online Qualtrics survey among primary care providers including physicians, physician assistants, and nurse practitioners, all of whom are eligible to possess a valid DEA registration and prescribe FDA-approved MOUD including buprenorphine. Qualtrics surveys are produced and distributed at zero cost with no additional resources required for this project. No demographic, geographic or hard descriptive collection or analysis were collected with no IRB-approval required (Appendix 1 – IRB-determination Form).

Initially, this survey was conducted to explore their current practices, attitudes and perceived challenges regarding prescribing MOUD (Appendix 2). Question one aimed to identify whether practitioners are doing risk assessments to identify patients at greatest risk for misuse or abuse to target harm mitigation strategies. The second question of the survey was to assess the practitioners' comfort discussing general harm reduction strategies for people who use opioids with the concern that while practitioners may not be comfortable with prescribing medications, discussion with patients to reduce or prevent complications of their use is essential to providing quality care. Our third question was to identify a relative percentage of primary care practitioners who have a current DEA registration who have authority to prescribe MOUD in a post-X-waiver landscape. Question four asked participants rate their comfort prescribing different MOUD which may allow us to focus future efforts on a medication with low comfort to begin to ask questions why providers prefer one over another. If practitioners are authorized to prescribe and they have some level of comfort, the fifth and sixth questions were intended to quantify how often practitioners are writing for these

medications. The last four questions were free responses allowing practitioners to write what factors facilitated their prescribing MOUD, what barriers there are including the single biggest barrier and then offer practitioners an opportunity to share what can be done to support them in this context. These free responses were intended to be tremendously important to identify opportunities to relieve perceived challenges and will guide future outreach. However, after immense discussion and thought, survey questions numbers 1,2 and 7 were removed with the goal of focusing on questions to those pertinent to our goals and to reduce survey time burden overall (Final survey can be found in Appendix 3).

Our survey was distributed myself through personalized, targeted email encounters with a goal of 100 responses. Initially, we proposed distribution through specialty organizations including but not limited to the American College of Physicians (ACP), American Academy of Family Physicians (AAFP) and American Academy of Pediatrics (AAP). It became clear that widespread dissemination through these societies was either not feasible or required a much greater burden of requirements including fees that I could not attain. Targeted email encounters were the only dissemination strategy taken for this project. Regional and critical access hospitals (CAHs) throughout Iowa, Illinois, Wisconsin, Missouri and Minnesota were targeted. Critical Access Hospitals were identified through the Flex Monitoring Team's National CAH Quality Inventory and Assessment National Report. Contact points for CAHs and regional hospitals included CEOs (42), CMOs (34), PR directors (15) and directories (39) with request for either a contact point or direct request for distribution to individual

primary care staff. When available, direct contact with staff including physicians, PAs and nurse practitioners was completed (157).

Given the nature of our survey questions and aims, quantifying the success of our project was a challenge. While every individual outgoing email has been documented, with uncertain dissemination after request for participation, a response percentage could not be obtained. With no demographic data, attempts at quantifying geographic outreach or demographic distribution of respondents are limited. Responses from free text Questions 4-6 were analyzed for common words or word strings utilizing an AI text analyzer. Despite minimal quantitation of this project, success to me has meant obtaining responses with several opportunities identified for improvement in access to MOUD at the level of practitioners out in communities.

Results

To date, Qualtrics has recorded 58 responses to our survey, just over half of our goal of 100 responses. Responses to Question 1 of “Have you completed 8 hours of accredited training or certification related to opioid use disorder treatment” resulted in 70% of respondents reporting having completed. For Question 2, of the four FDA-approved MOUD, responding practitioners were most comfortable with prescribing naltrexone with a mean comfort rating of 2.81 with scale of 1-5. Suboxone (buprenorphine/naloxone) was second among these medications in comfort with mean rating of 1.67 with a decline overall compared to naltrexone. Buprenorphine monoproduct had a mean comfort rating similar to methadone although most respondents rated their comfort 1/5. To Question 3, of the respondents, the majority of practitioners (62%) reported filling prescriptions for zero patients who have OUD

treatment while 38% had prescribed less than 100 times and 0% of respondents had prescribed more than 100 times for OUD treatment.

For Question 4, the most common themes from responses for respondents' top 3 barriers are, in order of most commonly occurring, training support, logistical/time constraints, lack of subspecialty support, patient perception and willingness and regulatory/efficacy concerns. The most common greatest barrier (Question 5) was logistical/time constraints. For question 6, the most common responses were education commonly requesting a focus on clinical application, workflow assistance to reduce time constraints and dedicated specialist help.

Analysis

From these responses it is clear that although the majority of primary care practitioners are able to prescribe these medications, their comfort in prescribing them remains low in their practice. This low comfort appears to originate primarily from a perceived lack of education and experience. Although our sample size is small, this data of barriers is consistent with established literature in an X-Waiver era suggesting we have yet to see a shift in provider behavior in these primary care respondents.

Additionally, although practitioners were most comfortable with the non-FDA controlled MOUD, naltrexone, this medication has historically been challenged by the requirements of initiation including being completely opioid-free for 7-10 days. This has resulted in increased relapse rates compared to buprenorphine although once initiated, patients have similar relapse rate outcomes to buprenorphine [20]. This of course

leaves room for education on initiation and maintenance of buprenorphine whether that be with buprenorphine monoproduct or suboxone.

However, even if this educational barrier was alleviated with CME, workshops or direct mentorship, the task of overcoming logistical and time constraints remains. To me, this means that in order to improve access to MOUD for people with OUD through shifting primary care provider behavior, we must lower the logistical barriers whether that be with helping make streamlined workflows with standardized protocols or health information technology or helping develop protocols that utilize team-based approaches to handle specific aspects of OUD management to lighten the load for providers.

Challenges & Lessons Learned

There were two major challenges to this project. The first major challenge was survey dissemination and obtaining responses. The second major challenge was data accuracy and representation with significant sampling bias and self-reporting bias. While these were big challenges to the project, we instituted many strategies to reduce these.

For the first challenge, we are aiming to survey very busy individuals which can lead to low rates for survey. I attempted to get over this with personalized invitations to the survey when possible as well as reminders. I relied heavily on others to disseminate these responses based on limitations in direct communication including no available email address or phone number. I additionally attempted to increase response numbers by simplifying the survey itself, but our low response numbers continued. I learned what the other side of the many survey requests I receive looks and feels like with an

important cause of my own. I learned the hard way the importance of incentives to increase responsiveness as well.

The second major challenge was data accuracy and representation. Although we had no intention of generalizing these results to a population at large, our survey is susceptible to both sampling bias and self-reporting bias. Moreover, we avoided collection of demographic or location data to simplify the survey in order to see demographic variance to lower concern for sampling bias. Are practitioners that were less busy more likely to fill out the survey? Were CAH practitioners more likely than regional practitioners to respond? There are many questions and possibilities contributing to sampling error in this project reinforcing our intention to avoid generalization of these data. Moreover, it is difficult to overcome self-reporting bias. This project is less susceptible to self-reporting bias given respondents were tasked with providing answers based on their true practices and opinions rather than general practice questions that would lead respondents to report what they believe they are expected to report. Additionally, my outreach email was clear to the survey's purpose and benefits which would hopefully reduce this bias as well. Overall, I learned to cast as wide of a net as possible and always consider these biases.

Sustainability

My hope for this project was to build a foundation for future projects with those identified opportunities. There have been two major opportunities identified including primary care practitioner-focused training with a focus on clinical practice and disseminating standardized protocols leveraging EHR tools and team-based approaches to reduce logistical/time constraints for providers. Through discussions with

students in various student interest organizations including those in psychiatry, harm reduction alliance, internal medicine and family medicine there have been multiple students who have stepped forward with strong interest and passion in pushing these forward.

Personal Reflection

In my introduction I talked about my path to this project being partially laid by my own reflection of my own biases and my discomfort with those biases. Through this project, I have found myself becoming more aware of the impact each provider has on those in this underserved population of people. As one of those future providers, I found myself striving to be more empathetic, seeing myself as an advocate for people with substance use disorders and committing myself to providing compassionate, evidence-based care. One of the main reasons I entered medicine was the ability to continuously expand my knowledge as well as develop and learn new skill sets. Over the course of this project, I have found myself ever more motivated to be, in the words of several respondents, be “a champion” for initiatives that I am passionate about. I was reminded that I’m never satisfied with the status quo, and medicine holds many opportunities to live the goal of improving medicine and people's lives. This project made me reflect that as much as I want to provide that care to this population, there are barriers that are challenging to overcome and in order to see a change, I’ll have to be the change.

During my Substance Use Disorder clerkship, I worked with this population of people every day and all day mostly seeing people with OUD often with polysubstance use and often people without a stable home or job. Through those moments with those people and this project, my awareness of the impacts that marginalization and

discrimination have on them has heightened. I have focused on barriers that primary care providers have to prescribing these medications, but the barriers those with SUDs face to get treatment in addition to the fear of stigma are too much to conceptualize for myself. While I will never fully understand their plight, understanding the dynamics of these challenges and how that impacts their access to these medications has been essential to finding opportunities to help, at least from a point of access. During my clerkship, I often got a look into people's lives before and after suboxone and what an amazing opportunity we have to impact these people if we can get them the care they desperately need and deserve.

With that being said, I have always known that I wanted to be a leader in a community for people's health but this project has pushed me to work towards being a leader among my peers. I hope to match into family medicine with consideration of an addiction medicine fellowship afterwards. I plan to find any opportunity I have to advocate for these people and collaborate with others to create structural and cultural changes to promote understanding and support for individuals with OUD. I have no doubt that it will be deeply fulfilling and will enhance my professional and personal growth by continually challenging me to be a more compassionate and effective physician. I will forever consider it a privilege to be a physician and even more a privilege to work with this vulnerable population hand in hand.

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Human Subjects Office / IRB

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October 15, 2024

TO: Patrick Allen
Cmed-Pathology

FROM: Catherine Woodman, MD
IRB Chair or Chair Designee

RE: Not Human Subjects Research Determination

I have reviewed the information submitted with your project titled 202403292 Barriers and Opportunities to Prescribing Buprenorphine in Primary Care. I have determined that the project described in the application *does not* meet the regulatory definition of human subjects research and does not require review by the IRB, because it is a quality improvement project without the intent to generalize knowledge.

We appreciate your care in submitting this application to the IRB for review. If the parameters outlined within this Human Subjects Research application request change, re review and/or subsequent IRB review may be required.

Please don't hesitate to contact me if you have any questions. The Human Subjects Office can be reached via phone (319)-335-6564 or email irb@uiowa.edu.

****Important note for researchers conducting research in the University of Iowa Health Care domain:** Research involving a Quality Improvement\Quality Assessment component involving UI Health Care processes or data requires registration in UI Clinical Quality Safety and Performance Improvement Database. To register the research, use this link: https://webapps1.healthcare.uiowa.edu/CQSPIPIP/

Medications for Opioid Use Disorder

How often do you use a risk assessment tool when prescribing opioids or have a clinical suspicion a patient has opioid use disorder. (Opioid Risk Tool, Brief Risk Questionnaire, Current Opioid Misuse Measure)

- Never
- Sometimes
- Always

I am comfortable discussing harm reduction strategies with patients who use opioids.

- Strongly Disagree
- Disagree
- Neutral
- Agree
- Strongly Agree

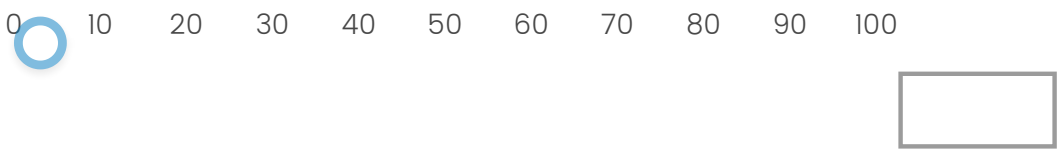
I have completed 8 hours of accredited training or certification related to opioid use disorder treatment.

- ○ No
- ○ Yes

Rate your comfort in prescribing the following with 0 representing not comfortable at all and 5 representing full comfort.

	0	1	2	3	4	5	
Buprenorphine Monoproduct	○						☐
Buprenorphine/Naloxone (Suboxone)	○						☐
Naltrexone	○						☐
Methadone	○						☐

Approximately what percentage of your practice is prescribing any FDA approved medications for opioid use disorder?



In the past year, approximately how many patients have you prescribed FDA approved medications for opioid use disorder?

- Zero
- Less than 100
- More than 100

If comfortable with prescribing opioid use disorder medications and is part of your practice, what factors positively contributed to the establishment of that practice?

What are your top 3 barriers to prescribing opioid use disorder medications?

What is your single biggest barrier to prescribing opioid use disorder medications?

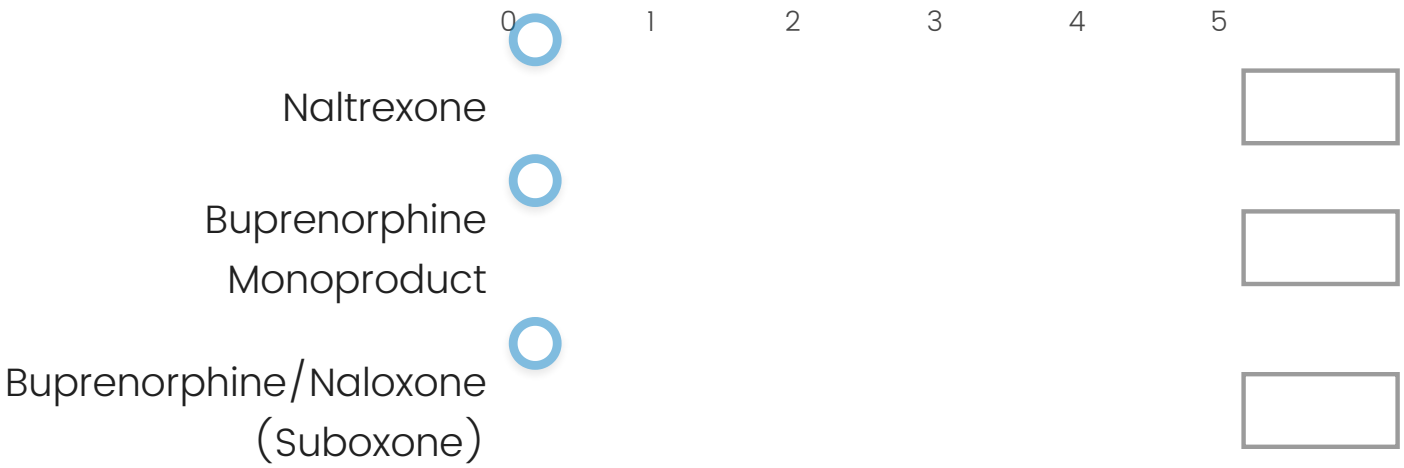
When considering the barriers above, what resources or support would enhance your comfort in prescribing opioid use disorder medications?

Medications for Opioid Use Disorder

Have you completed 8 hours of accredited training or certification related to opioid use disorder treatment?

- No
- Yes

Rate your comfort in prescribing the following FDA-approved medications for opioid use disorder with 0 representing not comfortable at all and 5 representing full comfort.



0 1 2 3 4 5

Methadone

Approximately what percentage of your practice is prescribing any FDA approved medications for opioid use disorder?

0 5 10 15 20 25 30 35 40 45 50 55 60 65 70 75 80 85 90 95 100

In the past year, approximately how many patients have you prescribed any of the above FDA approved medications for opioid use disorder?

- Zero
- Less than 100
- More than 100

What are your top 3 barriers to prescribing opioid use disorder medications?

What is your single greatest barrier to prescribing opioid use disorder medications?

When considering the barriers above, what resources or support would enhance your comfort in prescribing opioid use disorder medications?