

Title

Indiana Community Pharmacist Preceptors' Knowledge and Perceptions of Medication-Assisted Treatment

Incentive Grant Category

Residents and their Preceptors

Project Description

This study aims to characterize the baseline knowledge and perceptions community pharmacist preceptors in Indiana hold regarding medication-assisted treatment (MAT) (i.e., methadone, buprenorphine products, and naltrexone). The significance of this study is reflected in the current and ongoing opioid epidemic in the United States. In 2017, more than 47,000 people died from a drug overdose involving an opioid.¹ Of these opioid overdose deaths in 2017, 1,118 were in Indiana alone.² Opioid overdose deaths have followed three key trends nationally starting with prescription opioids in the 1990s, heroin in 2010, and illicitly-manufactured fentanyl in 2013.¹ These national trends were observed in Indiana as opioid-related death rates rose from 4.5 per 100,000 people in 2008 to 17.2 opioid-related deaths per 100,000 people in 2017 and deaths related to synthetic opioids, including fentanyl, and multiple opioids have increased sharply since 2013.²

In response to this startling increase in opioid-related deaths, mechanisms for treating opioid use disorder (OUD) have become a national focus as it is vital that patients with OUD receive treatment in order to prevent overdose and death;³ effective treatment with strong scientific evidence is medication-assisted treatment (MAT).^{4,5} MAT is a combination of FDA-approved medications (methadone, buprenorphine products, or naltrexone), counseling, and cognitive behavioral theory. MAT is safe and effective when used appropriately, and MAT has significant treatment benefits by facilitating the opportunity for patients to improve their own health and functioning.³⁻⁶ In the United States, methadone used as MAT can only be accessed and provided through opioid treatment programs (OTPs).⁴ Buprenorphine products can be prescribed by a healthcare provider federally approved to manage OUD.^{4,5} Buprenorphine buccal and sublingual formulations may consist of buprenorphine alone or in combination with naloxone, a short-acting mu opioid antagonist.^{4,7} Buprenorphine formulations approved for OUD also include an implant and extended-release subcutaneous injection.^{4,8} Naltrexone can be prescribed by any healthcare provider. Naltrexone is available in an oral formulation, but only its extended-release intramuscular formulation is recommended for OUD.⁴

National attention regarding OUD treatment centers on improving access to MAT. In 2018, Indiana added five new OTPs and signed legislation to add nine more resulting in a total of 27 OTPs statewide serving over 15,000 Hoosiers. Since 2014, Indiana has had a 42% increase in addiction providers.⁹ With this ongoing national and Indiana statewide effort to expand access, MAT is being frequently used in the community setting. As readily accessible medication experts, community pharmacists are in a unique position to increase access to MAT by collaborating with healthcare providers treating addiction and providing optimal MAT-directed patient care and education.⁴

In many countries, pharmacists can dispense methadone from the community pharmacy and some have an expanded role beyond dispensing involving supervising daily patient methadone or buprenorphine administration. There is extensive existing research evaluating community pharmacists' role and perceptions regarding MAT internationally where pharmacists are more directly involved in MAT patient care. In Australia, studies evaluated community-based pharmacists' perceptions of dispensing and supervising dosing buprenorphine¹⁰ and methadone and/or buprenorphine for opioid substitution treatment.¹¹ A study in New Zealand evaluated an opioid substitution treatment online training for

community pharmacists; the online training showed improvements in pharmacist confidence and skills plus changes in attitudes.¹² In Scotland, a study evaluated community pharmacy managers' attitudes towards drug misusers and found that attitude was an independent predictor of providing services like selling syringes, dispensing methadone, and supervising methadone consumption.¹³ Another study in Scotland of community pharmacy managers found that care evolved from mainly supplying the drug to a broader more clinical approach in which pharmacists were engaged from 1995-2006.¹⁴ In Finland, a study looked at dispensing practices, service experiences, and problems for community pharmacists dispensing and supervising buprenorphine-naloxone directly to patients.¹⁵

In contrast, there is very little research evaluating MAT and community pharmacists in the United States. Existing research in the US focuses on how primary care-based treatment is effective and results in more access to treatment for substance use disorder but doesn't look at pharmacist involvement.¹⁶⁻¹⁷ In a study on pharmacists and pharmacy technicians involved in an office-based opioid dependence treatment program using buprenorphine-naloxone, the majority expressed positive attitudes and perceptions regarding patients treated in that setting.¹⁸ As the literature lacks evidence involving community practice pharmacists in MAT, evaluating community pharmacist preceptors may yield beneficial and applicable data to ensure optimal patient care and access to MAT for OUD. Preceptors are on the frontline of teaching student pharmacists; ensuring that preceptors are appropriately educated and without preconceived perceptions of patients with OUD will improve the MAT knowledge and perceptions of future pharmacists in order to provide comprehensive patient care for years to come.

By evaluating community pharmacist baseline knowledge and perceptions of MAT, this study aims to facilitate the creation of additional educational resources that will enable community pharmacists to provide optimal patient care for those utilizing MAT to treat OUD. The opportunity to evaluate existing knowledge and perceptions and create/provide pertinent resources aligns with the vision of the American Pharmacists Association (APhA) to create "opportunities for members and pharmacists... to optimize medication use." This study data and the resources identified from it will help to inform community pharmacy practice which helps APhA achieve its mission to provide pharmacists "timely relevant information... and resources" in order to provide medication-specific patient-centered care. With the opioid epidemic and OUD having such a large impact in American society, this study will also help APhA achieve its mission to raise "societal awareness about the role of pharmacists as essential in patient care for optimal medication use" specifically regarding impacting patient care through optimal MAT use. Since this study specifically evaluates pharmacist preceptors, the study may also impact opportunities for Indiana colleges of pharmacy to provide preceptor education in their program development thus improving the knowledge and perceptions of future pharmacists graduating from those colleges. Making a positive impact on students and activating student pharmacists to increase MAT access and patient education bolsters the mission of the APhA Academy of Student Pharmacists (APhA-ASP) "to provide opportunities for professional growth, to improve patient care, and to envision and advance the future of pharmacy."

Project Objectives

The objective was to characterize Indiana community pharmacist preceptors' knowledge, perceptions and desired resources on medication-assisted treatment (MAT) for opioid use disorder (OUD).

Methods

Population and participant recruitment

The study population consisted of pharmacists who were 18 years of age or older, English-speaking, maintained an active Indiana pharmacist license, had been in their current community pharmacy practice

setting for at least six consecutive months, and were active preceptors for Indiana based colleges of pharmacy. Participants were recruited by contacting experiential education directors at each Indiana college of pharmacy and obtaining buy-in from the three colleges to have them send email communications to the pharmacists listed as preceptors for experiential learning experiences in community pharmacy practice. The total number of eligible community pharmacist preceptors is unknown as these pharmacists may precept for more than one college. The study and study protocol were reviewed and approved at the exempt level by the Purdue University Institutional Review Board.

Survey development and administration

The 38-item survey was used to collect information on preceptors' knowledge and perceptions of MAT in the community pharmacy setting. Knowledge questions were based on Substance Abuse and Mental Health Services Administration (SAMHSA) Treatment Improvement Protocol (TIP) Series 63,⁴ American Society of Addiction Medicine (ASAM) National Practice Guideline,¹⁹ and Lexicomp Online.²⁰ All knowledge items utilized a multiple-choice/multiple-select format with "I don't know" as an answer option. Perception questions were developed through the application of the *social cognitive theory* as a conceptual framework with questions adapted from Raisch et al (2005),¹⁸ Friedmann et al (2015),²¹ and Knudsen et al (2011)²² with study investigator permission. The *social cognitive theory* describes the relationships between 3 constructs: behavior, personal factors, and environmental factors. The theory describes how people start and continue behaviors by emphasizing the relationship between people, their behavior, and their environments.²³ Four of the survey items were adapted from the 45 item total survey in Raisch et al (2005).¹⁸ Three of the survey items were adapted from the 67 item total survey in Friedmann et al (2015).²¹ One survey item was adapted from the 36 item total survey in Knudsen et al (2011).²² All perception items were rated on a 5-point Likert scale from 1 (strongly disagree) to 5 (strongly agree). The survey also included optional open-response, open-ended questions for additional comments and desired additional resources. The survey included pertinent questions about participant demographics.

To improve aptitude and clarity, the survey instrument was pilot tested by seven ineligible community pharmacists as they were not current pharmacy preceptors for Indiana colleges of pharmacy. This feedback resulted in minor modifications and the finalization of the survey instrument. The final survey contained 10 demographic questions, 9 knowledge questions, 16 perception questions, and 3 open-ended additional questions. For the final perception questions, the survey contained all 3 constructs of the *social cognitive theory* with 5 items measuring behavior, 6 items measuring personal factors, and 5 items measuring environmental factors.

Surveys were administered electronically. Community pharmacist preceptors were sent an email by their respective college of pharmacy for which they precept students which included the survey link. Indiana colleges of pharmacy sent an initial email invitation to preceptors in mid-February 2019. Repeat email invitations were sent every two weeks through the end of March 2019 for a six week total survey duration. To prevent duplicate responses, researchers used the Qualtrics feature that does not allow a specific internet provider (IP) address to complete the survey more than once. Participants provided waived consent prior to initiation of the survey. After completion of the survey, study participants were redirected to an optional web-based gift card raffle as an incentive for participation. The correct answers to the survey knowledge items were then displayed to participants for their reference.

Data analysis

Survey data were compiled using Qualtrics, an online survey software. Aggregate response data were analyzed using Qualtrics and Microsoft Excel. Descriptive statistics (percentages, means, and standard

deviations) were computed to summarize survey responses and respondent demographics. Text-based responses to open-ended items were assessed individually by the primary author to identify desired additional resources and/or training on MAT, worries or concerns about dispensing MAT in the pharmacy, and if/how these preceptors involve students in the MAT counseling process. All responses were included in final results.

Results

Participants

Of the 116 pharmacy preceptors who responded to the survey, 104 were eligible study participants (89.7%). Of the 104 eligible participants, 79 completed the survey yielding a 76.0% response rate. Respondents were mostly white, were equal rates male and female, held more than a Bachelor of Pharmacy degree, had 0-10 years of experience as a pharmacist in the community setting, worked in either a chain or grocery store pharmacy, precepted both Introductory Pharmacy Practice Experience (IPPE) and Advanced Pharmacy Practice Experience (APPE) students, had minimal education or training on MAT, worked in a pharmacy that dispenses MAT products, believed that addiction is a combination of a disease that can be attributed to a combination of environmental, genetic, and biochemical factors and a result of conscious behavioral and/or lifestyle choices, and did not have personal experience of any kind using MAT products for OUD (Table 1). Of the 79 participants who completed the survey, 66 entered the gift card raffle (83.5%).

Knowledge items

Table 2 includes descriptive statistics for community pharmacist preceptor knowledge survey items on MAT for OUD. About one-third of participants were able to correctly identify which MAT products are FDA-approved for OUD (32.6%). Only 2 participants correctly answered the question about which medications require an opioid-free interval before initiating (2.5%); 17 participants selected the “I don’t know” option (19.5%). It is true that buprenorphine may not be as effective due to its ceiling effect when comparing methadone and buprenorphine for the management of severe OUD; 37.0% of participants selected the correct response, but, of those that answered the question incorrectly, 43.2% selected the “I don’t know” option. While 65.4% selected the correct answer that it is recommended to continue methadone or buprenorphine for OUD if a patient becomes pregnant, an equal number of participants picked an incorrect option as selected the “I don’t know” option. Related to medication access, almost all participants selected the correct answer that buprenorphine requires a DATA 2000 waiver ("X" DEA number) to be dispensed for OUD (91.4%) and naltrexone can be prescribed for OUD by any licensed practitioner and dispensed by any pharmacy (81.5%).

Perception items

Table 3 includes descriptive statistics for community pharmacist preceptor perception survey items on MAT for OUD. These perception questions are categorized based on the associated *social cognitive theory* construct. For perception items related to behavior, participants reported to agree that buprenorphine (45.0% agree, 8.8% strongly agree) and naltrexone (41.3% agree, 6.3% strongly agree) are effective in helping patients achieve remission versus methadone (28.8% agree, 5.0% strongly agree) but the responses for neither agree nor disagree is high for all MAT products.

For perception items related to personal factors, the majority of participants responded either agree or neither agree nor disagree to feeling comfortable dispensing MAT and counseling patients with OUD (55.7% agree, 25.3% neither). To the survey item “Dispensing MAT does not align with my own personal and/or religious beliefs,” the majority of participants selected either strongly disagree or disagree (34.2%

strongly disagree, 45.6% disagree) and no one selected strongly agree. Most respondents selected either strongly disagree or disagree to the item “I have increased concerns about break-ins, theft, and pharmacy safety due to my involvement with dispensing MAT” (44.3% disagree, 24.1% strongly disagree). Half of participants agreed they were concerned about diversion and misuse of MAT products (49.4% agree) and no one selected strongly disagree.

For perception items related to environmental factors, more than half of participants reported they either strongly agreed or agreed that patients receiving MAT should be restricted to a single pharmacy (34.2% agree, 29.1% strongly agree). More than half of participants reported they agreed that pharmacists who dispense MAT should have specialized training (63.3% agree) with zero responses for strongly disagree.

Of the three optional open-ended survey questions, 36 respondents answered at least one open-response question.

Desired MAT resources

For desired additional resources or training on MAT for community pharmacists, 36 respondents reported they would like different kinds of continuing education. A common response related to wanting updates on efficacy of different MAT products and counseling points for patients. A variety of resources participants listed would be useful included “Training on what occurs at the cognitive sessions and how prescribers obtain their authorization to prescribe MAT products” and “Dose reduction schedules or timelines.”

Concerns about dispensing MAT

Regarding worries about dispensing MAT in the pharmacy, 36 respondents reported a variety of responses. One response related to safety stating “The biggest one is once they know I have it I become a prime target for robbery/theft which occurs a lot in my area. This leads to huge safety concerns for me and my staff.” Another respondent said “Diversion of products” while another said inventory was a worry stating it is “Hard to keep all forms of all drugs in stock at all times.” Other participants stated they had no concerns.

Precepting and MAT counseling process

For respondents who dispense MAT in their pharmacies, 31 respondents described if they involve students in the MAT counseling process and how they do so. Responses ranged from involving APPE and IPPE students directly, indirectly involving students, and not involving students in this aspect of patient care while on rotation.

Discussion

Much of the existing literature addressing community pharmacists’ attitudes and perceptions of MAT for OUD exist in other countries where methadone and buprenorphine are dispensed from retail pharmacies and pharmacists supervise the administration of these drugs, whereas community pharmacists in the United States cannot dispense methadone as MAT and do not formally supervise dosing of any medications. Due to these differences in the pharmacist’s role in MAT for OUD, pharmacists internationally often have more baseline training compared to the respondents of this study as 28.1% reported no formalized education or training on MAT and otherwise had very mixed experiences. In particular, one Australian study of community pharmacists involved in dispensing and supervising MAT reported 74% had attended opioid substitution treatment training sessions, of which 95% believed these trainings were sufficient to meet their needs to deliver patient care.¹¹ This difference in training illustrates an opportunity for providing additional training to community pharmacists in the United States.

Even with this difference in training, a commonality in perceptions regarding drug diversion exists between community pharmacist preceptors and pharmacists supervising MAT in other countries. In this study, no participants responded to strongly disagree with a concern for diversion while 49.4% of participants agreed to being concerned about diversion and misuse of MAT products. The concern for diversion of MAT also appeared in the open-ended survey item regarding worries about dispensing MAT in the pharmacy. Of the dispensing community pharmacists in Australia surveyed, 74% believed that a significant level of diversion was occurring with buprenorphine specifically. Authors of this study speculated that their findings suggested the potential for buprenorphine diversion was a major issue that concerned pharmacists dispensing and supervising buprenorphine and that “the existence alone of these negative perceptions can be damaging” to patient care.¹⁰ Of the community pharmacies surveyed in Finland that dispense buprenorphine-naloxone directly to patients, all pharmacies perceived that dispensing this medication had gone well or very well but 11% reported suspecting diversion and 7% reported suspecting that patients had abused the drug during the last 6 months.¹⁵ As this United States study’s population can only dispense buprenorphine products for MAT, these results are similar which describes a common concern and potentially negative perception community pharmacists hold when providing care to patients with OUD that these patients will misuse MAT including buprenorphine products. Results of a Scottish study of community pharmacy managers demonstrated a link between attitude and providing services to patients with addiction including dispensing methadone¹³ which suggest that, if pharmacists continue to believe patients may divert and misuse medications for MAT, these pharmacists may be hesitant to dispense MAT even for patients with legitimate medical need. However, a positive perception reported in this study that does not hinder dispensing MAT is the strong sentiment that 34.2% strongly disagreed, 45.6% disagreed, and no one strongly agreed with the sentiment that “Dispensing MAT does not align with my own personal and/or religious beliefs.”

Regarding MAT knowledge survey items, participants performed well on questions related to medication access, specifically the questions about access to buprenorphine and naltrexone. Based on survey responses, it appears that the most opportunity to fill community pharmacist preceptor gaps in MAT knowledge lie in survey questions with low correct responses ($\leq 50\%$) as well as questions with higher responses for the “I don’t know” option ($\geq 15\%$) because preceptors may be more willing to admit that this is a self-identified area for learning and growth. In this way, a strength of the survey design was including the “I don’t know” option for knowledge items. A MAT knowledge question that was commonly missed was identifying which MAT products are FDA-approved for OUD (buprenorphine products, methadone, and naltrexone); this must be addressed with preceptors in future trainings. While a majority of participants correctly answered the question that it is recommended to continue methadone or buprenorphine in pregnant patients, it is interesting that half of respondents who missed the question selected “I don’t know.” A few knowledge questions were both commonly missed and had high “I don’t know” responses including that both buprenorphine products and naltrexone require an opioid-free interval before initiating and that buprenorphine may not be as effective as methadone for severe OUD due to its ceiling effect. Walters et al in New Zealand showed that an online opioid substitution treatment training for community pharmacists showed improvements in pharmacist confidence and skills.¹² Since many respondents reported a desire for different kinds of continuing education on MAT for OUD, this study suggests that targeted online trainings may be a viable platform for future MAT educational material for community preceptors in order to fill gaps in knowledge. Filling these gaps in knowledge may in turn impact preceptors to involve more pharmacy students in the MAT counseling process as these preceptors will feel more confident in their understanding of the medications and disease state.

While respondents generally reported positive perceptions on utilizing MAT for patients with OUD, a few perception questions highlighted a discrepancy between correct information from guideline-driven medicine and reported beliefs. For example, based on patient-specific factors, all FDA-approved medications for OUD are safe and effective yet respondents reported different responses for the efficacy

of each medication in helping patients achieve remission (buprenorphine, 45.0% agree, 8.8% strongly agree; naltrexone, 41.3% agree, 6.3% strongly agree, and methadone, 28.8% agree, 5.0% strongly agree) with many indifferent responses for all MAT products.

Overall, the four perception items adapted from Raisch et al had very similar responses. Although the survey participants differed since Raisch et al included community pharmacists and pharmacy technicians in an outpatient pharmacy (n=40) and this study surveyed community pharmacists (n=79), this is the most similar population in existing literature. Participants in both studies reported being comfortable dispensing MAT and counseling patients with OUD (55.7% agree, strongly agree 8.9% versus Raisch et al agree 37.5%, strongly agree 27.5%), disagreed with being concerned about pharmacy safety related to dispensing MAT (44.3% disagree, 24.1% strongly disagree versus Raisch et al 45.0% disagree, 32.5% strongly disagree), think MAT patients should be restricted to a single pharmacy (34.2% agree, 29.1% strongly agree versus Raisch et al 47.5% agree, 25.0% strongly agree), and agreed pharmacists who dispense MAT should have specialized training (63.3% agree, 15.2% strongly agree versus Raisch et al 67.5% agree, 10.0% strongly agree).¹⁸ These similarities suggest community pharmacists' perceptions of MAT are consistent in different outpatient settings.

Limitations

Although the study provides an insightful look into the minds of pharmacist preceptors in the community setting, the authors recognize several limitations. First, the survey duration was short at six weeks total. One Indiana college of pharmacy was inconsistent in sending reminder emails every two weeks to their preceptors and one college only agreed to send the initial email invitation to preceptors. It is also possible that the Indiana colleges of pharmacy may not have the most up-to-date or accurate preceptor email thus resulting in a lower response rate for active community pharmacist preceptors. All of these factors could have contributed to a reduced overall response rate. As the total population of Indiana community pharmacist preceptors is unknown, researchers were unable to identify if a nonresponse bias potential existed and authors were unable to compare if participant demographics were representative of all Indiana community pharmacist preceptors. This presents potential limitations to external validity, because researchers were unable to compare respondents to the demographics of non-respondents or overall Indiana community pharmacists.

Regarding the survey itself, the survey instrument was a non-validated survey. However, authors worked to ensure survey integrity through utilizing reputable guidelines for knowledge questions, utilizing the *social cognitive theory* as the conceptual framework for perception questions, and adapting perception questions from previously published MAT survey research. However, there may have been a limitation regarding the knowledge question "When comparing methadone and buprenorphine for the management of severe OUD (as defined by the DSM-5), buprenorphine may not be as effective due to its ceiling effect." While it is true that buprenorphine may not be as effective for severe OUD compared to methadone, the difference is more accurately attributed to the lower potency of buprenorphine rather than its ceiling effect.²⁴⁻²⁵ Additionally, some articles suggest that long-term outcomes are similar for buprenorphine and methadone for severe OUD, and the question did not specify the time frame for this comparison.²⁵⁻²⁷ Also, including the option for "neither agree nor disagree" in the Likert scale for perception questions could have resulted in less decisive results as it did not force participants to choose a side on perception questions.

Conclusion

Overall, opportunities exist to address gaps in knowledge for Indiana community pharmacist preceptors and additional education on MAT for OUD is welcomed by this population. Community pharmacist preceptors held positive perceptions on utilizing MAT for patients with OUD, but a few negative

perceptions persist that could be addressed in future research. The survey provided insight into Indiana community pharmacist preceptors' knowledge and perceptions of MAT for OUD and contributes new information to the literature as this population has not been studied previously. Future research is merited to examine the impact a targeted education intervention may have on knowledge and perceptions of MAT for OUD.

Timetable

September 2019	<ul style="list-style-type: none"> • Submit manuscript to JAPhA Community-Based Pharmacy Residency Issue
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Evaluation Strategy

Research project progress was evaluated by peer pharmacy residents, pharmacy fellows, and residency research mentors and advisors on a biweekly basis. PGY-1 Community Pharmacy Residents participated in a structured Research Project Development Program created by **Dr. Margie Snyder**. The Program was facilitated by Dr. Snyder's research fellow, **Dr. Lola Adeoye**, under Dr. Snyder's supervision. Dr. Adeoye completed the Program as a PGY-1 community pharmacy resident with Kroger/Purdue and successfully published her research in the Journal of the American Pharmacists Association. Moreover, Dr. Adeoye has positioned herself as a rising scholar in community pharmacy health services research with accolades such as selection as a 2018 AcademyHealth Diversity Scholar, receipt of a 2018 American College of Clinical Pharmacy travel award, and receipt of the 2018 Consortium for Research in Administrative Pharmacy award which recognizes the best research and presentation at the biannual Midwest Social and Administrative Pharmacy Conference. Dr. Snyder is an Associate Professor at the Purdue College of Pharmacy and Co-Director of Community Pharmacy Programs. In this role, she founded and directs the Medication Safety Research Network of Indiana (Rx-SafeNet), which is a statewide practice-based research network of approximately 140 community pharmacies. Dr. Snyder has published over 30 peer-reviewed journal articles and mentored over 40 residents and fellows on research; 14 of which who have received grant funding for their work. Dr. Snyder's total extramural funding support to date exceeds \$1,000,000 as Principal Investigator and \$450,000 as Co-Investigator. Dr. Snyder serves as a temporary reviewer for the NIH HSOD and AHRQ HCRT study sections. She received the 2016 APhA Excellence in Community Pharmacy Residency Award, the 2017 Joseph E. McSoley Pharmacist of the Year Award from the Indiana Academy of Community Pharmacists, and the 2018 Mentor of the Year Award for the Purdue College of Pharmacy Department of Pharmacy Practice.

Dr. Monica L Miller, PharmD, MSc served as primary research mentor and principal investigator on this project. She has authored 17 book chapters, 15 peer reviewed articles, and was lead editor on two published books. She was the principal or co-investigator for 29 grants totaling approximately \$750,000 for her global engagement activities and 38 grants totaling \$40,000 for her service learning initiatives. Dr. Miller has experience mentoring approximately 32 students and 7 global health residents on research projects. Dr. Miller served as the research mentor and co-investigator for the previous Walgreens/Purdue University PGY1 resident, Dr. Alex Mills, who was a 2018 Incentive Grant Recipient for Community Pharmacy Residents and their Preceptors for the project proposal titled: Assessment of HIV-positive Patients' Perception and Referral Sources for Immunizations Compared to the HIV-negative Population.

Areas of evaluation included IRB protocol compliance via a protocol checklist, manuscript draft review, resolution steps, and identification of professional presentation opportunities which included poster presentations at the 2018 ASHP Midyear Clinical Meeting, 2019 APhA Annual Meeting, and 2019 Indiana Pharmacists Alliance Spring Meeting. The residency program director and clinical review office at Walgreens also monitored the progress of this project.

Budget

Category	Specific Items	Budget
Participant Incentives	\$20/gift card x 50 gift cards (raffled)	\$1,000
		Total: \$1,000

The 50 gift cards were distributed to study participants via mail on May 15, 2019.

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Appendix: Survey Instrument

Pharmacist Preceptors' Knowledge and Perceptions of Medication-Assisted Treatment in Indiana Community Pharmacies

Investigators

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Purdue University

Description

The purpose of this research project is to characterize community pharmacist preceptors' knowledge and perceptions about dispensing and counseling on medication-assisted treatment (MAT), for the treatment of opioid use disorder (OUD) as well as characterize desired MAT resources. Eligible study participants include all pharmacists 18 years of age or older who are English-speaking, maintain an active Indiana pharmacist license, have been in their current community pharmacy practice setting for at least 6 consecutive months, and are active preceptors for Indiana based colleges of pharmacy. We would like to enroll all community pharmacist preceptors for Indiana colleges of pharmacy in this study. After stating you would like to participate in the survey, you will be directed to the secure online Qualtrics® survey. Completing the survey should take no more than 10-15 minutes in duration.

Cost and Payments

There is no cost to participate in this research. After completing the survey, study participants will be directed to an optional web-based gift card raffle. There are 50 available Starbucks gift cards valued at \$20 each, limit one per participant. Depending on survey participation, the chance of winning a gift card is approximately 1 in 10. Raffle winners will be selected at random using Microsoft Excel®, notified via their preferred email in March 2019, and asked via this email for an address where the gift card can be mailed. The gift card will be mailed no later than the end of April 2019. Participant information will be stored on a secure hard drive. This data will be destroyed after no more than 5 years and will be accessed only by the principal investigator and co-investigators for the purposed of notifying raffle winners.

Risks and Benefits

Risk to study participants is minimal and no greater than the participant would encounter in everyday activities. Participants may enjoy being surveyed and knowing that their survey responses may facilitate the creation of additional educational materials on MAT in order for Indiana community pharmacists to provide optimal patient care and be better MAT patient advocates. The study may also impact opportunities for Indiana colleges of pharmacy to provide preceptor education in their program development thus benefiting the preceptors involved in the study.

Confidentiality

No identifying information will be recorded or transmitted to researchers and nothing will link participants to their surveys. Since the collected survey data will be de-identified and no code key will be used, participants will not be able to withdraw data from the study after the electronic survey is completed. Data will be stored on a secure hard drive, and this data will be destroyed after no more than 5 years. Data will be accessed by the principal investigator and co-investigators for data analysis and interpretation of results. The project's research records may be reviewed by the study sponsor, US DHHS Office for Human Research Protections, and by departments at Purdue University responsible for regulatory and research oversight.

Right to Withdraw

Your participation in this study is voluntary which means that you may choose not to participate at any time without penalty or loss of benefits to which you are otherwise entitled. If you have questions, comments or concerns about this research project, please contact Elizabeth Davenport, PharmD at elizabeth.s.davenport@walgreens.com. To report anonymously via Purdue's Hotline see www.purdue.edu/hotline.

IRB Approval

This study has been reviewed by Purdue University's Institutional Review Board (IRB). If you have questions about your rights while taking part in the study or have concerns about the treatment of research participants, please call the Human Research Protection Program at (765) 494-5942, email (irb@purdue.edu) or write to:

Human Research Protection Program - Purdue University
Ernest C. Young Hall, Room 1032
155 S. Grant St.
West Lafayette, IN 47907-2114

Statement of Consent

I have read and understand the above information. By completing the survey I consent to participate in the study.

Are you an active preceptor for an Indiana based college of pharmacy, maintain an active Indiana pharmacist license, been in your community pharmacy practice setting for ≥ 6 consecutive months, English-speaking, and 18 years of age or older?

- Yes
- No

Survey Instrument

Section 1 – Indiana Community Pharmacist Preceptor Characteristics (Demographics)

The following questions are designed to gather information about preceptor demographics. Please answer the questions truthfully and to the best of your ability.

1. What is your gender identity?
 - a. Male
 - b. Female
 - c. Other
 - d. Prefer not to answer

2. What is your race? (Select all that apply)
 - a. American Indian or Alaska Native
 - b. Asian
 - c. Black or African American
 - d. Native Hawaiian or Other Pacific Islander
 - e. White
 - f. Other
 - g. Prefer not to answer

3. What is the highest level of education you have attained?
 - a. Bachelor of Pharmacy (BS)
 - b. Doctorate of Pharmacy (PharmD)
 - c. Postgraduate education (Residency, Fellowship, PhD, etc.)
 - d. Other [free text box]
4. What are the total years of experience that you have working as a community pharmacist in Indiana (with any employer)?
 - a. [free text box] years
5. What type of pharmacy is your current practice site?
 - a. Chain (CVS, Walgreens, etc.)
 - b. Grocery store (Giant Eagle, Kroger, etc.)
 - c. Hospital outpatient (Community, Eskenazi, IU Health, St. Vincent, etc.)
 - d. Independent
 - e. Mass merchandiser (Costco, Kmart, Meijer, Sam's Club, Walmart, etc.)
 - f. Other
6. What type of pharmacy rotations do you offer to precept? (Select all that apply)
 - a. IPPE
 - b. APPE
7. What type of education and/or training have you received on medication-assisted treatment (MAT)? (Select all that apply)
 - a. Accredited organization certifications
 - b. Conferences
 - c. Continuing education (CE)
 - d. On-the-job training
 - e. No formalized education or training on MAT
 - f. Pharmacy school classes
 - g. Specialized postgraduate training
 - h. Webinars
 - i. Other
8. Does your pharmacy dispense MAT products?
 - a. Yes
 - b. No
 - c. I don't know
9. Which statement most aligns with your general beliefs on addiction?
 - a. Addiction is a disease that can be attributed to a combination of environmental factors, genetic factors, and biochemical factors
 - b. Addiction is a result of conscious behavioral choices and/or lifestyle
 - c. Addiction is a combination of A and B
 - d. I am unsure what my general beliefs are on addiction
 - e. None of these options reflect my general beliefs on addiction
 - i. Please explain. [free text box]
10. Have you had any personal experience through yourself, a family member, friend, or loved one with using MAT products for opioid use disorder (OUD)?
 - a. Yes

- b. No
- c. I don't know
- d. Prefer not to answer

10b. [10b contingent on "Yes" response to 10a] Based on your personal experience, what was the outcome of the MAT therapy in regards to remission?

- a. Remission was achieved and maintained while using MAT.
- b. Remission was achieved but not maintained while using MAT.
- c. Remission was never achieved while using MAT.
- d. Different MAT therapies resulted in different remission outcomes.
- e. I don't know
- f. Prefer not to answer

Section 2 – MAT Knowledge

The following questions are designed to assess preceptor current knowledge of MAT. Please do not look up information or answers. Answer each question to the best of your ability. All responses are anonymous and will be presented in aggregate form. An answer key is available for your reference at the end of the survey.

11. Which MAT products are FDA-approved for the management of OUD? (Select all that apply)

- a. Acamprosate (Campral®)
- b. Buprenorphine (Subutex®, Belbuca®, Buprenex®, Sublocade®, Probuphine®)
- c. Buprenorphine/naloxone (Suboxone®, Zubsolv®, Bunavail®)
- d. Disulfiram (Antabuse®)
- e. Methadone (Dolophine®, Methadose®)
- f. Naltrexone (Revia®, Vivitrol®)
- g. I don't know

12. What purpose does the naloxone component serve in oral buprenorphine/naloxone combination products?

- a. It increases the absorption of the buprenorphine component
- b. It reduces the addictive properties of the buprenorphine component
- c. It prevents euphoric effects from the buprenorphine component if crushed prior to use
- d. It prevents respiratory depression due to the buprenorphine component
- e. I don't know

13. Which medication(s) can cause respiratory depression? (Select all that apply)

- a. Buprenorphine
- b. Methadone
- c. Naltrexone
- d. I don't know

14. Which medication(s) require(s) an opioid-free interval before initiating to prevent the precipitation of acute opioid withdrawal? (Select all that apply)

- a. Buprenorphine
- b. Methadone
- c. Naltrexone
- d. I don't know

15. When comparing methadone and buprenorphine for the management of severe OUD (as defined by the DSM-5), buprenorphine may not be as effective due to its ceiling effect.
- True
 - False
 - I don't know
16. It is recommended to continue methadone or buprenorphine for OUD if a patient becomes pregnant.
- True
 - False
 - I don't know
17. Which MAT product can only be dispensed for OUD through certified opioid treatment programs (OTPs)?
- Buprenorphine
 - Methadone
 - Naltrexone
 - I don't know
18. Which MAT product requires a DATA 2000 waiver ("X" DEA number) to be dispensed for OUD outside of certified OTPs?
- Buprenorphine
 - Methadone
 - Naltrexone
 - I don't know
19. Which MAT product can be prescribed for OUD by any licensed practitioner and dispensed through any pharmacy?
- Buprenorphine
 - Methadone
 - Naltrexone
 - I don't know

Section 3 – MAT Perceptions

The following questions are designed to identify preceptor perceptions of MAT. Please answer the questions truthfully and to the best of your ability.

Likert Scale:

1 – Strongly Disagree

2 – Disagree

3 – Neutral

4 – Agree

5 – Strongly Agree

Prefer Not to Answer – [free text box] Please explain why you prefer not to respond.

Safety and Efficacy of MAT

For Questions 20-23, please evaluate the following statements for each MAT product listed. MAT products for OUD are defined as methadone, buprenorphine (+/- naloxone), and naltrexone.

20. MAT products are effective in helping patients with OUD achieve remission.
 - a. Methadone
 - i. Likert Scale (1-5)
 - b. Buprenorphine
 - i. Likert Scale (1-5)
 - c. Naltrexone
 - i. Likert Scale (1-5)

21. MAT products for OUD are substituting one addiction for another.
 - a. Methadone
 - i. Likert Scale (1-5)
 - b. Buprenorphine
 - i. Likert Scale (1-5)
 - c. Naltrexone
 - i. Likert Scale (1-5)

22. MAT products reduce criminal activities in patients with OUD.
 - a. Methadone
 - i. Likert Scale (1-5)
 - b. Buprenorphine
 - i. Likert Scale (1-5)
 - c. Naltrexone
 - i. Likert Scale (1-5)

23. MAT products decrease the risk of death in patients with OUD.
 - a. Methadone
 - i. Likert Scale (1-5)
 - b. Buprenorphine
 - i. Likert Scale (1-5)
 - c. Naltrexone
 - i. Likert Scale (1-5)

24. MAT in combination with cognitive behavioral therapy (CBT) helps patients with OUD achieve remission with more success than CBT alone.
 - a. Likert Scale (1-5)

Personal Perceptions of MAT

25. I am comfortable dispensing MAT and counseling patients with OUD.
 - a. Likert Scale (1-5)

26. Dispensing MAT for OUD does not align with my own personal and/or religious beliefs.
 - a. Likert Scale (1-5)

27. By dispensing MAT, I attract an unwanted clientele.
 - a. Likert Scale (1-5)

28. I have increased concerns about breaks-ins, theft, and pharmacy safety due to my involvement with dispensing MAT to patients with OUD.

- a. Likert Scale (1-5)
- 29. I believe the benefits of using methadone or buprenorphine in pregnant patients with OUD outweighs the potential risks.
 - a. Likert Scale (1-5)
- 30. I am concerned about the potential for diversion and misuse of MAT products.
 - a. Likert Scale (1-5)

Pharmacy Environment

- 31. MAT products for OUD should be kept in stock as part of the normal inventory.
 - a. Likert Scale (1-5)
- 32. The patient population at my pharmacy does not have the financial means to pay for MAT.
 - a. Likert Scale (1-5)
- 33. MAT is overprescribed.
 - a. Likert Scale (1-5)
- 34. Patients receiving MAT should be restricted to a single pharmacy.
 - a. Likert Scale (1-5)
- 35. Pharmacists who dispense MAT should have specialized training.
 - a. Likert Scale (1-5)

Section 4 – Additional Questions

The following open-response questions are designed to identify preceptor desired additional MAT resources and for additional comments. Please answer the questions truthfully and to the best of your ability.

- 36. If any, what worries or concerns do you have about dispensing MAT in your pharmacy?
- 37. What additional resource(s) and/or training on MAT would be beneficial for community pharmacists to have before dispensing these medications?
- 38. If you dispense MAT in your pharmacies, describe if and how you involve your IPPE and/or APPE students in the counseling process.

Gift Card Raffle

Optional

Enter for the chance to win a \$20 Starbucks gift card!

If you would like to be entered to win, please provide the following information!

Name [free text box]

Preferred Email [free text box]

50 winners will be selected at random using Microsoft Excel®. Winners will be notified via their preferred email in March 2019, and asked via this email for an address where the gift card can be mailed. The gift card will be mailed no later than the end of April 2019. Participant information will be stored on a secure hard drive. This data will be destroyed after no more than 5 years and will be accessed only by the principal investigator and co-investigators for the purpose of notifying raffle winners.

Correct Answers to Knowledge Questions for Participant Reference

Optional

Please see below for the answer key to the survey questions designed to assess preceptor current knowledge of MAT. Again, all survey responses are anonymous and will be presented in aggregate form.

Which MAT products are FDA-approved for the management of OUD? (Select all that apply)

- **Answer:**
 - **Buprenorphine (Subutex®, Belbuca®, Buprenex®, Sublocade®, Probuphine®)**
 - **Buprenorphine/naloxone (Suboxone®, Zubsolv®, Bunavail®)**
 - **Methadone (Dolophine®, Methadose®)**
 - **Naltrexone (Revia®, Vivitrol®)**

What purpose does the naloxone component serve in oral buprenorphine/naloxone combination products?

- **Answer: It prevents euphoric effects from the buprenorphine component if crushed prior to use**

Which medication(s) can cause respiratory depression? (Select all that apply)

- **Answer:**
 - **Buprenorphine**
 - **Methadone**

Which medication(s) require(s) an opioid-free interval before initiating to prevent the precipitation of acute opioid withdrawal? (Select all that apply)

- **Answer:**
 - **Buprenorphine**
 - **Naltrexone**

When comparing methadone and buprenorphine for the management of severe OUD (as defined by the DSM-5), buprenorphine may not be as effective due to its ceiling effect.

- **Answer: True**

It is recommended to continue methadone or buprenorphine for OUD if a patient becomes pregnant.

- **Answer: True**

Which MAT product for OUD can only be dispensed through certified opioid treatment programs (OTPs)?

- **Answer: Methadone**

Which MAT product for OUD requires a DATA 2000 waiver (“X” DEA number) to be dispensed outside of certified OTPs?

- **Answer: Buprenorphine**

Which MAT product for OUD can be prescribed by any licensed practitioner and dispensed through any pharmacy?

- **Answer: Naltrexone**