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

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Abstract

Opioid agonist therapy 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 In May 2018, Health Canada rescinded the requirement for obtaining a federal exemption for methadone prescribing.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 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 to 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.

Introduction

Opioid-related harms continue to escalate in Canada, impacting people of all ages, communities, and socioeconomic 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 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, Alberta, Saskatchewan and Yukon (Government of Canada 2023). For example, apparent opioid-related deaths in Alberta were 32.4 per 100,000 in 2022, nearly twice the national mean. Specific regions in British Columbia have mortality rates of 42.9 per 100,000 (including other illicit substances) (Government of Canada 2023) which is comparable to some of the hardest-hit regions in the United States (CDC 2021). 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 mortality rate in 2020 was 3.7 per 100,000 (Government of Canada 2023). The drug supplies in Eastern and Atlantic provinces are less likely to be affected by non-prescription opioids and fentanyl contamination. In Nova Scotia, as of 2021, mortality rates due to prescription opioids were more than triple those of non-prescription opioids (3.0 vs 0.9 deaths per 100,0000) (Nova Scotia Open Data Portal 2018).

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, 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 despite important initiatives to expand access, access to OAT in Canada continues to be limited 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* in order to prescribe, sell, provide, or administer methadone (CRISM 2017). In addition to having had 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 growing opioid-related harms across Canada, Health Canada rescinded the requirement for the subsection 56 exemption for methadone (Health Canada 2017). This Canadian policy change is keeping with some international examples of federal OAT deregulation (Sud et al., 2023). For example, in late 1990s France instituted federal policy reform, particularly as a response to growing rates of HIV transmission related to injection drug use, which substantively increased access to buprenorphine in primary care (Kankanam Gamage et al., 2023). At the end of 2022, the United States 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 multilevel 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 OAT policies and policy changes in response to the removal of the federal methadone exemption requirement within each territory 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. 2018). First, the changes in the content of health policies regulating methadone for OAT pre- and post- the May 2018 federal policy change were documented, inductively categorised, organised on a timeline, and then compared across jurisdictions. Second, we examined for 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 consisted of accessing the official medical regulatory college websites of each province and territory to obtain

official 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 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 prior to 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 so 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 respective timelines for accuracy and relevance. Of note, we were unable to obtain expert review for the Yukon. 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 license 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 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 actions 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 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, were 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 the content of the references (education/training program, clinical guideline, regulatory standard) and the strength of the reference (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 - May 2018: Pre-removal of exemption
Prior to removal of the federal 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 Quebec and Prince Edward Island (PEI), also required mentorship or preceptorship. All provinces except Quebec required regular renewal or continuing education and training. Notably, several of the Eastern provinces (Quebec, New Brunswick and Newfoundland and Labrador) 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 prior to removal of the exemption, Western provinces demonstrated tighter education and preceptorship regulation compared to Eastern provinces. For instance, providers in Alberta 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 maintaining providers) and had requirements specific to maintenance (attend an MMT/equivalent course again within five years and maintain association/collaboration with another provider). Saskatchewan had near identical

requirements. In contrast, Eastern provinces such as Newfoundland and Labrador, New Brunswick, Nova Scotia and Ontario 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 fewest requirements pre-exemption removal was Quebec, only requiring a one-day professional development course and naming of a mentor willing to support if needed.

Table 1. Requirements for Methadone Prescribing Regulation Across Jurisdictions Pre- and Post-Removal of the Federal Section 56 Exemption

Jurisdiction	**Initial education and training**		**Mentorship or preceptorship**		**Regular renewal or continuing education and training**		**College registration**		**Auditing or practice review**	
	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 prior to removal or no prescribing within the past 3 years

June 2018 - onwards: Post-removal of exemption

After removal of the exemption, several provinces including Ontario, New Brunswick, Newfoundland and Labrador, Nova Scotia and PEI removed all or the majority of their pre-exemption requirements. In other provinces, including British Columbia, Yukon, Alberta, Saskatchewan and Manitoba, 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.

British Columbia 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 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.

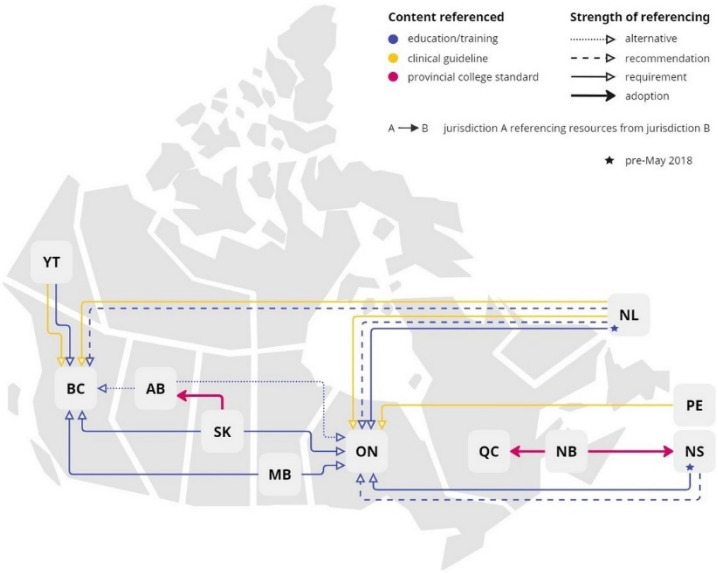
Cross-jurisdictional referencing

British Columbia and Ontario were the two major “nodes” from which other provinces drew references (Figure 1). We identified seven references to BC documents and nine to Ontario documents, while documents from these provinces did not reference documents from any other provinces. More specifically, their major education and guideline providers, the British Columbia Centre on Substance Use and the Centre for Addiction and Mental Health, are highly referenced by other provinces. Generally, British Columbia operates as a reference node for Western provinces and territories (Yukon, Alberta, Saskatchewan, Manitoba and also Newfoundland) while Ontario does so for Eastern and some Western provinces.

We identified college standards from two provinces (Saskatchewan and New Brunswick) 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 (Nova Scotia and Newfoundland), 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 Centre for Addiction and Mental Health, 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 Pre-Removal of the Federal Section 56 Exemption>



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 (British Columbia, Alberta, Saskatchewan, Manitoba and Yukon) had tighter prescribing regulations prior to removal of the federal exemption, many of which were maintained post-removal of the federal exemption. Eastern provinces (Quebec and the Atlantic provinces), on the other hand, had relatively loose regulatory regimes prior to the removal of the exemption, which became even looser after the removal of the exemption. Ontario, 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, British Columbia has 11,743 registered physicians while Saskatchewan has 2,387 (Canadian Medical Association 2019). This means that the regulators in the more populous provinces are better resourced to develop and enact 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 towards abstinence-based approaches while jurisdictions with less restrictive OAT policies being more oriented towards 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 harms 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 Quebec who 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 compared to 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 Council of Western Premiers (a forum of the premiers from the three territories, British Columbia, Alberta, Saskatchewan and Manitoba) 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, Ontario 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 Ontario'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 on 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.

Additionally, 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 the 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, which 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 the Yukon. While both policy-wise and epidemiologically, the Yukon 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 analysis of policy development, nor motivations for 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 nuance and revisions of this characterization of policy trajectories.

Conclusion

This study demonstrated greater restriction of methadone prescribing in Western provinces compared to 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 opioid agonist therapy.

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