RESEARCH PAPER

Methadone Prescribing Regulation for Opioid Use Disorder in Canada: Evidence for an East–West Policy Divide

Règlement sur la prescription de méthadone pour les troubles liés à la consommation d'opioïdes au Canada : preuves d'un fossé entre l'Est et l'Ouest



CHLOE CAMPBELL, BHSc
Medical Student
Temerty Faculty of Medicine
University of Toronto
Toronto, ON

KELLIA CHIU, BPHARM (HONS), PhD
Postdoctoral Fellow
Department of Family and Community Medicine
Temerty Faculty of Medicine
University of Toronto
Toronto, ON

ABHIMANYU SUD, MD, PhD
Assistant Professor
Department of Family and Community Medicine
Temerty Faculty of Medicine
University of Toronto
Research Chair
Primary Care and Population Health Systems
Humber River Health
Toronto, ON

Abstract

Opioid agonist therapy (OAT) is a key element in the response to opioid-related harms in Canada. In May 2018, Health Canada rescinded the requirement for obtaining a federal exemption for methadone prescribing. This comparative analysis examined provincial OAT policies and policy changes in response to this federal policy change. Policies and changes

were regionalized; despite having lower rates of opioid-related harms, eastern provinces had looser regulatory regimes compared with western provinces, which became even looser after the federal policy change. Diverse knowledge and policy networks need to be fostered to bridge this east–west divide in substance use care policy.

Résumé

Le traitement par agonistes opioïdes (TAO) est un élément clé de la réponse aux effets néfastes des opioïdes au Canada. En mai 2018, Santé Canada a annulé l'exigence d'obtenir une exemption fédérale pour la prescription de méthadone. Cette analyse comparative porte sur les politiques et les changements de politiques concernant le TAO en réponse à l'annulation de l'exigence fédérale. Les politiques et les changements ont été régionalisés; malgré des taux plus faibles d'effets néfastes liés aux opioïdes, les régimes de réglementation des provinces de l'Est, qui étaient déjà plus souples que ceux de l'Ouest, le sont devenus encore plus après le changement de la politique fédérale. Il faut favoriser la diversité des réseaux de connaissances et de politiques pour combler ce fossé Est–Ouest dans la politique sur les soins offerts aux toxicomanes.

Introduction

Opioid-related harms continue to escalate in Canada, impacting people of all ages, communities and socio-economic groups. Between 2016 and 2022, there was a near doubling in the number of people dying due to opioid toxicity from 2,830 to 5,360 people, even with the 2022 data only available until September (Government of Canada 2023). Hospitalizations for opioid poisoning have continued to stay elevated, averaging 14 per day in 2022 (Government of Canada 2023).

These harms are not distributed evenly across the country. There are substantially higher mortality and hospitalization rates in western provinces and territories, including British Columbia (BC), Alberta (AB), Saskatchewan (SK) and Yukon (YT) (Government of Canada 2023). For example, apparent opioid-related deaths in AB were 32.4 per 100,000 in 2022, nearly twice the national mean. Specific regions in BC have mortality rates of 42.9 per 100,000 (including other illicit substances) (Government of Canada 2023), which is comparable with some of the hardest-hit regions in the US (CDC 2023). These devastating trends in the western provinces have been driven primarily by the contamination of the drug supply by fentanyl and other potent synthetic opioids (Belzak and Halverson 2018). Although eastern provinces have also had significant and growing opioid-related harms, the overall rates are substantially lower. For example, Quebec's (QC) mortality rate in 2020 was 3.7 per 100,000 (Government of Canada 2023). The drug supplies in the eastern and Atlantic provinces are less likely to be affected by non-prescription opioids and fentanyl contamination. In Nova Scotia (NS), as of 2021, mortality rates due to prescription opioids were more than triple those of non-prescription opioids (3.0 versus 0.9 deaths per 100,0000) (Open Data Portal 2024).

Opioid agonist therapy (OAT) is a key element in the response to opioid-related harms. It is an effective, safe and widely used treatment for opioid use disorder (OUD), or opioid addiction, that involves treatment with long-acting opioid medications such as methadone, buprenorphine or slow-release oral morphine in order to manage withdrawal and cravings (Neale et al. 2019). As in many other jurisdictions internationally, despite its effectiveness and the important initiatives undertaken to expand access, Canadians continue to have limited access to OAT due to a number of intersecting structural forces, such as stigma related to drug use, insufficient training of prescribers and stringent regulation of prescribing (Pijl et al. 2022).

Medications for OUD are among the most highly regulated pharmaceuticals (Sud et al. 2022). Opioid agonists are considered controlled substances and, until recently, providers were required to obtain a Canadian federal Section 56 Exemption from the *Controlled Drugs and Substances Act* (1996) in order to prescribe, sell, provide or administer methadone (CRISM 2017). In addition to having to comply with this federal regulation, health professionals must also comply with the distinct provincial/territorial prescribing and dispensing regulations for education, training and monitoring under the oversight of the provincial/territorial medical, nursing and pharmacy regulatory colleges (CRISM 2017; Pijl et al. 2022). These provincial/territorial regulations have, to a great extent, been influenced by federal exemption requirements. In contrast, opioid analgesics for the management of chronic pain such as hydromorphone, morphine or even transdermal fentanyl have not been subject to the same complex regulations. This complex, multi-level regulation has made medications for OUD challenging and onerous to prescribe and dispense, and likely acted as a deterrent for health professionals to be engaged in OUD care.

After a focused consultation on this issue, in May 2018, in an attempt to reduce this complexity and address the growing opioid-related harms across Canada, Health Canada rescinded the requirement for the Section 56 Exemption for methadone (Health Canada 2017). This Canadian policy change is in keeping with some international examples of federal OAT deregulation (Sud et al. 2023). For example, in the late 1990s, France instituted federal policy reform, particularly in response to the growing rates of transmission of the human immunodeficiency virus related to injection drug use, which substantively increased access to buprenorphine in primary care (Gamage et al. 2023). At the end of 2022, the US abolished the requirement for a federal waiver from the Drug Enforcement Agency for buprenorphine prescribing (*Mainstreaming Addiction Treatment Act* 2021). Similar to Canada, variation in continuing state-level regulation may very much determine the impacts of this US federal policy change.

Given this multi-level and federalist nature of methadone regulation in Canada, the removal of the federal methadone exemption requirement provides an opportunity to compare regulatory policy responses to OAT within and across the provinces and territories. In addition to the differing regulations, the diverse epidemiology of opioid-related harms means that such comparisons are essential for understanding variable policy trajectories and responses as well as possible opportunities for cross-jurisdictional learning. Therefore, the

aim of this study is to document, compare and analyze the OAT policies and policy changes in response to the removal of the federal methadone exemption requirement within each territory's and province's particular health system contexts.

Methods

Study design

We conducted a two-stage comparative analysis of provincial/territorial OAT regulations using documentary data sources (Blank et al. 2017). First, the changes in the content of health policies regulating methadone for OAT before and after the May 2018 federal policy change were documented, inductively categorized, organized on a timeline and then compared across jurisdictions. Second, we investigated cross-referencing of provincial/territorial guidance documents to identify any cross-provincial or national relationships.

Data sources

We drew from publicly available policies, guidelines, reports and education/training materials relevant to provincial and territorial methadone prescription requirements for OAT. To obtain documents for analysis, an online search was performed in two stages. The first involved accessing the official medical regulatory college websites of each province and territory to obtain guidelines, policies and public releases of information. Subsequently, a general online search was performed using keywords including province or territory name, methadone and provider type (physician), and keywords were combined using Boolean operators. Documents published in English or French describing provincial/territorial requirements for methadone prescribing for OAT were included in the analysis. Exclusion criteria included documents not from a direct provincial/territorial or scientific source (e.g., news articles), those only referencing the use of methadone for analgesia and those outlining changes implemented before 2014, about five years prior to the federal removal of the exemption requirement. We elected to focus on medical regulations rather than pharmacy regulations as these would be the most directly impacted by the removal of the exemption. Likewise, during the study period, there was significant interprovincial variability in nurse practitioner prescribing rights and, thus, clear pre- and post-exemption removal patterns could not be discerned and were not included in this study.

Data analysis

DESCRIBING PROVINCIAL OAT PRESCRIBING REQUIREMENTS

For each province and territory, a timeline was constructed from 2014 onwards documenting all changes relevant to methadone prescribing requirements. Once timelines were constructed, clinicians and policy makers with OAT expertise from each province were consulted to review the respective timelines for accuracy and relevance. Of note, we were unable to obtain expert review for YT. From the policy documents and our constructed timelines, we inductively identified five broad categories of requirements: (1) initial education and training;

(2) mentorship or preceptorship; (3) regular renewal of licence and continuing education and training; (4) registration with the relevant college; and (5) auditing or practice review. These categories were identified across all provincial/territorial policies, and they align with previous literature on OAT prescribing requirements (Eibl et al. 2017; Priest et al. 2019; Sachidanandan et al. 2022). Requirements in each category were coded as either mandatory or recommended.

Initial education and training refers to any mandated action that must be taken by the healthcare professional to increase knowledge or aptitude regarding methadone prescribing in order to obtain initial prescribing permission. This may include different kinds of educational programs such as webinars or accredited provincial programs. Mentorship or preceptorship refers to any shadowing, residency, preceptor-based courses or ongoing relationships with mentors.

Regular renewal and continuing education and training refers to any requirement for a prescriber to undergo education or training to qualify for re-application to their college for continuing approval to prescribe methadone. These are additional, ongoing education requirements above and beyond the initial education and training requirements.

Registration with the relevant college refers to a mandated requirement for physicians to apply and obtain approval from their medical college to prescribe methadone.

Auditing and practice review refers to any regulation by which physician practices are subject to formal review, either by peers or a regulatory body. Any province that was explicitly stated to invoke ongoing auditing or practice review was identified as such. Any province where auditing/practice review was not commented on – or where most other educational/collegial requirements were removed – was assumed to have no official requirements for standard auditing or practice review.

MAPPING EDUCATION AND GUIDELINE USAGE ACROSS PROVINCES AND TERRITORIES

To further explore any cross-jurisdictional patterns, we examined individual provincial/territorial medical regulatory college OAT standards for references to documents, policies, training programs and standards from other provinces and territories. We inductively categorized and then visualized these references in terms of their content (education/training program, clinical guideline, regulatory standard) and strength (identified as an alternative to consider, a recommendation, a requirement or wholesale adoption).

Institutional ethics

Research ethics board approval was not required as this study only used data from publicly available documentary sources.

Results

Relevant documents for all provinces and territories except the Northwest Territories and Nunavut were identified and included in the analysis.

2014 to May 2018: Pre-removal of exemption

Prior to the removal of the Section 56 Exemption, all provinces and territories required prescribers to undergo initial education and training related to methadone prescribing as well as college registration (Table 1). All provinces except QC and Prince Edward Island (PEI) also required mentorship or preceptorship. All provinces except QC required regular renewal or continuing education and training. Notably, several of the eastern provinces (QC, New Brunswick [NB] and Newfoundland and Labrador [NL]) did not have any auditing or practice review requirements even prior to the removal of the exemption.

While there were fewer high-level differences in the categories of requirements across jurisdictions before the removal of the exemption, western provinces demonstrated tighter education and preceptorship regulation compared with eastern provinces. For instance, providers in AB were required to take a methadone maintenance treatment (MMT) course, gain experience in an OAT setting or evidence of training, potentially undergo an interview with a registrar of the College of Physicians and Surgeons of Alberta or equivalent, complete requirements specific to initiation (preceptorship until determined competent with documentation of competence, complete a course within two years and 40 hours of continuing medical education every five years and maintain association with providers) and have requirements specific to maintenance (attend an MMT/equivalent course again within five years and maintain association/collaboration with another provider). SK had near identical requirements. In contrast, eastern provinces such as NL, NB, NS and Ontario (ON) required an online course (or similar), eight-hour to two-day preceptorships and completion of additional training every three to five years. The province with the fewest requirements before exemption removal was QC, only requiring a one-day professional development course and naming of a mentor willing to support, if needed.

June 2018 onwards: Post-removal of exemption

After the removal of the exemption, several provinces, including ON, NB, NL, NS and PEI, removed all or the majority of their pre-exemption requirements. In other provinces, including BC, YT, AB, SK and Manitoba (MB), there was little to no change in requirements following removal of the exemption. It should be noted that all provinces without mandatory education or training still strongly recommended ongoing training and education to providers.

BC had unique requirements where new prescribers (and those who have not prescribed for over three years) post-exemption removal were required to complete education and preceptorship and report to the provincial college, while those who previously held an exemption under Health Canada did not have these requirements and could continue to prescribe with no specific requirements. As regulations for new prescribers are particularly important to consider with respect to increasing the system capacity to prescribe, these changes were included in the table as required education and training, required mentorship/preceptorship and required college registration for BC.

TABLE 1. Requirements for methadone prescribing regulation across jurisdictions pre- and post-removal of the Section 56 Exemption

	Initial education and training		Mentorship or preceptorship		Regular renewal or continuing education and training		College registration		Auditing or practice review	
Jurisdiction	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**	**Pre**	**Post**
British Columbia[a]	●	●*	●	●*	●		●	●*		
Yukon	●	●	●	●	●	●	●	●		
Alberta	●	●	●	●	●	●	●	●	●	●
Saskatchewan[b]	●	●	●	●	●	●	●	●	●	●
Manitoba	●	●	●	●	●	●	●	●	●	●
Ontario[c]	●		●		●		●	●	●	●
Quebec[d]	●						●			
New Brunswick	●		●		●		●			
Newfoundland and Labrador	●		●		●		●			
Nova Scotia	●		●		●		●		●	
Prince Edward Island	●	●			●		●		●	

● Indicates required to prescribe in jurisdiction.
a Removed requirement for Section 56 Exemption in 2016.
b Requires continuing medical education with no regular renewal.
c Removed education/training requirements in March 2021.
d Required to name a mentor willing to support, if necessary.
* Applies only to those with no previous Section 56 Exemption before removal or no prescribing within the past three years.

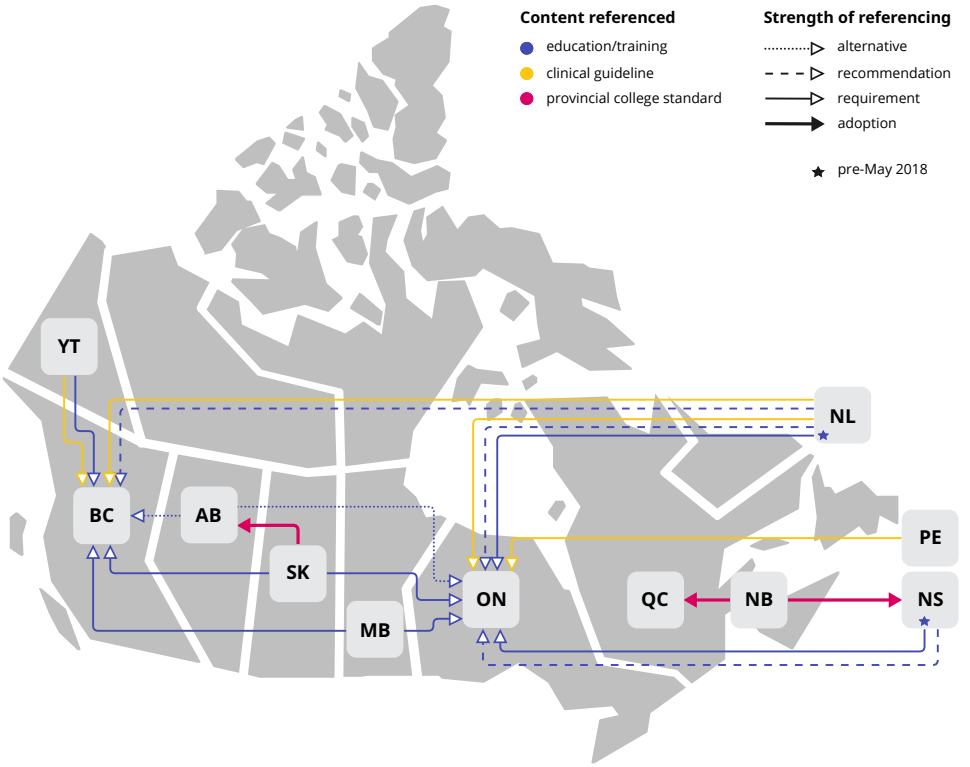
Cross-jurisdictional referencing

BC and ON were the two major "nodes" from which other provinces drew references (Figure 1). We identified seven references to BC documents and nine to ON documents, while documents from these provinces did not reference documents from any other province. More specifically, their major education and guideline providers, the British Columbia Centre on Substance Use and the Centre for Addiction and Mental Health (CAMH), are highly referenced by other provinces. Generally, BC operates as a reference node for western provinces and territories (YT, AB, SK, MB and also NL), while ON does so for eastern and some western provinces.

We identified college standards from two provinces (SK and NB) that explicitly adopted another province's standards, which would not only include training requirements and guidelines but also other requirements such as preceptorship, registration and auditing. In both cases, these adoptions occurred within geographically regionalized west versus east networks.

The removal of the federal exemption had a minimal impact on this cross-jurisdictional referencing. For two provinces (NS and NL), we identified a change in the type of referencing after the removal of the exemption. While both provinces had previously *required* physicians to undertake the training from Ontario's CAMH, this was downgraded to a *recommendation* contemporaneous with the exemption removal (also seen in Table 1).

FIGURE 1. Cross-jurisdictional methadone document referencing across Canadian provinces and territories before removal of the Section 56 Exemption



AB = Alberta; BC = British Columbia; MB = Manitoba; NB = New Brunswick; NL = Newfoundland and Labrador; NS = Nova Scotia; ON = Ontario; PE = Prince Edward Island; QC = Quebec; SK = Saskatchewan; YT = Yukon.

Discussion

Regionalized and hierarchical policy responses

Analysis and comparison of methadone policies and changes across provinces and territories demonstrated multiple important patterns relevant to the larger context of opioid-related harms in Canada. On the one hand, western provinces and territories (BC, AB, SK, MB and YT) had tighter prescribing regulations before the removal of the federal exemption, many of which were maintained post-removal. Eastern provinces (QC and the Atlantic provinces), on the other hand, had relatively loose regulatory regimes before the removal of the exemption, which became even looser after the removal. ON – both geographically and also in terms of policies – sits in between these two regions with several pre-exemption removal restrictions removed but some maintained. The cross-jurisdictional referencing of prescribing policies was similarly regionalized and was also hierarchical: documents referencing resources of another province tended to be within the same geographic region and tended to reference resources from more populous provinces.

While this study was not designed to determine the reasons for these regional and hierarchical patterns, they are likely affected by geographical, political and/or professional factors. Regulatory colleges of the more populous provinces have much larger dues-paying registrants than their counterparts in less populous provinces. For example, BC has 11,743 registered physicians while SK has 2,387 (CMA 2019). This means that the regulators in the more populous provinces are better resourced to develop and enact the regulatory policies for methadone prescribing. This greater resourcing is also true with respect to health systems and, in this case, health education institutions. Likewise, values specific to different jurisdictions play important roles in drug policies, including OAT regulations. For example, our previous cross-national research has identified important differences in OAT policies based on value orientations around drug use with jurisdictions with more restrictive OAT policies being more oriented toward abstinence-based approaches while jurisdictions with less restrictive OAT policies being more oriented toward harm reduction (Chiu et al. 2023).

Missed opportunities and locked-in policy trajectories

Considering this east–west regionalization of the policy response against the epidemiology of opioid-related harms in Canada raises some additional important questions. There are higher rates of harm and specifically fentanyl use in western provinces, and increasing access to and utilization of OAT (particularly using methadone) is an essential policy response. Removal of the federal exemption provided a window of opportunity for provinces and territories to address these high rates of harm and improve access to care. For example, previous efforts to decrease regulatory control of methadone have been associated with increases in treatment availability and use (Kurdyak et al. 2018). It might, therefore, be expected that western provinces would have elected to relax methadone regulations. However, our findings show the opposite – eastern provinces such as QC that already had more relaxed regulations and lower rates of opioid-related harms relaxed their methadone regulations even further, while western provinces mostly stood pat in the face of growing harms.

This raises the possibility that restrictive policies around methadone may, in fact, be important *contributors* to higher rates of harm in western provinces compared with eastern provinces, while looser regulation in the eastern provinces could, in fact, be relatively protective. Poorer access to care, more use of the contaminated drug supply and greater opioid-related harms may all be knock-on effects of tighter regulatory control of methadone. The failure of western provinces to respond to the policy opportunity of the federal exemption removal may indicate that they are locked into a policy trajectory of restrictive methadone prescribing. This may then be reinforced by the regionalization of cross-jurisdictional referencing and communication. This phenomenon of regionalized policy communication is also seen in established horizontal intergovernmental relations between provinces/territories enacted through institutions such as the Western Premiers' Conference (a forum of the premiers from the three territories and the provinces of BC, AB, SK and

MB) and the Council of Atlantic Premiers (Atkinson et al. 2013). While these relationships are particularly evident in macro-level policy arenas such as trade and labour, their influence on health or social policy is less known (Berdahl 2011). Therefore, further exploration of whether and how political and geographical factors may influence drug policy and treatment regulation is warranted.

Applications to policy practice

Moving forward, developing more diverse policy and knowledge networks across the east–west division may facilitate a corresponding greater diversity and appropriateness of policy responses to opioid-related harms. For instance, ON is a populous, central and "intermediate" province with a balance of policy restriction and relaxation following the removal of the federal exemption. Likewise, cross-jurisdictional referencing demonstrated ON's high influence across both eastern and western provinces. These factors suggest that it could play an important mediating response across these regional networks. Other institutions with national reach and connectivity such as the Federation of Medical Regulatory Authorities of Canada and the Canadian Research Initiative in Substance Misuse may play important mediating roles as well. As initiators and implementors of this policy change, Health Canada would be particularly well-placed to support cross-jurisdictional policy learning, including through its federal Opioid Response Team. A first step in this direction could be through supporting a comprehensive evaluation of the healthcare and population health impacts of this policy change at national and subnational levels.

In addition, this analysis further emphasizes the need to recognize the substantial variation of the Canadian opioid crisis across provinces, in terms of both epidemiology and policy responses. While the earliest national reporting on the opioid crisis began in the Atlantic provinces, over time attention has shifted to western provinces with a focus specifically on fentanyl-related harms (Webster et al. 2020). Such a focus may not do justice to other provinces that face unique challenges and particularities regarding opioid-related harms and thus need policy responses specific to their jurisdictions.

Limitations

This study is limited by the absence of available data for the Northwest Territories and Nunavut, as well as the lack of expert review for YT. While both policy wise and epidemiologically, YT does seem to pattern with the western provinces, it is possible that the territories may constitute a distinct pattern that may not fit the east–west divide identified here.

We did not include the analysis of policy development nor motivations for the implementation of these policies. Thus, we are unable to explain why the described patterns in prescribing policy exist. Future work should aim to examine the underlying reasons for

the observed patterns, as well as investigate how they can be improved to better respond to opioid-related harms. Additionally, it will be important to determine the impact of these policy changes on important outcomes, such as access to treatment for OUD, and on opioid-related harms. While there will be challenges in doing such impact evaluations given the variability in (and sometimes paucity of) relevant data systems across provinces and territories, approaches to evaluating policy impacts such as interrupted time series analyses could be conducted to support such efforts, and doing so would be in keeping with the pressing need for ongoing and accelerated policy learning in response to the crisis of opioid-related harms.

Given these limitations, it is important to characterize our major findings of an east–west policy divide as provisional and defeasible. Further investigation as outlined above may identify important nuances and revisions of this characterization of policy trajectories.

Conclusion

This study demonstrated greater restriction of methadone prescribing in western provinces compared with eastern provinces as well as regionalized and hierarchical cross-jurisdictional referencing. Greater restriction in the west despite higher rates of harm indicates potential contributory effects of these policies on opioid-related harms, as well as inflexible policy trajectories reinforced by regionalized cross-jurisdictional referencing. There is an ongoing need to explain these policy patterns, develop pathways for alternative policy development and consider the impacts of these policy changes on access to OAT.

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Correspondence may be directed to Abhimanyu Sud by e-mail at abhimanyu.sud@utoronto.ca.

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