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Pharmacist administration of long-acting injectable medications for substance use disorders: A scoping review

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Abstract

Introduction: Using long-acting injectable (LAI) medications increases treatment adherence and promotes positive outcomes for patients with substance use disorders (SUD). Despite documented benefits that LAI medications can have over their oral counterparts, they continue to be underused. With the expansion of pharmacists' scope of practice for medication administration services, there is a need to document and evaluate the benefits of pharmacist engagement in LAI administration services for SUD and identify growth opportunities.

Methods: A PubMed database search for articles related to a pharmacist's role in LAI administration services for buprenorphine and naltrexone was conducted. Articles published before December 15, 2023, and in English describing or reporting outcomes of pharmacists administering LAI buprenorphine or LAI naltrexone in the United States were included.

Results: A total of 56 articles were identified in the search process. After removing duplicate citations and exploring references and similar article recommendations, a total of 5 articles were included in the final analysis. All 5 articles discussed pharmacist administration of LAI naltrexone, and no articles discussed pharmacist administration of LAI buprenorphine. Outcomes for each article varied and included cost analyses, implementation procedures, and identified barriers.

Discussion: Current literature on pharmacist-administered LAI services is limited. With many states allowing pharmacist administration of LAI medications, there is a significant opportunity to expand patient access to LAI medications for SUD in the pharmacy setting. Standardized training on LAI administration, development of standard operating procedures, and clarity on reimbursement policies are needed to help accelerate the implementation of pharmacist-administered LAI services.

Keywords: pharmacist, medication administration, long-acting injectable, naltrexone, substance use disorder

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Introduction

In the United States, 17.3% of people aged 12 and older were reported to have a substance use disorder (SUD) in 2022. Among this same population, only 25% of people received SUD treatment.[1] Medications represent an important component of comprehensive treatment for individuals with SUDs, and several options exist for the treatment of alcohol use disorder (AUD) and opioid use disorder (OUD).[2] Further, the introduction of long-acting injectable (LAI) medications in the treatment of

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SUDs has demonstrated improved adherence, improved functioning, and reduced drinking days and opioid use.[3-5] Currently, buprenorphine and naltrexone are available as LAI formulations in the US for the treatment of SUDs. Buprenorphine is classified as a schedule III medication and is available as a weekly and monthly subcutaneous injection, whereas naltrexone is not a controlled medication and is available as a monthly intramuscular injection.[6,7]

Despite the well-documented benefits that LAI medications can have over their oral counterparts, they continue to be significantly underused.[8] Several barriers have been documented related to LAI use, including cost, stigma, the misperception that patients will view LAIs negatively, and increasing shortages of mental health providers.[9-11] Previous studies have demonstrated that pharmacists improve patient outcomes, including medication adherence, chronic disease control, and reduced hospitalizations, when integrated with the mental health care team.[12,13] Less evidence exists regarding the specific impact of pharmacists practicing in community settings. However, with advancing technology and expanding scopes of practice, community pharmacists can play an important role in addressing SUDs.[14] As the healthcare providers most accessible to patients, pharmacists are in a strong position to contribute to interdisciplinary mental healthcare teams across practice settings.[15]

The American Pharmacists Association revised a report in 2005 advocating for pharmacist administration of prescription medications as a component of pharmacy practice.[16] Aligned with these efforts, the National Alliance of State Pharmacy Associations provides insight as to which states allow pharmacist administration of LAI medications. However, policies and types of medications authorized vary from state to state.[17] For example, in Texas, pharmacists may administer LAI antipsychotics and opioid antagonists to state-insured patients pursuant to a prescription (Texas Occupation Code section 554.004).[18] Whereas in the state of Florida, pharmacists may only administer LAI medications under physician direction (eg, collaborative practice agreement) with an established protocol (Florida Statute 465.1893).[19] Despite the expansion of pharmacist medication administration services (MAS), there are limited data describing such services related to pharmacist administration of medications for SUDs. With the expansion of the pharmacists' scope of practice for MAS, there is a need to document and evaluate the benefits of pharmacist engagement in LAI administration services and identify opportunities for future growth. This study aimed to review the available literature regarding the pharmacists' role in administering LAI medications for SUDs in the US and identify opportunities for further expansion.

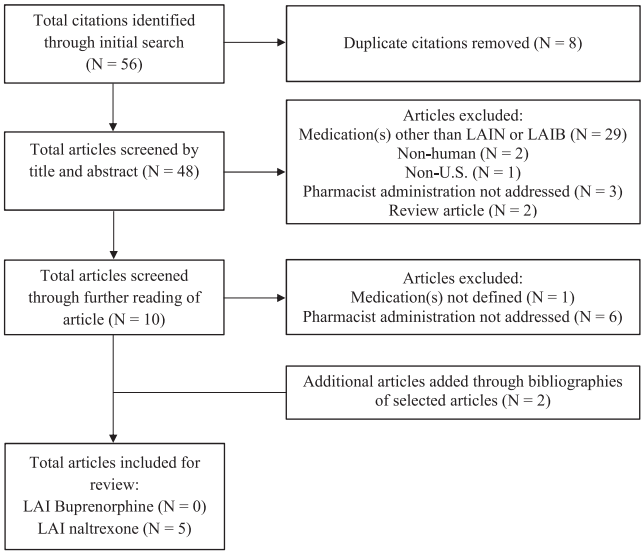

FIGURE: Flow diagram of the literature review process

Methods

The PubMed database was searched for articles published before December 15, 2023, related to a pharmacist's role in LAI-administration services of buprenorphine and naltrexone in the US. The following search keywords were used: pharmacy, pharmacist, injection, long-acting injectable, buprenorphine, and naltrexone. Three reviewers participated in the initial screening of article titles and abstracts (PH, MS, AC). Original research articles in English describing or reporting outcomes of pharmacists administering LAI buprenorphine (LAIB) or LAI naltrexone (LAIN) were included for abstract review. Articles were excluded if the LAIs administered were medications other than buprenorphine or naltrexone (ie, antipsychotics), if a provider other than a pharmacist was administering the LAI medication, if the study was conducted outside the US, and if the article was a review article. After screening, the included articles received a full-text review from all reviewers (SC, PH, MS, AC) to determine final inclusion and further explore citations.

Results

A total of 56 articles were identified in the initial search process. After removing duplicate citations, 48 articles remained. After reviewing article abstracts, a total of 10 articles were selected for further review. From this assessment, an additional 2 articles were included from exploring citations. A total of 5 articles were included in the final analysis (Figure), all of which discussed pharmacist administration of LAIN.[20-24] No articles were identified discussing pharmacist administration of LAIB.

The focus and outcomes of each article varied. All articles described some aspect of the implementation and scope of

the pharmacist-administered LAI service. Three articles described a community pharmacy LAI service, and 2 described clinic-based LAI service.[20-24] Two articles discussed pharmacist training requirements, and all 5 articles discussed operating procedures (eg, referral process, scheduling, and/or communicating patient information to the prescriber).[18-22] Three articles described using collaborative drug therapy management (CDTM) protocols or collaborative practice agreements (CPAs).[20-22] Four articles described or reported cost estimates related to the LAI service.[20,21,23,24] The results of these articles are summarized in chronological order below and the Table.

Development of a Collaborative Drug Therapy Management Protocol for Extended-Release Intramuscular Naltrexone[20]

Hebbard and colleagues[20] wrote a discussion article describing a LAIN protocol developed in collaboration with an SUD treatment program within an academic medical center in South Carolina. Clinics within the program treat 1200 patients annually with SUDs, including AUD and OUD. The article describes implementing a LAIN protocol at an outpatient clinic led by pharmacists to enhance monitoring, education, and patient follow-up. Requirements for a pharmacist to participate in LAIN administration included acquiring a credentialing from the Department of Pharmacy, completing an annual education module based on FDA-approved guidelines, and passing an annual test. Once the appropriate credentials were received, pharmacists were granted authorization to order lab tests and urine drug screenings in addition to administering LAIN. Referrals were only accepted from university-credentialed attending psychiatrists who must sign a CDTM agreement with a credentialed pharmacist for LAIN. Patients enrolled in the LAIN protocol were 18 years or older, able to be seen in the outpatient setting, opioid-free for at least 7 days, carried emergency identification, and signed an informed consent form. Patients must have also tolerated oral naltrexone and had recent liver enzyme labs within 3 times the normal upper limit.

Further, the protocol required pharmacists to discuss preestablished education points with patients at each appointment. These include reviewing information in the patient's physician referral, informed consent, the naltrexone medication guide, and performing medication reconciliation. While the authors did not report on specific patient outcomes, they alluded that patients returned for a follow-up visit by scheduling recurrent injection visits every 4 weeks and ensuring missed appointments were rescheduled. They concluded that most patients in the clinic reported success with LAIN administered by the pharmacist and that the service was a viable option for patients.

Systematic Analysis of the Service Process and the Legislative and Regulatory Environment for a Pharmacist-Provided Naltrexone Injection Service in Wisconsin

Ford and colleagues[21] aimed to explore how community pharmacists Wisconsin are providing injectable naltrexone treatment to individuals with OUD. A small sample of pharmacists providing LAIN services were surveyed via telephone or in-person interviews to assess the development, implementation, and potential barriers to these services. A secondary objective of this study included reviewing available legislation and regulatory policies that may influence a pharmacist's ability to engage in administering LAIN in the community setting. From interview data, all pharmacists administering LAIN did so under a CPA and had completed additional training on administering LAIN. While not required, pharmacists noted that signed protocols with a prescriber helped facilitate communication and follow-up care and ensure the quality of the service rendered.

Further, most pharmacists worked closely with a behavioral health or psychiatry provider to engage in telehealth services on the day of the injection appointment. This enabled billing for the services using Common Procedure Coding System (HCPCS) code Q-3014 (telehealth-originating site facility fee). Other pharmacists charged an injection administration fee if the patient could provide their naltrexone medication. Through these interviews, the authors organized the activities that must happen before, during, and after LAIN administration into a "straw model." Preliminary internal and external barriers to LAIN services were also identified, including costs associated with implementing the service, liability risks of providing medications for OUD in the pharmacy, time to coordinate care, and lack of access to wraparound services. While the study highlighted the need for LAIN services and affirmed the feasibility of implementation in Wisconsin, solutions to practical barriers, including service infrastructure, reimbursement, and service coordination, remain understudied.

Community Pharmacy-Based Injectable Naltrexone Service Delivery Models and Best Practices

A second study by Ford and colleagues[22] examined delivery models developed by pharmacists for administering LAIN using a prospective mixed-methods analysis based on a pharmacist survey and focus group interviews. This study explored the reasons why pharmacists should administer LAIN to treat OUD and AUD in a community setting in Wisconsin. Surveys were administered to 460 pharmacies within designated high-risk geographical areas for opioid-related harms, overdoses, and death. Of 460 pharmacies

TABLE: Summary of articles assessing pharmacist-administration of LAIN

Study (y)	Study Characteristics	Main Objective(s)	Financial Infrastructure	Pharmacist Training	Other Finding(s)
Hebbard[20] (2013)	Retrospective study Population: Patients with AUD or OUD *N* = not defined	Explore pharmacist administration of LAIs at a pharmacist-run outpatient clinic	Facility charge ticket submitted to insurance for reimbursement	CDTM certification Annual module on LAIN with passing test score	Manufacturer support services assisted with logistical needs Viable service over 10-mo period for patients needing LAIN
Ford[21] (2019)	Prospective qualitative study Population: Pharmacists who administer LAIN to patients with OUD *N* = 5 pharmacists	Explore development, implementation, and barriers of pharmacist administration of LAIN in the community	Billed HCPCS code Q-3014 (Telehealth originating site facility fee), or Charged injection administration fee	General training on administering injectable medications Additional training through nurse educators/ manufacturer	All administered LAIN through CPA Protocols created for obtaining rapid UDS before LAIN administration Patients were accepting of receiving LAIN in the pharmacy
Ford[22] (2021)	Exploratory sequential mixed-methods study Population: Pharmacies designated as high-risk for opioid-related harms, overdose, and death *N* = 68 survey responses (15% response rate) *N* = 14 interviews (pharmacists, prescribers, community stakeholders)	Explore pharmacist administration of LAIN in community pharmacies	Not discussed	Not discussed	29% of responding pharmacies administered LAIN 378 injections provided over 1 yr Independent community pharmacies provided most injections Half of all injections were provided through a CPA Physicians reported confidence in pharmacists providing service
Ford[23] (2022)	Prospective study Population: Pharmacists who administer LAIN (diagnosis not defined) *N* = 9 pharmacists	Survey community pharmacists to develop a tool to determine total costs and time associated with pharmacist administration of LAIN	Calculated average expense of administering LAIN Estimated LAIN reimbursement between USD $46,000-$65,000 Compared LAIN cost with pharmacist and technician salaries	Not discussed	Average cost per injection for a new patient was $93 (range $48-$164) Average cumulative time spent per injection was 123 min (range 63-220 min) Roles and responsibilities varied across pharmacies
Thompson[24] (2017)	Descriptive report Population: Patients with OUD, AUD, and schizoaffective disorder (other diagnoses not defined) *N* = Not defined	Describe a pharmacist LAI administration service at an outpatient clinic	Dispensing fees captured Collaborates with health-system specialty pharmacy	Not discussed	Administered various LAI medications Average of 2-3 LAIs daily 25%-30% of injections were LAIN Main barrier identified was access to a prescriber for LAIs

AUD = alcohol use disorder; CDTM = collaborative drug therapy management; CPA = collaborative practice agreement; LAI = long-acting injectable; LAIN = long-acting injectable naltrexone; OUD = opioid use disorder; UDS = urine drug screen.

identified, 68 responded, with 20 (29.4%) reporting that their pharmacy provided naltrexone injections. Half of the injections administered at these pharmacies were provided through a CPA. Interviews with community pharmacists and prescribers were conducted to gather additional information related to naltrexone administration practices. Investigators interviewed 14 of 20 community pharmacies that provided LAIN services. The prescriber group referred an average of 15 patients per month to different pharmacy locations, with 67% to 80% of patients diagnosed with OUD. Providers appreciated the competency of community pharmacists in administering LAIN and received faxed records of the administration details. Most pharmacists interviewed universally agreed that collaborating with local prescribers and healthcare institutions was imperative to beginning LAIN services. Reasons reported by pharmacists for not providing LAIN injections included lack of equipment, insufficient reimbursements, limited access to electronic health records, time constraints in incorporating services into existing workflow, and lack of training. The mixed-methods approach developed 3 best-practice models for administering LAIN in a community pharmacy. Similarities across models included pharmacist administration, post-injection education, follow-up appointments, and sharing administration details with the patient's prescriber. Unique activities dependent on the specific model were also identified, including obtaining external urine drug screening and offering behavioral health telemedicine counseling. A best-practice checklist was also developed to be used in any model structure as a guide for establishing LAIN services. Overall, the authors helped define 3 distinct practice models based on current practices accepted and supported by community pharmacists actively administering LAIN.

Pilot Testing a Tool to Determine the Costs and Time Associated With Community Pharmacy-Based Administration of Injectable Naltrexone

Ford and colleagues[23] developed a tool to estimate the administrative costs and time to administer LAIN by pharmacists in community pharmacies using a cost estimator survey. The small sample included pharmacists providing LAIN services and adhering to the previously described best-practice checklist.[20] Activities in the LAIN process were analyzed using descriptive statistics, and information was collected on who was performing each task (ie, pharmacist, technician, or both). Specific tasks included patient scheduling before the appointment, benefits coordination, urine drug screening and interpretation, behavioral health consultation, supplies for injection, monitoring period, patient follow-up, administrative documentation, and billing. Activity-related costs were calculated based on the average pharmacist and technician hourly salaries. The cumulative time to perform each activity was also calculated, including preinjection, injection, and postinjection activities. Of 9 respondents, 1 pharmacist reported they suspended LAIN administration due to insufficient patient volume. For a new patient, the LAIN administration cost ranged from $48 to $164, averaging $93. It was identified that this was $27.55 more than administering LAIN to a returning patient. For a new patient, the cumulative time spent on administering LAIN ranged from 63 to 220 minutes, averaging 123 minutes. The time spent for a returning patient ranged from 29 to 140 minutes, averaging 83 minutes. The mean time spent administering LAIN (acquiring supplies, administering the injection, and postinjection monitoring) was 26.38 minutes. Time spent beyond administering LAIN included scheduling patient appointments, benefits coordination, urine drug screening, patient education, administrative documentation, and billing. This study identified that the cost and time for LAIN services vary per pharmacy and are significant commitments compared with the time necessary for other pharmacist tasks, such as administering common vaccinations.

Pharmacists Provide Novel Injection Services for the Community

Thompson[24] wrote a news review article describing a pharmacist-run injection clinic after the expansion of Kentucky's state pharmacy laws that enabled pharmacists to administer LAIs in an outpatient setting. KentuckyOne Health - Our Lady of Peace has a pharmacist-run clinic that administers LAIs in an outpatient setting to treat mental health conditions, including SUDs. Pharmacists administered an average of 2 to 3 injections per day, with 25% to 30% of LAIs administered for treating OUD and AUD (ie, administered LAIN). Difficulty accessing a prescriber was identified as a primary barrier to LAI injection accessibility, with some patients expressing a desire for treatment but no willing prescriber available. The authors discussed active plans for overcoming this barrier, including collaborating with a nurse practitioner as an on-site partnering prescriber.

Discussion

A total of 5 articles were identified that discussed pharmacist administration of LAIN. No studies describing or assessing services related to pharmacist-administration of LAIB were identified. Possible reasons include differences in controlled status, an earlier FDA approval date of LAIN, and naltrexone's labeled use for 2 indications (ie, AUD and OUD). Further, the storage requirements and subcutaneous administration of LAIB may pose additional barriers related to procurement and pharmacist training.[25,26] While state-specific guidance for the administration of LAIN and LAIB is lacking, state restrictions surrounding insurance

coverage and prior authorization requirements for LAIB may pose another barrier to increasing patient access and pharmacist administration.[27] The inability to find available evidence of pharmacist-administration of LAIB in the US speaks to the additional challenges pharmacists and providers may face when providing opioid-agonist treatment for OUD.

During this review, it was found that pharmacist-administered LAIN services were provided in either a clinic or community pharmacy setting, varying in population size and duration of assessment time. When describing the development of the pharmacist-administered LAI service, the setting (ie, clinic or community pharmacy) impacted the use of specific protocols versus state-dictated authority in administering LAI medications. However, pharmacists in both the clinic and community settings referred to the use of CDTM or CPAs, which allowed further adjustment of LAI medications, as well as the authority to prescribe medications for LAI-emergent side effects and order labs for ongoing monitoring.[20-22,24] Using CDTM protocols and CPAs can afford pharmacists the privilege to provide various clinical services, including administering specified medications in collaboration with physicians.[28] Despite such protocols being a commonality on providing LAIN services, details of such protocols were not provided, which may limit replicability in similar practice settings. Further, pharmacists providing LAI injections in a community pharmacy most often referenced their state's scope of practice, which generally limits the service to administration of an LAI pursuant to a prescription.[21-23] Such barriers have also been described by pharmacists providing LAI services for other medications, including antipsychotics.[29-32]

Using a scheduling system was a key component across services, though some allowed walk-in appointments. The use of such software can help pharmacy staff predict future workflow, LAI procurement, and staffing needs based on scheduled appointments. This is similar to the process described by community pharmacists administering LAI antipsychotics (LAIAs). These studies describe using a medication coordinator or collaboration with a specialty pharmacy team who facilitated prior authorizations, enrollment in prescription assistance programs, and medication shipping needs.[29,30] Pharmacists without such support report prior authorizations and delays in medication procurement as a barrier to increasing patient volume. Depending on the location and staffing support of a pharmacist-administered LAI service, such logistics need to be considered when developing standard operating procedures and reimbursement models.

Follow-up and coordination with the prescribing provider are imperative in providing pharmacist-administered LAI services. While most articles alluded to specific policies and procedures for documenting LAI administration and sharing information with the prescribing provider, few outlined specific information required to be shared or in what timeframe. Other articles focusing on LAIA administration by pharmacists provide guidance on relevant information to fax to the prescribing provider, including when the injection was given and any issues that occurred during administration.[31] Another study reported that a notification must be faxed to the patient's physician within 48 hours after the LAI injection.[29]

Patient satisfaction surveys have been conducted for patients receiving LAIAs in community pharmacies. These studies reported a high level of patient satisfaction, as well as the convenience of receiving the injection in a community pharmacy.[29,31] Similarly, another article assessed medication adherence and found that 78% of patients receiving pharmacist-administered LAIAs were adherent when using a proportion of days covered of 80% or more.[30] While no studies directly assessed patient satisfaction or adherence in this review, patient acceptance of community LAIN services can be concluded from focus group interviews. Pharmacists providing injectable naltrexone offered benefits such as reduced stigma, increased patient comfort discussing treatment challenges and urgent needs in the pharmacy environment, counseling on the LAI, proactive follow-up, and medication management.[22] Given that stigma is reported as a barrier to accessing care, receiving such care in a community pharmacy may help increase patient engagement.

Several barriers to expanding pharmacist-administered LAI services were identified. Key drawbacks included a lack of standardization of policies and procedures, insufficient reimbursement, limited access to electronic health records, and time constraints in incorporating services into existing workflow. Other LAI studies have identified similar barriers to expanding pharmacist-administered LAI services, including stigma, patient access to a prescriber, patient charges for LAI administration, maintaining a consistent patient volume, and delays due to prior authorization procedures.[24,31] Further, the financial sustainability of pharmacist-administered LAI services is a legitimate concern from a business model perspective. Based on this review, no standard reimbursement model was identified. For example, Hebbard's outpatient clinic model, describes recovering a "facility fee," which was billed for reimbursement following the injection visit.[20] The applicability of this business model beyond an outpatient clinic setting is unknown and may vary even in the outpatient clinic setting. Thompson[24] describes capitalizing on dispensing and administration fees in community-based pharmacies; however, such fees may be influenced by insurance payors or enrollment in prescription assistance programs with the LAI manufacturer.[31] To date, no in-depth financial analysis of

pharmacist-administered LAI services has been conducted in the community setting.

These articles offer a positive outlook for pharmacist-administered LAIN services. This supports the nationwide increase in pharmacist scope to provide such services, particularly considering anticipated shortages of psychiatric providers in the next decade.[33] Additionally, some pharmacists can provide other valuable clinical services, including comprehensive medication management and prescriptive authority, which can further build on their role as an accessible healthcare provider for LAI administration.[34] Owing to the heterogeneity of articles discussing LAI administration by pharmacists and variability in state-to-state scope of practice, additional research detailing the practices and impact of pharmacists administering LAIs for the treatment of SUD is greatly needed. Further, few articles assessed patient outcomes and were limited to satisfaction and convenience or medication adherence measures. The impact of pharmacist involvement in LAI administration has not been evaluated for metrics such as symptom recurrence, hospitalizations, abstinence rates, or absenteeism from employment/school. Further investigation on sustainable financial models will likely be required to support the growth of such services across the practice landscape, and LAI administration services will need to be balanced among other responsibilities of pharmacists practicing in outpatient settings. The need for standardization regarding pharmacist training and business procedures must be balanced with inherent differences across state lines, practice settings, and patient populations.

Conclusion

The current literature on pharmacist-administered LAI services for SUDs is limited to describing practice development, assessing short-term financial impact, and evaluating the volume of patient care load. Additional findings indicate the feasibility of collaborative practice agreement models for community pharmacists and the overall patient acceptability of receiving LAIN in the community setting. However, the lack of documented pharmacist involvement in LAIB administration calls for future changes in federal and state regulations to facilitate the pharmacist's role in providing comprehensive SUD care. These descriptions of practice development can help set the foundation for a systematic approach to creating pharmacist-administered LAI services. With many states currently allowing pharmacist administration of LAI medications, there is a significant opportunity to expand patient access to treatment by administering LAI medications in both the clinic and community pharmacy settings. Standardizing the training of LAI administration, developing standard operating procedures, and clarifying billing and reimbursement policies are needed to help accelerate the implementation of pharmacist-administered LAI services.

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