use disorder: A qualitative study

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U.S. student pharmacist perceptions of the

pharmacist's role in methadone for opioid

and Gerald Cochran³

Abstract

Background: Of the over 20 million Americans reporting an opioid use disorder, only around 3 million report receiving treatment of any kind. The gold standard for opioid use disorder treatment is medication in combination with psychosocial support, but despite robust evidence supporting treatment, barriers are substantial and include limited insurance coverage, patient beliefs, ease of access, regulatory hurdles, and stigma. Although trained as medication experts, U.S. pharmacists are not routinely involved in opioid use disorder treatment and may represent an underutilized care team member.

Objective: To explore U.S. pharmacy students' perspectives on pharmacists as providers of methadone-based medications for opioid use disorder treatment.

Methods: A qualitative design with focus groups of student pharmacists in a U.S. college of pharmacy in the Southeastern United States.

Results: Over 2 months in 2020, three focus groups were conducted with 15 students in each group participating, and including second-, third-, and fourth-year student pharmacists. Three overarching themes emerged from the data: (1) student pharmacists desire exposure to therapeutic knowledge and lived experiences related to opioid use disorder and methadone treatment, (2) students perceive stigmatizing views held by practicing pharmacists toward opioid use disorder and methadone treatment, (3) pharmacists should play a role in methadone treatment.

Conclusion: Student pharmacists desire an active and larger role in the care of patients managing opioid use disorder. Findings indicate these students perceive less stigma toward opioid use disorder than currently practicing pharmacists. Pharmacy curricula should emphasize stories of lived experiences of patients with opioid use disorder, therapeutic knowledge and guidelines related to medications for opioid use disorder, and the regulatory environment surrounding opioid use disorder treatment.

Keywords

Opioids, pain management, community practice, pharmacist/physician issues, opioid use disorder, methadone, OUD, MOUD

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Introduction

Although the number of opioid prescriptions has declined in recent years, in 2019 an estimated 10.1 million Americans reported misusing prescription pain relievers, with an estimated 8%-12% continuing on to develop an opioid use disorder (OUD).^{1,2} Around 2 million Americans currently have OUD.¹ Restricting opioid supply has limited opioid availability and may have had an impact on prescription opioid death; however, drug overdose deaths due to both illicit and

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prescription opioids continues to be a staggering number, with 46,802 deaths in 2018.³ The gold standard for OUD treatment is medication in combination with psychosocial support, including methadone, buprenorphine, and naltrexone.⁴ Despite robust evidence supporting the efficacy of medications for OUD (MOUD), barriers to treatment are substantial and include limited insurance coverage, patient beliefs, ease of access, regulatory hurdles, and stigma.^{5–8}

Historically, in the U.S. OUD treatment is provided in specialized treatment centers, also known as opioid treatment programs (OTP). These are separate sites from primary care offices and are regulated differently than traditional care sites. These regulators include both the state and federal government, including the Substance Abuse and Mental Health Services Administration (SAMHSA). SAMHSA works in partnership with the Drug Enforcement Administration (DEA) to specifically regulate medication prescribing within these OTPs—restricting both prescribing and dispensing of MOUD to the OTP itself. This is notable as these regulatory restrictions limit both the prescribing and dispensing of MOUD to OTPs—a substantial hurdle for patient access.

Some improvements were seen with the Drug Addiction Treatment Act of 2000, which expanded MOUD access to certified providers (i.e. "DATA-waived") in traditional medical offices.⁹ Importantly, these "waivered" physicians are restricted to schedule III-V prescriptions (the U.S. Controlled Substance Act establishes special rules for prescription drugs which are commonly misused or abused-with five prescription "schedules" with schedule I being most prone to abuse or misuse and schedule V being the least); in effect, only expanding access to buprenorphine (given that extended-release injectable naltrexone is one of three Federal Drug Administration approved medications for OUD, but is not a scheduled substance), while continuing to restrict methadone use to OTPs. In an effort to further reduce barriers to OTP access, the Comprehensive Addiction and Recovery Act and Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities (SUPPORT) Act expanded prescribing of MOUD beyond physicians. This included permitting officebased opioid treatment prescribing of buprenorphine for Advanced Practice Registered Nurses (APRNs) and physician assistants (PAs) and increased treatment coverage for the Centers for Medicare and Medicaid Services (CMS) beneficiaries; although it also limited the number of patients each practitioner is permitted to treat.¹⁰

Despite these regulatory changes to increase overall access to MOUD, to date there have been no U.S. policy changes expanding access to methadone and so its access continues to be restricted solely to OTPs, sometimes called "methadone clinics." This is concerning because although there is an increasing number of individuals with OUD, the number of patients in treatment has remained constant.¹¹ Further exacerbating limited access to MOUD is the public stigma related to treatment—and in particular visiting the

OTP itself.^{12–14} This stigma is particularly seen with health care professionals and serves as both a barrier to referral and quality treatment.^{14,15} Moreover, research on overcoming stigma in the addiction crisis is underdeveloped.¹⁴

One untapped opportunity to support patients managing OUD is more fully incorporating the pharmacist into OUD treatment. In countries outside of the United States, the pharmacist's role in MOUD (also known as "opioid substitution") varies substantially, but many Western countries include provision of MOUD in community pharmacies.¹⁶ For instance, in Canada, New Zealand, France, and Australia the community pharmacist is an accepted provider of MOUD by both the lay public and other health care providers.^{16–20} In particular, these pharmacists serve to expand access to otherwise underserved patient populations-such as rural Canadians.¹⁸ Currently, a U.S. pharmacist's role is limited to dispensing buprenorphine to manage OUD in the community pharmacy setting, which is often accompanied with its own set of challenges.^{21,22} Because methadone may only be provided to patients through certified OTPs, the pharmacist's role has been even further limited, as few practice in this setting. Despite this, a recent study surveyed 104 medical professionals about their perspectives on pharmacists' roles in MOUD-results showed 58% favored adding pharmacists to the MOUD care team.⁷

Despite substantial limitations to care and the potential value of adding a pharmacist to the OTP treatment team, there is a lack of research on the pharmacist's role in this setting within the United States. Given the limited expansion of access to methadone-based MOUD specifically over the past few decades, it is of particular interest to understand what role, if any, pharmacists may play in treatment into the future. As the future of the profession, students in Doctor of Pharmacy programs in the United States represent an important population of interest—in particular because these students have different lived experiences of the opioid epidemic than their practicing pharmacist counterparts. Therefore, we aimed to explore U.S. pharmacy students' perspectives on pharmacists as providers of methadone-based MOUD treatment.

Methods

We used a qualitative design with focus groups of student pharmacists in a U.S. college of pharmacy in a Southeastern U.S. state. Focus groups were selected over in-depth, semistructured interviews to promote brainstorming and allow participants to build upon each other's ideas.²³ The University of Tennessee Institutional Review Board approved this study.

Contrary to the quantitative studies that are hypothesis driven, the qualitative research does not test hypothesis. The use of qualitative methodology to investigate pharmacy students' perspective on methadone may instead generate new hypotheses for future investigation.^{24,25} To this end, a semi-structured interview guide was used to facilitate the focus group sessions. A panel of experts in pharmacy practice and qualitative research developed the interview guide based on previously published theory and a previously administered survey that collected close-ended responses from the same student sample just before the interviews. This survey included a final question at the end of the questionnaire asking students if they would be willing to participate in a focus group to further discuss their perceptions and that an incentive of lunch would be provided. The study was based on theoretical elements from the Transtheoretical Model proposed by Prochaska, stigma proposed Link, and Phelan, and Social Cognitive Theory proposed by Bandura.^{26–28}

Two experienced University researchers trained in qualitative data collection led all focus groups over a period of 3 months in the spring of 2021 and subsequently coded results (A.C. and K.C.H.). The semi-structured strategy allowed the researchers a structure to ensure consistency across focus groups, while allowing for flexibility to incorporate additional questions raised from earlier discussions into the later focus groups, enhancing the external validity of the study findings.²³ Interviewers noted any biases, assumptions, and reasons of interest in the research topic via a written memo prior to data collection. Focus group sessions were recorded on-campus at the student's university and transcribed by a third party to avoid any biases. Given the homogeneity of the focus group sample and to best use participant time during the focus group session, demographic information was not collected. No repeat interviews were conducted. Field notes were also collected during group interviews to note non-verbal expressions and interactions and incorporated into the data analysis process.²⁹

Qualitative studies do not rely on large sample sizes to claim validity for the concepts generated. Sample size in qualitative studies has a different meaning than in quantitative studies and does not rely on power. A target sample size is four to six participants for each focus group or until detailed descriptions and rich themes emerge from the focus groups, therefore reaching a level of saturation.^{30,31} Saturation has been defined as a point beyond which no significantly new information is obtained.³²

Analysis occurred via a thematic analysis approach, as outlined by Braun and Clarke.³³ Recruitment continued until a point of saturation whereby no new themes emerged with subsequent focus groups.¹⁶ Transcripts were uploaded into qualitative analysis software (Dedoose, California, USA), which was used for generating initial codes and developing and reviewing themes. The research team used Lincoln and Guba's³⁴ criteria for demonstrating the quality of qualitative research to ensure the rigor of data collection and analysis. For example, each of the four criteria for trustworthiness were achieved at different stages of the data collection and analysis. In this study, the credibility criteria were obtained by audio recording, transcription, and analytical memos written during data analysis. Furthermore, the analytical memos were kept organized by Dedoose, an analytical software that allowed all the memos to receive a time stamp and be easily retrieved with the analyzed text.³⁴

Dependability criteria were obtained by careful documentation that occurred in the focus group process. Both researchers used reflective journaling and captured non-verbal responses during Focus Groups data collection.³⁴

Confirmability criterion was accomplished by careful documentation, intercoder checks, and the development of the codes. Intercoder checks refer to the codes being checked by another researcher. In this study, the codes were reviewed by two independent researchers. A third member of the research team assisted in the resolution of disputes during the thematic analysis process.³⁴

Results

Over 2 months in 2020, three focus groups were conducted with 15 students in total. All interviews were capped at 1 h in length. Participants included second-, third-, and fourth-year student pharmacists.

Three overarching themes emerged from the data: (1) student pharmacists desire exposure to therapeutic knowledge and lived experiences related to OUD and methadone treatment, (2) students perceive stigmatizing views held by practicing pharmacists toward OUD and methadone treatment, and (3) pharmacists should play a role in methadone treatment. The first theme, "student pharmacists desire exposure to therapeutic knowledge and lived experiences related to methadone treatment," centers on students desire for a holistic picture of OUD and subsequent treatment with methadone—including stories and perceptions of patients with OUD before and during treatment. The second theme presents the students' perspectives on stigma with the profession of pharmacy. The third theme relates to students' feelings about the current and future roles of the profession.

Theme 1: student pharmacists desire exposure to therapeutic knowledge and lived experiences related to OUD and methadone treatment

Students expressed that the current curriculum did not provide enough exposure to therapeutic knowledge related to treatment for OUD, and methadone specifically. Moreover, students felt that exposure to methadone treatment and OUD patients at practice sites was also limited.

... just interactions with patients who are currently going to methadone clinics are just really limited because we won't dispense the methadone for them. (Informant 1)

I don't really have much experience or knowledge in how methadone clinics really work . . . (Informant 2)

Students noted that faculty did not prioritize or emphasize methadone treatment, leading students to believe that it was not used or will be "phased-out" in the coming years. . . .the topic is always usually glazed over by professors where it's like, oh, this is running out of popularity. We're switching to different therapies as alternatives to stop opiate addiction. (Informant 3)

A holistic approach to teaching OUD treatment which centered on patients' lived experiences was suggested as a pedagogical model. Students felt that because of the uniqueness of this patient population, traditional teaching methods may not be as effective.

I think it was a very moving and powerful speech that he gave to us and as he was a pharmacist it something that we could all relate to because this is our profession. . . So I think if we had somebody that is a pharmacist that works regularly with these patients who are on methadone, I think it would be very helpful not just to educate, but to be able to relate to these patients that come in with opioid dependence. So it's not just like a blatant PowerPoint presentation on what methadone is, how it's treatment, how it's used. Something that's more relatable, I think it helps to influence a lot more students and not just in terms of what it's used for, but also how we should address this as either community or clinical pharmacists. (Informant 4)

Theme 2: students perceive stigmatizing views held by practicing pharmacists toward OUD and methadone treatment

Students were acutely aware of stigmatizing views held by health care providers, and pharmacists specifically, toward patients with OUD. Students suggested that the dual, conflicting role held by the pharmacist as both a regulatory enforcer and patient care provider served to promote stigma and, in some cases, stereotyping. Students noted that time constraints worsened this phenomenon by preventing pharmacists from appropriately assessing patients.

... during the pharmacy law course we learn about how it's so strict to be on methadone and how clinical you have to be to make sure that a prescription is valid or invalid when looking at it. The stigma of it in general is much higher [than other treatments] where we don't have to go through as many strict processes as it would be with a methadone clinic. (Informant 3)

We do have a lot of patients who go to the recovery clinics around our pharmacy and bring in their [opioid-related] prescriptions. There are some patients that I've seen on these prescriptions for the past three years. Some come and go. And then some people you can tell they're misusing it by how they're purchasing it. Whether it be a full cash price for the brand name, when you could do generic inexpensive [or something else]. (Informant 5)

Theme 3: pharmacists should play a role in methadone treatment

The final theme related to informants' views on the pharmacist's role in methadone treatment. Students described a pharmacists training as being aligned with the needs of this patient population.

. . .but just as knowing like the expertise that we as pharmacists have, I think we can add some values to a methadone clinic with our knowledge of drugs and interactions. . . (Informant 2)

I think that is a great niche that we can fill. And that's our job, to be the medication expert and to monitor. So, I think that would be a great route for us to take. (Informant 7)

However, students also felt that although there were immediate roles for the pharmacist to play in methadone treatment, the lack of provider status recognition on the part of federal and state policies represents the largest hurdle to placing pharmacists in this setting (because provider status is required for medical billing).

Methadone is notoriously known for its drug interactions, but. . . I don't know if you can justify a pharmacist's salary [without billing third party medical payers]. (Informant 1)

Beyond drug therapy expertise, students felt that pharmacists' accessibility is a facilitator of destignatization by increasing patient access to treatment.

I think the first step to destignatization is access. And, as we all know, pharmacists are the most accessible healthcare providers. For us to be able to help our patients, I think we need to be even more accessible to our patients who suffer from substance use disorders. And one way we could do that, I think, is through more collaborative practice agreements to be able to dispense [OUD treatment]. I think that would greatly increase our efficacy in our community so that we could help battle this disorder even more and help save more lives. I'm not exactly sure about how difficult it is to obtain a collaborative practice agreement, but I think in that case, if we were to obtain it more and be able to extend it to more pharmacists, I think that's the point that we can kind of jump off of and then help start affecting our communities a little bit more. (Informant 4)

Discussion

OUD affects millions of U.S. patients, but access to evidence-based treatment, such as with methadone through OTPs, is limited due to state and federal regulatory policies. Although its access is the most restricted of all MOUD, methadone continues to have an important role and offers distinct advantages over buprenorphine/naloxone and nal-trexone.^{4,35} Our exploratory study of student pharmacist perceptions of methadone in the treatment of OUD found that pharmacy students hold non-stigmatizing views of patients receiving methadone. Furthermore, these students believe there exists an opportunity for pharmacists to take on a larger role in methadone-based treatment in OTPs given their education and training.

OTPs have stringent federal mandate rules regarding patient's attendance to the clinic to receive the treatment, and public, patient, and provider stigma toward patients seeking MOUD may further serve as a barrier to methadone treatment. These patients are confronted with a variety of impediments to treatment access, yet patients continue to seek out such treatment in an effort to maintain their recovery.^{12,36} Findings from our study point to the fact that pharmacists may serve as facilitators for methadone-based treatment. Student participants were found to both (1) hold non-stigmatizing views of MOUD conducive to providing quality treatment, and (2) support expanding methadone-based MOUD to community pharmacy settings.

Reducing stigma through pharmacist-provided care to normalize treatment

Our study suggests that despite witnessing stigmatizing views toward MOUD held by patients and health care providers, student pharmacists themselves hold non-stigmatizing views. Participants felt that destigmatization starts with increasing overall access to methadone as a means for normalizing treatment. They suggested this is where pharmacists can play a major, future role in treatment via their ability to monitor therapy and assist in methadone administration.

Although, five states already allow pharmacists to administer and dispense controlled substances, scheduled II through V, they are not included as MOUD prescribers in the DATA waiver.³⁷ Participants in this study noted a need for collaboration with MOUD prescribers, potentially under a collaborative practice agreement, to allow patients better access to MOUD treatment.³⁸ Along with collaboration with prescribers, students noted that further exposure to MOUD treatment within the U.S. Doctor of Pharmacy curriculum is necessary—noting that immersion in the lived experiences of these patients would be preferential. This need has also been identified at colleges of pharmacy across the United States and has recently sparked a wide range of educational approaches to this end, some of which have been already reported in the literature.^{39–41}

Community pharmacies and expanded methadone treatment access

Although community pharmacies are not legally permitted today to dispense methadone, there may be a more immediate ability for pharmacist to practice within an OTP, or potentially even use their community pharmacy as a satellite-OTP for methadone dispensing. This idea of removing barriers to access, often called "low-threshold opioid treatment programs," has been shown to be safe and effective outside of the United States.^{42–44} Despite this evidence, however, the United States has been slow to adopt such policies. This is unfortunate as these "low-threshold" OTPs may be an especially impactful solution for patients living in rural areas. Patients in rural areas reported a travel time average of 60 min to the clinic and often patients must rely on public transportation and many must visit the clinic daily for treatment.^{45–47} With over 300,000 pharmacists in the United States and over 93% of the U.S. population being within 5 miles of a pharmacy, pharmacists can easily be argued as the most accessible health care professional.^{48,49}

This study had limitations, including dominant voices steering conversation. Subjects therefore may have been subject to social desirability bias especially in light of the highly polarized nature of the topic. However, given the fact that student themes were consistent across several focus groups with different participants and across several locations, this is likely of little concern. Furthermore, we cannot generalize the data considering this sample is from one specific university within one geographic area of the country.

Conclusion

Student pharmacists desire an active and larger role in the care of patients managing OUD. Findings indicate these students perceive less stigma toward OUD than currently practicing pharmacists. Pharmacy curricula should emphasize stories of lived experiences of patients with OUD, therapeutic knowledge and guidelines related to MOUD, and the regulatory environment surrounding OUD treatment.

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Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval

Ethical approval for this study was obtained from University of Tennessee Health Science Center Institutional Review Board (19-06977-XM).

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Informed consent

Verbal informed consent was obtained from all subjects before the study. Verbal consent was chosen because focus groups were held both in person and across the College's satellite campuses. Given that interviewees and interviewers were sometimes separated by distance, and because focus groups were recorded allowing for record keeping of verbal consent, it was deemed that alteration of consent would be necessary. An appeal was made to the Institutional Review Board (IRB) for alteration of consent based on local and federal IRB rules and was granted.

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Supplemental material

Supplemental material for this article is available online.

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