CoLab Network

Environmental Scan

Buprenorphine-Based Formulations for the Treatment of Opioid Use Disorder in Correctional Settings

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Key Messages

Various buprenorphine-based formulations — buprenorphine extended-release depot injection , buprenorphine-naloxone sublingual tablet (transmucosal tablet), and sublingual or buccal films (transmucosal film) — are available for the treatment of opioid use disorder, but there is no definitive evidence favouring any 1 formulation.

A total of 29 individuals from across the country responded to a survey about provision of buprenorphine formulations for treatment of opioid use disorder in correctional facilities.

Every responding facility offered the depot injection, 1 facility in 1 jurisdiction did not offer the transmucosal tablet, and 1 or more facilities in 3 jurisdictions did not offer the transmucosal film.

To be eligible for opioid agonist therapy, an opioid use disorder diagnosis, a positive urine test, or a standing prescription is usually needed. Individuals with opioid withdrawal symptoms or who are at high risk of relapse are assessed for opioid agonist therapy initiation upon admission. Dosing regimens for buprenorphine-naloxone formulations generally follow established guidelines but can vary by jurisdiction. Transition to the depot injection from a transmucosal form may occur in as few as 2 to 3 days (at physician discretion) rather than the recommended 7-day period. Typically, a nurse administers the medication, and a correctional officer observes the person for a set period. Transition plans after release were reported in 7 jurisdictions.

The depot injection has limited patient acceptance due to discomfort with injections, but it is favoured for its reduced risk of diversion and lower administrative workload. The transmucosal film formulation did not achieve the anticipated reduction in diversion. Respondents emphasized the importance of patient-driven treatment decisions.

Table of Contents

List of Tables

Abbreviations

CDEC	Canadian Drug Expert Committee
COWS	Clinical Opioid Withdrawal Scale
CSC	Correctional Service Canada
DSM-5	*Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*
OAT	opioid agonist therapy
OUD	opioid use disorder
VODP	Virtual Opioid Dependency Program

Background

In recent years, the number of individuals with an opioid use disorder (OUD) and the number of overdose deaths associated with opioids has increased at an alarming rate in Canada, including within correctional facilities.[1-3] In Canada, a significant majority of male inmates in federal facilities — more than 70% — acknowledge struggling with substance use issues.[1] Between 2006 and 2009, 16% of individuals who were incarcerated admitted to being under the influence of opioids at the time of their offences.[1] Approximately 4 of 5 women who are incarcerated also reported having a substance use disorder upon admission, and this figure is notably higher among Indigenous women. Other data from Canada also report high rates of opioid usage before and during imprisonment,[1] with a substantial prevalence of OUD diagnoses among those who are incarcerated, and occurrences of overdose. For instance, between 2012 and 2017, there were 330 reported overdoses within federal correctional institutions; more than 90% of fatal cases were linked to opioids, notably involving fentanyl in 36% of instances.[1]

The primary approach for treating OUD in both community and correctional settings in Canada is opioid agonist treatment (OAT), which includes methadone and buprenorphine-naloxone (Suboxone). OAT is a proven and secure method, reducing withdrawal symptoms and associated risks while effectively curbing opioid use.[4] Recent Canadian clinical guidelines prioritize buprenorphine-naloxone–based OAT as the first choice for OUD treatment, echoing the policies within federal correctional institutions, and align with international human rights guidelines advocating equal health care rights for individuals who are incarcerated.[1,4-6]

In Canada, there has been a notable increase in demand and coverage of OAT in correctional facilities in recent years, with availability now widespread in federal and most provincial or territorial correctional facilities.[7,8] For more than 2 decades, Correctional Service Canada (CSC) has administered methadone to individuals with OUD who are incarcerated, expanding to include buprenorphine-naloxone in 2008.[1] The number of people who have received OAT in federal correctional facilities has more than doubled from 920 in 2016 to 2,481 in January 2021, constituting approximately 15% of all individuals who were incarcerated.[1,9] Similarly, a study investigating OAT prescribing rates in Ontario's provincial prisons compared to those in the community between 2015 and 2018 found that approximately 6.9% to 8.4% of individuals in prisons received methadone.[3] During that period, 0.8% to 4.8% were prescribed buprenorphine-naloxone and 8.2% to 13.2% received either treatment. Methadone prescriptions remained stable, but buprenorphine-naloxone prescriptions in prisons notably increased by 1.7 times annually.[3]

The options for buprenorphine-based OAT formulations have broadened in recent years and now encompass buprenorphine extended-release depot injection (Sublocade), buprenorphine-naloxone sublingual tablet (Suboxone and generic versions), and buprenorphine-naloxone sublingual or buccal film (Suboxone film). Refer to Appendix 1 for additional information about buprenorphine-based OAT formulations, including Health Canada–approved indications, Canadian Drug Expert Committee (CDEC) recommendations, and the drug listing status for public drug plans in Canada.

The transmucosal formulations (tablet and film) contain a combination of buprenorphine and naloxone, while the depot injection contains only buprenorphine. Buprenorphine, an opioid partial agonist, produces effects similar to opioids, such as euphoria, but to a lesser degree. When used correctly, it reduces physical dependence on opioids, diminishes cravings, and decreases the risk of overdose. Naloxone, an opioid antagonist, binds to brain receptors that opioids would typically target, blocking the effects of drugs such as heroin and methadone. Naloxone is not orally bioavailable; its presence in transmucosal formulations neutralizes the effect of the product if injected intravenously, preventing abuse. Patients typically take the transmucosal formulations (tablet or film) daily or every other day, whereas the depot injection formulation is administered as an abdominal subcutaneous injection by a trained physician or nurse practitioner once a month. Each depot dose of the depot provides about a month of coverage.[10] Transmucosal formulations (tablet and film) demonstrate effectiveness in treating OUD, although the pharmacokinetics of transmucosally administered buprenorphine vary considerably between individuals partly because of differences in absorption; drug bioavailability may vary threefold or more between individuals. Issues such as diversion, whether accidental or intentional, present significant challenges to adherence to prescribed dosages, adding to the complexity. The transmucosal film formulation of buprenorphine-naloxone is suggested to offer a specific advantage by reducing diversion risk under supervision compared to the transmucosal tablet formulation.[11]

The depot injection eliminates the possibility of intentional or unintentional diversion because it is administered in a health care setting via injection. It also provides a longer duration of exposure to OAT, which has been linked to improved outcomes.[11] Furthermore, a significant portion of fatal opioid overdoses are deliberate, so consistently binding the mu opioid receptors with a medication such as buprenorphine, which has high affinity and slow receptor association-dissociation kinetics, should reduce the risk of a fatal outcome from impulsive opioid overdose.[11] Although the depot injection is more expensive compared to a monthly supply of buprenorphine-naloxone tablets, the depot injection may be more cost-effective when considering the additional expenses of medication preparation, administration, monitoring, and personnel.[12]

The availability of multiple buprenorphine-based formulations for treatment of OUD has also led to increasing calls for access to these formulations in correctional settings. However, there is uncertainty about which formulations afford better effectiveness, safety (including aspects such as diversion), and adherence, as well as their relative cost-effectiveness. A 2019 CADTH report[13] identified several studies examining different buprenorphine formulations which found statistically significant differences in outcomes, yet whether these differences had clinical significance remained unclear. No distinct superiority of 1 formulation over another emerged. In terms of safety, none of the studies reported significant differences in the safety profiles among the buprenorphine formulations, suggesting they are generally safe and well tolerated for treating OUD. Two evidence-based guidelines were identified, with 1 strongly recommending buprenorphine-naloxone as first-line therapy for OUD and which was supported by high-quality evidence. The other guideline suggested offering either buprenorphine-naloxone or methadone, depending on patient preference, for individuals with an OUD, and also provided a strong recommendation. There were similar findings from a 2024 CADTH report,[14] which examined the relative clinical effectiveness, safety, and cost-effectiveness of depot injection and transmucosal formulations, including tablets and/or film. The included studies did

not provide conclusive evidence to favour 1 formulation of buprenorphine over another in terms of either clinical effectiveness or safety. None of the studies identified in the CADTH reviews were conducted in a correctional setting.

Although various buprenorphine-based formulations are available, there is an absence of definitive evidence favouring any specific formulation.[13,14] Insights drawn from practical real-world experiences with these formulations, including any implementation considerations in federal and provincial correctional facilities could play a critical role in informing reimbursement-related decision-making processes.[13]

Objective

This survey-based Environmental Scan aimed to gather real-world experiences from correctional facilities across Canada about the provision of the various buprenorphine-based formulations for the treatment of OUD. The objective of this Environmental Scan is to present a summary of following aspects of buprenorphine-based formulations at correctional facilities across Canada, for the treatment of OUD:

- availability, eligibility criteria, and treatment protocols
- experience with and rationale for use of specific formulations
- implementation considerations, such as risk of misuse and diversion, drug administration, and monitoring.

The findings of this Environmental Scan are expected to inform decisions about procurement and implementation of various buprenorphine formulations for the treatment of OUD in correctional facilities.

Methods

Information was gathered through an online survey of individuals in the federal, provincial, and territorial correctional health care systems who are involved in decision-making and management of OUD treatment in these facilities. The survey questionnaire is presented in Appendix 2. The components of the information presented in this Environmental Scan are shown in Table 1. A list of the survey respondents' organizations is provided in Appendix 3.

Table 1: Components for Information Gathered Through a Survey on Buprenorphine Formulations in Correctional Settings

Component	Description
Population	Adults (> 18 years of age) with OUD who are incarcerated in federal or provincial correctional facilities across Canada
Intervention	Buprenorphine extended-release injection (Sublocade) Buprenorphine-naloxone sublingual tablet (Suboxone and generic versions) and Buprenorphine-naloxone sublingual or buccal film (Suboxone film)
Setting	Federal, provincial, or territorial correctional facilities across Canada
Information gathered	Buprenorphine-based formulations provided by correctional facilities across Canada for the treatment of OUD, their respective eligibility criteria, and treatment protocols. Rationale and experience (positive and negative) regarding provision of various buprenorphine-based formulations. Implementation considerations regarding provision of buprenorphine-based formulations, including protocols on initiating therapy for people recently incarcerated, monitoring to avert diversion, and transitioning to other formulations after these individuals are released from the facility.

OUD = opioid use disorder.

Findings

A total of 29 individuals representing correctional facilities or health authorities supporting correctional facilities in 8 provinces (Alberta, British Columbia, New Brunswick, Newfoundland and Labrador, Nova Scotia, Ontario, Quebec, Saskatchewan), 1 provincial public drug plan (Saskatchewan) and 1 federal drug plan (CSC) responded to the survey. The findings from the survey are presented by jurisdiction. There are 3 buprenorphine-based formulations of interest: buprenorphine extended-release injection formulation (hereafter, depot injection), buprenorphine-naloxone sublingual tablet (hereafter, transmucosal tablet), and buprenorphine-naloxone sublingual or buccal films (hereafter, transmucosal film). Table 2 presents a summary of findings related to availability, eligibility, administration and monitoring, and transition plan.

Table 2: Summary of Findings From the Survey on Buprenorphine Formulations in Correctional Settings

Jurisdiction	Available formulations	Patient eligibility criteria	Administration and monitoring	Transition to community
Correctional Services Canada	Depot injection Transmucosal tablet Transmucosal film	• Meets *DSM-5* criteria for OUD • Positive UDS (not mandatory)	Administered by nurse and observed after administration by a correctional officer for 5 minutes.	A comprehensive plan including provincial and territorial coverage; continuity of care; availability of medication and/or prescription on release; take-home naloxone kit; harm

Jurisdiction	Available formulations	Patient eligibility criteria	Administration and monitoring	Transition to community
				reduction education and counselling; connection to harm reduction resources, such as needle exchange programs and safe consumption sites; housing; and other psychosocial supports as required
Alberta	Depot injection Transmucosal tablet Transmucosal film	• Diagnosis of OUD (all formulations); moderate to severe OUD (for depot injection) • History of OUD • History of OAT in the community • Stabilized for 2 to 3 days on transmucosal film or tablet (for depot injection) • At the request of the patient	Patients receiving OAT are no longer removed from the unit for dosing and are no longer subjected to pat searches. Instead, they are instructed to wait 5 to 10 minutes for the transmucosal tablets or films to dissolve. Security staff may conduct "mouth checks" afterward at their discretion.	Referred to Alberta's VODP upon release from the correctional facility or to a prior community provider through a comprehensive discharge plan
British Columbia	Depot injection Transmucosal tablet Transmucosal film	• Diagnosis of OUD • At the request of the patient • Ordered on intake as OAT for acute withdrawal • Positive urine test • Documented history of OUD • Previous treatment with an OAT • Stabilized for 7 days on 8 mg transmucosal film or tablet (for depot injection) • Only to be prescribed by a physician or nurse practitioner	Administered by nurse and observed after administration by a correctional officer for a period of time (varies per facility). Correctional officers also conduct mouth checks.	Transition nurse sets patients up with public drug plan program
New Brunswick	Depot injection Transmucosal tablet Transmucosal film (2 out of 5)	• OUD determined by social worker • Standing OAT prescription in community	Administered by nurse and observed after administration by a correctional officer for 20 minutes.	Appointments are booked with providers in the community (pharmacy or physician) before discharge and discussed at the time of release

Jurisdiction	Available formulations	Patient eligibility criteria	Administration and monitoring	Transition to community
Newfoundland and Labrador	Depot injection Transmucosal tablet Transmucosal film	• Meets *DSM-5* criteria for OUD • Standing OAT prescription in community	Correctional facility staff observe proper ingestion of the medications and monitor for possible diversion.	When released from the correction facility, individuals receiving OAT are connected with a community pharmacy and prescriber who will help assist with OAT in the community.
Nova Scotia	Depot injection Transmucosal film	• Standing OAT prescription in community • Positive UDS	Administered by nurse and observed after administration by a correctional officer for 30 minutes in a windowed vestibule. Correction officers also conduct mouth checks.	None reported
Ontario	Depot injection Transmucosal tablet Transmucosal film	• Meets *DSM-5* criteria for OUD • Positive UDS (not mandatory) • Stabilized for 7 days (or sooner if clinically appropriate) on 8 mg transmucosal film or tablet (for depot injection)	Administered by nurse and observed after administration by a correctional officer for 10 to 15 minutes in a sequestered area.	Prescriptions for OAT are provided to bridge the gap between release from the correctional facility and when patients can see their community prescribers. For patients on the transmucosal film formulation, the transmucosal tablet formulation is prescribed instead at the time of release from the correctional facility.
Quebec	Depot injection Transmucosal tablet	• Meets at least 2 diagnostic criteria for OUD • Have a COWS score of 8 or higher • Provided informed consent • Positive UDS (strongly recommended)	Administered by nurse and observed after administration by a correctional officer for 10 minutes in a dedicated area. Correctional officers also conduct mouth checks.	Not uniform across the province. An initial prescription covering the period until an outpatient medical appointment is provided and linked with the patient's pharmacy. Patients with a community doctor (before incarceration) can continue their care at the clinic after release. Those who began OAT in prison will be connected with a community doctor for ongoing treatment.

Jurisdiction	Available formulations	Patient eligibility criteria	Administration and monitoring	Transition to community
Saskatchewan	Depot injection Transmucosal tablet	• Moderate to severe OUD • Patients stabilized for 7 days on 8 to 24 mg transmucosal tablet (for depot injection)	Correctional officers observe administration.	None reported.

COWS = Clinical Opioid Withdrawal Scale; *DSM-V = Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition*; OAT = opioid agonist therapy; OUD = opioid use disorder; UDS = urine drug screen; VODP = Virtual Opioid Dependency Program.

Federal

One individual representing the federal drug plan administered by CSC responded to the survey.

Availability

All 3 buprenorphine formulations, including depot injection, transmucosal tablet, and transmucosal film, are listed as open benefits in the CSC National Formulary.

Eligibility Criteria

Patients who meet the *Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5)* criteria for OUD, as confirmed by the attending nurse, who have completed a urine drug test and consented to OAT are deemed eligible for treatment with OAT. However, a positive urine test is not required to start a patient on OAT, and, in some instances, a client may not be able to provide a urine sample. Starting OAT in these cases is based on clinical decision.[9]

Treatment Protocols

Buprenorphine-based formulations (depot injection and transmucosal tablets and films) are considered first-line treatment for OAT. Methadone is considered second-line treatment for OAT and cannot be inducted without physician or nurse practitioner examination. For pregnant individuals, both buprenorphine-naloxone and methadone are considered first-line therapy for OAT. Pregnant individuals who are in opioid withdrawal can be inducted on methadone without a physician or nurse practitioner examination if there is a risk of precipitated withdrawal with buprenorphine-naloxone or if the client prefers methadone.[9]

Individuals admitted to CSC correctional facilities who are in opioid withdrawal should start OAT on the day of admission. Individuals who are currently using opioids or were previously using opioids and are at high risk of relapse should start OAT as soon as possible. Patients with urgent criteria for OAT, or patients with a history of nonfatal opioid overdose in the past 30 days, a recent history of nonfatal opioid overdose, or medical or psychiatric complications of OUD are seen in person or by telemedicine by the physician or nurse practitioner as soon as possible and no later than 3 days.[9]

Individuals who are already on OAT at the time of arrival at the correctional facility are continued on OAT, unless specifically directed otherwise. Within 24 hours of arrival at the facility, a nurse completes the medication-reconciliation process. A physician or nurse practitioner reviews the patient's OAT medication and authorizes continuation of the OAT treatment and other medications based on available transfer

documents and the nurse's assessment. The individual will be seen by a physician or nurse practitioner in person or by telemedicine at the next available clinic but no later than 7 days after arrival.[9]

For other requests for OAT, a nursing assessment will be conducted within 7 days of receiving a request. This is followed by an assessment by the institutional physician or nurse practitioner within 7 days after the nursing assessment is completed. Buprenorphine-naloxone is initiated within a day of being assessed and approved by the institutional physician or nurse practitioner, whereas methadone is initiated on the next business day from being assessed.[9]

All individuals will be offered psychosocial support, OAT, and other treatment interventions, if necessary, within 15 days of a nursing assessment. All individuals will be offered holistic integrated primary health care, psychosocial support, OAT, and other treatment interventions, if necessary, within 15 days of a nursing assessment. The Canadian Research Initiative in Substance Misuse (CRISM) National Guideline For The Clinical Management Of Opioid Use Disorder (June 5, 2017) references a spectrum of psychosocial interventions, including medically focused, unstructured, informal counselling provided by the treating clinician such as "health and wellness checks, support and advice, assessing motivation and identifying barriers to change creating a treatment plan, fostering medication adherence, optimizing dosing, supporting treatment adherence and relapse prevention, and providing referrals to appropriate health and social services."

Administration and Monitoring

A nurse observes the administration of OAT. All postadministration security observation is done by correctional officers to prevent diversion. The minimum observation period for methadone and slow-release oral morphine is 20 minutes. The minimum observation period for buprenorphine-naloxone film and tablet is 5 minutes.[9]

Transition to Community

A transition plan is developed for the individual's return to the community, which includes provincial and territorial coverage; continuity of care; availability of medication and prescription on release; take-home naloxone kit; harm reduction education and counselling; connection to harm reduction resources, such as needle exchange programs and safe consumption sites; housing; and other psychosocial supports as required.[9]

Experience With and Rationale for Use of Specific Formulations

The respondent noted that provision of all 3 buprenorphine-based formulations (depot injection, transmucosal tablet, and transmucosal film) offer alternate options for the treatment of OUD and recommended the same for other correctional facilities. However, the respondent noted there was no significant difference between the transmucosal tablet and film formulations. However, the respondent noted the depot injection helped improve adherence to the medication and was less administrative burden for both patients and health care staff.

Alberta

Two individuals representing the provincial health services providing support to provincial correctional facilities responded to the survey.

Availability

The depot injection, transmucosal tablet, and transmucosal film are provided by the provincial health services.

One respondent noted that all strengths of the transmucosal tablet and film formulation are availed by the correctional formulary. Depending on the contract, brand or generic versions of the transmucosal tablets are available. The respondents also noted that 2 mg, 8 mg, 12 mg, and 16 mg of the transmucosal tablets are available for the branded product.

Eligibility Criteria

A diagnosis of OUD was noted by both respondents as an eligibility criterion for all 3 formulations.

One respondent noted that the patient should be diagnosed with moderate to severe OUD to be eligible for the depot injection, and that it is optimal to stabilize patients for 2 to 3 days on a transmucosal tablet or film before initiation with depot injection.

One respondent also noted that there is provincial withdrawal protocol, but dosing (microdosing which is initiation with a small dose with incremental increases in dose and frequency versus macrodosing which is initiation with a high dose) is left at the discretion of the prescribers at each correctional site who can prescribe OAT based on patient-specific needs. The respondent noted that the transmucosal formulations are generally prescribed up to 24 mg through assessment and reassessment by OAT coordinators. The respondent also noted that transmucosal film are preferred over the transmucosal tablet formulation for patients with a history of diversion.

Treatment Protocols

One respondent noted that OUD treatment is based on an acute withdrawal protocol upon admission for patients with significant withdrawal symptoms (Clinical Opioid Withdrawal Scale [COWS] score ≥ 13). As per the provincial protocol, OAT should be expediently continued at the correctional facility, and authorized prescribers (limited to nurse practitioners and physicians who have met the professional regulatory standard to initiate and adjust the dosage of the OAT) can adjust the dosage, as clinically required. Each site has an OAT coordinator, typically a registered nurse, who facilitates the OUD screening process (including COWS assessment) for maintenance starts and communicates with prescribers for medication orders.[15]

The following dosing regimen is followed for buprenorphine-naloxone–based OAT initiation for opioid withdrawal:[15]

- Day 1: Initial dose of buprenorphine 4 mg–naloxone 1 mg sublingual followed by additional doses of buprenorphine 4 mg–naloxone 1 mg each hour for continued opioid withdrawal symptoms to a maximum total day 1 dosage of buprenorphine 12 mg–naloxone 3 mg.

- Day 2: Administer the total dose from day 1, 24 hours after the first dose on day 1 and administer additional doses of buprenorphine 4 mg–naloxone 1 mg sublingual each hour for continued opioid withdrawal symptoms to a maximum total day 2 dosage of buprenorphine 16 mg–naloxone 4 mg.
- Day 3 onward: Administer the total dose from day 2 each day.[15]

The following dosing regimen (for buprenorphine-based OAT) is followed for buprenorphine-naloxone taper and discontinuation:[15]

- Day 1: buprenorphine 4 mg–naloxone 1 mg sublingual once and repeat in 1 hour for continued symptoms of opioid withdrawal
- Day 2: buprenorphine 8 mg–naloxone 2 mg sublingual once
- Day 3: buprenorphine 8 mg–naloxone 2 mg sublingual once
- Day 4: buprenorphine 6 mg–naloxone 1.5 mg sublingual once
- Day 5: buprenorphine 4 mg–naloxone 1 mg sublingual once
- Day 6: buprenorphine 2 mg–naloxone 0.5 mg sublingual once
- Day 7: buprenorphine 2 mg–naloxone 0.5 mg sublingual once, then discontinue buprenorphine-naloxone[15]

For acute opioid withdrawal, switching from the transmucosal formulation to depot injection includes buprenorphine 8 mg–naloxone 2 mg sublingual twice daily for 1 day, followed by 2 monthly doses of a 300 mg depot injection. Further treatment requires a follow-up with the OAT prescriber.[15]

Another dosing regimen for buprenorphine-naloxone–based OAT for management of withdrawal was reported as follows:

- Day 1: buprenorphine 8 mg–naloxone 2 mg twice daily
- Days 2 and 3: buprenorphine 20 mg–naloxone 5 mg each day
- Day 4 and onward: buprenorphine 24 mg–naloxone 6 mg for 6 months[15]

The respondent noted that dose escalation is stopped at 16 mg for youth and any patient who has not reached 24 mg previously.[15]

Although there are provincial protocols, the respondents noted that most centres have adapted newer protocols to address patient needs, such as macrodosing and polypharmacy drug use. Patients have the option to be screened throughout their stay for initiation of maintenance therapy and stabilization upon release.

One respondent noted that self-identified opioid users were promptly evaluated by prescribers for pharmacological therapy, which is initiated within 24 hours. Patients experiencing opioid withdrawal are managed with the goal of transitioning them to maintenance therapy for long-term stabilization. However, the respondent reported variations in treatment protocols at different correctional settings and noted that treatment is personalized as per the needs of the patients. The respondent noted that treatment with depot

injection is initiated with 300 mg every 28 days, usually for 3 doses depending on patient history of drug use. After the initial high dose, it is tapered down to 100 mg every 28 days.

Administration and Monitoring

One respondent noted that transmucosal films or tablets are distributed during medication lines without direct patient monitoring. Routine searches are conducted by correctional officers, and health care staff are alerted if any substances resembling medication are discovered.

Another respondent noted that nurses and correctional officers observe the patients. Patients receiving transmucosal film or tablet are no longer removed from the unit for dosing and are no longer subjected to pat searches. Instead, they are instructed to wait 5 to 10 minutes for the transmucosal tablets or films to dissolve, typically with security staff conducting "mouth checks" afterward at their discretion.

Transition to Community

One respondent highlighted that the Safe Transitions policy in Alberta[16] dictates that patients should leave the correctional facility with a prescription for OAT and be provided a bridge supply of medication if needed. The respondents noted that patients are referred to Alberta's Virtual Opioid Dependency Program (VODP) upon release from the correctional facility.[17] The VODP referral form provides information on whether the patient has opioid addiction, is medically stable, has significant respiratory illness, is pregnant, and/or uses benzodiazepines.[18] VODP is a gap coverage program that helps set up emergency funding and coverage for all 3 buprenorphine-based formulations. One respondent also suggested that patients are referred back to a previous community program if it fits the patient's needs. However, 1 respondent noted that patients may be switched to the formulation that their community coverage funds, irrespective of what they were receiving at the correctional facility.

One respondent noted that they encourage the depot injection over the transmucosal formulation for stability on release.

Experience With and Rationale for Use of Specific Formulations

One respondent noted that the reasons to use the transmucosal film formulation were reduced risk of diversion associated with this formulation and results of studies indicating that its efficacy is not compromised compared to other formulations. The respondent cited the same reasons for recommending the provision of the transmucosal film formulation at other facilities. Although the respondent noted they have substantially reduced diversions, it is difficult for the nurses to dispense the transmucosal film with their current medication processes. The respondent also noted that the transmucosal films are more costly, but just providing either the transmucosal film or the transmucosal tablet (but not both) along with the depot injection would be helpful.

However, another respondent suggested that the transmucosal film, despite initial expectations, is easier to divert than anticipated. Although there were optimistic expectations regarding its role in managing OUD within correctional facilities, there has not been the widespread adoption initially envisioned. Prescribers tend to limit the quantity of films prescribed at a time because it appears that the risk of diversion escalates when more than 2 films are used at a time. This respondent stated that the rationale for approving the

transmucosal film formulation was to have all possible resources, including medications, at their disposal to effectively address OUDs within the facility. This respondent did not recommend that the transmucosal film be used at other correctional facilities because no significant advantage of the transmucosal film formulation was observed over the transmucosal tablet formulation. Further, the respondent suggested that having multiple different formulations led to confusion because patients received different formulations at different facilities within the same system, which was not ideal for the patients.

One respondent highlighted that the depot injection provides the opportunity to set patients up for 28 days upon release. This longer duration is preferred because it aligns better with the challenges faced by these individuals, who often have short periods of incarceration and numerous needs upon release. Providing a 28-day supply instead of the typical 1 to 3 days is seen as more feasible for supporting continuity of care. The respondent noted minimal staff training is required for the administration of the depot injection and highlighted significant adoption of depot injections, particularly among female patients. However, some patients reverted to transmucosal tablets due to discomfort associated with the injection, despite the initial uptake. Another respondent noted that, initially, this medication was seen as a solution to diversion issues, with its long duration of action which was considered advantageous for patients transitioning out of correctional facilities, a high-risk period for relapse and overdose. However, patient uptake has been limited, resulting in significant product waste due to patient refusals after doses are removed from refrigeration. Both respondents recommended the depot injection. Despite the underwhelming uptake, those who do consent to the medication were noted to be managed effectively and remain stable, particularly during transitions between correctional facilities and community settings, suggesting potential long-term benefits of this formulation. One respondent also suggested that the injection site discomfort can be managed with medication.

Implementation Considerations Such as Risk of Misuse and Diversion, Drug Administration, and Monitoring

One respondent shared that when buprenorphine was first introduced approximately 5 years ago, strict monitoring for diversion and misuse was implemented, resulting in limited patient access due to stringent prescribing practices. However, after removing these restrictions and establishing a provincial protocol, there has been a significant decrease in the number of overdoses within their correctional facilities.

One respondent advised that the doses of the transmucosal film be limited to no more than 2 films per dose to minimize the risk of diversion. They also suggested that programs should consider using either the transmucosal tablet or film, but not both, as having both formulations has led to confusion and errors in product selection. Orders are frequently written without specifying a formulation, resulting in inadvertent switching between formulations. Although the clinical significance of this has not been assessed, the respondent expressed concerns about destabilizing patients unnecessarily, considering that the doses of the 2 transmucosal formulations are not equivalent. Patients receiving the depot injection appear to have better long-term stability according to the respondent's observations. Additionally, the respondent also suggested that some patients who refuse the extended-release formulation may do so because they cannot

divert it. However, another respondent suggested that treatment should be client driven and based on their preferences rather than forcing a specific treatment option.

British Columbia

A total of 15 individuals representing the provincial health services authority who support correctional health services responded to the survey.

Availability

Two buprenorphine formulations, including depot injection and transmucosal tablet, are provided by the provincial health services authority. Treatment options for OUD also include methadone and slow-release oral morphine, as reported by 2 respondents.

Two respondents noted that they use either brand or generic versions of transmucosal tablets depending on their availability at the pharmacy. One respondent noted that they only offer 2 mg and 8 mg strengths of transmucosal tablets.

Eligibility Criteria

One respondent noted a diagnosis of OUD as the eligibility criteria for treatment with buprenorphine-based formulations. Two respondents also noted that OAT is provided at the request of the patients, while 1 noted that it is also ordered on intake as OAT for acute withdrawal. Other criteria noted were positive urine test (2 respondents), documented history of OUD (1 respondent), and previous treatment with an OAT (1 respondent).

Two respondents noted that depot injection is offered once the patient is stable on transmucosal formulations, with 1 respondent specifying that the patient must be stable at 8 mg per day or greater for 7 days. One respondent noted that the depot injection can only be prescribed by a physician or nurse practitioner, not by nurse prescribers.

Treatment Protocols

Respondent noted the following aspects are considered in the treatment protocol to initiate OAT: patient screening at intake including urine drug screening for opiate, OAT, or concomitant substance use such as respiratory depressants (8 respondents), baseline lab work (1 respondent), patient request for OAT (2 respondents), COWS score (3 respondents), history of substance use, OAT use or OUD (10 respondents), review of CareConnect for emergency department visits for overdose and withdrawal or review of PharmaNet (3 respondents), and pregnancy test (1 respondents).

One respondent noted that the need for OAT initiation is determined based on clinical assessment and discussed with a physician. Another respondent noted that patients can request to start OAT at any time. At 1 facility, there is a dedicated OAT clinic staffed with a physician and nurse once a week. Acute OAT is provided for acute withdrawal at intake, and OAT (methadone or transmucosal tablet) is ordered by an on-call physician. At another facility, an on-call physician will initiate treatment if the client is past the point when it would put them into precipitated withdrawal, or they are booked to an agency physician if they need more time. An OAT assessment is conducted, following which the client is evaluated by the physician who

initiates the OAT. Lab work is also done to ensure there are no health issues that would contraindicate the use of the OAT.

One respondent mentioned that patients are required to sign a contract before initiating treatment with transmucosal tablets. One respondent noted that clients arriving in acute withdrawal receive macrodosing for withdrawal management, followed by continuation of OAT for OUD treatment.

As per the provincial health authority, treatment protocol for the depot injection recommends clients be inducted on transmucosal tablet or film (8 mg/day to 24 mg/day) for a minimum of 7 days.[19] However, the protocol also states clinical judgment may warrant other induction strategies.[19] The following dosing regimen was noted by respondents:

- For acute withdrawal, 1 respondent noted macrodosing of 8 mg to 16 mg.
- If deemed safe, patients are initiated on an 8 mg transmucosal tablet. If patients tolerate the 8 mg transmucosal tablet, they may be switched to the depot injection the same day.
- Patients are stabilized on a 4 mg transmucosal tablet and then given a 300 mg depot injection.
- Depending on the physician, a smaller test dose (4 mg transmucosal tablet) may be given initially, and then patients may be reassessed in an hour to ensure there is no precipitated withdrawal. This is followed by another 4 mg to 8 mg transmucosal tablet, or they may order the depot injection the same day or the next day. Some physicians may give an 8 mg transmucosal tablet immediately and continue patients on that dose or increase it the next day. Others may give an 8 mg transmucosal tablet twice the first day then 16 mg once daily after that.
- Treatment is initiated with an 8 mg transmucosal tablet daily and reassessed in a week. If there is history of heavy opioid use and/or severe withdrawal, patients will start with an 8 mg transmucosal tablet twice on the first day, then a 16 mg transmucosal tablet daily thereafter, followed by a reassessment in 1 week. If the patient is willing to be treated with the depot injection, patients are started on an 8 mg transmucosal tablet 1 to 2 times for at least 1 day, then switched to the 300 mg depot injection.

One respondent noted that for acute withdrawal, with positive urine drug screen for opioids and COWS score greater than 12, patients can be started on intake if suitable or at a later date. However, patients are only allowed daily doses, which prevents microdosing administration.

Administration and Monitoring

All respondents noted that the nurses administer the transmucosal tablets and the correctional officers monitor the patients, for a specified period of time that could vary by the correctional facility. The correctional officers also conduct the mouth checks.

Transition to Community

All respondents noted that the formulation provided in the correctional facility is also covered by the public drug plans and suggested that there are no issues in transitioning to community regarding access to OAT.

One respondent noted that the transition nurse sets patients up with Plan G and Medical Services Plan (MSP) (public drug plan program).

Experience With and Rationale for Use of Specific Formulations

All respondents recommended the use of the depot injection. The most cited reason was their experience of reduced or no risk of diversion with the formulation (all respondents). Other reasons included reduced barrier to access because of less frequent dosing requirement, that is, monthly dosing as opposed to daily dosing with transmucosal formulations (3 respondents); protection from accidental overdose (1 respondent); reduced administrative burden, such as nursing time, reduced medicine dispensing time, and monitoring time (7 respondents); better medication compliance (2 respondents); and fewer security risks for the inmates because they cannot be harassed to divert their OAT (1 respondent). In addition, 6 respondents also noted that the depot injection makes it easier to maintain continuity of care when inmates are released and that there is a higher chance of the individual staying on the treatment regimen upon release. One respondent also noted that their facility encourages use of the formulation at the time of release as well as for patients whose duration of incarceration is unknown because the depot injection offers the quickest way to stabilize a patient. One respondent also noted higher patient acceptance due to reduced stigma for clients because it eliminates the need for them to visit a pharmacy for daily-dispensed OAT. Similarly, another respondent noted that patients prefer to switch to the depot injection upon release because it is administered at a health care setting as opposed to provision in a public setting (as with transmucosal tablets or films).

Respondents also noted good symptom relief, fewer withdrawal symptoms, and fewer injection site infections with the depot injection. One respondent also highlighted that it allows steadier levels of the drug in bloodstream as well as greater physical and mental stability. Because patients are not diverting the medicine, they do not experience fluctuating levels, mood swings, and withdrawal. Respondents noted increased uptake in females who are incarcerated. One respondent noted that they provide all patients information on the transmucosal tablet and education about the depot injection and its benefits. They highlighted that most clients decide to start on or switch to depot injection based on peer feedback. However, 2 respondents also noted that the depot injection may not be preferred by some due to the pain, trauma, and the persistent lump or by those with the intent to divert. One respondent noted that, despite the benefits, there are few inmates on the depot injection, whereas another noted that patients committed to abstaining from opioids do prefer the depot injection over the transmucosal formulations.

One respondent mentioned considering transmucosal film as a potential strategy to reduce diversion while also potentially enhancing adherence to buprenorphine therapy. They suggested that, in theory, the film's quicker dissolution compared to tablets might make it easier to administer. Compared to the transmucosal tablets that are difficult to dissolve and maintain in the mouth (for 10 minutes or more), the film's faster dissolution may improve clients' response to buprenorphine, better alleviate withdrawal symptoms, and increase the patient's likelihood of staying on buprenorphine treatment, including transitioning to the depot injection. Four respondents recommended using the transmucosal film formulation at their facility citing reduced risk of diversion as the rationale. However, 3 did not recommend the transmucosal film formulation,

with 1 stating that diversion is still common with the transmucosal film formulation. Another noted that cost could be an issue as well with the transmucosal film formulation.

Implementation Considerations Such as Risk of Misuse and Diversion, Drug Administration, and Monitoring

One respondent noted that both formulations, transmucosal film and depot injection, offer advantages in reducing the risk of diversion. One respondent noted that although a significant portion of inmates may not be receptive to the depot injection formulation, but for those who are, it presents an excellent option. One respondent strongly recommended including coverage upon release and involving clients in shared informed decision-making in any protocol development. In addition, prioritizing education for clients on OAT, including proper administration of transmucosal tablets, is crucial.

New Brunswick

Five individuals representing the correctional centres (3) and health authorities supporting correctional centres (2) responded to the survey.

Availability

The depot injection, transmucosal tablet, and transmucosal film were provided by 1 health authority and 1 correctional centre. Two correctional centres and 1 health authority only provided depot injection and transmucosal tablet.

Eligibility Criteria

Respondents from 1 correctional centre and 1 health authority noted that patients are accepted based on the provincial drug plan criteria, whereby depot injection and transmucosal tablet are open benefit. Respondents from 1 health authority noted that they only offer the generic version of the transmucosal tablet formulation.

The 1 health authority and 1 correctional centre that also offered transmucosal film noted that patients are accepted based on the provincial drug plan criteria, which stipulates the formulation is an open benefit.

One respondent from a correctional facility noted that they conduct an intake assessment by a social worker to determine whether OUD is present, blood work, and physician assessment before initiating treatment. One respondent from a correctional facility and 2 respondents from a health authority noted that they only provide maintenance treatment for OUD based on previous prescriptions from when the inmates were being treated in the community. One respondent from a health authority also noted the use of these formulations to manage withdrawal, which is based on the COWS score.

Treatment Protocols

One respondent from a correctional facility noted that patients are initiated at 2 mg of transmucosal tablet because there is a period of sobriety since their incarceration. The doses are then increased by 2 mg weekly until patients reach 8 mg, which is the maximum dose allowed. Further dose increases must be requested until the patient is stabilized. The depot injection is offered to patients requiring more than 8 mg of transmucosal tablet. If patients decline the depot injection, they must remain on 8 mg of transmucosal tablet.

Administration and Monitoring

Four respondents noted that health staff administers the medication, and a correctional staff monitors clients for misuse or diversion. The drug is given outside of regular medication times to increase privacy (not done in front of other clients). Correctional officers monitor the client for 20 minutes after administration of the transmucosal tablet formulation.

Transition to Community

One respondent from a correctional facility noted that appointments to see the provider (pharmacist or prescribers) in the community are booked before discharge and discussed at that time. Most of their clients have a Medicare card upon release, which covers both the transmucosal tablet and the depot injection. The respondent also noted that they avoid transmucosal film formulations if it is not covered in the community. Another respondent from a health authority noted that they help inmates find a provider in the community, but do not have specific protocols for patient transitioning to community. Additionally, 1 health authority and 1 correctional centre also noted that they do not have specific protocols for patient transitioning to community.

Experience With and Rationale for Use of Specific Formulations

Reduced risk of diversion and shorter duration for postadministration observation were noted as the primary reasons for providing the transmucosal film, and reasons why the respondent recommended the use of the formulation. However, 1 respondent noted that they prefer the depot injection over the transmucosal film formulation due to reduced risk of diversion.

The rationale for using and recommending the depot injection included reduced risk of diversion and lesser administrative burden (time and cost) due to frequency of dosing (monthly versus daily), elimination of the need for pill counting, and elimination of need to monitor patients after administration. One respondent also noted that patients taking the depot injection cannot be harassed by other inmates to divert their medication opposed to those taking the transmucosal tablet formulation. Two respondents noted that those taking the depot injection do not require bridging upon release and can be seen at an opioid clinic later. A respondent also cited physician comfort, ease of administration for withdrawals compared to codeine, and recommendations from studies as the rationale for the use of the depot injection. One respondent also noted that there were no adverse consequences seen in several individuals who at the time of incarceration were on the depot injection. However, 1 respondent noted patients preferred the transmucosal tablet formulation over the depot injection, which may be due to their intent to divert. One respondent from a correctional centre noted that transmucosal tablets are easily diverted.

Implementation Considerations Such as Risk of Misuse and Diversion, Drug Administration, and Monitoring

Two respondents noted a preference for the depot injection as their first choice due to concerns about diversion with the transmucosal tablet formulation. They suggested obtaining client consent before starting or continuing treatment with the transmucosal tablet formulation and mentioned patient's treatment may be changed by the physician if there was evidence of them diverting the medication.

Newfoundland and Labrador

One individual representing the correctional health services responded to the survey.

Availability

The depot injection, transmucosal tablet, and transmucosal film are provided.

Eligibility Criteria

Patients who are on standing OAT in the community are continued on with the therapy. Patients who meet the *DSM-5* criteria for OUD are offered OAT.

Treatment Protocols

Buprenorphine-based formulation is used as first-line treatment for OAT. Initial assessment involves a history of a positive urine drug screen and a physical assessment based on the *DSM-5* criteria for OUD. Doses are based on withdrawal scale scorings, given 3 times in the first day, with a maximum dosage of 12 mg on day 1 of therapy.

The respondent noted that the transmucosal film formulation is primarily used in correctional settings. However, in rare cases when the film is not tolerated, transmucosal tablet formulations are offered. Further, if the patient is on transmucosal tablet formulation at the time of incarceration, they are continued on the transmucosal tablet formulation until the time they are transitioned to the transmucosal film formulation.

Administration and Monitoring

Correctional facility staff observe proper ingestion of the medications and monitor for possible diversion.

Transition to Community

Medications for OAT are funded by the provincial drug plans. When released from the correction facility, individuals are connected with a community pharmacy and prescriber who assist with OAT in the community.

Experience With and Rationale for Use of Specific Formulations

The respondent noted that the transmucosal film formulation is used to reduce the risk of diversion and reported that the formulation is well tolerated. However, the respondent noted that the transmucosal film formulations are still being diverted. The respondent recommended the use of transmucosal film formulation for other organizations.

The respondent noted that the use of depot injection is based on clinical indication. The respondent also reported that transition to community is easier with the depot injection compared with transmucosal tablet and film. However, the respondent noted lack of uptake of the depot injection by individuals, and that it can be destabilizing. The respondent also noted that the depot injection is costly. The respondent recommended the use of depot injection for other organizations.

Implementation Considerations Such as Risk of Misuse and Diversion, Drug Administration, and Monitoring

The respondent noted that treatment should be client driven and based on their preferences rather than forcing a specific treatment option. The respondent also reported that they do not do dose conversions when switching patients between transmucosal tablet and transmucosal film formulations, and the film and tablets have been tolerated well without the dose conversions.

Nova Scotia

One individual representing the correctional health services responded to the survey.

Availability

The depot injection and transmucosal film are provided.

Eligibility Criteria

The respondent noted that OAT is not initiated for inmates at the facility. Therapy is only provided to those who were on standing therapy from community providers following confirmation from the dispensing pharmacy and a confirmatory urine drug test.

Treatment Protocols

Therapy is based on the standing prescription from the community provider, including confirmation of last dose from the community pharmacy.

Administration and Monitoring

The drug is administered by the OAT nurse. A correctional officer witnesses the administration, performs mouth checks, and observes the patients for 30 minutes in a windowed vestibule following administration of the transmucosal film formulation.

Transition to Community

No specific transition plans were noted by the respondent. Given that only patients with a standing community prescription are provided OAT treatment at the facility, it is assumed that patients would follow up with their community OAT prescriber for any further care or alterations to therapy required after their release from the correctional facility.

Experience With and Rationale for Use of Specific Formulations

The respondent noted that buprenorphine-naloxone transmucosal tablets are no longer provided at the facility because of ongoing diversion and subsequent incidents of overdoses. Instead, buprenorphine-naloxone transmucosal film is currently provided and is the most-used formulation. The respondent reported a marginal decrease in diversion since the switch to the transmucosal film formulation, but not a complete absolution of diversion. The respondent recommended the use of transmucosal film formulation for other organizations to address issues of diversion because it is harder for inmates to “cheek” the films and divert compared to the tablet formulations.

The respondent noted that depot injection requires fewer staff due to less frequent administration (monthly) of the depot injection. Further, there is no risk of diversion with the injectable formulation. However, the respondent reported that many inmates are reluctant to be converted to depot injection. Some inmates even refuse therapy when given the option to be initiated on OAT therapy but only if open to receiving the depot injection. Regardless, the respondent recommended the use of depot injection formulation for other organizations to address issues of diversion as it requires less time for the patients and providers because it is only administered once a month.

Ontario

One individual representing Ontario's correctional services responded to the survey.

Availability

The depot injection, transmucosal tablet, and transmucosal film are provided.

Eligibility Criteria

Patients who meet DSM-5 criteria for OUD, preferably moderate to severe OUD, are deemed eligible for treatment with OAT. To be eligible for depot injection, patients must have a minimal induction period of 7 days with a minimum dosage of 8 mg for transmucosal film or tablet. However, if deemed clinically appropriate, the respondent noted that prescribers may prescribe the depot injection before completion of the 7 days of induction period.

Treatment Protocols

The respondent noted that transmucosal film or tablets are used as ongoing OAT for patients who at the time of incarceration are already receiving buprenorphine-naloxone in the community or who are experiencing opioid withdrawal and would benefit from OAT after initial treatment for opioid withdrawal. The respondent also noted that transmucosal film or tablet formulations are used to treat opioid withdrawal as measured by the COWS score. The respondent noted that the transmucosal film formulation is the preferred buprenorphine-naloxone treatment option. However, prescribers may also prescribe the transmucosal tablet as per their clinical judgment. Use of generic versions of the transmucosal tablet is encouraged, and patients do not choose the brands they receive. In addition to the 3 buprenorphine-based formulations, OAT with methadone and slow-release oral morphine (Kadian) are also used in the treatment of OUD at correctional facilities.

There is a strong recommendation to initiate OAT for people admitted to Ontario correctional facilities who are using opioids and meet the DSM-V criteria for OUD. Patients may be prescribed 1 of the medications used as OAT based on the clinical judgment of prescribers, patient preference, the possibility of drug interactions, and the patient's previous experience with OAT, if any. Patients admitted into custody who are already on a community OAT program have their treatment continued with minimal interruption as soon as community treatment details are verified.

Patients who are at risk of withdrawal from opioids are followed up for possible initiation to OAT. Withdrawal management without subsequent transition to OAT is not recommended due to the loss of opioid tolerance

and increased risk of overdose upon release from custody. Patients undergoing opioid withdrawal are monitored using COWS and may be offered, with a prescriber's order, buprenorphine-naloxone for withdrawal management. Pregnant patients who are experiencing opioid withdrawal are prioritized for withdrawal management and assessment for initiation of OAT within 24 hours of admission.

Higher doses of buprenorphine-naloxone formulations are suggested for withdrawal management in patients who use fentanyl due to the known safety of the buprenorphine-naloxone formulations and the low overdose risk as well as the severity of fentanyl withdrawal. OAT is recommended for patients who use a safer opioid supply (usually hydromorphone 8 mg tablets) in the community. Patients are not given a safer opioid supply in custody.

Although not mandatory, OAT is initiated based on meeting at least 1 of the following criteria: current active prescription for buprenorphine-based formulation in the community before incarceration, diagnosis of moderate to severe OUD as per *DSM-5* criteria, and/or presence of opioid withdrawal. Although urine drug screen is recommended as a clinical assessment tool, it is optional. The lack of a urine drug screen is not a barrier to receiving a buprenorphine-naloxone formulation for opioid withdrawal treatment or receiving OAT.

Patients who at the time of incarceration are already receiving buprenorphine-naloxone in the community are prescribed the same dose. The dosage is subsequently adjusted in accordance with withdrawal symptoms or cravings as per prescriber assessments. Patients who at the time of incarceration are using fentanyl or a safer supply or both are treated for withdrawal based on COWS and a urine drug screen (although not mandatory). Buprenorphine-naloxone is given in accordance with withdrawal symptoms and the prescriber's judgment. For instance, if a patient is using fentanyl, a minimal dose of buprenorphine 16 mg–naloxone 4 mg (up to maximum of buprenorphine 24 mg–naloxone 6 mg depending on the prescriber's comfort levels with macrodosing protocols and experience with these patients) for the first day is recommended. For further details, refer to McMaster University's prisonbupstart.ca. The respondent noted that microdosing protocols may also be used when transitioning patients from methadone to the buprenorphine-naloxone formulation or to transition patients to OAT with buprenorphine-naloxone formulation who are concurrently using other opioids and cannot tolerate being in withdrawal.

Administration and Monitoring

The drug is administered by a nurse. A correctional officer monitors the patients for 10 to 15 minutes in a sequestered area following administration of the transmucosal tablet or film formulations.

Transition to Community

The importance of discharge planning to avoid gaps in care is emphasized. Therefore, prescriptions for OAT are provided to bridge the gap between release from the correctional facility and when patients can refer to their community prescribers. For patients who are on the transmucosal film formulation at the time of release from the correctional facility, the transmucosal tablet formulation is usually prescribed instead due to the lack of coverage of the transmucosal film formulation by the Ontario public drug programs. The strength of the tablet prescribed is the same as that of the transmucosal film.

The respondent noted that the depot injection proves beneficial for individuals released by the court without notice. In these instances of no notice of discharge, the correctional facility may not have completed their discharge planning. Depending on when in the 28-day cycle the patient received the depot injection, the use of depot injection eliminates the need to urgently arrange community-based OAT.

Experience With and Rationale for Use of Specific Formulations

The respondent observed a necessity to transition using transmucosal film formulations due to widespread diversion of transmucosal tablets despite rigorous measures such as supervised administration, mouth checks, and preadministration tablet crushing. Although reports indicate attempts to divert the transmucosal film formulation, they are comparatively less prevalent, although more widespread than initially anticipated. Overall, nurses find administering the film easier due to the elimination of the time-consuming tablet crushing process, particularly when faced with administering hundreds of doses daily. However, a notable drawback is that the film is not covered by the Ontario public drug programs, prompting reminders to prescribers to order tablets for discharge prescriptions. Further, there is a risk of destabilization of patients when switched to transmucosal tablets due to the transmucosal film's slightly higher bioavailability.

The respondent noted that the correctional facility provides depot injection because they offer all available drugs used for OAT. The respondent also noted that there are data suggesting improved retention in treatment and reduced risk of relapse for individuals using fentanyl when treated with the depot injection compared to the transmucosal tablet and film formulations. The respondent further emphasized that the 28-day dosing interval of the depot injection offers additional benefits, including freeing patients from daily pharmacy visits and ensuring continuous saturation of mu receptors, thereby providing protection against overdose. The respondent stated that they encourage prescribers to maximize the utilization of buprenorphine depot injections, highlighting its significant advantage of reduced risk, or no risk, of diversion. However, the respondent noted challenges in patient acceptance of the depot injections. Although some prescribers can convince some patients to use the depot injection, it is challenging for some patients, particularly if they are resistant to transitioning from the transmucosal tablet and film formulations because of diversion intentions. The respondent also cited evidence[12] of potential for reduced cost associated with the use of depot injection in correctional settings. However, some patients experience ongoing withdrawal despite receiving 300 mg doses of the depot injection due to high opioid tolerance, often resulting from fentanyl use. This necessitates continued maintenance with a high dose (300 mg) instead of tapering down to 100 mg after 2 months of the initial 300 mg dose, as recommended by the product monograph.

Implementation Considerations Such as Risk of Misuse and Diversion, Drug Administration, and Monitoring

The respondent suggested that patients be monitored after administration for 10 to 15 minutes in a separate area before they return to their regular living unit. The respondent also suggested that patients caught hoarding or diverting should be offered the depot injection. Alternately, these patients may be tapered off buprenorphine-naloxone while in custody and restarted before release. The respondent highlighted that numerous individuals experience success in abstaining from nonmedical opioid use during their time in incarceration, yet express concern about the possibility of relapse upon returning to their home community.

Quebec

One individual representing a correctional facility responded to the survey.

Availability

The depot injection and transmucosal tablet are provided by the correctional facility.

Eligibility Criteria

The respondent noted that eligible patients for induction with transmucosal tablet for acute opioid withdrawal are those who have met at least 2 diagnostic criteria for OUD, have a COWS score of 8 or higher, and have provided informed consent. The protocol also strongly recommends a urine drug test before initiating treatment.[20]

The respondent noted that patients on the transmucosal tablet, if found diverting the medication for the second time, are given the choice to switch to the depot injection or wean over a period of 2 weeks. All patients on OAT are met at the start of incarceration to explain this regulation and sign a contract.

Treatment Protocols

Upon admission, all individuals displaying signs and symptoms of opioid withdrawal are attended to and, if they consent, induction with transmucosal tablet is commenced via telephone consultation with the on-duty physician. Given that admissions typically occur late at night when a physician may not be present onsite, assessment and initial care are provided by nurses. A specific prescription guides the nurse's subsequent follow-up and allows for treatment adjustments. Newly induced patients are scheduled for follow-up at the next medical clinic visit.

The following dosing regimen as per the induction protocol is followed:[20]

- Day 1: Patient is placed under medical observation via camera for 12 hours. An initial dose is administered of buprenorphine 4 mg–naloxone 1 mg sublingually. This is followed by additional doses of buprenorphine 4 mg–naloxone 1 mg if the COWS score is 7 or more 2 hours after administration of the first dose.
- Day 2: In the absence of withdrawal symptoms, the total dose from day 1 is administered (including the initial dose and the dose 2 hours after the initial dose).
- In the presence of withdrawal symptoms, the total dose from day 1 is administered (including initial dose and dose 2 hours after the initial dose) and an additional dose of buprenorphine 4 mg–naloxone 1 mg.
- Day 3 and subsequent days until appointment with physician: The total dose from day 2 is administered each day.

Administration and Monitoring

The respondent noted that the transmucosal tablets are administered by a nurse in a dedicated room in the presence of correctional officers, who then observe the patients in the room for 10 minutes and conduct mouth checks.

Transition to Community

The respondent noted that there are no uniform protocols for patient transitioning to community in the province, and it varies from 1 correctional facility to another. As per the respondent, their correctional facility provides an initial prescription covering the period until an outpatient medical appointment and links it with the patient's pharmacy. For those who already have a doctor in the community (before incarceration), they can resume their follow-up at their clinic. For patients who started on OAT during their incarceration period, the correctional facility finds them a community doctor who will ensure their care.

Experience With and Rationale for Use of Specific Formulations

The respondent noted that the depot injection is preferred over the transmucosal tablet formulation because it facilitates retention in treatment after release, limits the need for daily administration, and reduces risk of diversion. However, the respondent noted that only a small number of users agree to transition from transmucosal tablet formulation to the depot injection, many of whom cite concerns about "the bump," which they find aesthetically displeasing. However, for those who do make the transition, the treatment leads to improved retention, stability, and comfort for patients; reduces the risk of diversion; and eliminates the daily logistical challenge of mobilizing correctional officers to administer oral medication. Citing the same reasons, the respondent recommended the depot injection.

The respondent noted subpar experience with the transmucosal film formulation because it is easier to conceal and divert. The respondent also alluded to similar experiences at other correctional centres in Quebec, where the transmucosal film formulation is no longer used for the same reason. For these reasons, the respondent did not recommend the use of the transmucosal film formulation, noting it was more expensive with fewer benefits.

Implementation Considerations Such as Risk of Misuse and Diversion, Drug Administration, and Monitoring

The respondent suggested developing a "diversion register" form to be placed in the patient's file and completed by the nurse who witnesses any event of diversion or concealment with the intent of diversion. This practice was noted to make follow-up easier and provide legal protection for the prescriber. Similar to the practice at their facility, the respondent suggests having patients sign a contract committing to not diverting the transmucosal tablet formulation upon arrival in accordance with the regulations. The respondent also advised to train all nurses to administer the depot injection. Additionally, it was advised to have a list of pharmacies in the community that hold the depot, and a list of centre local de services communautaires, clinics, Centre de réadaptation pour les personnes ayant une dépendance, and pharmacies that agree to administer the depot injection, which can be provided to individuals upon their release. The respondent also suggested ensuring patients who are being released from the facility have a valid Régie de l'assurance maladie du Québec (RAMQ) card and are registered with RAMQ drug insurance because many patients are not registered with RAMQ and do not have private insurance either.

Saskatchewan

Two individuals representing the provincial drug plan and a health authority supporting a correctional centre responded to the survey.

Availability

The depot and transmucosal tablet are provided at the organization represented by the 3 respondents. The respondent representing the health authority noted that only generic versions of the transmucosal tablet (2 mg and 8 mg) are available.

Eligibility Criteria

Buprenorphine-naloxone transmucosal tablet is a full benefit with no specific criteria at the provincial drug plan level.

Patients eligible for the depot, through the provincial drug plan, are adult patients with moderate to severe OUD who have been induced and clinically stabilized on an equivalent of buprenorphine 8 mg–naloxone 2 mg to buprenorphine 24 mg–naloxone 6 mg per day of transmucosal tablet for a minimum of 7 days. The provincial drug plan representative noted ongoing advocacy to revise the exception drug status (EDS) criteria for the buprenorphine depot to eliminate the need for induction and stability with transmucosal tablets for 7 days. The provincial drug plan is also considering extending coverage for transmucosal film.

Similarly, the respondent representing the health authority noted that patients must have received the transmucosal tablet for at least 7 days before initiating the depot injection, as recommended by the product monograph.

Treatment Protocols

The regional health authority noted that buprenorphine formulations are used as first-line therapy in the initiation and maintenance of OAT, and the treatment is offered at the correctional centre through a team of physicians contracted by the Ministry of Corrections. The respondent also indicated that although methadone is also available, it is not typically used as first-line therapy, as per guidelines.

The regional health authority noted that treatment is initiated after confirmation of diagnosis of OUD through physician and nurse assessment and a positive urine drug screen.

Administration and Monitoring

The regional health authority mentioned that correctional officers observe administration of transmucosal tablets.

Transition to Community

One health authority noted that they do not have specific protocols for patients transitioning to the community.

Experience With and Rationale for Use of Specific Formulations

The respondents representing the health authority and the public drug plan noted reduced risk of diversion, ease of administration, reduced utilization of health care resources for administration, and elimination of

the need to monitor (witness) patients as reasons for preference for the depot injection opposed to the transmucosal tablets.

The respondents representing the health authority suggested positive experience with the use of depot injection, which worked “very well” in correctional settings. The respondent also stated that scarcity of transmucosal tablets has made diversion a serious problem. The representative also noted that the requirement for induction with the transmucosal tablet for at least 7 days before initiating the depot injection is problematic, particularly when the patient is being released from the correctional facility.

Both respondents representing the health authority and the public drug plan recommend the use of the depot injection. They stated that clinicians have provided feedback indicating practical advantages of depot injection over daily formulations for OUD, citing its effectiveness in stabilizing and maintaining patients who struggled with oral therapy, suggesting that it may be lifesaving in certain contexts. Further, the depot can effectively minimize diversion for patients committed to abstaining from opioids altogether.

Conclusion

Insights based on practical experiences related to provision of drug therapies can offer unique perspectives that complement experimental clinical evidence. According to health care administrators who took part in the survey, the risk of diversion remains a significant concern, along with the administrative burden on health care staff and correctional officers when availing a specific formulation for OUD treatment at a correctional facility. Maintenance of OUD treatment within correctional facilities is crucial, and although treatment protocols are established, deviations from product monographs and protocols may occur to address the unique needs of patients. Flexibility in dosing strategies and choice of formulations allows for personalized treatment approaches, with considerations for factors such as diversion risk, patient preference, and concurrent substance use. Transition plans upon release of the individual from the correctional facility to the community are vital to mitigate the risk of accidental overdose due to decreased opioid tolerance and to support successful reintegration into society. Despite limited patient acceptance, depot injection remains the preferred treatment option because it eliminates the risk of diversion and reduces administrative and care burden. Of note, the anticipated reduction in diversion with the transmucosal film formulation did not fully materialize in real-world settings, highlighting the complexities and challenges associated with treating individuals with OUD in correctional facilities.

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Clinical Review

Sirjana Pant prepared the topic brief, designed and revised the survey as per feedback, and analyzed survey responses, prepared the draft report based on survey responses, and revised the draft report as per feedback to finalize the report.

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Conflicts of Interest

Sirjana Pant disclosed the following:

Evaluation Consultant

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Research Funding or Grants

UNICEF Nepal — Partnership Management Research (health systems/policy), 2020

UNICEF ROSA — Evaluation of COVID-19 response in South Asia, 2023

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Appendix 1: Drug Information

Note that this appendix has not been copy-edited.

Table 3 outlines the approved indications for relevant buprenorphine formulations in Canada.

Table 4 provides the reimbursement criteria/criterion that are relevant to the query, as recommended by CDEC.

Table 5 provides the drug benefit listing criteria for the jurisdictions of interest.

Table 3: Approved Indications for Relevant Buprenorphine and Buprenorphine-Naloxone Combination

Approved use	Administration/strengths	NOC date	ATC code
SUBLOCADE			
For the management of moderate to severe opioid use disorder in adult patients who have been inducted and stabilized for a minimum of 7 days on a transmucosal buprenorphine containing product.	Subcutaneous Injection (Extended Release)[a] 100 mg / 0.5 mL 300 mg / 1.5 mL	2018-11-21	N07BC01 Buprenorphine
SUBOXONE Sublingual Tablet [b]			
For substitution treatment in adults with problematic opioid drug dependence.	Sublingual 2 mg / 0.5 mg 8 mg / 2 mg 12 mg / 3 mg 16 mg / 4 mg	2007-05-18	N07BC51 Buprenorphine, combinations
SUBOXONE Sublingual/Buccal Film			
For substitution treatment in adults with problematic opioid drug dependence.	Sublingual or Buccal 2 mg / 0.5 mg 4 mg / 1 mg 8 mg / 2 mg 12 mg / 3 mg	2020-07-17	N07BC51 Buprenorphine, combinations

ATC = Anatomical Therapeutic Chemical; NOC = Notice of Compliance

[a]Sublocade must only be administered subcutaneously in the abdominal region by a health care provider.

[b]Generics available: PMS-Buprenorphine-Naloxone (2 mg / 0.5 mg, 8 mg / 2 mg), Teva-Buprenorphine- Naloxone (2 mg / 0.5 mg, 8 mg / 2 mg), TARO-BUPRENORPHINE-NALOXONE (2 mg / 0.5 mg, 8 mg / 2 mg)

Source: Suboxone and Sublocade Product Monographs.[21,22]

Table 4: CDEC Recommendations

Indication	Date and recommendation	Reimbursement criteria	pCPA LOI date[a]
Sublocade			
For the treatment of moderate to severe opioid use disorder in adults. Sublocade should be used as part of a complete treatment plan that includes counselling and psychosocial support.	June 19, 2019 Reimburse with clinical criteria and/or conditions	Conditions for Reimbursement Initiation criteria Patients must be induced and stabilized on an equivalent of 8 mg to 24 mg per day of transmucosal buprenorphine for a minimum of 7 days. Administration conditions: 1. Patients are under the care of a health care provider with experience in the diagnosis and management of opioid use disorder. 2. As stated in the Health Canada indication, buprenorphine extended-release injection should be used as part of a complete treatment plan that includes counselling and psychosocial support. 3. As stated in the Health Canada indication, buprenorphine extended-release injection must be administered subcutaneously in the abdominal region by a health care provider. Pricing conditions: #.1.# A reduction in price.	2020-04-08 (Concluded with an LOI)
Suboxone (sublingual tablets)			
Opioid drug dependence (Substitution treatment)	September 24, 2008 List with clinical criteria and/or conditions	The Canadian Expert Drug Advisory Committee (CEDAC) recommends that Suboxone be listed for the treatment of opioid dependence for patients in whom methadone is contraindicated (e.g., patients at high risk of, or with QT prolongation, or hypersensitivity to methadone). Accordingly, CEDAC recommends that prescribing od Suboxone be limited to physicians with a licence to prescribe methadone in treating opioid dependence.	Not applicable
Suboxone (sublingual/buccal film) — Not reviewed by CDEC			
N/A	N/A	N/A	2021-07-15 (Concluded with an LOI)

CDEC = Canadian Drug Expert Committee; CDAC = Canadian Expert Drug Advisory Committee (now CDEC); LOI = Letter of Intent; pCPA = pan-Canadian Pharmaceutical Alliance.

[a]Date negotiation process concluded.

Source: Suboxone and Sublocade reimbursement reviews.[23,24]

Table 5: Drug Listing Criteria in Jurisdictions (Current as of May 1, 2023)

Jurisdiction	Buprenorphine depot	Buprenorphine HCL-naloxone HCL
Alberta[a]	RB	RB
British Columbia[b]	RB	RB[c]
Manitoba	P2B	P1B
New Brunswick	OB	OB
Newfoundland and Labrador	OB	OB
Nova Scotia	OB	OB
Ontario	LU	OB
Prince Edward Island	OB	OB
Saskatchewan	EDS	OB
Yukon	NAB	OB
Canadian Armed Forces	OB	OB
Correctional Service of Canada	OB	OB
Non-Insured Health Benefits	LU	LU
Veterans Affairs Canada	SB	SB

EDS = exception drug status; HCL = hydrochloride; LU = limited use; NAB = not a benefit; OAT = opioid agonist therapy; OB = open benefit; OUD = opioid use disorder; P1B = part 1 benefit; P2B = part 2 benefit; RB = regular benefit; SB = standard benefit.

Note: Data in the table specifically refer to formulations indicated for the treatment of OUD and reflect information in publicly available formulary lists and databases.

[a]The Alberta OAT Gap Coverage Program covers OAT medications for 120 days at no cost for individuals without health benefits coverage.

[b]Brand name drugs require special authorization for full coverage if a generic version is available.

[c]High-dose buprenorphine-naloxone requires special authorization.

Source: Mendell A. et al. (2023)[25] For details on criteria, please refer to Appendix 3: Public Funding Criteria for OATs by Jurisdiction of the report.

Appendix 2: Survey Questionnaire

Note that this appendix has not been copy-edited.

Availability of Buprenorphine-Based Formulations and Treatment Protocol for Opioid Use Disorder

1. Which formulations of buprenorphine are provided in your organization for the management of opioid use disorder? (Please select all that apply.)

- Buprenorphine depot (Sublocade)
- Buprenorphine-naloxone sublingual tablet (Suboxone and generic versions)
- Buprenorphine-naloxone sublingual film (Suboxone film)

2. Please provide any relevant eligibility criteria details (including the provision of brand name products or generic products, strengths, and clinical conditions).

- Buprenorphine extended-release injection
- Buprenorphine-naloxone sublingual tablet
- Buprenorphine-naloxone sublingual film

3. Please summarize how opioid use disorder is treated in your organization. Describe or provide treatment protocols and algorithms if available.

Evidence and Experience With Coverage of Buprenorphine-Naloxone Sublingual Film or Buprenorphine Depot

4. If your organization currently provides buprenorphine-naloxone sublingual film, please elaborate on the following:

- What factors led to the decision for provision (e.g., ease of administration, reduced risk of diversion, studies and/or evidence, administrative reasons, economic reasons, or others)?
- What has been your organization's experience after making buprenorphine-naloxone sublingual film available for the treatment of opioid use disorder? Please share your experience, including any unintended consequences.
- Based on your organization's experience, do you recommend that other organizations provide buprenorphine-naloxone sublingual film for the treatment of opioid use disorder?

  Yes OR No

Please provide reasons for your recommendation.

5. If your organization currently provides buprenorphine depot, please elaborate on the following:

- What factors led to the decision for provision (e.g., ease of administration, reduced risk of diversion, studies and/or evidence, administrative reasons, economic reasons, or others)?
- What has been your organization's experience with making buprenorphine depot available for the treatment of opioid use disorder? Please share your experience, including any unintended consequences.
- Based on your organization's experience, do you recommend that other organizations provide buprenorphine depot for the treatment of opioid use disorder?

  Yes OR No

Please provide reasons for your recommendation.

6. If your organization used to provide or considered providing buprenorphine-naloxone sublingual film or buprenorphine depot but **does not** currently provide it, please share the reasons for the decision.

Implementation Considerations for the Provision of Buprenorphine-Based Formulations for the Treatment of Opioid Use Disorder

7. If your organization currently provides buprenorphine-based formulations for opioid use disorder, please elaborate on the following:

- What initial assessments are conducted to determine the eligibility of a patient for opioid use disorder treatment with a buprenorphine-based formulation?
- How is the treatment initiated after eligibility for treatment with a buprenorphine-based formulation is confirmed? Please describe or share protocols for treatment initiation for opioid use disorder.
- Who observes the drug administration and what other (if any) measures are in place to avert drug misuse or diversion (e.g., monitoring at the point of drug administration, personnel [correctional officer or health staff] administering the medicine)?
- If the formulation given to the inmate is not covered by their drug insurance once released into the community, do you have a protocol for how patients can transition to other available formulations? If yes, please share the details of the protocol.
- If you recommend that other correctional facilities also provide buprenorphine-naloxone sublingual film or buprenorphine depot, please share any advice on what factors should be considered when making these formulations available to inmates, including dose conversion, drug monitoring measures to avert diversion and misuse, transition to and away from various formulations, any protocol and policies that need to be developed, or any other consideration.
- Thank you for your input. Do you agree to being contacted by CADTH by email should there be a need for follow-up questions or clarification? Agreement is completely optional.

  Yes OR No

Appendix 3: Survey Respondents' Organizations

Note that this appendix has not been copy-edited.

Table 6: Respondents' Organizations

Survey respondent number	Jurisdiction	Organization as entered in survey
1	Correctional Services Canada	Correctional Services Canada
2	Alberta	Alberta Health Services
3	Alberta	Alberta Health Services
4	British Columbia	British Columbia Corrections Health Services
5	British Columbia	Provincial Health Services Authority
6	British Columbia	Provincial Health Services Authority
7	British Columbia	Provincial Health Services Authority
8	British Columbia	Provincial Health Services Authority
9	British Columbia	Provincial Health Services Authority
10	British Columbia	Provincial Health Services Authority
11	British Columbia	Provincial Health Services Authority
12	British Columbia	Provincial Health Services Authority
13	British Columbia	Provincial Health Services Authority — Corrections Health
14	British Columbia	BC Mental Health and Substance Use Services — Correctional Health Services
15	British Columbia	Correctional Health Services
16	British Columbia	Provincial Health Services Authority — Correctional Health Services
17	British Columbia	Corrections
18	British Columbia	Provincial Health Services Authority - BC Mental Health and Substance Use Services — Corrections
19	Saskatchewan	Saskatchewan Drug Plan
20	Saskatchewan	Saskatchewan Health Authority
21	New Brunswick	Vitalite
22	New Brunswick	Horizon Health, Saint John Regional Correctional Centre
23	New Brunswick	Corrections. Horizon Health Network Community Portfolio
24	New Brunswick	Madawaska Regional Correctional Centre
25	New Brunswick	Southeast Regional Correctional Centre
26	Newfoundland and Labrador	Newfoundland and Labrador Health Services

Survey respondent number	Jurisdiction	Organization as entered in survey
27	Nova Scotia	Nova Scotia Health Authority — Corrections Health Services
28	Ontario	Ministry of the Solicitor General, Ontario
39	Quebec	Établissement de détention de Montréal et établissement de détention de St-Jérôme

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