HHS Public Access

Author manuscript

J Addict Med. Author manuscript; available in PMC 2023 January 11.

Published in final edited form as:

J Addict Med. 2022 ; 16(5): 499–504. doi:10.1097/ADM.0000000000000950.

Office-Based Methadone Prescribing for Opioid Use Disorder: The Canadian Model

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Abstract

In the context of the US overdose crisis, improving access to medications for opioid use disorder is urgently needed. The Canadian model of methadone treatment, whereby clinicians can prescribe methadone for opioid use disorder in office-based settings and methadone can be dispensed through community pharmacies, offers a compelling model for adoption in the US. Office-based settings in which methadone is prescribed often adopt a rapid-access model, allowing walk-in appointments and same-day initiation of methadone. Prescribing authorization requirements have been relaxed over the past 25 years to improve access to methadone. This paper summarizes the model of office-based methadone prescribing in Canada, highlighting the regulatory structures, prescribing practices, and interprofessional collaborations that enable methadone treatment in office-based settings. Potential implementation strategies for adopting office-based prescribing in the US are discussed.

Introduction

In the context of the US overdose crisis, improving access to life-saving medication treatment for opioid use disorder is urgently needed. Methadone is an evidence-based treatment for opioid use disorder (OUD) that is associated with reduced overdose-specific and all-cause mortality.[1] In the United States, outpatient clinicians cannot prescribe methadone as a treatment for OUD in office-based settings. Instead, outpatient methadone treatment for OUD is dispensed through opioid treatment programs (OTPs), subject to extensive federal and state regulations stipulating organizational structures, registration requirements, accreditation standards, and clinical practice parameters (including counselling requirements).

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In contrast, methadone treatment in Canada is regulated at the provincial and territorial level. Provinces and territories operate independent regulatory frameworks, some of which require providers to complete training before prescribing or dispensing methadone. Methadone treatment can be provided through various office-based settings, which may provide services beyond methadone, including treatment with buprenorphine/naloxone, harm reduction, psychosocial services, primary care, or complementary substance use disorder treatment services. Many office-based settings adopt low-threshold prescribing practices, and counselling, while offered, is not required.[2] Methadone can be dispensed either in pharmacies or in office-based settings.

The OTP system in the US creates several barriers to OUD treatment with methadone, including limited geographic accessibility and long travel distances, which are associated with decreased retention in treatment.[3,4] There have been increasing calls to adopt methadone prescribing for OUD in the US with dispensing in office-based settings or pharmacies, in a model that resembles the Canadian approach.[5–7]

This paper summarizes the model of office-based methadone prescribing in Canada, highlighting the regulatory structures, prescribing practices, and interprofessional collaborations that enable office-based methadone prescribing. Potential implementation strategies for adopting office-based prescribing in the US are discussed.

Prescribing Authorization

In the US, clinicians can prescribe methadone as an analgesic in outpatient settings; unfortunately, methadone prescribed for analgesia was associated with high rates of overdose deaths in the US in the early 2000s.[8] Given federal regulations restricting methadone to OTPs, there is limited experience in the US prescribing methadone in the outpatient setting, outside clinical trials, for OUD.[9]

Federal and regional health authorities have eased restrictions on methadone prescribing in Canada since the mid-1990s. After a period of methadone prescribing expansion in the mid-1960s, amendments to Canada's Narcotic Control Act in 1972 introduced new federal oversight, including training requirements, strict clinical practice guidelines, a prohibition on prescriptions of methadone, special authorization from Health Canada to provide methadone, and the threat of criminal sanctions for violations.[10] These changes paralleled US regulations introduced by the Food and Drug Administration in 1972 and through the Narcotic Addict Treatment Act in 1974.[10] Beginning in 1996, regulation of methadone became decentralized to regional medical licensing authorities.[10] However, physicians still had to obtain a federal exemption from Health Canada to prescribe methadone for either pain or OUD. In response to increasing opioid-involved overdose deaths and to facilitate access to methadone in Canada, the federal government removed the Health Canada authorization requirement in May 2018.[11] Provincial and territorial physician licensing organizations ('colleges') have similarly been relaxing policies restricting who may prescribe methadone. Selected provincial requirements for prescribing methadone and prescribing locations, as of November 2021, are listed in Tables 1 and 2.

Nurse practitioners (NPs) have recently been given the authority to prescribe methadone for OUD in Canada. In 2012, amendments to Canada's *Controlled Drugs and Substances Act* allowed NPs to prescribe controlled substances, and over the following several years, provinces developed their regulations for prescribing.[11] When the Canadian government removed the federal exemption requirement to prescribe methadone for OUD in 2018, NPs became eligible as methadone OUD treatment providers.[11] Canadian provinces have different regulations for the organization, scope, and reimbursement of NP practice. NPs can prescribe methadone in specialty addiction clinics and primary care practices to varying degrees.[11] In British Columbia, an order of the Provincial Health Officer in September 2020 authorized certain registered nurses and registered psychiatric nurses to prescribe methadone until the emergency from fentanyl-associated overdoses ends in the province.[20] Registered nurses and registered psychiatric nurses must follow standards from the British Columbia College of Nurses and Midwives.[20]

Methadone dispensing

Methadone, for either observed or home administration, can be dispensed in clinics or through pharmacies. Methadone can also be dispensed in assisted living facilities, long-term care facilities, and jails/prisons, similar to other controlled medications. Several provincial guidelines have described the importance of starting and continuing methadone during incarceration and the responsibilities of clinicians in ensuring continuity of care.[13,21,22]

When methadone is dispensed in pharmacies, there is a need for close collaboration between a pharmacy team and the methadone prescriber. The prescriber writes a prescription showing the dose, medication, route of administration, need for directly observed therapy and number of take-home doses ('carries').[23] The pharmacist assesses a patient before dispensing the medication; if the patient appears intoxicated or sedated, which could increase the risk for overdose if methadone were dispensed, the pharmacist holds the dose and notifies the methadone prescriber. Pharmacists also typically inform the prescriber of missed doses.[23]

Provincial colleges of pharmacists set standards for pharmacist training. In Ontario, each pharmacy dispensing methadone must have a manager and at least one pharmacist who takes part in the initial central training course. Pharmacies must notify the Ontario College of Pharmacists within one week of dispensing methadone and are recommended to develop written policies about methadone treatment.[24] In British Columbia, all managers, pharmacists, relief pharmacists, and pharmacy technicians at pharmacies dispensing methadone must complete a mandatory training program and follow provincial guidelines.[25] In Nova Scotia, no special authorization is required for pharmacists to dispense methadone.[23] Pharmacist training can also occur through undergraduate and continuing professional development courses; the Association of Faculties of Pharmacy of Canada has established a competency framework related to OUD for pharmacist education, which includes the ability to "assess patients presenting for observed opioid agonist therapy," "evaluate and manage dosing of opioid agonist treatment during initiation, stabilization and maintenance," "implement safe dispensing practices for opioid agonist therapy."[26]

COVID-19 Modifications

Before COVID-19, provinces had varying policies on eligibility for take-home doses of methadone. Several provinces have introduced more flexibility into take-home dose guidelines during COVID-19. In Ontario, urine drug screens have been deemphasized in determining take-home doses.[27] Take-home doses are now based on a person's ability to safely store and manage the doses instead of prior guidelines recommending negative urine drug screens. Examples of factors that would prevent individuals from receiving take-home doses are recent overdose, suicidality, intoxication at the time of assessment, or the use of substances (e.g. benzodiazepines or alcohol) in a high-risk way. Telemedicine assessments can be used to initiate, renew, or adjust methadone prescriptions, though urine drug screens are still recommended before methadone initiation.[28]

Insurance coverage

Each Canadian province and territory has a separate single-payer, publicly-funded health insurance program, which generally covers hospital care and physician visits. Medications, including methadone drug costs and dispensing fees, are generally only covered as part of supplemental drug benefits programs separate from provincial/territorial health insurance programs. For example, in Ontario, the Ontario Drug Benefit Program (ODB) covers individuals over 65, individuals under 24 without private insurance, people who receive disability benefits, and individuals who receive Ontario Works (government financial assistance to covers essential living costs). For individuals the ODB does not cover, insurance for medications is often provided through employers or purchased privately. Other people must pay for prescriptions, including methadone and related dispensing fees, out of pocket, which can be a barrier to treatment. Under the ODB, pharmacies are reimbursed a markup percentage for the medication cost and the standard medication dispensing fee for each dispensed day of methadone.[29] Nova Scotia's publicly administered Pharmacare drug benefits programs cover the medication costs and dispensing fees for people on income assistance and for any resident who enrolls in the program (with copayment and deductibles set according to family size and income).

Access and effectiveness

More patients receive methadone on a per capita basis in Canadian jurisdictions than in the US.[30,31] As of 2014, 312 physicians prescribed methadone for OUD in Ontario to 49 703 patients, reflecting a per capita rate of treatment over three times higher than in the US. However, these rates do not account for differences in the prevalence of OUD or differential use of buprenorphine between jurisdictions.[30,32–34]

Methadone provided through office-based settings remains effective in the treatment of OUD. Treatment retention among patients receiving methadone in Ontario was between 39% and 49% at 1-year in various regions of the province.[35] Researchers showed individuals released from incarceration in British Columbia with any methadone prescription to have hazard ratios of the overdose death of 0.39 and death from infectious disease of 0.20 while taking methadone compared to periods while not taking methadone.[36] Among people who

inject drugs in Vancouver, enrolment in methadone maintenance treatment was associated with a mortality hazard ratio of 0.73, adjusting for potential confounders.[37]

Limitations of methadone treatment in Canada

In parallel with rising access to prescribed methadone, some evidence suggests a similar expansion in access to illicit or diverted methadone. For example, in Vancouver, British Columbia, people who used drugs reported increased availability of diverted methadone between 2005 and 2015, though they also reported higher availability of other prescription opioids.[31,38] Researchers showed that 7.3% of overdose deaths with toxicology involving illicit drugs in British Columbia from 2015 to 2017 involved methadone.[39] Among individuals who died from methadone-involved overdoses, 38.5% had no active prescription for methadone in the 60 days before their overdose.

Methadone prescribing in Canada has been concentrated in high volume practices, which may interfere with the quality of care.[17] Concerns have been raised about excessive billing for urine drug screens within fee-for-service models of care.[17] Additionally, some methadone treatment providers have not adopted an intersectional approach to addressing the challenges and stigma faced by patients.[40]

Despite the relaxation of methadone prescribing authorization, barriers to prescribing methadone in primary care in Canada include lack of prescriber training and support and perceived complexity of patients with OUD.[41,42] Some regions have faced obstacles to specialized methadone clinics due to stigma, with some communities enacting legislation banning the establishment of methadone clinics.[43,44] Pharmacists have additionally reported concerns about workload, safety and inadequate training as barriers to offering methadone maintenance in rural community pharmacies.[45]

Approaches from the Canadian model for the US

Methadone treatment in Canada was subject to stringent federal treatment guidelines and restrictions on provider authorizations before 1996.[10] After regulation was devolved to individual provinces and territories, authorization procedures were relaxed, and access to methadone treatment increased. In Ontario, for example, 770 patients received methadone before 1996.[46] By the end of 1998, 4,023 patients were receiving methadone treatment, and 49,703 patients were receiving treatment by 2014.[30,46] In British Columbia, the number of patients receiving methadone for OUD increased from 2800 in 1996 to 16,900 in 2015.[7,31]

Developing a distributed model of methadone prescribing and dispensing can increase the number of patients accessing methadone treatment. Prescribing methadone through primary care improves access while helping to normalize and destigmatize methadone OUD treatment.[7] However, it also requires sufficient prescriber and pharmacist expertise and the appropriate regulatory framework to support clinicians providing methadone treatment while ensuring patient safety. How could the US integrate distributed methadone prescribing and dispensing into the existing frameworks while allowing individuals who do not want or cannot obtain methadone from OTPs to access this life-saving treatment?

First, regulatory barriers to prescribing methadone in the US would have to be amended, including the Controlled Substances Act, which prohibits methadone prescribing, and SAMHSA and DEA regulations governing OTPs.

Second, a clinical infrastructure for distributing methadone maintenance treatment would have to be created to allow more widespread access to methadone while mitigating risks of diversion and overdose. Patients are particularly susceptible to overdose during the first four weeks after starting methadone or when prescribed methadone for pain.[1,8] In Canada, although methadone can be prescribed in primary care, many patients begin treatment at more specialized addiction clinics (including RAAM clinics). OUD treatment and care may transition back to family medicine/primary care provider after a stable dose is found, provided the family physician is comfortable prescribing methadone. Similar methadone medical maintenance models have been investigated in the US and could be established using existing OTPs or addiction specialists to initiate methadone.[47]

Potential methadone prescribers such as primary care, addiction medicine, and addiction psychiatry providers outside of OTPs would require training in methadone prescribing, possibly through the use or adaptation of training modules required in Canadian provinces.[6] The Substance Abuse and Mental Health Service Administration could oversee the training, like its role in approving buprenorphine waiver training. Training requirements for methadone prescribing have received criticism in Canada for their effects in restricting access to treatment, dissuading clinicians from providing methadone treatment, and stigmatizing methadone. An appropriate balance between ensuring competence for a treatment modality that few in the US have experience with and avoiding creating unnecessary barriers or stigmatization of methadone would be necessary.

Third, prescribers and pharmacists would have to be supported. Some Canadian provinces have provider-facing clinical consultation lines or “hub-and-spoke” models with centralized specialty clinics supporting primary care practices. Similar provider-facing consultation lines exist in the US for buprenorphine, poison control, and post-exposure prophylaxis for HIV. Allowing pharmacists and prescribers to access on-demand consultation may reduce hesitancy to incorporate methadone evaluation, initiation and dispensing into their practices. It would also facilitate the incorporation of methadone prescribing into primary care practices and allow for the expansion, over time, of methadone availability.

Fourth, partnerships with pharmacists and pharmacies would be needed to allow pharmacy-based dispensing of methadone. Pharmacists and other pharmacy staff play an essential in creating a welcoming and stigma-free environment for patients, assessing patients, and alerting prescribers to missed doses or sedation at the time of assessment. Reimbursing pharmacists with a dispensing fee for each dispensed day of medications is one model to compensate and incentivize pharmacists to incorporate this into their practices.[29] Partnerships with corporate pharmacy chains, similar to partnerships allowing COVID-19 vaccine administration, may also be a way to foster pharmacy engagement.[48]

Once pharmacies provide daily or short-term dispensing of methadone, other medications can be prescribed for observed daily dosing, as is available in Canada. Medications with

either small safety margins (e.g. benzodiazepines co-prescribed with methadone) or that have evidence to co-administer with opioid agonists directly observed therapy (e.g. hepatitis C medications) can be co-administered through pharmacies in a distributed model.[49] Such a model would reduce the challenges of integrating the dispensing non-methadone medications into OTPs and would allow patients to obtain co-administered medications closer to home.[3]

Fifth, reimbursement systems for methadone dispensing would have to change. For example, many OTPs are currently reimbursed through bundled payments, whereas pharmacists and prescribers require reimbursement under the current system. Sixth, rapid access models, with same-day initiation of methadone, either through in-person visits tele-prescribing, should be available throughout the US for methadone treatment.[50]

Finally, a role for the unique expertise and wealth of experience developed in OTPs would have to be retained and incorporated into a new system for methadone treatment. Calcaterra et al. proposed a role for OTPs in a hub-and-spoke model, where patients with more severe illness courses (or patients who preferred OTP-based care) would be referred to OTP hubs for more intensive psychosocial support.[6] Alternatively, OTPs could be redeployed to provide other OUD treatments such as injectable opioid agonist therapy, if they become available in the US.

Conclusions

Providing office-based methadone treatment for opioid use disorder in Canada relies on interprofessional collaboration between pharmacists, physicians, and other healthcare providers. Prescribing authority for methadone is regulated by provincial and territorial medical licensing colleges, which expect that methadone is prescribed only if physicians have the necessary skill and expertise. Some colleges have additional training requirements before prescribing methadone. Pharmacy colleges and guidelines have established best practices about the role of pharmacists, and pharmacists can receive training through centralized courses.

Funding Sources:

RAK, TDB, and AB received support from the Research in Addiction Medicine Scholars Program (National Institute for Drug Abuse R25DAO33211). TDB is also supported by the Dalhousie University Internal Medicine Research Foundation Fellowship and a Canadian Institutes of Health Research Fellowship (CIHR-FRN no. 171259). AB is enrolled in the International Collaborative Addiction Medicine Research Fellowship, a US National Institute on Drug Abuse (NIDA)-funded research training fellowship offered in partnership with the BC Centre on Substance Use, St. Paul's Hospital, and the University of British Columbia. AB is also a recipient of the 2020 Friends of Matt Newell Endowment in Substance Use from the Cumming School of Medicine at the University of Calgary and an Impact of COVID-19 on Psychiatry Grant from the American Psychiatric Association.

Disclosures of Financial or Other Potential Conflicts of Interest:

Drs. Brothers, and Bahji report no conflicts of interest. Dr Danilewitz reports personal fees outside of the submitted work from Otsuka, Eisai Ltd and Winterlight Labs. Dr. Kleinman has received travel support from the American Academy of Addiction Psychiatry and American Psychiatric Association (within past 36 months).

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Table 1.

Requirements for physicians to prescribe methadone in selected provinces

Province	Prescribing authorization requirements
Ontario	None as of March 2021 when previous requirements were rescinded.[12] Physicians are expected to remain within scope of practice, skill and expertise.[12] Training for physicians is available.
Quebec	No formal requirements. Clinicians are strongly recommended to receive training before providing care for patients with OUD and undertake a preceptorship or have the ability to consult a practitioner experienced in providing care to patients with OUD[13]
British Columbia	Physicians are required to obtain education from the British Columbia Centre on Substance Use, which comprises a series of modules and two half-days of preceptorship.[14,15]
Alberta	Physicians are required to complete an online virtual training program (or an assessment of prior prescribing experience) before prescribing methadone.[16]

Table 2.

Models of methadone prescribing in selected provinces

Province	Selected prescribing setting
Ontario	Specialized opioid agonist treatment clinics Rapid access addiction medicine clinics Primary care Addiction medicine/addiction psychiatry Prescribing of methadone is concentrated in high-volume practices; as of 2014, 10% of methadone prescribers provided 56% of prescribed days of methadone in the province.[17]
British Columbia[18]	Specialized opioid agonist treatment clinics Rapid access addiction medicine clinics Primary care Addiction medicine/psychiatry practices
Alberta	Specialized opioid dependency programs (organized by Alberta Health Services) in major population centers Since March 2021, a province-wide virtual opioid dependency program with same-day initiation of methadone.[19] Primary care practices Addiction medicine/psychiatry practices