Clerk's Stamp

COURT FILE NUMBER	2003 15090
COURT	COURT OF QUEEN'S BENCH OF ALBERTA
JUDICIAL CENTRE	EDMONTON
PLAINTIFFS	TAYLOR ANTHONY MAXEY, AMANDA FRANCES MARIE ERVIN, BYRON BIRD, CAITLYNN WESTGARD, DUSTIN WESLEY ANDERSON, FABIAN POLE, GARY WAYNE FIDDLER, GREGORY LORNE CREOR, KEIGAN TIERNEY, MICHAEL SHANE CARSON, and SHANE PAUL MONETTE
DEFENDANT	HER MAJESTY THE QUEEN IN RIGHT OF ALBERTA
DOCUMENT	**SUPPLEMENTAL ELAINE HYSHKA**

ADDRESS FOR SERVICE AND CONTACT INFORMATION OF PARTY FILING THIS DOCUMENT	NANDA & COMPANY 3400 Manulife Place Edmonton, AB, T5J 4K1 Tel.: (780) 801-5324 Fax: (587) 318-1391 Email: avnish@nandalaw.ca File:

AFFIDAVIT OF ELAINE HYSHKA

Sworn on November 22, 2020

I, Elaine Hyshka, of the City of Edmonton in the Province of Alberta, MAKE OATH AND SAY THAT:

1. This is a supplemental affidavit to the affidavit I swore on October 1, 2020 (**"Initial Affidavit"**).

2. Counsel for the Plaintiffs provided me a copy of the letter issued by Her Majesty the Queen in Right of Alberta (**"HMQA"**) on November 16, 2020 that proposes a solution for those individuals who require access to injectable opioid agonist therapy ("**iOAT**") in Alberta to manage their severe opioid use disorder. Attached as "**Exhibit" 1** to this Affidavit is a copy of this letter.

3. I am an Assistant Professor in the University of Alberta's School of Public Health, with expertise in improving how health systems and services respond to substance use. Between May 31, 2017 and November 30, 2019, I was appointed by the provincial Minster of Health as Co-Chair of the Minister's Opioid Emergency Response Commission (**"MOERC**) alongside Alberta's Chief Medical Officer of Health.

4. As discussed in my Initial Affidavit, MOERC's mandate was to make recommendations to the Minister of Health on how to reduce opioid-related morbidity and mortality in Alberta. This included gathering the best available evidence and actively involving stakeholders in the development of concrete tactics, tools, and actions.[1]

5. During our tenure, MOERC made 32 recommendations to government for urgent actions, this included the recommendation to implement injectable opioid agonist treatment ('**iOAT**') in Alberta.[2] This recommendation was designed to address a significant gap in care for patients with severe refractory opioid use disorder who have not adequately benefited from oral opioid agonist medications (such as suboxone, methadone, or slow release oral morphine).

6. The specific wording of MOERC's iOAT recommendation was to: "support the proposal and funding request from Alberta Health Services ('**AHS**') for a phased implementation of a supervised injectable opioid agonist therapy program in Edmonton and Calgary." [3]

7. 'Phased implementation' referred to the idea that after a two-year pilot phase, during which small scale iOAT clinics were implemented in Edmonton and Calgary, the programs could potentially be expanded to accommodate more patients and other injectable formulations

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[1] Government of Alberta, "Opioid Emergency Response Regulation, Alta Reg 99/2017, Public Health Act," n.d., http://canlii.ca/t/535h0. Attached as **Exhibit "2"** to this Affidavit.

[2] Minister's Opioid Emergency Response Commission, "Minister's Opioid Emergency Response Commission Recommendations to the Minister - Updated July 5, 2018," July 5, 2018. Attached as **Exhibit "3"** to this Affidavit.

[3] Minister's Opioid Emergency Response Commission, "Minister's Opioid Emergency Response Commission Recommendations to the Minister - Updated July 5, 2018," July 5, 2018. Attached as **Exhibit "3"** to this Affidavit.

(e.g. diacetylmorphine), pending confirmation of patient benefit and the availability of additional funding.[4] MOERC's recommendation was based on an assumption that AHS would operationalize their iOAT proposal in alignment with scientific evidence and medical best practice.

8. As outlined in detail in my Initial Affidavit, international scientific evidence has established that iOAT is an effective treatment option for patients with severe, refractory opioid use disorder. Research has shown that in order to maximize patients' health outcomes and minimize risk of harm, injectable opioid agonist treatment must be open-ended, with no pre-determined end date, and that any decision to transition patients to oral medications must be made collaboratively with patients.[5]

9. Further, according to the College of Physicians and Surgeons of Alberta ('**CPSA**'), which establishes and enforces medical practice standards for physicians in Alberta,

> *the use of iOAT should be considered an integral component of the continuum of care for OUD [opioid use disorder], rather than a response to the opioid overdose emergency. The expansion of OUD treatment programs to include iOAT must be implemented in a way that supports long-term sustainability.*[6]

10. The CPSA also dictates that "[iOAT] policies and procedures… adhere to other recognized models of care for this type of practice."[7] To my knowledge, none of the iOAT programs currently operating internationally require patients to transition to injectable medications within a fixed time period.

11. It would thus be counter to scientific evidence, international best practice, and medical ethics to pilot iOAT under a mandate that the program end in two years and that all patients be subsequently transitioned to oral medications (despite the assertion by HMQA, in their November 16 2020 letter, that the iOAT pilot program was not designed to continue indefinitely). This is because the efficacy of iOAT as a treatment option for severe, refractory opioid use disorder is already established, and the target population of this treatment is patients who have not been able to achieve sustained remission with oral opioid agonist treatment, or for whom oral medications are contraindicated.

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[4] Elizabeth Cameron, "Why Alberta Plans to Offer Prescription Opioid Injections," *The Star*, May 1, 2018, sec. Calgary, https://www.thestar.com/calgary/2018/05/01/why-alberta-plans-to-offer-prescription-opioid-injections.html. Accessed on 22 November 2020. Attached as **Exhibit "4"** to this Affidavit.
[5] Nadia Fairbairn et al., "Injectable Opioid Agonist Treatment for Opioid Use Disorder: A National Clinical Guideline," *CMAJ* 191, no. 38 (September 23, 2019): E1049–56. Attached as **Exhibit "5"** to this Affidavit.
[6] College of Physicians and Surgeons of Alberta, "Safe Prescribing for Opioid Use Disorder - Advice to the Profession," April 2019. Attached as **Exhibit "6"** to this Affidavit.
[7] College of Physicians and Surgeons of Alberta, "Safe Prescribing for Opioid Use Disorder - Advice to the Profession," April 2019. Attached as **Exhibit "6"** to this Affidavit.

12. Alberta Health Services ('AHS') has not been operating iOAT with the expectation that the program would end and that patients would transition to oral medications. This is evidenced by comments made by Dr. Avininder Aulakh, Clinical Lead for AHS' Opioid Dependency Program and AHS Edmonton Zone Clinical Site Chief of Addiction Medicine. In an April 1 2019 media interview (**"Exhibit 7"**), Dr. Aulakh confirmed that iOAT was intended as an "alternative" option to oral medications "if all these mainstay treatments have failed."

13. HMQA has invested approximately $15 million in the AHS iOAT program, including significant capital investments and operational dollars to build specialized clinical facilities for iOAT in both Edmonton and Calgary, and to hire and train a large complement of interdisciplinary healthcare staff to serve the complex needs of this highly vulnerable patient group.

14. The need for purpose-built facilities and dedicated staff to adequately care for iOAT patients is confirmed by the fact that AHS was unable to fully operationalize iOAT in Edmonton until the city's iOAT clinic construction was completed in April 2019. Prior to that, AHS attempted to provide iOAT to a small number of patients out of the Edmonton Opioid Dependency Program clinic (using a similar model to what is now being proposed by HMQA).[8] However, as Dr. Aulakh stated in his interview, prior to the start of Edmonton's iOAT clinic, the opioid dependency clinic "just hadn't had the capacity to treat more than maybe 10 people [on iOAT] because of space and staffing limitations."[9]

15. Based on Dr. Aulakh's comments, I believe it is unlikely iOAT patients' complex needs will be adequately addressed if the iOAT clinics are closed, and the patients are required to transition to the opioid dependency clinics for care either for the duration of the court proceedings or indefinitely.

SWORN BEFORE ME at ~~Calgary~~ Edmonton, Alberta,)
this 22nd day of November 2020.)
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AVNISH NANDA
Barrister & Solicitor

ELAINE HYSHKA

[8] Alberta Justice and Solicitor General, "Re: Maxet et al v Her Majesty the Queen in Right of Alberta Court of Queen's Bench of Alberta File No. 2003 15090," November 16, 2020. Attached as **Exhibit "1"** to this Affidavit.

[9] Department of Psychiatry, Faculty of Medicine & Dentistry, University of Alberta, "Edmonton's First Injectable Opioid Agonist Treatment Clinic To Open at FACS Site on 106 Street," n.d., accessed on 22 November 2020 from https://www.ualberta.ca/psychiatry/news-and-events/news/2019/april/edmonton-first-inject-able-opioid.html. Attached as **Exhibit "7"** to this Affidavit.

This is Exhibit "1" referred to in the affidavit of Elaine Hyshka, sworn this 22nd day of November 2020

A Commissioner for Oaths in and for the Province of Alberta

AVNISH NANDA
Barrister & Solicitor

Alberta Justice and Solicitor General

Constitutional and Aboriginal Law
10th Floor, 102A Tower
10025 102A Avenue
Edmonton, Alberta T5J 2Z2
Canada
Telephone: (780) 422-9114
Fax: (780) 643-0852
E-mail: Lillian.Riczu@gov.ab.ca
Our File:

November 16, 2020

DELIVERED VIA EMAIL

Nanda & Company
3400, 10180 – 101 Street
Edmonton, AB T5J 4K1

Attention: Avnish Nanda

Dear Sir:

Re: Maxey, et al v Her Majesty the Queen in Right of Alberta
Court of Queen's Bench of Alberta File No. 2003 15090

The Supervised Injectable Opioid Agonist Treatment Program was a 2-year pilot study that was extended for a further 1-year period ending March 31, 2021. The core service of this pilot study is the access to injectable hydromorphone and an appropriate facility in which to administer the injection under medical supervision. The mandate of the pilot study is to stabilize clients with injectable hydromorphone and transition them to appropriate, non-injectable opioid agonist treatment options when clinically appropriate.

It is our client's positon that the cancellation of the pilot study does not violate your clients' constitutional rights. However, if your clients have not transitioned to an appropriate non-injectable opioid agonist treatment option as at March 31, 2021, Alberta Health, in conjunction with Alberta Health Services, will continue to provide the core service to them as required, based on the assessment of their prescriber in conversation with the care team, and consistent with the mandate of the pilot project. This core service will continue to be provided to your clients at the Opioid Dependency Program clinics in Calgary and Edmonton.

Your clients will also have access through the Opioid Dependency Program clinics in Edmonton and Calgary to the wrap-around psychosocial and health supports that are currently available to clients of those clinics which includes:

- Referral to social housing agencies
- Referral to financial support agencies
- Medication coverage
- Counselling services
- Liaison with other community services and providers.

The same core service and wrap-around support offered to your clients will be available to other clients who were enrolled in the pilot study and have not transitioned to an appropriate non-

injectable opioid agonist treatment option as at March 31, 2021 on the same terms and conditions. This is for your information only and is outside the litigation as your clients have no standing to represent these individuals.

In light of the above, it is our position there is no need for the interim injunction application presently scheduled for hearing on January 8, 2021 to proceed. Please confirm you will withdraw your application.

Yours truly,

FOR. **Lillian Riczu**
Barrister and Solicitor
LR/lr
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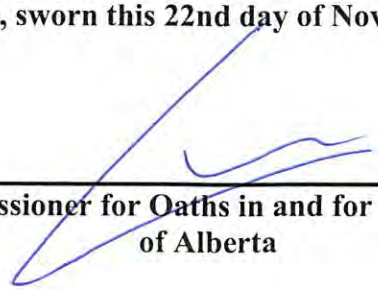
This is Exhibit "2" referred to in the affidavit of Elaine Hyshka, sworn this 22nd day of November 2020



A Commissioner for Oaths in and for the Province of Alberta

AVNISH NANDA
Barrister & Solicitor

Opioid Emergency Response Regulation, Alta Reg 99/2017

(Consolidated up to 87/2018)

ALBERTA REGULATION 99/2017

Public Health Act

OPIOID EMERGENCY RESPONSE REGULATION

Preamble

WHEREAS Alberta is experiencing an unprecedented rise in opioid-related overdoses and other harmful effects of certain uses of opioids, resulting in a public health crisis;

WHEREAS the Government of Alberta, along with its partners, has implemented numerous measures to address this public health crisis;

WHEREAS some of the measures previously implemented have included changes to the laws of Alberta, including the issuing of numerous extraordinary Ministerial Orders authorizing persons to engage in restricted activities aimed at preventing, combating or alleviating a public health emergency as defined in the *Public Health Act*, and the re-scheduling and de-scheduling of naloxone to increase Albertans' access;

WHEREAS the number of overdoses continues to increase despite all of the measures taken to date, and overdoses and other harmful effects of certain uses of opioids urgently need to be addressed;

WHEREAS numerous additional actions must be taken on an urgent basis and in a coordinated way to address this public health crisis as quickly and effectively as possible; and

WHEREAS the rapid deployment of resources and actions that adjust to changing conditions are urgently needed to combat the opioid crisis;

THEREFORE the Lieutenant Governor in Council enacts as follows:

Definitions

1 In this Regulation,

(a) "Commission" means the Minister's Opioid Emergency Response Commission established by section 3;

(b) "individually identifying health information" means individually identifying health information within the meaning of the *Health Information Act*;

(c) "personal information" means personal information as defined in the *Freedom of Information and Protection of Privacy Act*.

Purpose

2 The purpose of this Regulation is to declare that the unprecedented rise in opioid-related overdoses and other harmful effects of certain uses of opioids constitutes a public health crisis and to provide for the rapid and coordinated deployment of necessary resources and actions to combat this public health crisis.

Minister's Opioid Emergency Response Commission established

3 The Minister's Opioid Emergency Response Commission is established.

Mandate of Commission

4(1) The Commission reports directly, through the Chief Medical Officer, to the Minister.

(2) The Commission is mandated to develop recommendations for, and facilitate or monitor the implementation of, as the case may be, urgent coordinated actions to effectively combat the opioid crisis.

(3) In carrying out its mandate under subsection (2), the Commission will

(a) obtain the best information and evidence available respecting opioid use and responses to the opioid crisis, including, without limitation, information and evidence obtained through consultation with stakeholders;

(b) make recommendations to the Minister for timely coordinated actions to address opioid use and related issues, including, without limitation, actions in the following strategic areas:

(i) harm reduction initiatives;

(ii) treatment;

(iii) prevention;

(iv) enforcement and supply control;

(v) collaboration;

(vi) surveillance and analytics;

(c) prepare and submit to the Minister a proposed plan for implementing the recommended actions;

(d) prepare and submit to the Minister a proposed budget for the coordinated implementation of the recommended actions.

(4) In carrying out its mandate under subsection (2), the Commission will facilitate or monitor the implementation of the actions, plan and budget as approved by the Minister by

(a) working with the Government departments, agencies, organizations and individuals in a position to implement or assist or partner in the implementation of each action,

(b) consulting with stakeholders, as appropriate,

(c) monitoring the progress of the implementation, and

(d) monitoring the expenditures in the implementation.

(5) The Commission will consider possible additional actions on an ongoing basis and prepare and submit to the Minister a proposed plan and budget for implementing any recommended additions or changes.

(6) The Commission will monitor the outcomes and effects of the actions implemented.

(7) The Commission will provide communications as directed by the Minister, including communications respecting the approved actions, plan and budget.

(8) The Commission will periodically, and on the request of the Minister, in the form and time specified, submit reports, plans and recommendations to the Minister respecting the outcomes and effects of the actions.

(9) The Commission will undertake any other related tasks as requested or directed by the Minister.

(10) The Commission will create and retain documentation of all activities undertaken under this section.

Composition of Commission

5(1) The Commission consists of the following members:

(a) the Chief Medical Officer, who is designated as chair;

(b) the Deputy Medical Officer of Health appointed by order of the Minister;

(c) individuals appointed by order of the Minister.

(2) The Minister may, by order, designate one individual appointed under subsection (1)(c) as co-chair.

(3) A member of the Commission holds office during the pleasure of the Minister for a term not to exceed one year and is eligible for reappointment.

(4) The Deputy Medical Officer of Health appointed under subsection (1)(b) does not participate as part of the quorum of the Commission, unless the Deputy Medical Officer of Health is acting pursuant to subsection (5).

(5) Where the Chief Medical Officer is absent or unable to act as member and chair, the Deputy Medical Officer of Health appointed under subsection (1)(b) is designated to act as member and chair in place of the Chief Medical Officer for the period of the absence or inability to act.

(5.1) The Minister may, by order, appoint an individual as an alternate to act in the place of a member of the Commission during the member's absence or inability to act.

(6) Subject to subsections (5) and (5.1), no individual is permitted to act as an alternate for a member of the Commission who is absent or unable to act as a member.

(7) An individual who is invited by the Chief Medical Officer may, in accordance with the invitation, attend one or more meetings of the Commission as a guest.

(8) A majority of members of the Commission constitutes a quorum.

AR 99/2017 s5;87/2018

Authority for administration of, access to, naloxone

6(1) On the Minister's own initiative, or on the recommendation of the Commission, the Minister will, in accordance with Schedule 7.1 of the *Government Organization Act*, broaden the authority for the

administration of naloxone for emergency use for opioid overdose outside hospital settings beyond the authority granted under ministerial orders previously issued.

(2) On the Minister's own initiative, or on the recommendation of the Commission, the Minister will increase access to naloxone beyond the access granted through regulations previously enacted to re-schedule and then de-schedule naloxone.

Additional activities of Minister

7 On the Minister's own initiative, or on the recommendation of the Commission, the Minister will make recommendations to the Executive Council respecting the following, for the purposes of addressing opioid prescription, overdose prevention and opioid dependency treatment:

(a) in respect of colleges of professions regulated by the *Health Professions Act*,

(i) best practice standards, audits, enforcement and progress reporting to the Minister, and

(ii) the development and implementation of an opioid strategy, including, at a minimum, a strategy for training relating to harm reduction and addictions;

(b) mechanisms needed to ensure that any private insurance carrier remains engaged in the funding of opioid replacement therapy.

Additional recommendations, direction of Minister

8(1) On the Minister's own initiative, or on the recommendation of the Commission, the Minister, in accordance with the *Health Professions Act*, will make recommendations to the Executive Council, including recommendations respecting college standards of practice, bylaws, regulations or other mechanisms to address opioid prescription, overdose prevention and opioid dependency treatment, including, but not limited to, recommendations respecting physician competence to provide opioid replacement therapy and expanded pharmacist participation in the take home naloxone program.

(2) On the Minister's own initiative, or on the recommendation of the Commission, the Minister will give direction to a regional health authority in respect of facilities operated by the regional health authority providing addiction services or acute care services to adopt opioid overdose protocols, including, without limitation, protocols facilitating access to treatment, counselling, and further expansion of the take home naloxone program for patients attending the facilities.

Terms of reference, procedures, direction

9(1) The Minister may, by order, set terms of reference and procedures to be followed by the Commission in carrying out its mandate.

(2) The Minister may provide direction to the Commission through the Chief Medical Officer relating to the Commission's mandate, for the purpose of providing priorities and guidelines in its performance of its mandate and for the purpose of assisting the Commission in the coordination of its work.

Collection, use, disclosure, provision of information

10(1) The Minister and the Commission may directly or indirectly collect, use and disclose information, including personal information and individually identifying health information, as required for the purposes of this Regulation.

(2) The Minister may require a person, including, but not limited to, a health practitioner providing public mental health or addiction treatment services and a regional health authority, to provide any information required for the purposes of this Regulation.

Establishment of committees

11 The Commission may establish committees, which may include individuals who are not members of the Commission, to assist the Commission in carrying out its mandate.

Remuneration, expenses

12 The Minister may, by order, determine the remuneration and expenses payable to members of the Commission, other than members who are employees of the Government.

Support to Commission

13 If the Minister considers it necessary, the Minister shall provide to the Commission the services of employees of the Government under the Minister's administration to provide administrative, technical or other support to the Commission in carrying out its mandate.

Reporting to Executive Council

14 The Minister will report to the Executive Council on a quarterly basis, or as otherwise directed by the Executive Council, respecting the progress in combating the opioid crisis.

Safety, quality of diagnostic, treatment centres, services

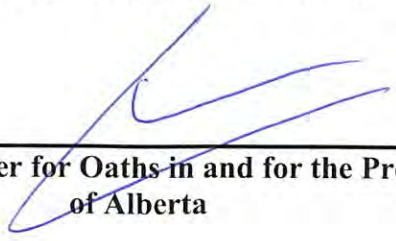
15 On the Minister's own initiative, or on the recommendations of the Commission, the Minister may make recommendations to the Executive Council for the purposes of regulating the safety and quality of public and private mental health diagnostic and treatment centres, public and private mental health or addiction treatment programs and services and individuals providing public and private mental health or addiction treatment programs or services in the provision of opioid-related treatment.

Expiry

16 For the purpose of ensuring that this Regulation is reviewed for ongoing relevancy and necessity, with the option that it may be repassed in its present or an amended form following a review, this Regulation expires on November 30, 2019.

AR 99/2017 s16;87/2018

This is Exhibit "3" referred to in the affidavit of Elaine Hyshka, sworn this 22nd day of November 2020



A Commissioner for Oaths in and for the Province of Alberta

AVNISH NANDA
Barrister & Solicitor

Minister's Opioid Emergency Response Commission
Recommendations to the Minister
Updated July 5, 2018

The Minister's Opioid Emergency Response Commission was established May 31, 2017 to support the Government of Alberta's urgent response to the opioid crisis. As part of its mandate, the Commission is responsible for making recommendations to the Minister for timely coordinated actions to address opioid use and related issues. The following are the Commission recommendations forwarded to the Minister to date.

Note: Subsequent to the Minister's review and acceptance of Commission recommendations, the implementation of recommendations will be undertaken by the appropriate parties, in collaboration with Alberta Health staff.

Recommendation 1: Operational Funding for Supervised Consumption Services

The Commission recommends the Minister provide operational funding for the four supervised consumption services exemption applications for locations in Edmonton (4 locations), Calgary (1 location) and Lethbridge (1 location), currently under review by Health Canada.

The exact budget allocations will be determined pending further analysis and due diligence by Alberta Health. Due diligence includes a review of operational funding proposals to ensure:

- Funding is limited to proposed components that are directly related to supervised consumption services;
- Linkages or the ability to connect clients to other social and health supports and services are demonstrated;
- Efforts to contain costs have been undertaken; and
- A commitment to participate in a coordinated and comprehensive provincial evaluation process is clearly articulated.

Future Funding Proposals/Applications to Health Canada

The Commission does not recommend the establishment of a pre-determined cap on budget allocation for supervised consumption services at this time. The Commission remains open to considering future proposals for supervised consumption services operational funding or other overdose prevention initiatives, if appropriate. Additional recommendations could be made by the Commission in the future, pending discussions on proposals, an assessment of overall intervention options to address the opioid crisis, and budget considerations.

Recommendation 2: Evaluation of Supervised Consumption Services

The Commission recommends the Minister provide funding for the development and implementation of a coordinated, comprehensive provincial evaluation framework for supervised consumption services, instead of funding separate, stand-alone evaluation projects for individual supervised consumption services locations or cities.

Minister's Opioid Emergency Response Commission
Recommendations to the Minister
Updated July 5, 2018

Recommendation 3: Alberta's Take Home Naloxone Program

The Commission recommends the Minister:

a) support the proposal and funding request from Alberta Health Services for the Take Home Naloxone Program which provides naloxone (injectable) kits to organizations for distribution to Albertans at risk of experiencing or witnessing an opioid overdose, and first responder organizations for administration to Albertans in overdose scenarios.
b) support the proposal and funding request from Alberta Community Council on HIV to expand the community based aspects of the Take Home Naloxone Program, with the stipulation of accountability measures provided by Alberta Health.

Recommendation 4: Scope and Mandate of Alberta's Take Home Naloxone Program

The Commission recommends that:

a) Alberta Health Services, in partnership with the Alberta Community Council on HIV, have the discretion to provide organizations not otherwise distributing kits but experiencing a high number of overdose situations, to obtain take home naloxone kits through the provincial program for provision to their employees for use in an overdose event.
b) Organizations seeking naloxone kits (any formulation) for occupational health and safety reasons be responsible for bearing the costs associated with the procurement of naloxone kits and the necessary training.
c) The Minister not publicly-fund naloxone intranasal formulation at this time. However, the Minister should subsidize the procurement costs of nasal spray naloxone for first responder organizations choosing to purchase it for their members' use in opioid overdose situations, with the following stipulations:
    - The organization is not eligible for other subsidy or reimbursement mechanism.
    - The subsidy is no more than the cost of the publicly-funded injectable naloxone kits. Additional incremental costs associated with the procurement of nasal spray naloxone are the responsibility of the first responder organization.
    - The organization being subsidized must develop, implement, and enforce organizational policies for members to administer naloxone to members of the public experiencing an opioid overdose, when indicated.

Recommendation 5: Treatment

The Commission recommends the Minister not fund universal coverage of methadone and Suboxone from the funding allocated to the urgent opioid response. The Commission acknowledges the critical role of opioid agonist treatment but prefers that current resources be allocated toward expanding the number of opioid agonist treatment spaces and other options to enhance the urgent response to the opioid crisis.

Recommendation 6: Supporting the Indigenous Response

The Commission recommends the Minister make a specific funding opportunity available to Indigenous Communities and organizations who serve Indigenous people for initiatives that address the urgent opioid crisis. The Commission recommends this be achieved through an open call for proposals for interventions that support a specific Indigenous Community or Indigenous people on a broader scale. The funding opportunity should be available for all Indigenous Communities (that is on and off Reserve or Settlement Communities). As appropriate, the Commission suggests that the Indigenous Opioids Advisory Sub-Committee Action Plan could act as a guide for the Community and organization proposals and response. The Commission respectfully suggests that people with lived experience are engaged in the development and implementation of these proposals.

Recommendation 7: Enhancing Alberta's Take Home Naloxone Program

The Commission recommends the Minister support the proposal and funding request from Alberta Health Services for enhancements to the Take Home Naloxone Program, including quality assurance and a risk assessment framework.

The Commission also supports the rebranding of the Take Home Naloxone program to decrease stigma and increase accessibility.

Recommendation 8: Increasing the Role of Primary Care in the Urgent Opioid Response

The Commission recommends the Minister support the proposal and funding request from Primary Care Networks and their partners to increase and accelerate the participation of primary care in the urgent opioid response in the following areas:

- Urgent Treatment
- Optimization of existing Primary Care Networks Programming
- Education and knowledge translation targeted to primary care
- Opioid related population based health service planning and integration

Recommendation 9: Supervised Injectable Opioid Agonist Therapy

The Commission recommends the Minister support the proposal and funding request from Alberta Health Services for a phased implementation of a supervised injectable opioid agonist therapy (siOAT) program in Edmonton and Calgary. The Commission suggests engagement with Community Health providers, relevant professional Colleges, and people with lived experiences in the design and delivery of this program.

Recommendation 10: OAT in Acute Care and Expansion of the ARCH Program

The Commission recommends the Minister support the proposal and funding request from Alberta Health Services to:

- Implement an opioid agonist therapy initiation program (using Suboxone) in the Emergency Departments for Calgary and Edmonton. The Commission strongly advises a formalized connection between the Emergency Departments, the Primary Care Networks, and related community providers is established to ensure continuity for clients is maintained;
- Expand the Addiction Recovery and Community Health (ARCH) program operating at the Royal Alexandra Hospital in Edmonton; and
- Initiate the expanded ARCH program in Calgary, once an appropriate site is determined.

Recommendation 11: Communications Strategy

The Commission recommends the Minister support the proposal from Alberta Health Communications to provide grants for community initiatives to support the urgent opioid response. The Commission recommends that these initiatives and subsequent urgent opioid response Communication products are developed with meaningful engagement of people with lived experience.

Recommendation 12: Punjabi Community Health Services Calgary Society Addiction Program

The Commission recommends the Minister support the proposal and funding request from Punjabi Community Health Services Calgary Society for the expansion of their Addiction program to support the urgent opioid response. The expansion of this program will include:

- An Opioid Prevention Support Group;
- Case Management;
- Family enhancement; and
- Enhancing currently offered programming to include opioid-use supports.

Recommendation 13: Overdose Prevention Sites

The Commission supports, in principle, the use of overdose prevention sites, regardless of the intent to establish a permanent site, as one tool to support Albertans using substances including opioids.

The Commission recommends the Minister direct the department to undertake efforts to facilitate access to overdose prevention sites in Alberta. The Commission also recommends the development of a process for the application, implementation, operations, and monitoring of overdose prevention sites for Alberta.

Recommendation 14: Drug Checking Services

The Commission recommends the Minister permit the use of drug testing within approved supervised consumption service sites and overdose prevention sites sanctioned by the Province.

The Commission recommends the Minister further explore the potential use of these drug checking services outside of supervised settings, with a focus on the experiences of other jurisdictions, and consultation with people who are using substances.

Recommendation 15: Universal Class Exemption (Methadone)

The Commission recommends the Minister support the Federal Government's proposal to allow practitioners to prescribe methadone to patients without application for an individual exemption, and support the Commission in providing feedback to Health Canada though the consultation mechanism to reflect their position. In addition, the Commission suggests ongoing provincial efforts among the Ministry and related partners to support appropriate training and standards for health professionals involved in the prescribing and dispensing of methadone to ensure that this drug is provided in a safe and effective manner.

Recommendation 16: Narcotic Control Regulation (Diacetylmorphine)

The Commission recommends the Minister support the Federal Government's proposal to remove some of the regulatory restrictions specific to diacetylmorphine in the *Narcotic Control Regulations*, and support the Commission in providing feedback to Health Canada through the consultation mechanism to reflect their position. In addition, the Commission suggests ongoing provincial efforts among the Ministry and related partners to support appropriate training and standards for health professionals involved in the prescribing and dispensing of diacetylmorphine to ensure that this drug is provided in a safe and effective manner.

Recommendation 17: National Harm Reduction & Drug Policy Conference

The Commission recommends the Minister work with related partners to coordinate avenues of available funding to support the organization of the 2018 National Harm Reduction & Drug Policy Conference.

The Commission supports, in principle, the National Harm Reduction & Drug Policy Conference. This event, to be hosted in Edmonton in October 2018, would reach a wide audience of people affected by the opioid crisis, such as, people who use substances, their families, frontline workers, people of Indigenous descent, ethno-cultural communities, researchers, and policy makers. The conference addresses topics such as changing behaviour, challenging stigma,

facilitating knowledge transfer, enabling cross country collaboration, identifying system challenges, and addressing policy issues that create barriers to addressing the opioid crisis and problematic substance use. Hosting the National Conference would highlight Alberta's opioid response efforts, nationally.

Recommendation 18: Remediation and Personal Protective Equipment Guideline

The Commission recommends the Minister develop provincial evidence-based guidelines addressing the public health risks associated with exposure to fentanyl and other substances suspected to be opioids. This should include guidance on appropriate personal protective equipment as well as standards for remediation of fentanyl contaminated sites such as buildings and vehicles.

Recommendation 19: Calgary Coalition on Supervised Consumption Services

The Commission endorses the proposal from the Calgary Coalition on Supervised Consumption for a mobile supervised consumption service, operated by HIV Community Link. The Commission recommends HIV Community Link apply for a federal exemption for this supervised consumption service in the City of Calgary, as one strategy to address the high number of fentanyl-related overdose fatalities experienced in that community.
Once a federal exemption is obtained, the Commission recommends the Minister make funds available for start-up costs and ongoing operational funding for this service. The Commission recommends these services are provided with a demonstration of:

- Linkages or the ability to connect clients to other social and health supports and services;
- Efforts to contain costs and seek efficiencies; and
- Commitment to participate in the provincial evaluation.

Recommendation 20: Medicine Hat Coalition on Supervised Consumption Services

The Commission endorses the proposal from the Medicine Hat Coalition on Supervised Consumption for an integrated supervised consumption service, housed within HIV Community Link. The Commission recommends HIV Community Link apply for a federal exemption for this service in the City of Medicine Hat, as a mechanism to: enhance harm reduction service options; provide a safe alternative for people who use drugs; and respond to the high rate of opioid related harms.
Once a federal exemption is obtained, the Commission recommends the Minister make funds available for start-up costs and ongoing operational funding for this service. The Commission recommends these services are provided with a demonstration of:

- Linkages or the ability to connect clients to other social and health supports and services;
- Efforts to contain costs and seek efficiencies; and

- Commitment to participate in the provincial evaluation.

Recommendation 21: HIV North Society

The Commission endorses the proposal from HIV North Society for a mobile supervised consumption service, operated by HIV North Society, Grande Prairie. The Commission recommends HIV North Society apply for a federal exemption for this service in the City of Grande Prairie, as one strategy to address the high rate of fentanyl-related overdose fatalities experienced in that community.
Once a federal exemption is obtained, the Commission recommends the Minister make funds available for start-up costs and ongoing operational funding for this service. The Commission recommends these services are provided with a demonstration of:

- Linkages or the ability to connect clients to other social and health supports and services;
- Efforts to contain costs and seek efficiencies; and
- Commitment to participate in the provincial evaluation.

Recommendation 22: Red Deer Coalition on the Opioid Crisis

The Commission acknowledges that Red Deer continues to have one of the highest rates of opioid overdose deaths in the province, and recommends the availability of supervised consumption services in the City of Red Deer, as one strategy to address these fatalities. The Commission endorses the proposal from the Red Deer Coalition on the Opioid Crisis to establish a fixed site supervised consumption service, operated in the current Turning Point facility. It is the opinion of the Commission, based on all the evidence, that a fixed site will best address the service needs of the community and support the response to the opioid crisis.
If this option is not attainable, the Commission recommends that additional supervised consumption service models are considered for Red Deer. Supervised consumption services in Red Deer should address the needs of service users as articulated in Red Deer's 2017 needs assessment; and be hosted by Turning Point Society Central Alberta, due to their connection to persons who may participate in the services and supports provided.

Recommendation 23: Increasing Community Awareness

The Commission recommends the Minister allocate additional funding to the communications strategy presented in October, 2017 due to the high number of quality applications that were initially received. The Commission recommends that the additional funding be allocated to community-based awareness initiatives developed in response to the Alberta Health December 2017 call for proposals on the opioid response. The Commission recommends that these initiatives, and any subsequent products, be developed with meaningful engagement of people with lived experience.

Recommendation 24: Support for Justice and Solicitor General Strategies to Address the Opioid Crisis

The Commission recommends that:

a) The Minister endorse the continued support from the Ministry of Justice and Solicitor General, for the Alberta Law Enforcement Response Teams (ALERT) and joint force operations in Alberta.
b) The Minister endorse efforts from the Ministry of Justice and Solicitor General to develop evidence-based, standardized approaches for drug treatment court (DTC) programs in Alberta. This will facilitate future expansion of existing DTCs, and aid in the development of additional programs within interested communities.
c) The Minister support the department in working with Ministry of Justice and Solicitor General to explore opportunities for pre-charge and post-charge diversion for individuals with substance use issues, with specific focus on the expansion of Case Development Groups and Situation Tables as tools to address the opioid crisis.
d) The Minister, in conjunction with the Minister of Justice and Solicitor General, send a letter to Health Canada in support of additional resources for the Drug Analysis Service to expedite access to results from drug checking.

Recommendation 25: Addiction & Mental Health Protection

The Commission recommends that the Minister support the department to expedite the development of legislation to strengthen the Government's capacity to ensure safe, quality care and consumer protection for Alberta's addiction and mental health facilities, services and care providers. The Commission endorses that legislation is required to enable Government to employ mechanisms to address safety, quality and consumer protection issues as they arise.

Recommendation 26: Increasing the Indigenous Response

The Commission recommends the Minister allocate additional funding to the Indigenous specific opioid response. These additional funds are recommended to be used to enhance the proposals for interventions supporting Indigenous Communities (as previously recommended by the Commission) as well as the provision of additional funding for provincial in-scope initiatives.

Recommendation 27: Engagement

The Commission recommends that those with lived experience, and those they identify as family and/or a part of their support network, be actively engaged in the development and implementation of programs and services related to substance use, including those associated with prevention, treatment, and harm reduction.

Recommendation 28: Contamination & Safe Supply

The Commission is concerned by the extreme toxicity of illegally manufactured fentanyl (and analogues), and the increasing degree to which it is contaminating the illegal drug market and contributing to overdose mortality.

The Commission recommends the Minister support the department to engage in opportunities to address the contamination crisis related to street-sourced drugs. This may include the provision of a safer opioid supply to people at risk of overdose, a strategy the Commission supports in principle, as one tool to address Alberta's opioid crisis, which is among the worst in Canada.

Recommendation 29: Low Barrier, Oral Hydromorphone Distribution Project

The Commission recommends the Minister support the department in undertaking efforts to facilitate Alberta initiating a low-barrier, oral hydromorphone distribution project, as one opportunity to address the opioid crisis and related contamination of street-sourced opioids. The Commission suggests that an Alberta-specific proposal be developed as an arm of the British Columbia Centre for Disease Control's low barrier, oral hydromorphone distribution project. The Alberta project will build off early learnings in British Columbia, and will reflect the Alberta context of the opioid crisis. The Commission recommends the Minister initiate the Alberta project by supporting the department to engage in actions that facilitate an application for funding from the Substance Use and Addiction Program (Health Canada).

Recommendation 30: Terminology

The Commission recommends the Minister support the department in engaging in conversations within the Ministry and amongst relevant stakeholders, including Alberta Health Services and professional regulatory bodies, to harmonize terminology and promote the use of non-stigmatizing, person-centered language as it relates to those who use substances.

Recommendation 31: Substance Use Prosecution

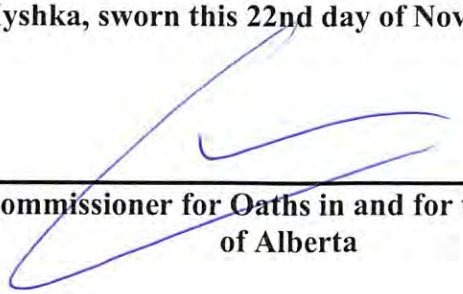
The Commission recommends the Minister support the department in engaging in conversations with provincial and federal prosecution services and judges to facilitate knowledge transfer related to substance use language and terminology, and evidence-based treatment options for people who use substances.

Recommendation 32: Corrections Data and Opioid Agonist Therapy

The Commission recommends the Minister support the department in working with the Ministry of Justice and Solicitor General (JSG) to facilitate Alberta Health access to provincial

corrections specific data, as it relates to those who use substances. In addition, the Commission recommends that the Minister support the department in facilitating the work of JSG and Alberta Health Services to expand opioid agonist therapy initiation and maintenance within provincial correctional facilities, and to support post-discharge community transitions.

This is Exhibit "4" referred to in the affidavit of Elaine Hyshka, sworn this 22nd day of November 2020



A Commissioner for Oaths in and for the Province of Alberta

AVNISH NANDA
Barrister & Solicitor

THE STAR

CALGARY

Why Alberta plans to offer prescription opioid injections

By Elizabeth Cameron StarMetro Calgary
Tue., May 1, 2018 | 6 min. read

CALGARY—If it was as simple as just quitting, most of the people Tanis Petry works with would have already done so.

Petry is part of a team that works to address their client's medical, social, mental health and addictions needs at Calgary's The Alex Community Health Centre's Complex Care Clinic (CCC).

Many of them are addicted to opioids, and in an effort to better serve these clients, the clinic in late 2017 began offering Suboxone treatment, an opioid agonist therapy meant to replace the substance someone has been using with another medication that prevents them from getting "dope sick," or experiencing withdrawal symptoms.

"It's not as easy as just stopping," Petry said. "They've tried mainstream programming, they've tried abstinence, they've tried holistic measures, or mindfulness for pain – you know, whatever that's been recommended – and haven't experienced success."

Nearly 700 people died in Alberta last year from opioid-related overdoses, a number that has been steadily rising since 2011.

As part of its efforts to curb the deaths, the province recently accepted a recommendation from the Minister's Opioid Emergency Response Commission to fund the phased implementation of a supervised injectable opioid agonist therapy (siOAT) program in Edmonton and Calgary.

In plain language, Alberta is planning to prescribe hydromorphone in injectable form, rather than orally, which is currently available on the street or with a prescription under the brand name Dilaudid.

The two-year pilot program is likely to be rolled out by the end of the year, according to Alberta Health's deputy medical officer of health and acting commission co-chair Dr. Kristin Klein.

"We at the commission think it's really important that people that use substances have as many options in their treatment as possible," Klein told StarMetro.

Initially, she said each city's program will have capacity for 50 people, but that could be expanded in the future based on demand.

"We know opioid agonist treatment doesn't work for everybody. The way that (siOAT) will be implemented in Alberta, it is going to be just for people who have failed conventional, oral opioid agonist therapy treatments, such as Suboxone or methadone," Klein said.

People like so many of the CCC's clients, for example.

In Vancouver, Providence Health Care's Crosstown Clinic has been prescribing injectable hydromorphone and diacetylmorphine (pharmaceutical grade heroin) to a small group of patients since 2012, after successful clinical trials in 2004 and 2011.

Similar programs have been offered in Victoria and Ottawa, but it's still a relatively new concept.

"It's a little bit unknown territory," said Barry Andres, executive director of provincial addiction and mental health for Alberta Health Services (AHS), which started working on the program's model after the commission first approached them in the fall of 2017.

"The details are yet to be finalized ... but it'll be a small group, and the plans are for the two largest urban areas – Edmonton and Calgary – where there's greatest need at this point," he said, adding AHS has been consulting with other health care providers who have experience in the area.

The province knows there is a small subset of people who are going to be injecting regardless of the danger opioids such as fentanyl present, Andres explained, but with the street drug supply being increasingly contaminated, many aren't getting the chance to seek treatment if they want it.

"To support those individuals in being stable on a safe and secure drug supply is really the best option for them, at least in the interim, until for some, they get connected to other services and maybe make other changes in regards to their drug use," he said.

At Crosstown, if someone's prescription requires them to visit three times a day, that's the expectation, according to Julie Foreman, the clinic coordinator.

"It's kind of like the carrot that brings them into the clinic," Foreman said.

"The injectable hydromorphone and diacetylmorphine is the treatment they're able to agree to because they're not ready yet to stop injecting, and then they meet the nurses and the physicians and the social workers and the dietician and the nurse practitioner –– and we slowly create relationships with them."

After their ID is checked and provided they're not intoxicated, patients are given a pre-filled syringe with their own personal dose of hydromorphone or diacetylmorphine, and then go to inject it in a dedicated room that is monitored by staff.

They're assessed post-injection and can leave if they're awake and alert –– the point isn't to get them high, Foreman explained, but to avoid the agonizing withdrawal symptoms from opioids.

"We're not going to give them doses that have them overdosing, or nodding off," she said.

"The users that come to our clinic have been using street heroin, for on average, 10 to 15 years – some up to 40 years – so their body is very used to having this drug, they feel like they need it to survive. We try to make their doses so they're not getting dope sick, but it's not a dose that's making them nod off for four hours. It's a fine line."

Like Crosstown, siOAT patients in Edmonton and Calgary will be required to take their prescription in person (exact locations are still being determined, according to Andres).

"We have to work with the whole person to understand the complexity and the uniqueness involved in their experiences," Petry said. "Because what we find is that when people come in here, likely the issue that they came in here for was actually not the issue that's causing them the most difficulty in their life."

Requiring in-person consumption also cuts down on the chances of a prescription being abused, something The Alex already offers to patients living with psychosis, Petry said.

"Not only are they coming in and connecting with a whole span of support of resources and folks that want to support them, but they're not going home with a bottle of pills that they can take as they see fit," she explained.

"(If you have an addiction), you may very well have the best intentions to take that bottle of pills home and take them as prescribed, but what happens is the addiction kind of gets you to place where you're convincing yourself that you need five, rather than the one prescribed."

Because it's meant to target a specific population that hasn't responded to other treatment options, Andres said Alberta's siOAT patients will need a referral.

"There's a network of physicians who are currently providing opioid agonist therapy in other formats — methadone and Suboxone — and they'll be well connected to this program," he said.

"They know the individuals for whom an augmented service like this would be most appropriate for."

Although hydromorphone is a starting point, he said diacetylmorphine could be an option in the future.

"We need to understand what is the size of the population, what do they need, and how are they best served — so from our perspective we're not certainly tied to the program model we're going to start with," Andres said. "If through the evaluation and evidence we find these individuals can best be served in another format, we'll definitely transition to that."

Foreman commended Alberta for bringing in the program, which she said has made a huge difference in the lives of Crosstown's siOAT patients.

"Everyone's lives have improved. Everyone has started to heal," she said.

"Once other parts of their lives become stable, they don't feel that need to inject as much – their need for the needle has changed. And because they've stopped needing to support their (use) with crime, they can start to look after the other things that are really important to them –– like reconnecting with family, or finding housing.

"So this isn't the end of the line for people. I think this is the beginning for a lot of them."

EC

Elizabeth Cameron *is a Calgary-based reporter covering Indigenous affairs, drugs and health. Follow her on Twitter: @e_s_cameron*

Read more about: Calgary, Edmonton

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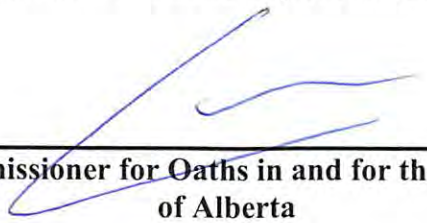
This is Exhibit "5" referred to in the affidavit of Elaine Hyshka, sworn this 22nd day of November 2020



A Commissioner for Oaths in and for the Province of Alberta

AVNISH NANDA
Barrister & Solicitor

Injectable opioid agonist treatment for opioid use disorder: a national clinical guideline

Nadia Fairbairn MD, Josey Ross MA, Michael Trew MD, Karine Meador MD, Jeff Turnbull MD, Scott MacDonald MD, Eugenia Oviedo-Joekes PhD, Bernard Le Foll MD, Marie-Ève Goyer MD, Michel Perreault PhD, Christy Sutherland MD

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CMAJ Podcasts: author interview at https://soundcloud.com/cmajpodcasts/190344-guide

In 2018, at least 4460 Canadians died from an opioid overdose, of which 94% were determined to be unintentional (accidental) overdoses. This represents a 9% increase in overdose deaths from 2017 and a 48% increase from 2016.[1] The recent emergence of street fentanyl, carfentanil and other highly potent synthetic opioids increasingly cut into heroin and other street drugs is a pressing public health concern that has contributed substantially to the overdose emergency. Contamination of street drugs is ongoing and progressive, with new agents such as benzodiazepine analogs being found in substances sold as opioids.[2] Fentanyl and other synthetic analogs were implicated in 73% of opioid-related deaths in Canada in 2018, compared with 67% in 2017 and 50% in 2016.[1] Although pan-Canadian opioid-related deaths were not tracked before 2016, at least 655 fentanyl-related deaths occurred between 2009 and 2014,[3] compared with an estimated 3256 deaths involving fentanyl or fentanyl analogs in 2018 alone.[1]

Opioid agonist treatment has proven to be the most effective approach to reducing all-cause mortality in individuals with opioid use disorder[4] and harms associated with illicit opioid use, including morbidity and mortality.[5–9] However, individuals with severe opioid use disorder who inject opioids may not adequately benefit from oral opioid agonist treatment medications for a variety of reasons, including cravings that persist despite optimal opioid agonist treatment dosing; inability to reach a therapeutic dose; or intolerable adverse effects or contraindications. Individuals who are unable to achieve stabilization or cessation of illicit opioids from first-line medications, or whose circumstances and risks otherwise indicate that they may benefit from injectable opioid agonist treatment, like other individuals using illicit opioids, face substantial risks, including premature death, nonfatal overdose, blood-borne infectious diseases (e.g., HIV and hepatitis C), violence and arrest.[10,11]

Meta-analyses have shown that, among individuals who are refractory to treatment with methadone, supervised injectable diacetylmorphine is beneficial in terms of reducing illicit opioid use, premature treatment discontinuation (or "treatment dropout"), criminal activity, incarceration and mortality, as well as improving overall health and social functioning, quality of life and stability.[12–17] In response to regulatory barriers limiting the provision of diacetylmorphine for the treatment of opioid use disorder in Canada, the Study to Assess Longer-term Opioid Medication Effectiveness (SALOME) trial compared injectable hydromorphone to injectable diacetylmorphine and found that both medications, delivered in identical conditions, showed positive outcomes such as high retention rates and reduction of street opioid use (from daily to a few days per month) and illegal activities.[14] Thus, in jurisdictions where diacetylmorphine is currently not available, or for patients in whom it is contraindicated or unsuccessful, hydromorphone may provide an effective, licensed alternative.[14]

KEY POINTS

- Individuals with severe opioid use disorder who inject opioids and have not adequately benefited from oral opioid agonist treatment face substantial risks, including premature death, nonfatal overdose, blood-borne infectious diseases, violence and arrest.
- Individuals with severe opioid use disorder who inject opioids may not benefit adequately from oral opioid agonist treatment medications, for a variety of reasons.
- This guideline recommends that injectable opioid agonist treatment be considered for individuals with severe, treatment-refractory opioid use disorder and ongoing illicit (nonmedical or illegal or both) injection opioid use.
- For patients who are determined to be likely to benefit from injectable opioid agonist treatment, both diacetylmorphine and hydromorphone are acceptable treatment options.
- Injectable opioid agonist treatment should be provided as an open-ended treatment, with decisions to transition away from injectable opioid agonist treatment made collaboratively with the patient.

This clinical guideline provides 3 key recommendations focused on defining the patient population that should be considered for injectable opioid agonist treatment and outlining considerations for medication selection and length of treatment. Additionally, this document contains expert opinion on clinical care approaches, including eligibility, titration and missed doses.

Scope

This guideline was created to provide Canadian health professionals with clinical recommendations and guidance for the treatment of severe opioid use disorder with injectable opioid agonist treatment. These recommendations are relevant for the clinical management of severe opioid use disorder in adults who inject opioids and have continued to experience substantial health or social consequences related to their opioid use disorder, despite past experience with oral opioid agonist treatment at appropriate dosages, previous attempts on opioid agonist treatment without being able to achieve a therapeutic dose, or other circumstances and risks that indicate the patient may benefit from injectable opioid agonist treatment. Individuals who are not appropriate candidates for injectable opioid agonist treatment should be treated according to Management of Opioid Use Disorders: A National Clinical Practice Guideline[18] developed by the Canadian Research Initiative in Substance Misuse (CRISM).

Methods

Composition of the guideline committee

The CRISM National Injectable Opioid Agonist Treatment Steering Committee, funded by CRISM, a research network funded by the Canadian Institutes of Health Research, was assembled to coordinate activities to prepare the guideline, which included recruiting the guideline review committee. Representation was sought from each of the 4 CRISM nodes (British Columbia, Prairies, Ontario and Quebec–Atlantic) for the steering committee. The steering committee (N.F, B.L.F., M-E.G., M.T., J.T., K. M., M.P.) included representation from British Columbia, Alberta, Ontario and Quebec; each member had relevant expertise, including in prescribing, research and service planning of injectable opioid agonist treatment.

The steering committee decided to create 2 complementary documents: a clinical guideline and an operational guidance document. To that end, the steering committee assembled the National Injectable Opioid Agonist Treatment Clinical Guideline Review Committee and the National Injectable Opioid Agonist Treatment Operational Guidance Review Committee for the operational guidance document.

Each member of the steering committee was invited to nominate relevant experts from their own province and across the country. As guideline review committee members accepted the invitation to join, they were encouraged to nominate additional members to ensure a diverse guideline review committee that represented a range of experience and expertise. Final committee composition was determined by consensus of the guideline review committee co-chairs (N.F. and C.S.). The guideline review committee was composed of 30 individuals, including the 2 co-chairs, and physicians, nurses and nurse practitioners, pharmacists, people with lived experience, researchers, treatment providers and front-line staff. A full list of the guideline review committee is available in Appendix 1, available at www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.190344/-/DC1.

Guideline development

The guideline review committee co-chairs (N.F. and C.S.) and medical writer (J.R.), on behalf of CRISM, used a structured literature review approach to develop the recommendations. We used relevant search terms and structured search strategies to search PubMed, the Cochrane Library databases, and reference lists (up to Aug. 1, 2018) using a hierarchical approach (J.R.), whereby meta-analyses and systematic reviews were given the most weight, followed by individual randomized controlled trials (RCTs), quasi-experimental studies, observational studies and, lastly, expert opinion.

The medical writer manually reviewed titles, abstracts and full text of identified citations; selected evidence for inclusion; and compiled narrative evidence reviews, including cost-effectiveness data, for the co-chairs and the guideline review panel. The medical writer also conducted grey literature searches for any other existing guidelines on injectable opioid agonist treatment, and engaged international researchers and other experts in the field to determine whether injectable opioid agonist treatment guidelines exist anywhere in the world. Although some individual clinics have various protocols and manuals, this process helped us to ascertain that the British Columbia Centre on Substance Use's 2017 provincial guidance document for injectable opioid agonist treatment[19] is the only clinical guidance document in existence, to date. The medical writer brought any questions or uncertainties in the literature search, evidence review and synthesis processes to the co-chairs for clarity and consensus. A detailed description of the methods used to compile evidence summaries for each recommendation, including search terms, can be found in Appendix 2, available at www.cmaj.ca/lookup/suppl/doi:10.1503/cmaj.190344/-/DC1.

Development of recommendations

The guideline review committee co-chairs in conjunction with the medical writer developed key questions and developed and graded draft recommendations (Box 1), using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) tool[20–23] through an iterative consensus process. This guideline also contains clinical guidance that is distinct from the recommendations, which were formally categorized using the GRADE system. The rest of the guidance in this guideline can be understood as clinical guidance informed by the existing literature, expert opinion and clinical expertise, and reached by consensus of the experts on the guideline review committee.

Review of recommendations

The review process consisted of 2 rounds of revisions of the draft guideline recommendations and evidence review by the guideline review committee. The medical writer and committee co-chairs

Box 1: GRADE approach and interpretation of grading

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach[20–23] to rating quality of evidence starts with a simplified categorization of study types (meta-analyses and randomized controlled trials (RCTs), quasi-experimental studies, observational studies and expert opinion), accompanied by initial estimated levels of confidence (high, moderate, low or very low) in the estimate of a treatment effect. The rating scheme allows for factors that would raise or lower a level of confidence. Factors that would lower confidence in evidence include risk of bias, inconsistency across the RCTs, indirectness and publication bias; factors that would increase confidence include large effect size and an observed dose–response effect. The final quality ratings are reflective of the confidence in the estimated effect in context of bias and limitations that have been identified, as described below:

- **High:** We are very confident that the true effect lies close to that of the estimate of the effect.
- **Moderate:** We are moderately confident in the effect estimate. The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different.
- **Low:** Our confidence in the effect estimate is limited. The true effect may be substantially different from the estimate of the effect.
- **Very low:** We have very little confidence in the effect estimate. The true effect is likely to be substantially different from the estimate of effect.

The GRADE approach uses a binary system to classify strength of recommendations as either strong or weak — also known as "conditional." For this guideline, "conditional" was used rather than "weak." It is important to note that, although quality of evidence is an important factor when classifying strength of recommendations, "strong" or "conditional" in this case does not refer exclusively to the quality of evidence underlying a given recommendation. Except for cost and resource allocation, the recommended GRADE factors to classify strength of recommendations were considered:

- Balance between desirable and undesirable effects: The larger the difference between the desirable and undesirable effects, the higher the likelihood that a strong recommendation is warranted. The narrower the gradient, the higher the likelihood that a weak recommendation is warranted.
- Quality of evidence: The higher the quality of evidence, the higher the likelihood that a strong recommendation is warranted.
- Values and preferences: The more values and preferences vary, or the greater the uncertainty in values and preferences, the higher the likelihood that a conditional recommendation is warranted.

Interpretation of strength of recommendations

Examples of how a strong versus conditional recommendation could be interpreted by selected audience or user groups are listed below.

A strong recommendation indicates the following:

- **For patients:** Most people in your situation would want the recommended course of action and only a small proportion would not; you should request discussion with your care provider if the intervention is not offered.
- **For clinicians:** Most patients should receive the recommended course of action. As an example, in this scenario, an algorithm or decision-making tool would not be necessary — the benefits of the recommended course of action would clearly outweigh any advantages of alternative interventions.
- **For health care administrators:** The recommendation can be adopted as a policy in most situations.

A conditional recommendation indicates the following:

- **For patients:** Most people in your situation would want the recommended course of action, but many would not.
- **For clinicians:** You should recognize that different choices will be appropriate for different patients and that you must help each patient to arrive at a management decision consistent with her or his values and preferences. In this scenario, an algorithm or decision-making tool would be advantageous to determine the best course of action.
- **For health care administrators:** Policy-making will require substantial debate and involvement of many stakeholders.

consolidated guideline revisions as needed to address committee feedback. Differences in opinion or interpretation with regard to the guideline recommendations or the evidence review were resolved through facilitated discussions by the guideline review committee through teleconference or direct communication. A final decision was reached for all cases, without the need for arbitration.

All 30 guideline review committee members participated in multiple rounds of review and revision of the draft and granted final approval of the guideline contents and clinical recommendations.

External review process

This guideline was reviewed by the National Injectable Opioid Agonist Treatment Operational Guidance Review Committee, which was responsible for the development of its partner document. After this review, 10 international experts, individuals with lived experience of opioid use disorder, and 1 family member affected by opioid use disorder reviewed and provided input on the final draft. These external reviewers provided input on the clinical guidance, not on the 3 key recommendations.

After external review, the guideline review committee reviewed the entire guideline a final time and signed off on it, after which the guideline review committee co-chairs did the same (a more detailed explanation of the development of recommendations is available in Appendix 2).

Schedule and process for updates

In line with Appraisal of Guidelines for Research & Evaluation (AGREE) II criteria,[24] every 2 years, a structured literature search from the last date update will be conducted, and the guideline review committee will be reconvened to determine which updates from research evidence and expert consensus should be added.

Management of competing interests

This guideline was entirely funded through the CRISM network, which in turn is funded by the Canadian Institutes of Health Research, and without pharmaceutical industry support. Competing interests were assessed using the Guidelines International Network's Principles for Disclosure of Interests and Management of Conflicts in Guidelines.[25] No current or ongoing direct competing interests were disclosed by the 30 members of the clinical subcommittee on screening for participation in the review committee. Twenty-one individuals disclosed special interests in relation to the guideline content, pertaining to specific expertise or clinical experience or both, involvement with provincial programs and committees for opioid agonist treatment or injectable opioid agonist treatment, or research interests and publications. No individual reported that their clinical revenue would be influenced by the guideline recommendations. Upon review by the committee co-chairs, none of the potential direct or indirect conflicts of interest or bias disclosed by committee members were deemed to be of sufficient relevance or weight to warrant the members' exclusion from the committee.

Recommendations

The 3 key recommendations are based on the existing literature on injectable opioid agonist treatment, including 2 systematic reviews and meta-analyses. The rest of the guidance in this guideline can be understood as clinical guidance informed by the existing literature and reached by consensus of the experts on the guideline review committee. A list of the recommendations is shown in Table 1, and a summary of the clinical guidance is shown in Table 2. The complete guideline is available in Appendix 1 and includes additional commentary on each of the 3 key clinical recommendations, as well as clinical guidance.

Injectable opioid agonist treatment

Injectable opioid agonist treatment should be considered for individuals with severe, treatment-refractory opioid use disorder and ongoing illicit injection opioid use (quality of evidence: moderate; strength of recommendation: conditional).

The accompanying full guideline in Appendix 1 provides additional guidance and tools for providing injectable opioid agonist treatment, including eligibility considerations, the pre- and postinjection evaluation tool (the Pasero Opioid Sedation Scale[26]), titration protocols and missed-dose protocols.

Evidence summary

Meta-analyses and systematic reviews of clinical trials involving patients with long-term, refractory heroin addiction have shown the efficacy of diacetylmorphine in comparison with methadone in terms of reducing illicit heroin use, criminal activity and involvement in sex work, as well as improving overall health and social functioning.[12,13] These meta-analyses include a 2011 Cochrane Review that found that supervised injection of diacetylmorphine, paired with flexible doses of methadone, was superior to oral methadone alone in retaining treatment-refractory patients in treatment (4 RCTs; *n* = 1388, relative risk [RR] 1.44, 95% confidence interval [CI] 1.19 to 1.75)[12] and a 2015 systematic review and meta-analysis that found supervised injectable heroin treatment to be superior to methadone in treating treatment-refractory opioid use disorder (4 RCTs; *n* = 1377, RR 1.37, 95% CI 1.03 to 1.83).[13] Both systematic reviews also reported greater reductions in illicit drug use (both heroin and other illicit substances), but owing to heterogeneity in reporting, these were reported narratively rather than included in the meta-analyses.

The SALOME trial compared diacetylmorphine to injectable hydromorphone in a population of patients (*n* = 202) with long-term, treatment-refractory opioid use disorder. Both per-protocol (PP) and intention-to-treat (ITT) analyses found that injectable hydromorphone was not inferior to injectable diacetylmorphine for long-term injection street opioid users not currently benefiting from oral opioid agonist treatment, in terms of retention rates (≥ 92% PP; ≥ 77% ITT) and reduction of any street opioid use (–0.15, 90% CI –2.09 to 1.76) PP; –0.85, 90% CI –2.97 to 1.25, ITT) and illegal activities (–1.06, 95% CI –3.46 to 1.14, PP; –0.98, 95% CI –3.11 to 1.04, ITT).[14] Per-protocol analysis also found noninferiority for reduction in street heroin use (–1.44, 90% CI –3.22 to 0.27). Thus, in jurisdictions in which diacetylmorphine is currently not available, or for patients in whom it is contraindicated or unsuccessful, hydromorphone provides an effective, licensed alternative.[14]

The quality of evidence is rated moderate to reflect a moderate confidence in the effect estimate. This is owing to the low number of trials and the possibility (although low) that a single study with results strongly in favour of oral opioid agonist treatment could substantially alter the effect size in the direction of no effect. This recommendation is rated as conditional given that although there are many patients who would choose injectable opioid agonist treatment, there will be some who would find the attendance requirements onerous or otherwise not have their needs met by injectable opioid agonist treatment.

Medication selection

For patients who are determined to be likely to benefit from injectable opioid agonist treatment, both diacetylmorphine and hydromorphone are acceptable treatment options (quality of evidence: low; strength of recommendation: strong).

The accompanying full guideline in Appendix 1 provides additional guidance on medication selection, preparation and dispensation.

Evidence summary

As outlined above, 2 systematic reviews support the recommendation of diacetylmorphine for the treatment of severe opioid use disorder.[12,13] Both PP and ITT analysis in the SALOME trial found that injectable hydromorphone was not inferior to injectable diacetylmorphine for long-term injection street opioid users not currently benefiting from oral opioid agonist treatment, in terms of retention rates (≥ 92% PP; ≥ 77% ITT) and reduction of any street opioid use (–0.15, 90% CI

Table 1: Recommendations summary*

Category	Recommendation	Quality of evidence	Strength of recommendation
Injectable opioid agonist treatment	Injectable opioid agonist treatment should be considered for individuals with severe, treatment-refractory opioid use disorder and ongoing illicit injection opioid use.	Moderate	Conditional
Medication selection	For patients who are determined to be likely to benefit from injectable opioid agonist treatment, both diacetylmorphine and hydromorphone are acceptable treatment options.	Low	Strong
Treatment end date	Injectable opioid agonist treatment should be provided as an open-ended treatment, with decisions to transition to oral opioid agonist treatment made collaboratively with the patient.	Low	Strong

*Protocols and other clinical guidance can be found in the full guideline in Appendix 1. The 3 key recommendations were formulated using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) framework and are based on the existing literature on injectable opioid agonist treatment, including 2 systematic reviews and meta-analyses.

Table 2: Clinical guidance summary*

Category	Clinical guidance
Eligibility	Guideline recommendations for eligibility should be considered in concert with clinical judgment and precautions.
Titration process	The titration protocol should be followed.
Pre-intake assessment	This must be performed by a qualified health professional or other trained staff member supervised by a health professional to ensure the patient is not intoxicated or in any other contraindicated acute clinical condition.
Administration of injectable medications	• Generally, up to 3 visits per day are recommended. • Individuals should self-administer under supervision of a qualified health professional. • Patients may inject intravenously, intramuscularly or subcutaneously. • Intravenous injection is recommended in upper extremities only. Lower extremity injection should be discussed and risks identified for those who cannot find an appropriate site in their upper extremities or who otherwise prefer intravenous injection in their legs or feet. • Intramuscular sites should be identified by a qualified health professional and rotated according to established practice standards.
Postintake assessment	This must be performed by a qualified health professional or other trained staff member supervised by a health professional to ensure safety and attend to dose intolerance or other adverse event.
Co-prescription of oral opioid agonist treatment	Co-prescription of slow-release oral morphine or methadone should be considered, to prevent withdrawal and cravings between injectable opioid agonist treatment doses, particularly overnight.
Missed doses	The missed-doses protocol should be consulted.
Ongoing substance use	Ongoing substance use while on injectable opioid agonist treatment may be an indication to intensify treatment, which may include increasing dosage, transferring to a more intensive model of care, or increasing psychosocial and other supports. The substance-specific guidance should be consulted.

Stabilization	Stabilization will be patient specific, depending on each patient's circumstances and needs and how these change over time. Patients' DSM-5 diagnoses, physical and mental health comorbidities, and social determinants of health (e.g., poverty, homelessness) should be identified at baseline and tracked over time. Stabilization includes:
	• Clinical stabilization, which includes
	  • Lack of cravings
	  • Improved sleep quality and duration
	  • Overall well-being
	• Psychosocial stabilization, which may include
	  • Integrating new activities
	  • Reconnecting with family
	  • Attaining safe housing

Note: DSM-5 = *Diagnostic and Statistical Manual of Mental Disorders*.
*Protocols and other clinical guidance can be found in the full guideline in Appendix 1.

–2.09 to 1.76, PP; –0.85, 90% CI –2.97 to 1.25, ITT) and illegal activities (–1.06, 95% CI –3.46 to 1.14, PP; –0.98, 95% CI –3.11 to 1.04, ITT).[14] Per-protocol analysis also found noninferiority for reduction in street heroin use (–1.44, 90% CI –3.22 to 0.27).[14]

Although diacetylmorphine has substantially more evidence supporting its efficacy in treating opioid use disorder, it may pose an increased risk of adverse events (e.g., histamine reactions, seizures and overdose) compared with injectable hydromorphone.[14,27] Hydromorphone was associated with a significantly lower risk of both adverse events (0.60, 95% CI 0.39 to 0.90) and serious adverse events (0.21, 95% CI 0.06 to 0.69) compared with diacetylmorphine.[14] For these reasons, either medication can be considered a reasonable choice, based on availability, patient choice and prescriber judgment.

The quality of evidence is rated low owing to the discrepancy in evidence supporting each medication, with 2 systematic reviews supporting the use of diacetylmorphine, and only a single study supporting the use of hydromorphone. The recommendation is rated as strong based on expert consensus, substantial clinical experience in British Columbia, reduced risk of adverse events for hydromorphone compared with diacetylmorphine, and the lack of regulatory and supply barriers affecting access to hydromorphone.

Treatment end date

Injectable opioid agonist treatment should be provided as an open-ended treatment, with decisions to transition to oral opioid agonist treatment made collaboratively with the patient (quality of evidence: low; strength of recommendation: strong).

The accompanying full guideline in Appendix 1 provides additional guidance on continuing care and treatment transitions, including considerations for transitioning off injectable opioid agonist treatment, short-term transition to oral treatment for travel and continuity of care.

Evidence summary

A loss of treatment benefit when prescription diacetylmorphine treatment was discontinued at a predetermined end date has been found in 2 post-RCT observational cohorts.[28,29] Both of these studies found an increase in street heroin use after end of treatment, to levels comparable with that of the control group. One study found a rapid deterioration in 82% (94/115) of responders in the diacetylmorphine group 2 months after treatment discontinuation, with mean scores on the constituent scales of the multidomain outcome index returning to pretreatment levels,[29] while the other showed a significant increase of street heroin use in the diacetylmorphine group 3 months after treatment discontinuation (p = 0.005, mean number of days of heroin use in past month = 8 days at 12 months, mean = 14 days at 15 months).[28] Another study compared individuals who voluntarily transitioned from injectable diacetylmorphine to oral methadone before the completion of an RCT against those who were involuntarily transitioned at the end of the 12-month trial, and found that the mean prior 30 days of illicit heroin use was higher in the involuntary group than in the voluntary group at 24 months (adjusted mean difference –5.58, 95% CI –11.62 to 0.47) and treatment retention was significantly lower (adjusted odds ratio 5.55, 95% CI 1.11 to 27.81).[30]

The quality of evidence is rated low owing to the low number of studies evaluating the impact of predetermined treatment end dates. This recommendation was rated strong despite the low quality of evidence, owing to the risk associated with fentanyl-contaminated illicit opioid use and its alignment with a recommendation from the World Health Organization that opioid agonist treatment be provided as an open-ended treatment.[31]

Implementation

Policy-makers and program planners in each province will have to determine the model or models of care most appropriate for each setting. Considerations will include the number of patients who would benefit from injectable opioid agonist treatment, the infrastructure and services already in place, available funding and staffing requirements. The National Injectable Opioid Agonist Treatment for Opioid Use Disorder — Operational Guidance document provides (available at https://crism.ca/projects/ioat-guideline/) in-depth guidance on planning, implementation, operation and evaluation of injectable opioid agonist treatment programs and is intended to guide the development of new injectable opioid agonist treatment programs across the country. With the release and dissemination of a national clinical guideline and operational guidance document, the primary barrier to treatment will be funding. Thus, jurisdictions will need to ensure adequate funding in order to expand access to injectable opioid agonist treatment across the country.

As with the clinical guideline, every 2 years a structured literature search from the last update will be conducted to inform the operational guidance document and the guidance committee will be reconvened to determine which updates from research evidence and expert consensus should be added.

Other guidelines

Three main guidelines on the treatment of opioid use disorder were published in the past decade, 1 by the American Society of Addiction Medicine,[32] 1 by the World Health Organization,[33] and 1 by CRISM (the same group funding and leading this guideline).[18] In 2017, the BC Centre on Substance Use released a provincial guidance document for injectable opioid agonist treatment.[19] However, this guideline — a clinical guideline for injectable opioid agonist treatment for opioid use disorder — is the first of its kind in the world, to our knowledge. Although earlier guidelines present evidence and guidance on the use of (oral) opioid agonist treatment, the 2017 BC provincial guidance document and this clinical guideline are the first to provide clinical guidance for injectable opioid agonist treatment for severe opioid use disorder. This guideline also provides more in-depth guidance, including 3 key clinical recommendations using the GRADE approach, on managing ongoing substance use, comprehensive guidance on patient-centred care and guidance on treatment transitions

for patients in hospital or correctional facilities. Additionally, this guideline is national in scope.

Gaps in knowledge

Although treatment with diacetylmorphine is a standard of care in several countries,[34] some gaps in knowledge remain. Because of restrictions on accessing diacetylmorphine in Canada, hydromorphone has been used to expand access to injectable opioid agonist treatment, based on a 2016 noninferiority study.[14] Additional research is required to identify whether certain patients benefit more from hydromorphone or diacetylmorphine, and expanded access to diacetylmorphine across Canada is needed.

To date, published evidence on injectable opioid agonist treatment in special populations is limited. Published evidence on the feasibility and safety of injectable opioid agonist treatment during pregnancy is limited to 2 European case reports, both of which attribute positive pregnancy outcomes to the continuation of treatment with diacetylmorphine in the case of women with severe opioid use disorder and multiple comorbidities.[35,36] In addition, no research has been conducted that specifically looks at injectable opioid agonist treatment in youth.

Most clinical trials evaluating injectable opioid agonist treatment have restricted participation to individuals who have previously undergone oral opioid agonist treatment; thus, the evidence base can be understood as being supportive of injectable opioid agonist treatment for the treatment of patients who have not benefited from oral opioid agonist treatment. However, clinical practice in British Columbia has shifted to broader eligibility considerations, which are aligned with the expanded eligibility considerations presented in the full guideline (Appendix 1). These expanded eligibility considerations should be evaluated.

Finally, for individuals who have stabilized on injectable opioid agonist treatment and wish to transition to a less intensive approach, more research is needed to determine optimal approaches to transitioning to other treatments.

Conclusion

Individuals with severe opioid use disorder who inject opioids may not adequately benefit from oral opioid agonist treatment medications, for a variety of reasons. This guideline provides a framework for how to build a clinical practice of injectable opioid agonist treatment and recommends that this treatment should be considered for individuals with severe, treatment-refractory opioid use disorder and ongoing illicit injection opioid use. For those individuals determined likely to benefit from injectable opioid agonist treatment, both diacetylmorphine and hydromorphone should be considered appropriate treatments. Finally, injectable opioid agonist treatment should be provided as an open-ended treatment, with decisions to transition to oral opioid agonist treatment made collaboratively with the patient.

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Contributors: Nadia Fairbairn and Christy Sutherland co-chaired the guideline review committee, conceptualized the guideline and provided feedback and guidance to the medical writer on all drafts. As medical writer, Josey Ross conducted literature reviews, summarized and synthesized evidence, and led the research, writing and editing of the guideline, with support from the guideline review committee co-chairs. All authors were actively involved in the various cycles of corrections and revisions of the manuscript and contributed substantially to the interpretation of the findings. All of the authors gave final approval of the version to be published and agreed to be accountable for all aspects of the work.

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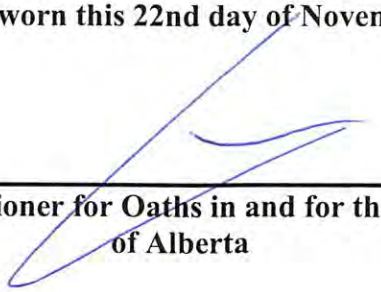
This is Exhibit "6" referred to in the affidavit of Elaine Hyshka, sworn this 22nd day of November 2020



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ADVICE TO THE PROFESSION

Safe Prescribing for Opioid Use Disorder

Related Standards of Practice: *Continuity of Care*, *Safe Prescribing for Opioid Use Disorder*, *Transfer of Care*

The College of Physicians & Surgeons of Alberta (CPSA) provides advice to the profession to support physicians in implementing the *CPSA Standards of Practice*. This advice does not define a standard of practice, nor should it be interpreted as legal advice.

Table of Contents

Scope

Opioid Use Disorder (OUD) is one of the most challenging forms of addiction and a major contributing factor to the recent rise in opioid-related morbidity and mortality. In recent years, the non-medical use of pharmaceutical opioids and the emergence of highly potent, illegally manufactured opioids have increasingly impacted the evolving landscape of opioid use.

OUD is best conceptualized as a chronic, relapsing illness which has the potential to be in sustained, long-term remission with appropriate treatment. OUD can involve misuse of prescribed opioid medications, use of diverted opioid medications or use of illicitly manufactured heroin, fentanyl or fentanyl analogues. For more information, refer to the DSM on Diagnostic Criteria for OUD.[1]

The intention of the *Safe Prescribing for Opioid Use Disorder* standard of practice is to provide physicians with clear requirements that allow for safe and responsible management of OUD with evidence-supported, full opioid agonist treatments. The standard is deliberately nonprescriptive in requiring use of specific treatment guidelines, as the treatment modalities for OUD are changing rapidly. It is our expectation that physicians provide care based on the most current guidelines and recommendations available, as well as evidence-based best practices (see Appendix 1). Opioid Agonist Treatments (OAT) are described in the medication list provided (see Appendix 2).

The current guidelines strongly recommend buprenorphine/naloxone and methadone as the first-line treatments for OUD. The advantages provided by buprenorphine/naloxone are well-recognized and include a superior safety profile, greater flexibility and patient autonomy (which allows for earlier take-home dosing), and unobserved home inductions where appropriate. The use of buprenorphine/naloxone can be safely provided with access to laboratory services and a collaborative relationship with a community pharmacist.

Physicians should **not** refuse to accept patients from an initiating prescriber based on access to services. There is no difference in how services would be accessed to support other areas of practice, and the access can be indirect: the services do not need to be located in the same location as the physician, nor in the same location to each other.

There are **no** requirements for an approval from the CPSA to prescribe buprenorphine/naloxone, or proof of certain educational or training certification. The expectation is that physicians will acquire the required knowledge and skills to diagnose OUD and provide front-line treatment and medication in accordance with the current guidelines and best practice information, as they would for any other chronic medical condition and medication. For the purpose of this standard, buprenorphine/naloxone is excluded.

[1] DSM-5 Clinical Diagnostic Criteria for Opioid Use Disorder

Providing Safe and Compassionate Care

Evidence-informed, comprehensive treatment is known to improve the lives of patients who are in pain and living with OUD. These patients need patient-centered, holistic care, delivered with compassion and support.

It is **never** acceptable to abruptly discontinue a patient's prescription opioids because an opioid use disorder is suspected or diagnosed. Patients with OUD, as those living with any other chronic/relapsing illness, benefit most when engaged as partners in their care along with their physician. Actions that undermine such a relationship are not only problematic for obvious reasons, but can also put a patient at serious risks in the context of a contaminated drug supply. For complex patients or where the diagnosis of an OUD is challenging, a consultation with an experienced OAT provider is strongly recommended. (see Appendix 3).

It is **never** acceptable to abruptly discontinue a patient's prescription opioids because an opioid use disorder is suspected or diagnosed.

Patients with OUD may benefit from harm-reduction interventions, including education about:

- sterile syringe use and safer injection practices, to reduce the risk of blood-borne (HIV, hepatitis C) and soft tissue infections;
- access to take-home naloxone; and
- syringe distribution programs and supervised consumption services, to reduce the risk of blood-borne infection and fatal overdose (particularly amongst high-risk patients or patients with ongoing opioid use).

Stigma is a major barrier to seeking treatment and maintaining recovery, and respectfully treating people who use substances improves health outcomes and helps save lives. All efforts should be taken to reduce stigma, which contributes to isolation and means patients are less likely to access services. We must all work to change the conversation about OUD. Language matters and we support and encourage the use of language that puts people first, reflects the medical nature of OUD and promotes recovery.

"We must all confront the intangible and often devastating effects of stigma. The key to recovery is support and compassion. Patients in pain and patients with a substance use disorder need comprehensive treatment, not judgment." - Patrice A. Harris, MD, MA, chair AMA Opioid Task Force"

Education and Experience

Knowledgeable and experienced physicians are an integral part of providing patient-centered care in the treatment of OUD. The ability to choose the most appropriate treatment in complex situations, in the context of rapidly evolving treatment options, requires that physicians have current knowledge, relevant experiential training and can maintain their knowledge and skills through Continuing Professional Development (CPD).

Physicians who do not have an OAT approval[2] must complete a CPSA-recognized Opioid Dependence Training Program and provide evidence of experiential training, supervision, mentorship and/or completion of an approved preceptor-based course or residency.

To provide readily-accessible education and experiential training options for physicians, the Alberta Opioid Dependency Virtual Training Program was developed by Alberta Health Services (AHS), in collaboration with the CME Office at Calgary's Cumming School of Medicine. The focus of this program is to give healthcare providers the knowledge, skills and attitudes necessary to provide care to patients with OUD by teaching the complex integration of technical and behavioral competencies required for addiction and mental health in day-to-day clinical practice. AHS also has the Alberta ODT Virtual Training Program available through Provincial Addiction Curricula & Experiential Skills Training (PACES), which can be accessed at any time through their website.

Successful completion of this program will meet the educational and experiential training required for an approval to initiate OAT for OUD. Upon completion of this course, a certification of completion is provided directly to the CPSA, and an approval is granted without the need for physicians to submit an application or any other evidence.

The program takes a proactive approach—it streamlines the approval process and provides Alberta physicians with access to education and training necessary to ensure competency in OAT, regardless of their location. Physicians who complete other recognized courses (e.g., BC Center on Substance Use (BCCSU) or Center for Addiction and Mental Health (CAMH)) need to submit the following to obtain an approval to initiate OAT for OUD:

- an application for approval;
- evidence of course completion; and
- evidence to support experiential training.

Physicians who presently have an OAT approval (formerly known as a Methadone Exemption/Methadone Approval) for initiating or maintaining treatment for patients with OUD will not be required to have any further training to maintain their approval. It is expected that these physicians maintain their competence in OAT

[2] Per clause 1 of the *Safe Prescribing for Opioid use Disorder* standard of practice, OAT approval refers to full opioid agonist therapies for opioid use disorder treatment.

through ongoing education (as part of their mandatory CPD) and provide evidence of the relevant Continuing Medical Education (CME) upon request.

Renewal requirements for prescribing approvals for OAT have been relaxed from those under the previous Health Canada Methadone Program. Physicians with a CPSA approval to initiate OAT (or a pre-existing Methadone Exemption/Approval for initiation) will now only need to renew their prescribing approval once every five years. Physicians with a prescribing approval to maintain OAT are exempt from the renewal requirement. The physician will receive notification of renewal from the CPSA and renew by return email.

Appropriate Settings, Continuity and Transfer of Care

Appropriate Settings

OAT for OUD must be initiated where there is access to Alberta Netcare/PIN data, medical laboratory services and pharmacy services. Physicians are expected to be able to refer patients to appropriate multidisciplinary support and other resources and services, as indicated by patient preference and suitability to the patient's care. These services do not necessarily need to be located at the same site as the clinic providing OAT for OUD, but should be easily accessible for collaboration and continuity of care. Evidence shows that pharmacotherapy should not be offered in isolation, but rather should include ongoing assessment, monitoring and support for all aspects of physical, emotional, mental and spiritual health. These are equally important components of treating OUD—addressing these needs should be considered the standard of care. Evidence-based psychosocial supports focused on individual circumstances (e.g., housing, employment, etc.) and other survival needs (e.g., social assistance) may also be helpful in supporting recovery from OUD.

Continuity of Care

Continuity of care is also an important aspect of medical management in all settings. In the absence of the initiating provider, physicians must have access to other prescribers with the ability to prescribe OAT. It is expected that physicians working within groups have a process to manage continuity of care and provide coverage for each other. This may be challenging for those who work in rural or remote locations, but physicians need to be aware of the resources available to help manage this aspect of their practice. Alberta's Virtual Opioid Dependence Program supports physicians in rural/remote locations in maintaining continuity of care for their patients. The AHS Opioid Use Disorder Telephone Consultation service, a province-wide, e-consult service, is another resource for prescribers.

Continuity of care remains a vital part of patient safety and maintaining prescribers must have arrangements in place to provide patient care in their absence. Collaboration with colleagues, mentoring networks and educational resources will ensure that patient safety is not compromised.

Patients who are hospitalized, treated in emergency room settings or who are incarcerated are particularly vulnerable to loss of continuity of care. Physicians who temporarily provide OAT in these circumstances must ensure the patient has a sufficient amount of medication on discharge to allow them to contact their community physician. The community physician must also be notified of their patient's discharge. Direct contact with the community physician is preferred, to allow timely communication about the patient's treatment while under the temporary prescriber. Written communication should also be provided to the community physician.

If a change in medication becomes necessary during the course of the patient's hospitalization, emergency room stay or incarceration, the temporary prescriber must consult with the initiating prescriber or a qualified colleague to ensure any changes are made appropriately and safely. It is expected that all initiating prescribers have a process in place which allows for prompt accessibility of themselves or a delegate prescriber. In the event of urgent or emergent situations, it is expected that the temporary prescriber use best practices to inform their clinical decision.

Collaboration between prescribers during transitions of care is essential to providing continuity and safe patient care.

Transfer of Care

Stable patients can be maintained in a community setting by their primary care provider. Transfer of care to a community physician requires the initiating prescriber to provide the maintaining physician with a letter of support (sample letter) and an information checklist. The letter of support should indicate that the initiating prescriber (or appropriate delegate) will be available to provide support, accessibility and advice to the maintaining physician. The information checklist should provide the maintaining prescriber with information about any potential risks from the OAT, possible adverse effects and red flags that may indicate a loss of stability requiring further consultation with the initiating prescriber (or their delegate).

The success of transferring the care of stable patients to community physicians is dependent on the ability of the initiating prescriber to provide accessible support for the maintaining physician, so patient care is provided safely. Establishing and maintaining a collaborative environment between both physicians is an integral part of this success.

It is expected that community physicians will accept transfer of care to maintain prescribing of OAT for stable patients and provide patient-centered, holistic care to patients with OUD. Evidence demonstrates that patients receiving team-based health care have improved outcomes, more patient satisfaction and reduced use of hospital, emergency room and specialty clinic services. This treatment also has the advantage of integrating addiction, medical and psychiatric services into mainstream services, reducing the stigma of addiction and the professional isolation of medical staff. Patients may prefer to receive treatment for their OUD in specialty clinics, so it is necessary to support patients as they integrate into a team-based health care setting.

An approval for maintaining a patient on OAT for OUD is provided to the maintaining physician upon receipt of a support letter from the initiating prescriber. After accepting a patient transfer from the initiating physician, the maintaining prescriber must complete an approved educational course within six months. Module 5 of the Alberta Opioid Dependence Virtual Training Program meets this educational requirement. This online program is free and can be used for CME credits. The program also streamlines the approval process by providing the CPSA with confirmation of completion.

Physicians who already hold an approval for OAT for OUD–Patient Specific are **not** required to complete further educational training to maintain treatment for present or future patients. It is expected that physicians ensure their competency through relevant CME.

When a physician with an approval to maintain OAT for OUD accepts the responsibility of maintaining OAT for OUD for additional patients, a letter of support from the initiating prescriber is required for each additional patient.

Injectable Opioid Agonist Treatment

Injectable OAT (iOAT) is an evidence-based, high-intensity treatment option for patients with OUD who have not benefited from other treatments. It is important to note that the use of iOAT should be considered an integral component of the continuum of care for OUD, rather than a response to the opioid overdose emergency. The expansion of OUD treatment programs to include iOAT must be implemented in a way that supports long-term sustainability.

Optimizing patient safety is an important factor in the designation of iOAT as a alternative intervention, when oral OAT has not been successful. It is important to remember that any frequently-administered injectable treatment comes with higher risks of cutaneous and infectious complications. It should be considered that intravenous or intramuscular injections such as iOAT have a more rapid onset of action, and peak effects (including respiratory depression) are reached faster than with oral ingestion of high-dose, full agonist opioid medications.

To provide iOAT, physicians **must** have an active CPSA approval to initiate or maintain OAT for OUD. Doses must be administered in a facility operated by AHS, or in a community setting approved by the CPSA, with sterile supplies, safe conditions and qualified staff trained to intervene in the event of an emergency.

Community settings that wish to provide this treatment option must submit a letter of intent to Methadone.Info@cpsa.ab.ca, outlining the policies and procedures under which their setting will operate. It is expected the policies and procedures provided will adhere to other recognized models of care for this type of practice, such as those in use by AHS or the BCCSU guideline documents. The physician competency

requirements are outlined in Appendix 4, and additional training for all physicians providing this option in the community is strongly recommended.

The guidance document from BCCSU (Injectable Opioid Agonist Treatment for Opioid Use Disorder) outlines the current best practices available. Physicians using this treatment option are expected to be familiar with these guidelines (or other recognized iOAT guidelines/best practices) and practice within them.

Conclusion

A stepped and integrated-care approach, where choice and intensity of treatment is continually adjusted to accommodate both the circumstances and preferences of patients, while recognizing that many individuals may benefit from the ability to move between evidence-based treatments, is an integral part of the safe, effective and sustainability of treatment for OUD.

Educational and Training Resources

CPSA Physician Prescribing Practices: Prescribing Resources and Tools

Provincial Addiction Curricula & Experiential Skills Training (PACES)

ODT Virtual Health Training Sessions: 2018-2019

Alberta Opioid Dependence Virtual Training Program

CAMH – Opioid Dependence Treatment Core Course

British Columbia Center for Substance Use

Reducing Stigma Resources

Naloxone Kits – where to access

Supervised Consumption Services

Safe Needle Disposal/Needle Exchange Programs – Streetworks, Turning Point Society, Safeworks

Appendix 1: Current Guidelines for the Management of OUD

Best Practices for the Treatment of Opioid Use Disorder

British Columbia Center for Substance Use – OUD Guidelines

CRISM National Guidelines for the Clinical Management of OUD

American Society of Addiction Medicine – National Guidelines for the use of Medication in the treatment of addiction involving opioid use

Appendix 2: Medications Including in the Treatment of OUD

- Methadone
- Slow-release oral morphine
- Injectable OAT (hydromorphone)
- Medical-grade heroin (diacetylmorphine)

Appendix 3: Specialty Clinics and Consult Resources

Virtual Opioid Dependency Program (AHS)
Opioid Agonist Therapy, Emergency Medication Treatment & Transition Support
Phone: 1-844-383-7688
Fax: 403-783-7610

Opioid Use Disorder – AHS Telephone Consult
This telephone consult service is for primary care physicians and prescribers seeking advice regarding:

- Initiating and managing opioid agonist therapy
- Prescribing drugs like buprenorphine/naloxone, methadone or naloxone
- Treating patients with existing opioid use disorder
- Managing opioid withdrawal and consideration of opioid agonist therapy

This service will not provide advice on pain management using opioids or alternatives. Primary care providers who want to consult a pain management specialist may benefit from resources listed by the Calgary Pain Management Centre.

For patients **north** of Red Deer, access the service by calling RAAPID North at 1-800-282-9911 or 1-780-735-0811.

For patients **south** of Red Deer, call RAAPID South at 1-800-661-1700 or 403-944-4488.

Addiction and Mental Health – Opioid Dependency Program

Alberta Health Services' Opioid Dependency Program (ODP) clinics are available in Edmonton, Calgary, Fort McMurray, Cardston, Grande Prairie, High Prairie and through the Rural ODP clinic, which serves patients from 60 central Alberta communities.

What is an eReferral advice request?

An eReferral advice request is a secure and efficient process within Alberta Netcare, for physician-to-physician advice. *Addiction, Medicine & Mental Health – Opioid Agonist Therapy* joined eReferral in February 2018.

If you have a non-urgent question, are seeking guidance with the management of a patient's opioid use disorder, or are wondering if a referral is appropriate, send an advice request. The response target is five calendar days.

Appendix 4

Injectable Opioid Agonist Treatment for Opioid Use Disorder (BCCSU)

Example Framework for Prescriber Competencies (excerpted from AHS IOAT Medical Protocols)

Due to the intensity of this model of care and highly supervised nature of this medical intervention, it is important that prescribers have experience with OAT prescription and an up-to-date understanding of the evidence and best practices with regard to iOAT provision.

As such, prescribers who wish to administer iOAT must meet the following criteria:

- Licensed to practice medicine in Alberta by CPSA or Nurse Practitioner by CARNA.
- Hold a methadone exemption/OAT approval.

Prescribers should obtain knowledge and competency in addiction medicine, OAT and iOAT through the following resources:

- AAAP – American Academy of Addiction Psychiatry
- Certification in Addiction Medicine and/or Addiction Psychiatry via CSAM (Canadian Society of Addiction Medicine), ISAM(International Certification in Addiction Medicine), ABAM(American Board of Addiction Medicine)
- College of Family Physicians of Canada Certificate of Added Competence (CAC) in Addiction Medicine
- Fellowship and/or Residency training in Addiction Medicine
- At least two years of clinical experience in Addiction Medicine/Psychiatry
- At least two years of clinical experience in OAT
- Extra training completed in iOAT (i.e. the iOAT module of the Provincial Opioid Addiction Treatment Support Program offered through the BCCSU, or equivalent)

This is Exhibit "7" referred to in the affidavit of Elaine Hyshka, sworn this 22nd day of November 2020

A Commissioner for Oaths in and for the Province of Alberta

AVNISH NANDA
Barrister & Solicitor

Edmonton's First Injectable Opioid Agonist Treatment Clinic To Open at FACS Site on 106 Street

The word 'crisis' is often overused in a world where hyperbolic news headlines scream at us 24/7.

01 April 2019

The word 'crisis' is often overused in a world where hyperbolic news headlines scream at us 24/7. But it's hard to overstate the magnitude of the fentanyl crisis.

Hundreds of Albertans die from fentanyl overdoses every year. In 2018, the province's fentanyl death count averaged almost two a day.

Alberta's Opioid Dependency Program (ODP), operated by Alberta Health Services (AHS), gives users a fighting chance to beat their addictions to opioids like fentanyl, heroin, oxycodone and Percocet.

By providing methadone and suboxone (both synthetic opioids) as well as Kadian (morphine) maintenance treatments - a process formally known as Opioid Agonist Therapy (OAT) - the ODP's nurses, psychiatrists, social workers and others do their best to keep some 700 opioid users who live in the Edmonton Zone alone alive.

"People can come here on a short-term or a long-term basis, but our recommendation is to come for at least six months," says Ali Thompson, a Registered Nurse at the ODP's main downtown Clinic, near Edmonton City Hall.

"While these medications help to keep them from being sick or in withdrawal, we can also work on their psychosocial, physical or psychiatric issues as well. It's very rewarding when you see people go from rock bottom to progressing in treatment to getting some quality of life back."

Unfortunately, such treatments don't work for everyone. For the most severe opioid addicts, an even more aggressive and intense approach is needed.

That's why Alberta's second Injectable Opioid Agonist Treatment (iOAT) Clinic will be opening its doors at AHS's Forensic Assessment & Community Services (FACS) office on 106 Street in May. The first opened in Calgary earlier this year.

Before now, Edmonton's iOAT Clinic operated on a temporary, small-scale basis at the ODP's downtown site.

"If all these other mainstay treatments have failed then the Injectable Opioid Agonist Treatment is the alternative," says Psychiatrist Dr. Avininder (Avi) Aulakh, Clinical Lead for AHS's Opioid Dependency Program in Edmonton, and AHS Edmonton Zone Clinical Site Chief, Addiction Medicine.

"The iOAT Clinic is targeting individuals who have been using opioids intravenously for years, so they typically have multiple other medical co-morbidities like HIV or Hepatitis C. These are very high-risk individuals for whom the mainstay treatments have not been successful," says Dr. Aulakh, who is also a Clinical Lecturer in the Department of Psychiatry at the University of Alberta.

"So these individuals will come to the iOAT Clinic three times a day, where they're given high doses of hydromorphone (Dilaudid). They inject themselves, and the nurses are there to supervise so there are no adverse events or overdoses," he explains.

"After the third dose each day they are also given a dose of Kadian or methadone, so that dose lasts overnight, and they still have some opiate in their system until the next day."

The goal is to keep severely addicted people alive and off the street, so they're not constantly looking for illicit drugs to feed their habit, and are also relieved of the unending pressure to find cash - legally or illegally - to pay for those drugs.

In total, somewhere between 50 and 100 users are expected to seek treatment at Edmonton's new iOAT Clinic once it's fully up and running.

"It a fairly small number but we anticipate that the numbers will go up once we have fully transitioned to the new space at FACS. At the ODP Clinic downtown we just haven't had the capacity to treat more than maybe 10 people because of space and staffing limitations," says Dr. Aulakh, one of several psychiatrists who will staff both the iOAT Clinic and the long-established ODP Clinic.

Others include Dr. Krishna Balachandra - an Assistant Clinical Professor in the Department of Psychiatry - as well as Dr. Neil Parker, Dr. Lovneet Hayer, Dr. Roshan Hegde, and Dr. Mohit Singh, a Clinical Lecturer in the

Department of Psychiatry.

The Providence Crosstown Clinic in Vancouver's Downtown Eastside, where many heavy drug users reside, has offered Injectable Opioid Agonist therapy for about five years now.

Studies have found that patients in the program have cut back their use of illicit street drugs significantly.

"Canada's western provinces have been affected the most by the fentanyl crisis, and B.C. has historically been home to about half of the heroin users in Canada, so they are leaders in some of these treatments," says Dr. Aulakh.

About 150 chronic drug users were receiving iOAT Treatments at the Vancouver clinic as of a year ago, according to one news report, with a retention rate of more than 80 per cent. About one in five patients had graduated to less-intensive treatments such as methadone.

"Alberta is just the second province after B.C. to offer Injectable Opioid Agonist Treatments. This is a government-funded program and the Opioid Emergency Response Commission has set aside $5 million a year for the next three years to support it," he says.

The iOAT Clinic in Edmonton is likely to treat more males than females, and the average age is expected to be fairly young.

"Based on the experience of the OAT Clinic in Edmonton, I would say the male-to-female ratio is likely going to be about 60:40. This might change over time but we're dealing with more males right now in this area. And since the iOAT Clinic is only for severe users, we anticipate the users will be mainly in their 30s or above," he notes.

"This is not the program for people who have just started to use or have never tried any other treatment. This is only for severe or chronic users for whom nothing else has worked."

Since the iOAT Clinic will treat the most severely addicted opioid users, its metrics for measuring success will differ from those used by the ODP Clinic.

"At the ODP Clinic, I've seen people who have been treated successfully going from situations where they are literally homeless and living on the streets to going back to school, completing their education, having productive jobs and having a family. In cases like that we might see a turnaround within a few months," he says.

"But for the injectable patients, they are severe users and they've been affected by their use for years. So how we measure our success will be different. Success will be that they are not using anything else, they are not visiting the hospital so frequently, they are not involved with the law, or they are getting the treatment they need for infectious diseases."

Tara O'Mara, a Family Nurse Practitioner who has worked closely with Dr. Aulakh at the iOAT Clinic, shares his high hopes for its success.

"We have one patient who has been travelling (to the existing downtown ODP Clinic) 45 mins each way, three times a day, just to get treatment. That's a big commitment. But on the flip side, heavy users are probably spending lot of time obtaining substances or committing crimes to get those substances. So the new iOAT Clinic takes the need for all that away. If you were spending say, $400 a day on illicit substances just to feel well, imagine what you'd have to do to fund that."

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