HHS Public Access

Author manuscript

Subst Abus. Author manuscript; available in PMC 2021 January 01.

Published in final edited form as:

Subst Abus. 2020 ; 41(3): 269–274. doi:10.1080/08897077.2020.1787300.

Medication Treatment for Opioid Use Disorder and Community Pharmacy: Expanding Care During a National Epidemic and Global Pandemic

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Abstract

Medications for opioid use disorder (MOUD), such as methadone and buprenorphine, are effective strategies for treatment of opioid use disorder (OUD) and reducing overdose risk. MOUD treatment rates continue to be low across the US, and currently, some evidence suggests access to evidence-based treatment is becoming increasingly difficult for those with OUD as a result of the 2019 novel corona virus (COVID-19). A major underutilized source to address these serious challenges in the US is community pharmacy given the specialized training of pharmacists, high levels of consumer trust, and general availability for accessing these service settings. Canadian, Australian, and European pharmacists have made important contributions to the treatment and care of those with OUD over the past decades. Unfortunately, US pharmacists are not permitted to prescribe MOUD and are only currently allowed to dispense methadone for the treatment of pain, not OUD. US policymakers, regulators, and practitioners must work to facilitate this advancement of community pharmacy-based through research, education, practice, and industry. Advancing community pharmacy-based MOUD for leading clinical management of OUD and dispensation of treatment medications will afford the US a critical innovation for addressing the opioid epidemic, fallout from COVID-19, and getting individuals the care they need.

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The US has experienced a devastating opioid epidemic over the last decades—which continues to have tremendous negative impacts on public health across the nation.[1] While a reduction in opioid prescribing nationally is among the limited improvements observed in recent years,[2-4] rates of opioid use disorder (OUD) continue nevertheless to surge substantially, realizing 300-400% increases among some populations.[5-8] Clinic- and population-level data demonstrate medications for opioid use disorder (MOUD); such as methadone and buprenorphine; are effective strategies for treatment and reducing overdose risk.[9-11] MOUD—able to be prescribed or dispensed in a variety of clinical settings—is the gold standard treatment for OUD and has shown to reduce healthcare costs and prevent high-risk behaviors.[12-18] In addition, MOUD improves patients' quality of life.[19-22]

In the US, however, MOUD treatment rates among those with OUD continue to be low.[1,23] High overdose rates persist in communities with limited treatment capabilities.[24] Rates of OUD largely exceed rates of treatment capacity nationwide, with some areas altogether lacking OUD treatment providers.[24-26]

Clinicians and addiction investigators across the US are calling attention to the worsening realities of access to MOUD treatment stemming from the 2019 novel corona virus (COVID-19) coinciding with the significant vulnerabilities of patients with addiction.[27-29] With hospitalization and mortality rates increasing internationally, individuals with opioid and/or other substance use disorders have been recognized to have increased risk for infection.[29-32] There exists some evidence that use of addictive substances, including alcohol and opioids, increases during times of national crisis.[33-37] US federal agencies have worked to adjust rules to better facilitate OUD treatment; however, existing treatment shortages combined with social distancing and shelter-in-place orders aimed at flattening the COVID-19 curve have increased barriers to OUD evidence-based care.[29-32] A real concern during the COVID-19 pandemic—similar to concerns during natural disasters—is the potential for decreased access to and retention in addiction care.[27,38,39] Historically, such population-level crises have been particularly deleterious to patients with addiction, with access to care further impaired in spite of relaxed regulations and rules within the US addiction treatment system.[27,40-44]

Pharmacy to Address Treatment Shortage

A major setting to address these serious challenges in the US surrounding access to opioid treatment is *community pharmacy*. Community pharmacies have substantial potential as a ubiquitous service location—with >90% of Americans living within 2 miles of a retail pharmacy.[45] Pharmacists have extensive training in management, safety assessment, and effective use of medications.[46] These professionals enjoy some of the highest rankings for consumer trust,[47] and notably, prior research has demonstrated patients are willing to receive behavioral health information from pharmacists.[48,49] Research has shown pharmacists can play an important role in delivering evidence-based services to care for opioid related risk.[50,51] It is unfortunate that US pharmacists are not permitted to prescribe MOUD and are only currently allowed to dispense methadone for the treatment of pain, not OUD.

Pharmacists in Canada, Australia, and across Europe (particularly the United Kingdom [UK]) have been closely involved in delivery of treatment for OUD, particularly methadone maintenance services, for a number of decades. [52-54] In the present day, licensed pharmacists in Australia, Canada, and UK pharmacies are able to fill and dispense methadone prescriptions to verified patients, with procedures in place to ensure diversion does not occur.[55,56] An accreditation is optional in Australia[53,57] and not required in Canada and the UK. [58,59] Funding for pharmacy-based MOUD programs in Canada and the UK are paid for by governmental sources[55] (although Canada's system does not universally cover medication costs) and Australia's system is a public private payer mix.[53] Costs for operating pharmacy based programs in Canada, Australia, and the UK are similar to US methadone programs.[60]

Pharmacy delivery of methadone maintenance therapy has contributed to important outcomes for those receiving OUD treatment. One noteworthy example is population penetration among those with OUD. Compared to the US, rates of those who receive methadone treatment for OUD are 3-4 times higher in Canada[61] and 1.6 times higher in Australia.[62,63] Moreover, while rural methadone programs in the US are nearly non-existent, and very few rural providers have buprenorphine waivers,[64,65] rural areas of Canada have approximately similar methadone enrollment and retention rates as urban populations.[66] Remarkably, in the current wake of COVID-19, while the US has scrambled to develop solutions to facilitate treatment for those with OUD[28,67,68]—Canadian, Australian, and UK pharmacies have only needed to make modest shifts to keep vital treatment medications available to patients.[69-71] Notably, as a result of the pandemic, the roles and scope of practice of Canadian pharmacists have expanded. Under Section 56 (1) of the Controlled Drugs and Substances Act, Health Canada has issued temporary exemptions for prescriptions of controlled substances. [72] This expansion permits pharmacists to extend prescriptions, transfer prescriptions to other pharmacists, allows prescribers to issue verbal orders, and permits pharmacy employees to deliver prescriptions of controlled substances. Prescribers, pharmacists, and other healthcare providers are encouraged to work closely together to identify the best possible solution and outcome for patients.[72]

To date, buprenorphine products (including buprenorphine/naloxone) are the only opioid agonist treatments available to be dispensed—with a prescription from a valid, credentialed prescriber— in US community pharmacies. Buprenorphine products possess a number of benefits, which include (1) insurance coverage by Medicare, most Medicaid programs, and many commercial payers; (2) accessibility for patients who are not geographically located near a licensed opioid treatment program (a "methadone facility"), and (3) availability as a treatment option to those who do not seek or wish to engage in methadone care due to ideological and stigma concerns.[73,74] Yet, buprenorphine treatment is highly regulated in that it can only be prescribed by waivered practitioners, and pharmacists' attitudes/beliefs toward MOUD treatment may impede current and future implementation of pharmacist-led care models.[75-82]

Advancing the Field

Owing to the benefits of broader access of medications for opioid treatment, such as methadone and buprenorphine—we echo the call of others across the US of the paramount importance for US policy makers, regulators, and practitioners to work to enable licensed pharmacists to be an integral part of the strategy to screen, prevent, and manage MOUD.[27,55,60] Potential results of such actions would (1) continue the advancement for a solution to the US opioid epidemic; (2) provide a critically needed response to the rapidly evolving challenges faced by COVID-19; and (3) stage a foundation for future national readiness within the substance use prevention and treatment system. We set forth four pillars that support such a system transformation:

Research.

Recently completed, current, and future research projects demonstrate and will continue to expand the capacity of US pharmacists to engage patients with opioid related risk and use disorders. For instance, our research team at the University of Utah recently led a study in which pharmacists screened and provided a brief medication adherence intervention in collaboration with a telephone-based patient navigator to address prescription opioid misuse among community pharmacy patients.[50] Results of this study showed intervention feasibility, acceptability and significant improvements for patients compared to controls for opioid medication misuse, depression, and pain.[50] A second phase of this line of research will implement the intervention in a powered trial within a small system of community pharmacies. This program of research has begun to demonstrate pharmacists can successfully lead in the management of patients with opioid-related risk behaviors.

The National Institute on Drug Abuse Clinical Trials Network has also been a frontrunner in bringing pharmacy into the OUD continuum of care. For example, our Clinical Trials Network team is leading the *Validation of a Community Pharmacy-based Prescription Drug Monitoring Program Risk Screening Tool (CTN-0093)* study, which study is working in community pharmacies to validate a national prescription drug monitoring program-based metric that will enable pharmacists to triage and understand care needed by patients with prescription opioid-related risk, including OUD. Subsequent to this study, a clinical decision support tool will be developed and tested incorporating the validated metric that will empower pharmacists within their practice workflow to better provide care to patients with opioid related-risk health concerns. In addition to this study, Duke University Network members are leading the *Integrating Pharmacy-Based Prevention And Treatment Of Opioid And Other Substance Use Disorders: A Survey Of Pharmacists And Stakeholder (CTN-0095)* study. This survey is working to understand the current status, knowledge, and attitudes of pharmacists in the US towards identification, brief intervention, referral, and MOUD provision. Together, these studies demonstrate the increasing knowledge and resource base for pharmacists managing/treating patients with OUD.

Federal and state regulations limiting MOUD prescribing and dispensing, however, currently impede the capacity to test models of care in community pharmacies. One important avenue to facilitate such evaluation could be seeking exemptions for Investigational New Drug rules from the US Food and Drug Administration (FDA).[83] Guidance from the FDA allows for a

medication to be used for research purposes if it is lawfully marketed in the US, not intended to change labeling or advertising of the medication, does not significantly increase risk with use of the product, is conducted in compliance with human subjects projections requirements, and is not intended for product commercialization.[83] Leveraging this mechanism may allow for US-based development and testing of MOUD management within community pharmacies.

Practice.

A key framework for testing and implementing novel models for MOUD dispensation and management in community pharmacy is collaborative practice agreements (CPA). [84] Examples of well-known CPAs include influenza vaccinations,[85] diabetes care,[84] and naloxone rescue.[86] CPAs set forth criteria and procedures within which pharmacists can operate under a provider's prescribing authority to perform specified functions. For methadone or buprenorphine within community pharmacy settings, a CPA could include intake assessments and medication initiation, dispensation, monitoring, refills, and discontinuation. It is important to note that CPAs do not come without challenges, including resistance from some prescribers,[87] that necessarily should be addressed as these important agreements are implemented into practice.

Education.

Complementary to advancements for CPAs is development and implementation of training and education for pharmacists within the field and those soon to be practicing. While some efforts have taken place in the past for creating curricula and training materials for pharmacists to effectively practice with those who use substances, [88-90] pharmacy education in the US continues to have a limited focus on this area. Similar to the manner in which many states mandate continuing education credits in pharmacy law as a specific topic area,[91] it will likewise be important that credit requirements include addiction treatment topics, such as MOUD management. Furthermore, it is critical that pharmacy degree granting programs across the US increasingly incorporate initiatives to focus on both behavioral and medicinal approaches to substance use prevention, intervention, and treatment.

Industry.

Innovations in community pharmacy research, practice, and education create a professional environment that is also rapidly changing. Indeed, community pharmacy is quickly evolving from its roots in retail practice into crucial roles within interdisciplinary treatment teams, leaders for wellness management, and acute/chronic care providers.[92-94] It is thus key that as pharmacists continue to be recognized in much broader roles in the US—industry leaders and large-scale employers also recognize the critical addition of addiction health care services in community pharmacy. Such a transformation in industry can only be led by sustainable payment models to support pharmacists engaging in addiction care. Inroads currently underway that support such system-level transformation are based in state laws slowly being passed that distinguish and compensate pharmacists as health care providers. [95] Including MOUD management as a reimbursable service for pharmacists would facilitate successful long-term practice integration.

Conclusion

The opioid epidemic combined with the current COVID-19 pandemic have had a devastating impact across the globe. This impact has catapulted the need to increase the role of pharmacist as an important health care provider and integral part of the multidisciplinary team caring for those with OUD. Advancing community pharmacy-based MOUD services in terms of leading clinical management and dispensation of medication will afford the US a critical innovation for addressing the opioid epidemic, fallout from COVID-19, and getting individuals with OUD the care they need. Following the above outlined pillars of research, education, practice, and industry stands to facilitate this needed expansion of services for patients with OUD.

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