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Policy Analysis

Comparing Canadian and United States opioid agonist therapy policies

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ABSTRACT

Canada and the United States (U.S.) face an opioid use disorder (OUD) and opioid overdose epidemic. The most effective OUD treatment is opioid agonist therapy (OAT)—buprenorphine (with and without naloxone) and methadone. Although federal approval for OAT occurred decades ago, in both countries, access to and use of OAT is low. Restrictive policies and complex regulations contribute to limited OAT access. Through a non-systematic literature scan and a review of publicly available policy documents, we examined and compared OAT policies and practice at the federal (Canada vs. U.S.) and local levels (British Columbia [B.C.] vs. Oregon). Differences and similarities were noted between federal and local OAT policies, and subsequently OAT access. In Canada, OAT policy control has shifted from federal to provincial authorities. Conversely, in the U.S., federal authorities maintain primary control of OAT regulations. Local OAT health insurance coverage policies were substantively different between B.C. and Oregon. In B.C., five OAT options were available, while in Oregon, only two OAT options were available with administrative limitations. The differences in local OAT access and coverage policies between B.C. and Oregon, may be explained, in part, to the differences in Canadian and U.S. federal OAT policies, specifically, the relaxation of special federal OAT regulatory controls in Canada. The analysis also highlights the complicating contributions, and likely policy solutions, that exist within other drug policy sub-domains (e.g., the prescription regime, and drug control regime) and broader policy domains (e.g., constitutional rights). U.S. policymakers and health officials could consider adopting Canada's regulatory policy approach to expand OAT access to mitigate the harms of the ongoing opioid overdose epidemic.

Introduction

North America is in the midst of an opioid overdose epidemic. In 2017, approximately 4,000 people in Canada (Special Advisory Committee on the Epidemic of Opioid Overdoses, 2018) and 47,600 people in the U.S. died from an opioid-related overdose (Hedegaard, Miniño, & Warner, 2018). Opioid overdose commonly occurs in the context of an opioid use disorder (OUD), a chronic, but treatable condition. Cochrane reviews assert that the most effective, life-saving, OUD treatment is opioid agonist therapy (OAT) with either methadone (oral formulation) (Mattick, Breen, Kimber, & Davoli, 2009) or buprenorphine (sublingual film and sublingual tablets [with or without naloxone]) (Mattick, Breen, Kimber, & Davoli, 2014).

OATs are long-acting opioids that stimulate the mu-opioid receptors in the central nervous system to prevent withdrawal and reduce cravings (Schuckit, 2016). OAT use decreases mortality risk and improves treatment outcomes in persons with OUD (Sordo et al., 2017). National and international authorities recommend OAT as first-line OUD treatment (Bruneau et al., 2018; Kampman & Jarvis, 2015; World Health Organization, 2009). Our review examines the federal policies controlling the use of approved OAT formulations in each country (i.e., liquid oral methadone and sublingual buprenorphine tablets; with or without naloxone). The local coverage policy review in British Columbia (B.C.) and Oregon compares sublingual/oral OAT insurance coverage, and describes the other types of OAT allowed in B.C.

Regulatory approval for OAT has occurred at notably different

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timeframes in Canada and the U.S. Approval for the use of methadone to treat OUD occurred 57 years ago in Canada (Peachey & Franklin, 1985) and 46 years ago in the U.S. (Rettig & Yarmolinsky, 1995). Sublingual buprenorphine (with naloxone) approval occurred 11 years ago in Canada (Ottawa Canadian Agency for Drugs & Technologies in Health, 2016) and 16 years ago in the U.S. (with or without naloxone) (Food & Drug Administration, 2002). In both countries, despite decades of availability, and a demonstrable evidence-base, estimates of OAT use suggest that many patients with OUD do not receive OAT. In B.C., based on periodic interviews with people who inject drugs, researchers estimated that nearly 70% had access OAT in the past year (Socias et al., 2018). In the U.S., a study of OUD treatment in 154 community-based treatment programs, reported that only 10% of patients received either OAT or opioid antagonist therapy (Knudsen & Roman, 2012).

A variety of factors contribute to limited OAT utilization in both countries. In Canada, barriers include a lack of transportation to services in rural areas, a limited number of pharmacies offering onsite OAT, limited clinic and pharmacy hours, and out of pocket expenses (Boyd, Carter, & Macpherson, 2016). Similar treatment barriers exist in the U.S., these include: financial; geographic; health care professional attitudes; and regulatory factors (Sharma et al., 2017). Decreasing OAT regulatory barriers may be an effective intervention for increasing OAT access. In France, for example, all registered physicians may prescribe buprenorphine in the office-based setting without any special education or additional licensing (Auriacombe, Fatséas, Dubernet, Daulouede, & Tignol, 2004). The implementation of this policy in 1996 led to a 10-fold increase in the number of patients receiving treatment, allowing an additional 65,000 patients with OUD to be treated annually with an 80% decrease in opioid overdose fatalities (Auriacombe et al., 2004).

A lack of centralized data collection systems in the U.S. and Canada inhibit the evaluation of changes to national treatment polices; further, the heterogeneity of local policies create challenges for the assessment of treatment access. Evidence suggests, however, that changes to federal treatment policy may enhance treatment access. The U.S. capacity for providing buprenorphine, for example, theoretically doubled following a legislative change that permitted buprenorphine waivered physicians to increase the number of buprenorphine patients from 30 to 100 (Jones, Campopiano, Baldwin, & McCance-Katz, 2015).

This paper examines and compares the OAT federal policy regimes within Canada and the U.S. and assesses and contrasts provincial (B.C.) and state (Oregon) OAT coverage policies and locally available treatment data. We also discuss the potential contributions of differential access in B.C. and Oregon and the implications for national and regional interventions to address the North American opioid overdose epidemic. B.C. and Oregon were selected because of unique policy and administrative properties, as well as the expertise of the authorship team on OAT policies in those jurisdictions.

Methods

Jurisdiction & policy selection

The existence of federal Canadian and U.S. drug treatment policies and regulations are well documented in the contemporary and historic drug policy literature. This analysis, therefore, focused on the federal policies directly impacting access to OAT. Because the countries differ in the structure and implementation of publicly-funded health insurance, comparable (e.g., coverage for publicly funded OAT services) provincial and state policies were also assessed. Policies were obtained from publicly available online governmental sources and subsidiaries.

Analysis approach

This two-part analysis examined: 1) historic and contemporary federal OAT policies in Canada and the U.S, and 2) B.C. and Oregon OAT health insurance coverage policies. The differences and commonalities between the content and structure of the policies of the jurisdictions were compiled and categorized for final analysis and synthesis.

Results

Historic & contemporary federal OAT policies: Canada and United States

Canadian methadone policies

The Canadian federal OAT policy regime began in the 1960s with the 1961 Narcotic Control Act (Peachey & Franklin, 1985). The Act revised and consolidated Canadian drug policy and included authorization for the use of methadone for OUD treatment (Peachey & Franklin, 1985). A decade later, in 1972, amendments to the Narcotic Control Act imposed five federal requirements for methadone delivery: 1) registration of methadone prescribers; 2) use of specific diagnostic criteria; 3) daily urinalysis prior to stabilization; 4) daily clinic attendance for at least three months during the pre-treatment period; and 5) close-monitoring and mandatory counseling for home methadone administration (“take-home”) (Peachey & Franklin, 1985). Collectively, these regulations limited methadone availability and the number of patients receiving methadone decreased by 60% over the next 10 years (Peachey & Franklin, 1985).

Health Canada (the federal health department) primarily controlled methadone regulation until the mid-1990s (Eibl, Morin, Leinonen, & Marsh, 2017). During this time, Health Canada began transferring methadone oversight to provincial regulatory bodies and in 1995 the B.C. College of Physicians and Surgeons was the first provincial authority to assume responsibility of this policy domain (Brands, Brands, & Marsh, 2000). In 1996, a similar agreement was reached with the Ontario Ministry of Health (Brands et al., 2000). At present, provincial regulatory bodies oversee and control physician methadone practice for most of the population. Health Canada has retained control and oversight of delivery for First Nations people living on reserves, people who are incarcerated in federal correctional facilities, and people in the military (Boyd et al., 2016; Eibl et al., 2017).

The Food and Drug Act and the Narcotic Control Act, in 1996, were merged into the Controlled Drugs and Substances Act (Boyd et al., 2016), affecting OAT policy (Government of Canada, 2015). Section 56 of the Act allowed the Minister of Health to grant exemptions for the use of controlled substances for scientific purposes or in the public’s interest, and required physicians to apply for an exemption from Health Canada to prescribe methadone (Government of Canada, 2015). In addition to a federal exemption, physicians and nurse practitioners (NP) were required to have approval from their provincial regulatory college to administer methadone (Bruneau et al., 2018; College of Pharmacists of British Columbia, 2016). Since the methadone policy regime was transferred from federal to provincial authority, provinces had different requirements for filing the federal Section 56 exemption (2017, Bruneau et al., 2018; Health Canada, 1992). In Canada, methadone delivery occurs in six settings (Eibl et al., 2017): 1) addiction clinics; 2) outpatient physician clinics; 3) federal and provincial correctional facilities; 4) pharmacies; 5) home; and 6) hospitals. Provinces determine who is allowed to prescribe methadone; for example, NPs may prescribe methadone in Manitoba, Ontario, New Brunswick, and Nova Scotia (Bruneau et al., 2018).

Recent changes to Section 56 and the federal methadone policy regime began in 2017. Health Canada issued a section 56 class exemption for all providers who were administering methadone to hospitalized patients (Health Canada, 2018). Approximately one year later, in March 2018, federal health officials dismantled the Section 56 regulations by removing exemption requirements for all qualified methadone prescribers and dispensers (Canada Gazette, 2018). The purpose of these changes were to decrease “unnecessary regulatory barriers to access methadone and diacetylmorphine” (Canada Gazette, 2018) and was a direct response to the current opioid overdose epidemic. At present, the Canadian federal methadone regulatory mechanism no

longer exists and the federal government does not directly control methadone treatment policies.

U.S. methadone policies

The U.S. federal methadone policy regime began with the 1970 Comprehensive Drug Abuse Prevention and Control Act, further defined by 1972 FDA regulations, and the 1974 Narcotic Addict Treatment Act (Rettig & Yarmolinsky, 1995). The 1970 Comprehensive Drug Abuse Prevention and Control Act provided the foundation for contemporary opioid regulations controlling supply, education, research, treatment, and training (Courtwright, 2004). Title II, named the 1970 Controlled Substances Act, created a regulatory framework for opioids (illicit and licit) and other psychoactive drugs. President Richard Nixon's expansion of methadone access in 1971, led to the 1972 FDA regulations that are largely reflected in contemporary regulations (Jaffe & O'Keeffe, 2003; Rettig & Yarmolinsky, 1995). Prior to 1970, thousands of patients received methadone at research treatment centers (Gerstein & Harwood, 1990; Jaffe & O'Keeffe, 2003; Jaffe, 1975; Jonnes, 1996; Kreek & Vocci, 2002). In June of 1970, the FDA proposed new rules for the research treatment centers including strict requirements on entry into treatment, dosage, and duration (Jaffe & O'Keeffe, 2003). The 1972 FDA regulations removed methadone from general distribution and established a unique federal control system to limit methadone dispensing to federally licensed opioid treatment programs (OTP) requiring federal registration for physicians involved in methadone dispensing (Rettig & Yarmolinsky, 1995).

The 1974 Narcotic Addict Treatment Act amended the 1970 Controlled Substances Act and gave the Drug Enforcement Administration (DEA) authority over the storage and security of addiction treatment medications. (Jaffe & O'Keeffe, 2003). Physicians and OTPs were required to maintain annual DEA registration (Jaffe & O'Keeffe, 2003). The Secretary of Health, Education, and Welfare (now the Department of Health and Human Services [DHHS]) retained responsibility for setting standards for professional practice (Jaffe & O'Keeffe, 2003). These regulatory layers remained in place until 2001, when DHHS and the Substance Abuse & Mental Health Services Administration (SAMHSA) issued regulations establishing a new OAT oversight system, transferring the FDA's OTP administrative responsibilities to SAMHSA (SAMHSA). Title 42 of the Code of Federal Regulations Part 8 provides the current regulatory guidance for OTPs (Substance Abuse & Mental Health Services Administration, 2015).

In contrast to Canadian methadone delivery, the U.S. limits the physical location of methadone dispensing. In Canada, most methadone is prescribed by physicians who may require daily witnessed dosages at a pharmacy or take-homes. Conversely, in the U.S., methadone delivery is restricted to federally licensed OTPs with two exceptions: hospitalizations and take-homes. Hospitals may provide methadone for patients with OUD requiring acute medical care (Drug Enforcement Administration, 2005). However, if a patient is admitted specifically for opioid withdrawal, physicians are limited to providing methadone for a maximum of 72 hours (Drug Enforcement Administration, 2005). The use of take-home methadone must also meet explicit federal requirements (Substance Abuse & Mental Health Services Administration, 2015). Correctional facilities providing methadone must be a federally licensed OTP or work in partnership with an OTP. Further, OTP regulations require physicians to be the medical director and mandate that a licensed professional (i.e., pharmacist, registered nurse, licensed practical nurse, or any other healthcare professional authorized to administer pharmaceuticals) dispense the medication (Substance Abuse & Mental Health Services Administration, 2015). In contrast with Canada's methadone treatment policy regime, in the U.S. methadone policy control is retained federally.

Canadian buprenorphine policies

A federal buprenorphine treatment policy regime does not exist in Canada, aside from the 2007 federal approval of the product (with naloxone) for OUD treatment (Ottawa Canadian Agency for Drugs & Technologies in Health, 2016) and the federal regulations that restrict the use of buprenorphine without naloxone for special circumstances (e.g., pregnancy) (Bruneau et al., 2018). A federal buprenorphine/naloxone exemption program to monitor prescribers was never established in Canada.

Provincial authorities control the buprenorphine/naloxone policy regime. Subsequently, treatment policies vary by province; for example, only some provinces allow NPs as prescribers (B.C., Alberta, Manitoba, Ontario, New Brunswick, and Nova Scotia) (Bruneau et al., 2018). Similar to Canadian methadone delivery, buprenorphine/naloxone prescribing and administering occurs in a variety of settings, such as outpatient primary care clinics, specialized addiction treatment centers, or withdrawal management facilities. Further, stable patients receive take-home doses occurring as soon as seven to 10 days following treatment initiation (Bruneau et al., 2018).

U.S. buprenorphine policies

The contemporary U.S. buprenorphine (with or without naloxone) policy regime is based on the Drug Addiction and Treatment Act of 2000 and the Comprehensive Addiction and Recovery Act of 2016. The Drug Addiction and Treatment Act eliminated the federal prohibition of opioid prescribing for the treatment of OUD if the medication had FDA-approval specifically for OUD treatment (McCarty, Priest, & Korthuis, 2018). This Act also required qualifying physicians to apply for and receive a waiver from the federal government to write buprenorphine prescriptions (McNicholas, 2004) upon the completion of federally designated training and registration (SAMHSA). The FDA approved buprenorphine for OUD treatment in 2002 (Food & Drug Administration, 2002). In 2016, the Comprehensive Addiction and Recovery Act expanded the health professionals that could prescribe buprenorphine, allowing NPs and physician assistants to qualify for the federal waiver program (McCarty et al., 2018).

Buprenorphine is prescribed and administered in a variety of U.S. settings, similar to Canada, including but not limited to OTPs, and anywhere a qualified prescriber is licensed to practice (SAMHSA). Importantly, in contrast with Canadian buprenorphine/naloxone delivery, when patients receive buprenorphine in the outpatient setting in the U.S. (not while in an OTP) their starting dose may occur in the office or at home, dependent on the provider and patients preference (SAMHSA). Further, unlike Canadian buprenorphine regulations, U.S. prescribers have limits on the number of patients they may treat with buprenorphine—for physicians, this is 30 patients in year one, 100 patients in subsequent years, and with specialty training a maximum of 275 patients (SAMHSA). NP and physician assistants may only prescribe buprenorphine for up to 30 patients (SAMHSA). Table 1 provides a timeline highlighting relevant federal OAT policies and regulations in both countries.

The contemporary federal OAT treatment policies and practice, in Canada and the U.S., were assessed across six domains: 1) the policy locus of control; 2) the existence of federal prescriber registration programs; 3) the allowable prescribers; 4) observed dosing requirements; 5) the allowable delivery settings; and 6) the existence of prescription patient panel limits, see Table 2 for these findings.

Provincial and state case studies

Local OAT coverage policy regimes affect OAT access. In the U.S., whether a patient has health insurance or whether the insurance company provides OAT coverage determines OAT access. A retrospective analysis of the state-managed low-income public health insurance programs (Medicaid) found that only 31 of 50 programs covered methadone for OUD treatment (Substance Abuse & Mental Health Services Administration, 2014). OAT coverage variation exists in Canada as well. Five provinces—B.C., Alberta, Manitoba, Ontario, and Newfoundland—covered buprenorphine/naloxone as a regular,

Table 1
Regulatory and Policy Highlights.

Year	Country	
	Canada	U.S.
Methadone		
1961	Drug approval and the Narcotic Control Act	
1970		Comprehensive Drug Abuse Prevention and Control Act
1972	Amendments to the Narcotic Control Act	Drug approval and FDA regulations
1974		Narcotic Addict Treatment Act
1995	Federal oversight transfer to B.C. provincial health authority	
1996	Controlled Drug and Substances Act	
2001		Transferred FDA administrative OTP responsibilities to SAMHSA
Buprenorphine[a]		
2000		Drug Addiction and Treatment Act
2002		Approval of tablet formulations and regulations
2007	Approval of tablet formulation	
2016		Comprehensive Addiction and Recovery Act

Table Notes: Food & Drug Administration (FDA). Substance Abuse & Mental Health Services Administration (SAMHSA).
[a] Buprenorphine with naloxone in Canada and buprenorphine with and without naloxone in the U.S.

general, or open benefit; and five provinces (i.e., Saskatchewan, Quebec, New Brunswick, Nova Scotia, and Prince Edward Island) imposed additional coverage requirements (Bruneau et al., 2018).

A comparison of the differences and similarities in OAT coverage policies between B.C. and Oregon illustrates the ways in which broader federal control policies influence local coverage policices. B.C. permits access to five OATs through a variety of coverage mechanisms: three oral medications (buprenorphine/naloxone, methadone, slow-release oral morphine [SROM]) and two medications not allowed for use in the U.S. (injectable diacetylmorphine and injectable hydromorphone). In contrast, Oregon Medicaid follows U.S. federal requirements and limits OAT access to two oral OATs: buprenorphine (with or without naloxone) and methadone.

British Columbia

The Canadian Constitution assigns health service delivery to the provinces and territories (Boyd et al., 2016). Generally, provinces and territories receive funding for substance use disorder (SUD)-related services from their ministry of health and services, and are either delivered by centralized provincial health authorities or by regional health authorities (Boyd et al., 2016). The provincial authority and oversight for OUD-related treatment is different than other health services because of federal requirements for some types of OAT products. In April 2016, the B.C. health officer declared the opioid overdose epidemic a public health emergency under the Public Health Act, and the provincial government, in partnership with the federal government, allocated $322 million (Canadian dollars) in 2017 to improve mental health and addiction services. The health officer also launched the Overdose Emergency Response Centre to respond quickly to mobilize resources to address the crisis (British Columbia, 2019)

OAT (buprenorphine/naloxone, methadone, and slow-release oral morphine [SROM])

Prior to July 2016, the B.C. College of Physicians and Surgeons was the designated provincial regulatory body for the B.C. methadone program. In 2016, the B.C. Centre on Substance Use (BCCSU) became the responsible authority (British Columbia Centre on Substance Use & British Columbia Ministry of Health, 2017). In B.C., with provincial health authority approval, SROM (federally approved for pain management) became an allowable OUD treatment for clinical scenarios in which buprenorphine/naloxone or methadone was not available or appropriate (Express Scripts, 2014). The recently published Canadian national guidelines for OUD treatment recommend SROM as a third-line oral treatment approach when methadone and buprenorphine/naloxone are not effective (Bruneau et al., 2018).

Methadone, buprenorphine/naloxone and SROM prescribed for OUD treatment are covered, without restriction, under PharmaCare's Psychiatric Medications Plan (Plan G) (British Columbia Centre on Substance Use, 2018). PharmaCare also covers these medications under the income-based Fair PharmaCare plan, and provides 100% coverage under PharmaCare Plan C (Income Assistance) and Plan W (First Nations Health Benefits) (British Columbia Centre on Substance Use, 2018).

Injectable OAT (iOAT)

Presently, two self-administered iOAT are available for persons with severe OUD in B.C.—diacetylmorphine and hydromorphone (British Columbia Centre on Substance Use & British Columbia Ministry of Health, 2017). iOAT reimbursement occurs through the provincial Medical Services Plan or through extended health benefits. Access to diacetylmorphine began in 2013 using a special access request to Health Canada for research participants (Boyd et al., 2016; Oviedo-Joekes et al., 2009). The approved request was revoked almost immediately, and, in 2014, the B.C. Supreme Court granted an injunction allowing research participants to continue to receive diacetylmorphine (Boyd et al., 2016). In 2016, amended regulations enabled access to diacetylmorphine for non-study participants through the Health Canada Special Access Program (Government of Canada, 2016). Diacetylmorphine provision is highly regulated, with rules for importation, compounding, storage, and dispensing (British Columbia Centre on Substance Use & British Columbia Ministry of Health, 2017). The result of these stringent regulations is that diacetylmorphine is currently only available at one clinical site in Canada in Vancouver B.C (Providence Health Care, 2017).

Access to diacetylmorphine occurs through two federal regulatory mechanisms: 1) the Drugs for Urgent Public Health Need, and 2) the Special Access Program (British Columbia Centre on Substance Use & British Columbia Ministry of Health, 2017). The Drugs for Urgent Public Health Need is a federally maintained list of drugs requested by health officials to address local and urgent public health needs (British Columbia Centre on Substance Use & British Columbia Ministry of Health, 2017). Products accessed through this regulatory pathway allow public health officials to request a quantity of drug for their jurisdiction and for repeated importation (British Columbia Centre on Substance Use & British Columbia Ministry of Health, 2017). Two sections of the federal Narcotic Control Regulations restricted diacetylmorphine use to the hospital setting (British Columbia Centre on Substance Use & British Columbia Ministry of Health, 2017), but recent amendments now allow physicians and NPs to prescribe diacetylmorphine for OUD treatment outside the hospital (Canada Gazette, 2018).

The Special Access Program is another federal pathway to access unauthorized drugs in Canada (British Columbia Centre on Substance Use & British Columbia Ministry of Health, 2017). Special Access Program requests are reviewed, authorized, or denied on a patient-by-

Table 2
Treatment Policies and Practice.

Domain	Methadone		Buprenorphine[a]	
	Country		Country	
	Canada	U.S.	Canada	U.S.
Policy locus of control	Primarily provincial	Primarily federal	Primarily provincial	Primarily federal
Federal prescriber registration program	No requirement	Providers must follow Title 42 of the Code of Federal Regulations Part 8c	No requirement	Prescriber must obtain federal waiver
Allowable prescribers	Physician and NP*	OTP medical director is a physician; non-physician may administer	Physician, NP*	Physician, NP, physician assistant
Observed dosing	Yes, except for take-homes	Yes, except for take-homes	In some settings	Primarily in OTPs
Delivery setting(s)	Addiction clinic, outpatient clinic, correctional facility, pharmacy, hospital, and home	OTP, hospital, and home	Addiction clinic, outpatient clinic, correctional facility, pharmacy, hospital, and home	OTP, residential facility, outpatient clinic, hospital, and home
Prescription patient panel limits	No	NA	No	Yes

Table Notes: Nurse practitioner (NP); opioid treatment program (OTP); not applicable (NA);
* Provincially dependent.
[a] buprenorphine with naloxone in Canada and buprenorphine with and without naloxone in the U.S.

patient basis by Health Canada (British Columbia Centre on Substance Use & British Columbia Ministry of Health, 2017). If access is approved, the practitioner is required to report on drug use (e.g., adverse events) for that individual patient (British Columbia Centre on Substance Use & British Columbia Ministry of Health, 2017).

The regulatory framework impacting distribution, administration, and dispensing of injectable hydromorphone is less complicated than diacetylmorphine (British Columbia Centre on Substance Use & British Columbia Ministry of Health, 2017). Hydromorphone may be dispensed by approved pharmacies through compounding or single-use dose (British Columbia Centre on Substance Use & British Columbia Ministry of Health, 2017). Currently, injectable hydromorphone is covered by governmental insurance programs, through PharmaCare under the indication for pain, and through the Non-Insured Health Benefits program for registered First Nations and Inuit people (British Columbia Centre on Substance Use & British Columbia Ministry of Health, 2017).

Oregon

In the U.S., health insurance status (e.g., insured or uninsured) and the type of insurance enrollment (e.g., private or public) influences access to health care services. Oregon's public health insurance program for low-income individuals, the Oregon Health Plan (OHP), includes both fee-for-service and managed care insurance service design. Over 85% of OHP members are enrolled in one of 15 uniquely structured regional managed care programs called Coordinated Care Organizations (CCOs) (Oregon Health Authority, 2016). CCOs receive a global budget to care for enrollees (Oregon Health Authority, n.d). CCO administrators can choose to include the pharmacotherapies on the state formulary. CCO administrators, moreover, are allowed to impose pharmacy benefit management strategies to limit access to medications through coverage restrictions such as step-therapy, prior authorization, and quantity limits (Oregon Health Authority, 2017).

Oregon's Governor declared addiction and SUD a state public health crisis, in March 2018 (Guevarra, 2018). The deceleration was made the same day that she signed two bills into law (HB 4134 and HB 4137) that tasked the state Alcohol and Drug Policy Commission to create a statewide plan to tackle SUD prevention, treatment, and recovery (Guevarra, 2018). Federal funds from SAMHSA's State Targeted Response to the Opioid Epidemic program are being used to increase support for the development of new OTPs, physician training for buprenorphine waivers, and distribution of naloxone to first responders.

A review of the 15 CCO coverage policies observed that all 15 CCOs cover methadone for OUD without imposing any pharmacy benefit management strategies (AllCare Health Plan, 2017; Cascade Health Alliance LLC, 2017b; Columbia Pacific CCO, 2018; Eastern Oregon Coordinated Care Organization, 2018; Health Share of Oregon, 2018; InterCommunity Health Network CCO, 2018a; Jackson Care Connect, 2018b; PacificSource Community Solutions, 2018b, 2018c; PrimaryHealth, 2018; Trillium Community Health Plan, 2018a; Umpqua Health, 2017; Western Oregon Advanced Health LLC, 2016; Willamette Valley Community Health LLC, 2017a; Yamhill Community Care Organization, 2018). In contrast, all CCOs imposed pharmacy benefit management strategies for patients accessing buprenorphine products for OUD (AllCare Health Plan, 2018; CareOregon, 2018; Cascade Health Alliance LLC, 2017a; Columbia Pacific Coordinated Care Organization, 2018; Health Share of Oregon/Providence, 2018; InterCommunity Health Network CCO, 2018b; Jackson Care Connect, 2018a; Kaiser Permanente, 2018; PacificSource Community Solutions, 2018a; PrimaryHealth, 2017; Trillium Community Health Plan, 2018b; Tuality Health Alliance, 2018; Umpqua Health, 2018; Western Oregon Advanced Health LLC, 2018; Willamette Valley Community Health LLC, 2017b; Yamhill County Care Organization, 2018). Restrictions included quantity limits, prior authorization requirements, or the designation that buprenorphine was a non-preferred medication. Table 3 is a summary of local OAT coverage policies.

Table 3
OAT Coverage Policies: Provincial/State.

Pharmacotherapy	Jurisdiction	
	B.C.	Oregon
Buprenorphine/naloxone	Available	Available*
Methadone	Available	Available
Slow release oral morphine	Available*	Off-label prescribing is illegal
Injectable diacetylmorphine	Available*	Illegal
Injectable hydromorphone	Available*	Off-label prescribing is illegal

Table Notes: *With limitations.

Local OAT access

B.C. Ministry of Health data from 2017 observed that 66% of people with OUD in the province received OAT (36,483 of 55,470 people with OUD) (Bohdan Nosyk, personal communication December 10, 2018). OAT delivery included methadone, buprenorphine, and SROM. In contrast, in Oregon, OHP data for 2016 reported that 47% of individuals with OUD received OAT (7018 of 15,021 people with OUD). OAT delivery included methadone (35%) or buprenorphine (15%) (Dennis McCarty, personal communication December 14, 2018).

Discussion

The differences in local OAT access and coverage policies between B.C. and Oregon may be explained, in part, to the differences in the structure and content of Canadian and U.S. federal OAT policies; specifically, the use of special regulatory controls that either enhance or deter OAT access. Further, the findings from this paper highlight the complicating contributions, and likely policy solutions, that exist in other drug policy sub-domains (e.g., the prescription regime, and drug control regime) and broader policy domains (e.g., constitutional rights).

Special regulatory system

Historically, both countries at different times have had "special" regulatory requirements for OAT (e.g., prescriber enrollment programs). Special in this context means regulations for OAT that do not apply to other federally approved pharmaceutical products. Recently, however, in Canada these special federal controls for methadone were removed by dismantling the federal prescriber enrollment program, which still exists in the U.S.

The primary purpose of removing federal OAT control in Canada was to reduce OAT access barriers in the midst of a drug poisoning crisis. Another consequence of diminished federal involvement is increased local policy control, which may foster innovation, and the potential to positively influence practice in other jurisdictions. Invariably, there are also potential harms of local policy autonomy. Local control likely contributes to variable and inequitable OAT access across the population and may introduce a broader set of ethical and governance questions related to federalism, state and provincial autonomy, and legal rights. Recently, researchers have observed the harms of local policy autonomy for patients with OUD in the U.S. For states opting-in to Medicaid expansion,researchers observed a 70% increase in Medicaid-covered buprenorphine prescriptions and a 50% increase in Medicaid buprenorphine spending (Wen, Hockenberry, Borders, & Druss, 2017).

Prescription & drug control policy regimes

The dismantling of the special federal regulatory system that currently exists in the U.S. would not remove all regulations; instead, OAT would be regulated and overseen like all other federally approved pharmaceutical products through the robust prescription policy regime overseen by the FDA and the DEA (for controlled substances). The prescription system is considered, internationally, to be the normative approach to medication regulation (Babor et al., 2010). The prescription regime was established and ratified by the 1961 Convention on Drugs by ninety-seven nation states who were tasked with creating a worldwide opioid prohibition, except under license for medical treatment and research (United Nations, 2013).

The Canadian prescription regime permits the use of off-label prescribing for patients with OUD, allowing B.C. provincial health authorities to rapidly develop a wider spectrum of OAT coverage options. Unfortunately, U.S. federal law explicitly prohibits off-label opioid prescribing for OUD treatment (DEA); thus, two of the five OATs used in B.C. (i.e., SROM and injectable hydromorphone) are not allowed for use in the U.S.—limiting the OAT care continuum. However, this law could be amended to expand OAT options in the U.S.

In both countries, diacetylmorphine is categorized as a Schedule I substance, but the meaning of this designation differs in each jurisdiction. In the U.S., Schedule I substances are illegal to possess, have no accepted medical use, and the substance is not available in pharmaceutical-grade formulation. In contrast, in Canada, Schedule I designation imparts specific regulatory and enforcement authorities, but does not explicitly prohibit medical use (e.g., codeine is a Schedule I drug in Canada) (Government of Canada, 2018).

Constitutional rights

A final observation warranting further exploration is the difference in the rights afforded by the Canadian, U.S., and local constitutions. A review of the U.S. and Canadian constitutions was outside the scope of this paper, but is a relevant and important policy consideration. In Canada, in 2013, five research participants receiving diacetylmorphine, with the support of Providence Health Care of B.C., filed a motion with the B.C. Supreme Court arguing that contemporary federal regulations prohibiting access to diacetylmorphine infringed upon the individual rights bestowed by the Canadian Charter of Rights and Freedoms (Boyd, Murray, & MacPherson, 2017). The B.C. Supreme Court ruled in the research participants favor, stating that it was their constitutional right to health that allowed them to continue to receive diacetylmorphine (Boyd et al., 2016). The U.S. Constitution, in contrast, is silent on the right to health care, and unfortunately, recent efforts at the local level failed. Oregon legislators did not move forward a vote to amend the state constitution to make health care a right (Associated Press, 2018).

Limitations

Because the policies selected and included for review were based on the historic and contemporary literature, publicly available policy and regulatory documents, and the expertise of the authorship team, it is possible that other relevant OAT policies and regulations were overlooked. This study should not be viewed as a comprehensive review of all possible OAT policies and regulations in each of these jurisdictions, but as an analysis of some of the most prominent policies. Further, to limit the scope of the study we focused on oral methadone/buprenorphine coverage policies, and different types of OAT, versus the coverage of different formulations such as injectable and implantable buprenorphine or changes in formulation. There are also limitations in the transferability of the findings from local jurisdictions, as local contexts have unique cultural, political, and social elements, that may influence the formation and adoption of treatment policies.

Future directions

As illustrated in the findings, OAT regulations are only one component of the OUD treatment policy regime and only a small part of the broader drug policy and health regime. The drug policy regime is transdisciplinary (Boyd et al., 2016; MacCoun, Saiger, Kahan, & Reuter, 1993) comprised of policy tools (Stone, 2012) to produce administrative action to prevent drug use initiation; promote health and social

services for persons who use drugs, and authorize laws, regulations, and initiatives to control illegal drug supply and to minimize prescription diversion (Babor et al., 2010). Future international comparative policy analyses could include non-OAT related policies such as naloxone access and administration, safe consumption facilities, needle exchange, or access to residential treatment facilities. Beyond discussions of OUD treatment, policy discussions and proposed changes should also include drug decriminalization (Saloner et al., 2018).

Conclusion

If U.S. policymakers desire to effectively address the opioid overdose epidemic, as indicated by the national federal public health emergency declaration from President Trump (White House, n.d.) and the DHHS's 5-point strategy to address the crisis (DHHS, 2018)—elected officials and federal agency leadership (SAMHSA, DHHS, DEA, FDA) need to thoroughly assess and consider how contemporary U.S. federal OAT policies, and more broadly the U.S. drug policy regime, create barriers for accessing evidence-based OUD treatments. U.S. policymakers could look to Canadian public health officials, or other international systems (Auriacombe et al., 2004), to inform the redesign of an OAT policy regime that is less restrictive. The case study findings suggest that removing barriers to OAT access (insurance coverage barriers) and providing access to a broader range of OAT (SROM, iOAT) may enhance treatment access and contribute to the ongoing efforts to address North America's opioid overdose epidemic.

Author contributions

Kelsey Priest: conceptualization; data curation; formal analysis; investigation; methodology; project administration; supervision; roles/writing-original draft; and roles/writing-review & editing.

Lauren Gorfinkel: data curation; formal analysis; investigation; supervision; roles/writing-original draft; and roles/writing-review & editing.

Jan Klimas: conceptualization; data curation; formal analysis; investigation; supervision; roles/writing-original draft; and roles/writing-review & editing.

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Dennis McCarty: conceptualization; data curation; formal analysis; investigation; methodology; project administration; supervision; roles/writing-original draft; and roles/writing-review & editing.

Not applicable to this study: funding acquisition; software; validation; visualization; resources.

Competing interests

Manuscript authors have no competing interests to declare.

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