

Full title: Pharmacists and the Opioid Crisis: A Narrative Review of Pharmacists' Practice Roles

Running title: Pharmacists and the Opioid Crisis

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Abstract

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Introduction: Nearly 2.5 million Americans have an opioid use disorder (OUD) related to prescription and/or illicit opioids. Pharmacists, as one of the most accessible care providers, are essential in mitigating the mortality and morbidity of the opioid overdose crisis. Pharmacists are involved in numerous care activities related to this crisis and to caring for patients with an OUD.

Objective: The objective of this paper was to conduct a literature review to highlight several pharmacist-driven practices that provide a broad range of prevention, harm reduction, treatment, and recovery services to patients affected or potentially affected by the opioid crisis.

Methods: Articles had to meet the criteria of describing pharmacist-led practice related to providing care to patients at risk of an opioid overdose, with an OUD, or related to opioid safety. The literature search was conducted in 2018 and utilized numerous sources including: OneSearch (EBSCOhost), PubMed, ScienceDirect, and the Journal of the American Pharmacists Association Opioid Topic Collection.

Results: Seven articles were chosen for inclusion in this review. These studies report on innovative programs and practices that describe the role of pharmacists throughout the entire spectrum of the opioid crisis. Studies demonstrate the types of involvement pharmacists have in caring for patients throughout the care continuum: actively engaged in upstream interventions aimed at preventing misuse and improve safety; screening and monitoring opioid prescribing and usage; providing access to naloxone; and, assisting in the recovery and rehabilitation process of patients with OUD, including collaboratively managing OUD with evidence-based pharmacotherapy.

Conclusion: The studies included in our narrative review demonstrate how innovative programs and practices can expand the role of pharmacists throughout the entire spectrum of interventions applied to the opioid crisis by capitalizing on their existing skill sets and knowledge.

Nearly 2.5 million Americans have an opioid use disorder (OUD) related to prescription and/or illicit opioids, but according to some, this number may be even higher.(1) A minimum of 130 Americans die each day from opioid-related overdose.(2) The White House estimates that the total direct and indirect costs of the overdose crisis at \$504 billion in 2015 alone.(3) Opioid-related overdoses in the United States resulted in approximately 48,000 deaths in 2017, primarily from illicitly manufactured fentanyl (IMF).(4) Even with supply-side solutions like reductions in prescription opioid prescribing factored in, one research team has predicted that 700,000 people will die between 2016 and 2025 from opioid overdose.(5) These increases have led to a rarely observed multiple year decline in life expectancy, and overdose is the leading cause of death in people less than 55 years old.(6) Pharmacists most commonly address the crisis through naloxone dispensing and/or using the prescription drug monitoring program (PDMP).

A recent systematic review of pharmacists' roles, training, and barriers in dispensing naloxone,(7) a life-saving opioid antidote, reported widespread national and state policy support for pharmacists in overdose education and naloxone distribution. Identified barriers included lack of confidence making active naloxone recommendations to patients who use prescription and/or illicit opioids.(8) Similarly, a scoping review of pharmacist attitudes, knowledge, and use of PDMP suggested that use of this supply side tool increased parallel to knowledge and/or attitude about the PDMP. In both papers, the researchers called for more rigorous evaluations of their conclusions, more training as well as further research into the pharmacists' roles and motivations for dispensing naloxone, and using the PDMP.(7,8) Increasing access to medication-based

treatment are needed, as 1.4 million, or 80% of those diagnosed with an OUD, have not received an evidence-based treatment (such as methadone, buprenorphine, or naltrexone).(9) A majority of counties in the U.S. still lack waived providers of buprenorphine, with rural populations still facing OUD treatment access disparities.(10) Approximately 30% of rural Americans, as compared with 2% of urban Americans, lack access to outpatient buprenorphine prescribers.(11)

Pharmacists, as the most accessible care providers especially in rural areas, are essential in mitigating the mortality and morbidity of the opioid overdose crisis. Pharmacy organizations have advocated for pharmacists to have an increased role in providing care for patients at risk of opioid misuse or opioid overdose, as well as for patients diagnosed with an OUD. The American Association of Colleges of Pharmacy (AACP) has collected and cataloged the opioid crisis activities of its members as they relate to service, scholarship, and teaching.(12) The College of Psychiatric and Neurologic Pharmacists (CPNP) has produced convenient tools for pharmacists related to medications for addiction, naloxone, harm reduction, and opioid use disorder.(13) The Association for Medical Education and Research in Substance Use and Addiction (AMERSA), an interprofessional organization for substance use education, recently released their “Specific Disciplines Addressing Substance Use: AMERSA in the 21st Century – 2018 Update.”(14) The AMERSA publication documents the various skills, attitudes, and knowledge of pharmacists and other health care professionals necessary for optimal interprofessional OUD care.

Pharmacists are involved in numerous care activities related to the overdose crisis including screening and referral to specialized treatment, patient, community, and provider

education, harm reduction provisions such as sterile syringe provision and naloxone dispensing, medication recommendations, and modeling positive attitudes to reduce the stigma attached to OUD.(15–21) Pharmacists with specialty training and certification work in fully integrated interdisciplinary care teams to design, implement, monitor, and modify evidence-based pharmacotherapy-centered OUD care plans. Some innovative pharmacist practices involve directly managing medications for opioid use disorder (MOUD) through delegated authority of state-based collaborative practice agreements. Ideally, pharmacists should advocate for the ability to be independent OUD providers through provider status, coupled with waiver training that currently only physicians, physician assistants, and nurse specialists may obtain. Research has shown that pharmacists can effectively engage patients with OUD to improve their outcomes.(22,23) In turn, patients have reported positive attitudes when a pharmacist was included in their OUD treatment care.(24,25)

We conducted a narrative literature review to highlight several pharmacist-driven practices that provide a broad range of prevention, harm reduction, treatment, and recovery services to patients affected or potentially affected by the opioid crisis.

Methods

For our narrative review, we searched for articles that provided a broad cross-section of the work pharmacists are performing related to the opioid crisis. Articles considered for our review had to meet the main criteria of describing a pharmacist-led practice related to providing

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care to patients at risk of an opioid overdose, with an OUD, or related to opioid safety. We did not attempt to create an exhaustive or systematic review, rather we sought articles from the literature that highlighted pharmacists' care roles from different practice settings. We selected those articles that we felt described a unique service led by pharmacists and/or a pharmacist-involved service that occurred in a unique practice setting.

Our literature search was conducted in 2018, and utilized numerous sources including: OneSearch (EBSCOhost), PubMed, ScienceDirect, and the Journal of the American Pharmacists Association Opioid Topic Collection. Keywords related to the topics of clinical pharmacist, community pharmacist, role, opioid, crisis, buprenorphine, naltrexone, and naloxone were used in our search strategy. Methadone was not included because it is solely dispensed from an opioid treatment program for patients with OUD.⁽⁹⁾ Keywords were chosen based on the study authors' experiences in this topic area, and based on what they felt would garner appropriate literature for this publication. Articles that were identified as "related" or "citing" by the databases were also screened for relevance.

Three authors (KC, JRV, ZS) read the titles and abstracts of articles identified in our two-part literature search described above. Study authors KC, JRV, and ZS selected those articles that met our criteria and the spirit of this narrative review. Articles were discussed with authors AM and JB to confirm they met inclusion criteria and to ensure that the articles provided relevant examples of pharmacists' care models. Selected articles were read and relevant information was extracted.

Results

Seven articles were chosen for inclusion in our narrative review. Descriptions of the articles were synthesized and described below.

“Trends in Naloxone Prescriptions Prescribed After Implementation of a National Academic Detailing Service in the Veterans Health Administration: A Preliminary Analysis”(25)

This retrospective repeated measures cohort study was conducted to determine the impact of a clinical pharmacist-delivered Opioid Overdose Education and Naloxone Distribution-Academic Detailing (OEND-AD) program on naloxone prescribing patterns within the Veteran's Health Administration (VA). The educational intervention utilized the existing OEND materials, and delivered face-to-face educational outreach visits as part of the Academic Detailing (AD) program. The components of the outreach visit included education on opioid safety, risk identification and prevention of overdose, and naloxone. The outcome of interest was number of naloxone prescriptions written by active providers in primary care or substance-use disorder clinics between October 2014 and September 2016. Data was compared between providers who did not receive any OEND-specific AD programming and providers who received at least one OEND-AD session in this time period.

Of the 3313 providers included in the study, 750 (22.6%) received at least one OEND-AD session. At two years, exposed providers had a naloxone prescribing incidence rate that was

7.4 times greater than unexposed providers (95% CI 3.0-17.9). While both cohorts had increased rates of naloxone prescribing over the two-year period, providers exposed to OEND-AD had a 7.1% larger increase in prescribing rates than those unexposed (95% CI 2.0%-12.5%). Authors attributed the statistically significant rise in naloxone prescribing in both groups to overall awareness of the OEND program spurred by the addition of naloxone to the VA formulary; however, data concerning individual provider awareness of the OEND program was not gathered in the study.

“Impact of Pharmacist Pre-visit Input to Providers on Chronic Opioid Prescribing Safety”(26)

In this pilot study, researchers evaluated the impact of pre-visit pharmacist chart review for patients prescribed over 50 morphine milligram equivalents (MME)/day on subsequent adherence to prescribing guidelines and opioid safety outcomes.

The intervention was carried out by two pharmacists at a single family medicine clinic over a four-month period. Most patients had multiple pain diagnoses (84%) and/or comorbid psychiatric diagnoses (84%). The mean MME/day of the patient population was 151. Three hundred one recommendations were provided for 45 patients and 38% were implemented. Because of these interventions, the mean MME/day, determined by number of pills prescribed per month, was reduced by 14% ($p < .001$) without a statistically significant change in pain scores. In addition, there was statistically significant improvement on several secondary opioid safety measures, including 16% decreased co-prescribing of benzodiazepines, 36% increase in patients

offered naloxone, 27% increased requirement of current urine drug screen, 31% increased review of PDMP, and 9% increased referral to a pain specialist.

The authors felt that the actual recommendation implementation rate might be higher than detected considering that some recommendations require time to enact, such as a benzodiazepine taper. The authors also stated that because the pharmacist was only providing recommendations instead of implementing them, the intervention had a low impact on the pharmacist workload.

“Moving Opioid Misuse Prevention Upstream: A Pilot Study of Community Pharmacists Screening for Opioid Misuse Risk”(27)

This study evaluated the feasibility of an opioid misuse risk assessment for patients receiving opioid prescriptions in North Dakota community pharmacies. The intervention utilized an Opioid Misuse Risk Prevention Toolkit which included an opioid risk tool, accidental overdose screening tool, and a triage tool. Eleven pharmacists participated in this pilot study over a six-week period and were provided a three-hour training session on how to use the toolkit.

If a patient was determined to be at risk of an opioid use disorder or an accidental overdose, they were offered a naloxone prescription and provided education and community resources. Only a single patient refused to participate in the voluntary screening. Of the 107 patients screened using the toolkit, 25% were identified as at risk for an opioid use disorder and 30% were identified as at risk for an accidental overdose. The authors stated that these statistics align with national data on opioid use disorders in those receiving chronic opioid therapy.

Qualitative analysis on pharmacist interviews determined the toolkit was easy to implement. Pharmacists also indicated benefit in an objective tool for screening. There was consensus that the toolkit enhanced the ability of the pharmacists to identify patients at risk for misuse or accidental overdose. Limitations of this study's applicability can be attributed to its geographical location. North Dakota state law requires that all pharmacies be majority owned by a pharmacist and gives naloxone prescribing authority to pharmacists who meet certain criteria. Implementation of the Opioid Misuse Risk Prevention Toolkit was facilitated by the state's unique legal environment.

“Community Pharmacists’ Experiences in Mental Illness and Addictions Care: A Qualitative Study”(28)

This qualitative study conducted interviews with six community pharmacists using the Theoretical Domains Framework (TDF) and the Behavioral Change Wheels, which tailors a healthcare provider's opinion to their everyday work environment. The study designers recruited pharmacists who were licensed and had experience in dispensing psychotropic medications to patients with a history of addiction or mental illness. An interview guide was developed tailored to community pharmacy practice and the current understood role of community pharmacist with mental health treatment. The answers were recorded, transcribed, and coded the responses to the TDF model which linked the responses to common themes and behaviors.

The TDF model recognized five themes that pharmacists experience in managing patients with mental health or addiction. The pharmacists identified the following barriers to providing care to patients, including: lack of time, lack of relationship and trust from patients, mental health stigma, lack of collaboration, and pharmacist role expectation. The focus groups discussed possible solutions such as reimbursement to mental health medication therapy management, collaboration with training professionals or social workers, allowing pharmacists to discuss medications and listen to patients which can increase the trust between pharmacists and patients.

“Implementing an Opioid Risk Assessment Telephone Clinic: Outcomes From a Pharmacist-Led Initiative in a Large Veterans Health Administration Primary Care Clinic”(29)

Two clinical pharmacists were integrated into a Veterans Health Administration Medical Practice Primary Care Clinic to perform risk assessments for patients who request chronic opioid refills. The pharmacists utilized the Veterans Affairs extensive electronic medical record to form the Chronic Opioid Assessment Program (COAP) and were available to perform consultations and answer provider questions over the telephone, through electronic medical record (EMR) reports, emails, and instant messages. Patients were contacted two weeks prior to their opioid renewal and their regimen was reviewed according to the VA/Department of Defense (DoD) clinical guidelines. The pharmacists documented all of their recommendations, which include but were not limited to adjunctive non-opioid medications, laboratory monitoring, follow up visits, and opioid appropriateness. Data was collected from the documented COAP notes and a Fisher’s

exact test was used to determine the statistical significance from before and after the pharmacists were integrated into the clinic.

During the two years, 171 patients were recruited with over 50% of them showing aberrant behaviors, such as opioid misuse. The pharmacists conducted 447 chronic opioid assessments, with 32.4% of the recommendations being to change the current opioid regimen. One third of the changes were to decrease the current dose and 22.7% were recommending discontinuation of opioid. The COAP pharmacist recognized patients with illicit substances or non-prescribed opioid in their urine drug test and made recommendations to the providers.

The COAP pharmacist implementation resulted in several statistically significant results. The number of patients with an opioid consent form increased from 4.7% to 68.4% ($p < .0001$) and the number of patients who completed a urine drug screen increased from 62.8% to 79.7% ($p < .0001$). In addition, the number of patients with a current PDMP report increased from 30.4% to 100% ($p < .0001$). Overall, the pharmacist-driven telephone risk assessment clinic increased compliance to the VA/DoD clinical guidelines for chronic opioid management.

“The Drug Court Pharmacist: Expanding Pharmacy Practice and Addressing Substance Abuse”(30)

This program analysis explained the role of Drug Courts, which offers an alternative to drug-related prison charges or probation. There were over 2000 operational Drug Courts in Indiana and Michigan in 2009. The drug court consists of an interdisciplinary team composed of

public health professionals, probation officers, lawyers, a judge, and different mental health professionals. Drug courts have been shown to reduce re-arrest in these individuals by 8% to 26% and showed a 211% return on investment, reducing the cost on the criminal justice system.

Purdue University College of Pharmacy and the University of Minnesota College of Pharmacy have been including pharmacists in drug courts which usually are not included as part of the team. These pharmacists meet individually with participants before sessions, make recommendations to providers regarding current addiction treatment, and make referrals to valuable resources. The pharmacists offer patient counseling on a variety of topics including smoking cessation, nutrition, medication management, and over the counter medications.

“Physician–Pharmacist Collaborative Care Model for Buprenorphine-Maintained Opioid-Dependent Patients”(31)

This pilot program evaluated the impact of a physician-pharmacist collaborative practice on the management of patients receiving buprenorphine/naloxone therapy for OUD in a suburban health department. The authors cited the documented success of these collaborative practices for other disease states and noted that evaluation of only one other similar program been published, which used a physician-nurse practitioner collaboration.

The model examined in this article included an internist, clinical psychiatric pharmacist, and a medical assistant. This team worked together to manage 12 patients on buprenorphine/naloxone maintenance therapy after patients completed their induction phase in

another health care setting. The clinical pharmacist conducted the initial appointment with patients during where they gathered a detailed medical and substance use history and relayed the information to the attending physician who reviewed the case. The pharmacist then conducted 135 follow-up monitoring appointments, where they assessed adherence, reviewed toxicology screenings, and confirmed the ongoing treatment plan with the physician. Unique aspects of the program included: 1) urine toxicology screens which tested for both illicit drugs and buprenorphine, 2) requirement that all patients obtain the medication from a single pharmacy, and 3) patient referral to a single community pharmacy where the physician and clinical pharmacist had established a relationship with the employees. Referring patients to this pharmacy provided assistance in diversion monitoring, increased access to the medication, and resolved any issues in a timely manner.

After the one-year duration of the program, the authors determined that they were able to reduce physician burden, increase retention of patients compared with rates seen in office-based settings, reduce costs of treatment, and increase relapse and diversion monitoring. Both the relationship with the community pharmacy and toxicology screenings for buprenorphine aided in enhanced diversion and relapse screening. The pharmacist-led patient appointments decreased the physician load and the cost of out-sourcing monitoring to outside health care providers, saving the health department an estimated \$22,000. The retention rates of 100% at six months and 73% at 12 months was a promising outcome of this program and should be investigated further.

Discussion

The studies included in our narrative review demonstrate how innovative programs and practices can expand the role of pharmacists throughout the entire spectrum of interventions for the opioid crisis by capitalizing on their existing skill sets and knowledge. These studies demonstrate the types of involvement community or clinical pharmacists have in caring for patients affected by, or are at risk to be affected by, the opioid crisis: actively engaged in upstream interventions aimed at preventing abuse and improve safety, screening and monitoring opioid prescribing and usage, providing access to naloxone, and assisting in the recovery and rehabilitation process of patients with OUD, including collaboratively managing OUD with evidence-based pharmacotherapy.

Two articles presented programs that successfully decreased the overall amount of opioids prescribed and also increased safe opioid prescribing practices.(26, 29) These interventions mainly focused on a pharmacist reviewing patients charts before a visit or after a refill request. This provided an opportunity for the pharmacist to make recommendations on medication management or suggestions for other interventions including harm reduction or referral to care. Clinical pharmacists secure access to the electronic medical record, prescription drug monitoring programs, and proximity to other health care providers allows for collaborative programs that can shift the culture of opioid prescribing and patient management from one

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characterized by both patient and prescriber fears to one of stigma-free, team-based, chronic disease management.

Once opioids are prescribed, pharmacists are often one of the last line of health care providers capable of ensuring appropriate opioid use. This highlights why patient and caregiver involvement, including safe storage, disposal, and naloxone dispensing and education is essential. There are several critical aspects of opioid screening and monitoring that can be used by pharmacists to ensure appropriate use including: opioid misuse and accidental overdose risk assessments, urine or saliva toxicology testing, and monitoring through PDMPs. Importantly, these tools should be used to compassionately and universally engage patients in care, instead of punitive approaches that only harm the patient.

The study by Strand and colleagues provided evidence that community pharmacists can be involved in proactive screening solutions instead of reactive tactics to decrease opioid misuse.(27) In this report, pharmacists used a screening tool with accompanying triage algorithms that provided pharmacists a framework to deliver appropriate therapy, counseling, and resources. This screening was enacted at the dispensing of an opioid medication, and was positively received by both pharmacists and patients. Furthermore, Cox and colleagues(26), Jacobs and colleagues(29), and DiPaula and Menachery (31), report the ability of pharmacists to evaluate OUD by reviewing urine drug toxicology tests before the patient even reaches the pharmacy.

Several articles have discussed the potential of PDMPs to impact the pharmacist's role in the opioid crisis.(27,30) PDMPs aim to provide a comprehensive database to help pharmacists detect opioid misuse and refer patients to treatment. While these programs lay a good foundation, there are several shortcomings that need to be addressed to maximize their utility. PDMPs differ greatly between states, and legal mandates for PDMP use by prescribers and pharmacists have been limited until recently. Furthermore, there is a current lack of PDMP integration into EMRs and pharmacy operating systems which limits their accessibility and subsequent use.(32) Pharmacists should realize that electronic resources like PDMPs are one of several tools to be used together to evaluate opioid misuse risk and to maintain patient engagement. Some PDMPs and supply-side policies may potentially end up unintentionally harming patients if not combined with expansion of treatment and harm reduction interventions like naloxone.(32,33)

Naloxone has had a major impact on the prognosis of the opioid crisis due to its efficacy of opioid overdose reversal and ease of administration, and legal efforts to increase dispensing and distribution of naloxone are prevalent across the U.S.. The Department of Health and Human Services and two Food and Drug Administration (FDA) panels have both endorsed co-prescribing of naloxone for both lower overdose-risk users of high-dose, extended-use of prescription opioids, and higher-risk patients diagnosed with OUD and/or with a history of nonfatal overdose.(34) Co-prescribing naloxone policies were evaluated and showed dramatically increased naloxone dispensing after implementation.(35)

Studies by Bounthavong and colleagues(25), Cox and colleagues(26), and Jacobs and colleagues (29) all represent different interventions that can result in increased naloxone prescribing. Whether general educational outreach or patient-specific recommendations, these interventions were able to improve identification of patients who would benefit from naloxone and increase the overall amount of naloxone prescribed. Community pharmacists are situated closely to the public and can provide safety-net services for those at risk of overdose, particularly illicit opioid users, including dispensing naloxone through a standing order. Pharmacists can and should emphasize naloxone and referral to comprehensive, medication-centric addiction care through their harm reduction efforts, not only with naloxone, but also through sterile syringe sales.

The pharmacists' role in recovery goes beyond medication counseling alone. Palombi and colleagues (30) describes the pharmacist involvement in Drug Courts to aid in OUD recovery, in tandem with local law enforcement. Drug Courts provide an avenue for pharmacists to get involved in the legal aspects of the opioid crisis, outside of PDMPs and naloxone dispensing. While pharmacist involvement in drug courts is still new, their utilization has proved invaluable for the patient in both legal proceedings and long-term recovery. Finally, a study by DiPaula and Menachery demonstrated that pharmacists can play a vital part in the management of patients receiving MOUD.(31) The authors demonstrated how giving pharmacists more responsibility over the primary pharmacological management of patients could improve patient outcomes while also providing potential cost savings.

Conclusion

Opioid-related overdose deaths are increasing and are the cause of numerous deaths daily as the opioid crisis continues. Pharmacists are essential health care providers who interact with patients at risk of overdose, diagnosed with an OUD, and those who require opioid safety education. Pharmacy leaders and advocates need to continue their unwavering support for development and implementation of patient-centric and financially sustainable care models that maximize pharmacists' knowledge and skills to increase their role in caring for this patient population. This can be accomplished through pharmacists' involvement in universal screening and education, harm reduction promotion particularly through unrestricted naloxone and syringe access, and expansion of medication-based treatment access focusing on mortality-reducing buprenorphine therapy.

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