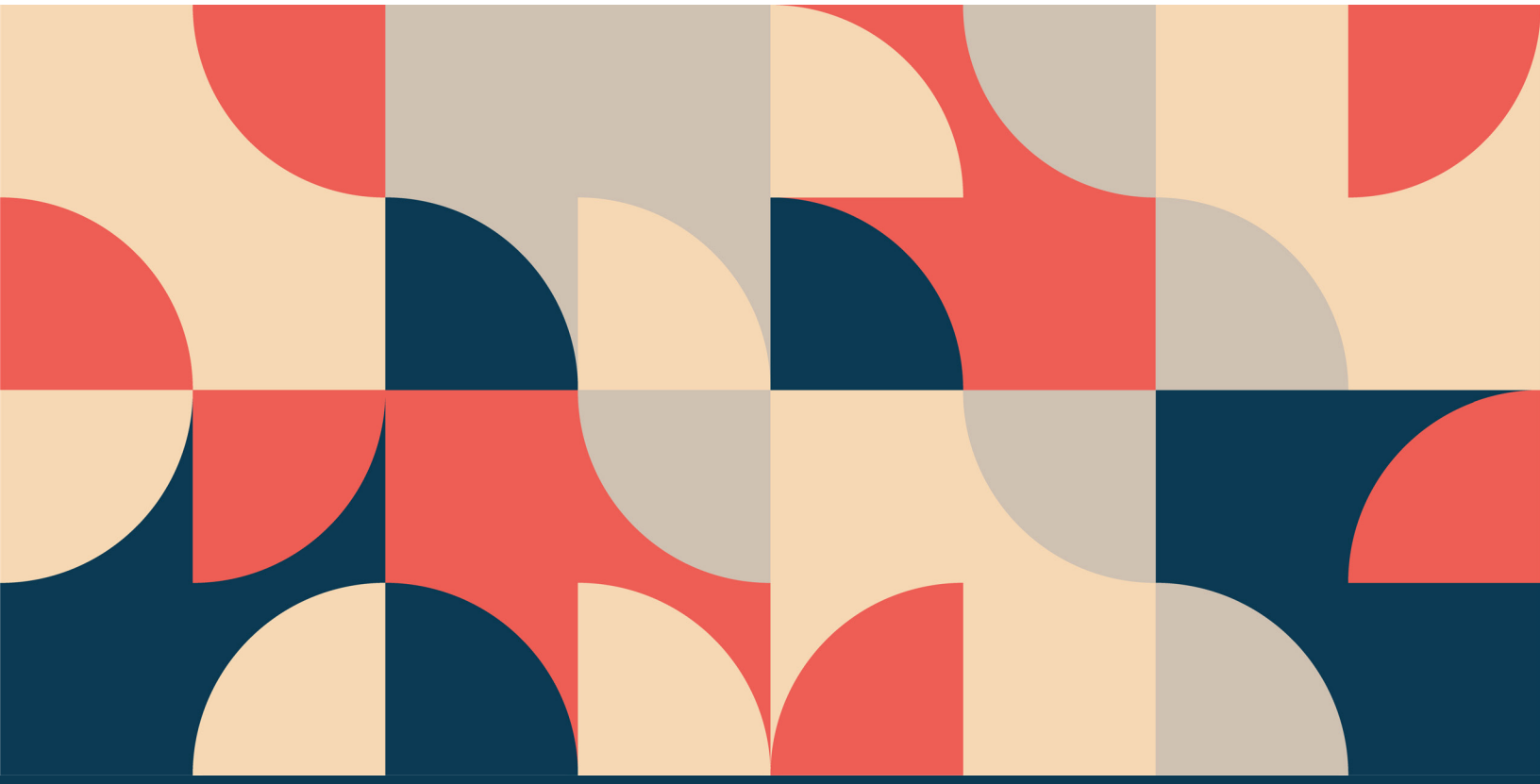
INJECTABLE OPIOID AGONIST TREATMENT:

A clinical approach to support the provision of take-home doses

January 2023



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Contents

Preamble

What is the purpose of this document?

The purpose of this document is to share with healthcare professionals the first approach to outline guidance on how to prescribe and monitor take-home doses of injectable Opioid Agonist Treatment (iOAT).

iOAT refers to injectable opioid agonist treatment. In Canada, there are two medications licensed to be prescribed in iOAT: diacetylmorphine (i.e., medical-grade heroin) and hydromorphone (an opioid analgesic).

Take-home doses refer to doses of iOAT dispensed to clients for use outside the clinical setting, therefore they are not directly observed by the site staff.

Take-home doses are also known as *Carries*, or *iCarries*.

We hope that this guidance support ideas and is a start place for physicians, nurse practitioners, health care workers, organizations, and other health care professionals to build upon. As every site present their own unique structures and processes, we intend to continue learning from each other to provide person-centered care that supports people who live with opioid use disorder and increase accessing to all care, including take-home doses of iOAT.

How do I read this document?

This document provides *suggestions* for implementing a take-home iOAT program. These suggestions are based on the experiences from the service providers and clients of Crosstown Clinic.

This document is not a provincial guideline, and it is not a standardized guide. The advisement reflected in this guidance have been extrapolated from the clinical practice of the team at Crosstown Clinic. While it is presented as a static document, clinical practice is flexible and changes according to policies and regulatory amendments.

There are two appendix sections in this document. In Appendix 1, you can find resources that may be helpful in supporting a clinical program for take-home doses of iOAT. In Appendix 2, you can find selected evidence surrounding iOAT, and take-home doses.

You will notice that there are beige text boxes throughout this guidance. These boxes indicate feedback provided from clients who have living experience with take-home iOAT, who have been consulted through the process.

Acknowledgements

Land acknowledgement

We would like to start by acknowledging that we were fortunate to be able to carry out this work on the ancestral and unceded traditional territory of the Coast Salish Peoples including the territories of the xʷməθkʷəy̓əm (Musqueam), Skwxwú7mesh Úxwumixw (Squamish), and səl̓ilwətaʔɬ (Tsleil-Waututh) First Nations. We celebrate and thank the diverse Indigenous people whose presence marks this territory.

About Crosstown Clinic

Located in the Downtown Eastside, Vancouver, Crosstown Clinic is the first clinic in North America to offer medical-grade heroin (diacetylmorphine) and the legal analgesic hydromorphone within a supervised clinical setting to chronic substance use patients.

Crosstown was the site of The North American Opiate Medication Initiative (NAOMI), a randomized control trial that evaluated heroin-assisted treatment. It was also the site of the Study to Assess Long-Term Opioid Maintenance Effectiveness (SALOME), a randomized clinical trial testing innovative treatments for severe, long-term opioid dependency. As such, Crosstown has been a trailblazer in establishing injectable opioid agonist treatment (iOAT) in Canada.

Crosstown Clinic continues to oversee the provision of different medications for various substance use disorders, provides interdisciplinary care services from doctors, nurses, pharmacy, social workers, addiction counsellors, and other allied health care professionals, and strives for excellent patient-centered care.

A client receiving iOAT services at Crosstown Clinic. (CHÉOS, retrieved November 2022).

Authors and contributors

The content of this document was originally co-developed by the clinical team at Crosstown Clinic in 2022. Funding from Health Canada's Substance Use and Addictions Program (SUAP), led by Dr. Eugenia Oviedo-Joekes allowed work with Crosstown Clinic clinical team and leadership, to review and produce a shareable document.

We acknowledge the contributions of the following individuals, in various roles, to reach this final version.

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- Karine Hudson, Coordinator, CIUSS Centre-Sud-de-l'île-de-Montréal
- Various clients who have living experiences with take-home iOAT

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- Canada Research Chairs (CRC)

Distribution and disclaimer

Distribution

This document is available for download at ioat-research.med.ubc.ca

We recommend sharing this link with healthcare professionals in your network who might be interested in using this guidance document to support their organisation's take-home iOAT program.

A French language version is also available.

Disclaimer

This document does not replace policy or care guidelines. The clinical team is in constant revision of processes according to changes in policy, funding and regulations.

This guidance document is not intended as a substitute for the advice or professional judgment of a health care professional. It is not intended to be the only approach of clinical management. Clinical leadership is responsible for reviewing all provincial and federal practice updates to ensure that best practices are adhered to at their respective clinics.

Author of this guidance cannot respond to clients or advocates requesting advice on issues related to medical conditions. If you need medical advice, please contact a health care professional.

Dr. Scott MacDonald, lead physician, Crosstown Clinic.

Introduction to OAT, iOAT, and take-home doses

This section provides a brief overview on OAT, iOAT, and take-home doses. It also contains some historical context of take-home doses.

What is opioid agonist treatment (OAT)?

Oral OAT with medications such as methadone, buprenorphine, or morphine engages and retains many opioid use disorder clients in care and reduces overdose mortality risk. Treatment delivery varies widely across settings and medications. In North America and Europe, oral OAT clients typically consume their medication at outpatient programs, pharmacies, detox/residential programs, or hospitals on a daily (or near daily) basis under health care providers' observation. In a limited number of settings, the clinical team has the discretion to provide clients with take-home doses for unobserved self-administration if, for example, they demonstrate clinical stability, the ability to safely store the medication outside the site, a series of negative urine drug tests, and sustained OAT adherence of typically two to three months (criteria vary by region).

The COVID-19 pandemic permitted agencies to adapt OUD treatment guidelines to align with public health safety measures that minimize the spread of the virus. Some of these temporary measures were long-overdue in the path to offer person-centered addiction care, including increasing the number of days and number of clients allowed to take opioid agonist treatment (OAT) medications off-site to consume without direct supervision (i.e., take-home). Urgent action such as policy reform and equitable access to a diverse selection of licenced medications/formulations is necessary to make these measures permanent so that the healthcare system can meet the diverse needs and preferences of OUD clients and support their continuity of care.

To accommodate public safety protocols during Covid-19, OAT programs worldwide had to opportunity to increase the availability and accessibility of take-home doses. For example, certified methadone treatment programs in the United States received a federal requirement exemption to provide up to 28 days of take-home doses. The increase in accessibility was a long-awaited expansion of OAT care, as travelling to the clinic daily, especially long distances, decreases engagement with and retention in OAT. Several studies reported early successes with the expansion of take-home OAT, such as high rates of treatment retention and no significant increases in opioid-overdose events.

What is injectable opioid agonist treatment (iOAT)?

To attract and retain into care the critical minority of clients for whom oral treatment is either undesirable or ineffective, injectable OAT (iOAT) with medications such as diacetylmorphine (i.e., pharmaceutical grade heroin) or hydromorphone (other medications such as fentanyl, buprenorphine, and methadone may become accessible) have been shown to be safe and effective in several clinical trials, as well as cost-effective. Clients who are at a stable, individualized dose, even at the high extreme, face no elevated risk of overdose, as the risk profile is primarily based each medication's specific safety profile and its interactions with other medications. Currently, daily observed iOAT (e.g., not take-home) is available in Canada, the UK, Netherlands, Germany, Switzerland, and Denmark. iOAT is typically administered under strict protocols and regulations. While it varies per setting, usually clients attend up to three in-person appointments at their iOAT clinic every single day for an observed injection. The in-person visits give opportunities for safety monitoring, therapeutic relationship building, and access to wraparound services (e.g., social workers, counselling, other medical care). These benefits are important for many clients, yet the demands of iOAT render it an extremely high-threshold treatment option.

What is take-home iOAT?

While clinical guidelines currently offer the possibility for OUD clients to be given oral OAT medication to take-home, this option had not been considered viable for iOAT despite oral take-home medications not being suitable for clients who are accustomed to injecting opioids. Early experiences in the UK provided a glimpse of the possibilities of take-home iOAT, as injectable diacetylmorphine was exclusively prescribed in pharmacies as take-home until the 1990s when the confluence of increased international acceptance of oral medications, fears of diversion, political pressure from the United States, and lack of research on effectiveness led to a drastic decline in prescriptions.

Presently, take-home iOAT is only available to a limited population of UK clients and is restricted to the geographic regions where prescribers who choose to offer the treatment practice. While the Swiss guidelines previously permitted prescribers to make exemptions based on clinical judgement, these exemptions were only granted in exceptional situations under strict eligibility criteria. The pressures of the Covid-19 pandemic eased the guidelines so that a greater number of clients could access take-home oral/injectable diacetylmorphine to a maximum of seven daily take-home doses. Temporary measures due to Covid-19 also made take-home iOAT available for the first time in North America to select clients in Vancouver, BC. These initial experiences with take-home iOAT, while small in scale, showed promising benefits for clients and supported an expansion/continuation of the program.

After the Covid-19 emergency risk mitigating guidelines enabled take-home iOAT (not previously available) to be prescribed for the first time in Canada, some BC iOAT sites expanded on these precedents to continue prescribing up to two of a possible three daily doses of injectable medications to select clients after the temporary guidelines concluded.

Developmental roadmap of take-home doses

Crosstown clinic envisions the iOAT take-home doses program expanding and scaling up into the future over three phases. The following table compares some of the changes that are anticipated in each phase:

Procedures	Phase 1	Phase 2	Phase 3
Injection supplies provided to client.	✓	✓	✓
Client injects the first dose at the clinic.	✓		
Remainder of the same day's dose(s) are dispensed as take-home doses.	✓		
Preparation and dispensing of take-home dose(s) are completed by pharmacy after receipt of an authorizing prescription.	✓		
Take-home dose(s) cannot be provided during initial dose titration, missed days order, or using clinic ward stock supply.	✓		
Client can be dispensed doses over a 24-hour period.		✓	✓
Client chooses the time for their witness dose.		✓	✓
For clients who choose an evening witness dose, the attending nurse dispenses the take-home doses.		✓	✓
Take-home doses must be selected in advance. If changes to dose times are desired, client must request.		✓	✓
Clients who attend clinic for BID or TID doses can choose whichever dose to be witnessed at the clinic. The remaining doses over a 24-hour period to be provided as take-home dose.		✓	✓
Multiple days of take-home doses offered (if medication stable).			✓
Take-home doses may be dispensed by Pharmacy or Nursing.			✓

Note: These procedures and phases are envisioned for the future take-home iOAT program. The specific procedures and order in which they occur may be different than what is shown on this roadmap.

Roles and responsibilities of the clinic staff

This section describes the roles and responsibilities of prescribers, pharmacists, and nurses in the context of a take-home iOAT program. The described roles and responsibilities are recommendations based on the staffing availability of Crosstown clinic, however, the list is not exhaustive and at other clinics there may be other individuals who are involved in client care.

The roles and responsibilities presented are in no particular order. It is recommended that all of those who provide services work collaboratively and within their professional scope of practice, education, and the requirements of their federal and regulatory structure and any applicable exemptions.

Prescribers

- Complete clinical assessments of the client
- Review client's health records
- Determine treatment plan with client and care team
- Provide prescription that meets regulatory requirements
- Indicate frequency of dispensing and witnessing—including by whom—on the prescription
- Determine which health professional will be responsible for the administration of medication and at what location
- Delegate transport of prescription from pharmacy to clinic
- Provide client with education as informed by client's treatment goals, health needs, and overdose risk
- Discuss safety plan with client (e.g., Where to get naloxone, use of mobile apps that support using alone, safe storage of medication, community services, etc.)
- Provide referrals to psychosocial supports and other health care services as needed
- Ensure all care is documented in clients chart

Pharmacists

- Review client's medication record
- Identify and resolve medication issues or drug therapy problems
- Fill prescriptions
- Provide counselling information to client, nurse, or prescriber prior to dispensing medication
- Provide consultations directly or virtually to client
- Ensure that administrative duties are complete by the end of the clinic day (e.g., Counselling, updating patients' medication records)
- Follow Health Canada's Controlled Drugs and Substances Act *Subsection 56(1)* (Appendix 1, item #10)
- Destroy unused stock and document this destruction in accordance with protocols

Nurses

- Follow Health Canada's Controlled Drugs and Substances Act Subsection 56(1) (Appendix 1, item #10) or applicable regulations for their facility
- Upon receipt of medication, ensure it is recorded and securely stored
- Follow their clinic procedures for the provision of prescriptions to client
- Provide counselling information to clients and document encounter(s) in client's chart
- Administer witnessed iOAT doses
- Provide pharmacy-prepared take-home prescription to client
- Record medication provisions in medical record
- Record missed doses, onsite dose adjustments, or doses provided by (ward) stock by the end of clinic day
- Inform the pharmacist or prescriber of any missed doses or dose changes by the end of clinic day
- Destroy all unused medications onsite and document destruction (or return medication to pharmacy for destruction) in accordance with protocols
- Keep controlled substances records and onsite prescriptions per regulations and protocols
- Meet all documentation requirements related to the storage and administering of onsite prescriptions

Assessing if take-home doses can improve client outcomes

This section suggests factors for prescribers and the clinical team to consider when they are assessing if take-home dose(s) would be beneficial for their client. It also recommends cases where caution should be used before prescribing take-home doses.

1. **Understand the client's individual needs and goals**
2. **Complete a clinical assessment**
3. **Identify further criteria that indicate if take-home doses could help the client reach their self-identified goals**

More details on these three considerations are provided in the following sections.

Understanding a client's individual needs

Take-home doses are recommended as part of a treatment plan that supports the needs and priorities of a client and improves their wellbeing and safety. The following list provides some of the questions to consider when determining a client's needs:

- Is the client requesting take-home doses?
- What are the clients self-identified needs and goals?
- Would take-home doses support the client in achieving their self-identified goals?
- Would take-home doses allow the client to attend work or school?
- Would take-home doses improve a clients' engagement with their treatment program?
- Is the client homebound due to a health status (e.g. physical disability, infectious illness)?

These considerations can be determined during a holistic clinical assessment. The next section describes further recommendations on what to consider during a clinical assessment.

Client receiving care at Crosstown Clinic. (CHÉOS, retrieved November 2022).

Feedback from clients with lived/living experience:

Clients wanted to highlight the importance of discussing their personal goals with a prescriber.

"Having these discussions makes me feel like [my prescriber] cares about me."

"I want to work, travel, and improve my relationship with my child."

Completing a clinical assessment

A clinical assessment is completed by the prescriber and may be evaluated by a Review Committee (See section titled "Making the decision to prescribe take-home doses" for more information on the Review Committee).

During a clinical assessment the following questions can be considered:

What are the client's needs?

- This can be a discussion between the prescriber and the client

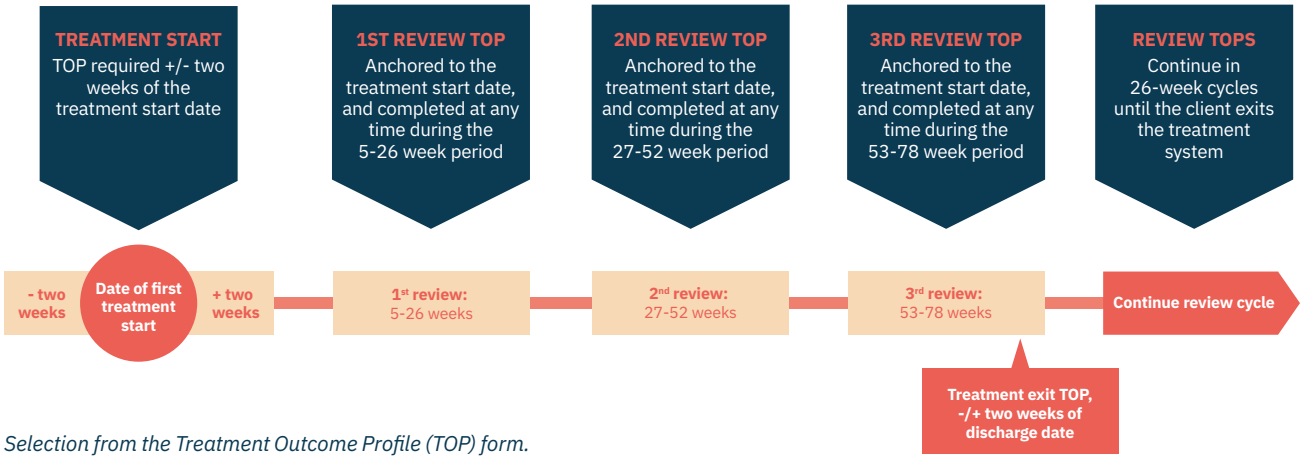
Has the client completed a *"Treatment Outcome Profile" (TOP)* form?

- This form can be found in the Appendix 1 (item #3)
- The TOP is a set of questions that can enhance assessment and care plan reviews

Has the client completed a Urine Drug Screen (UDS)?

- UDS helps determine if a client is currently using any other substances that might affect treatment with take-home doses
- It is required to satisfy potential regulatory concerns that are often present with OAT
- Crosstown Clinic completes UDS monthly when a new take-home dose prescription is given
- At Crosstown, clinicians send an EMR request to a nurse or clinic support worker to collect the sample
- Once UDS specimens are collected at the clinic and they can be tested on site (Rapid UDS) or sent to the lab for testing

The Protocol for TOP Reporting



Selection from the Treatment Outcome Profile (TOP) form.

Identifying further criteria that suggest take-home doses could be beneficial

Further criteria can help prescribers and clients determine if take-home doses could be helpful. The criteria below can be determined during clinical assessments, or discussions with clients. Consider the following questions:

- Has the client been on a therapeutic stable dose of iOAT (observed doses) for 3 to 6 months or earlier clinical remission?
- Has the client NOT shown post-dose complications due to dose intolerance (e.g., oversedation, seizures) within the last 3 months?
  - » Is the client regularly attending witnessed sessions for their iOAT doses?
  - » If they have missed doses, what are their reasons for missed doses?
- For clients who do not regularly attend their iOAT doses, or have been lost to care, would take-home doses improve their engagement with treatment?
- Is the client connected to appropriate community supports? If not, are there ways that the clinical team can work towards connecting a client to these supports?
- Is the client able to safely self-administer the medication independently outside of the clinic (i.e., proper injection practices, employ safety strategies)?
- Is the client able to safely able to safely transport, administer, and store take-home doses and injection supplies?

Feedback from clients with lived/living experience:

A client felt that it was important that they were stable on their witnessed iOAT before moving on to take-home doses. They want to be successful with take-home doses and share their success story with people in power in hopes that it could lead to greater acceptance of take-home dose.

Clients also expressed that they knew many people are not able to access take-home doses because it was too difficult for them to make it to the clinic every day.

When to use caution before prescribing take-home doses

Prescribers and clients may want to use caution before prescribing take-home doses in the following situations:

- If a client is using other substances such as alcohol, stimulants, and benzodiazepines
  - » Stable use of other substances is not in itself a contraindication to providing take-home doses
- If a client has a concurrent disorder that would affect their ability to self-administer their medication as directed (e.g., acute psychosis or mania)

In these cases, a specialized care plan and regular reviews by a Review Committee may be required. More information on the Review Committee is described in the next section titled "Making the decision to prescribe take-home doses".

Making the decision to prescribe take-home doses

This section provides guidance on what to do after a client and their clinician fully understand the clients needs and are ready to decide if take-home doses should be prescribed.

If take-home doses are recommended for a client

Before initiating a new prescription for take-home doses, the prescriber is responsible for discussing the eligibility of a new client with the Clinic Coordinator and Pharmacy coordinator. After this discussion has taken place and all parties agree to recommend take-home doses, the client can be notified, and the prescription process can start. This process is described in the section titled "Prescribing and dispensing take-home doses".

If take-home doses are NOT recommended for a client

If it is determined that take-home doses are not recommended for a client by the prescriber, Clinical Coordinator, and Pharmacy Coordinator, then the prescription process will not proceed.

However, individual situations vary. There may be other criteria that is not listed in this guidance that could make a compelling case for the admission to a treatment plan of take-home doses. If, for example, a client who is not recommended for take-home doses has a member of the clinical team advocating for them to receive take-home doses, then further evaluation may be needed.

If further evaluation is needed, the clinical team may consider meeting as a Review Committee. The next section outlines the potential role that a Review Committee might take.

Using a Review Committee to improve decision-making

The Review Committee meets when clinical team members want to review client cases and have further discussion about a client's care plan. Review Committees can be used to review clinical assessments, review unique cases, and make judgements on cases where a prescriber has not recommended take-home doses for a client.

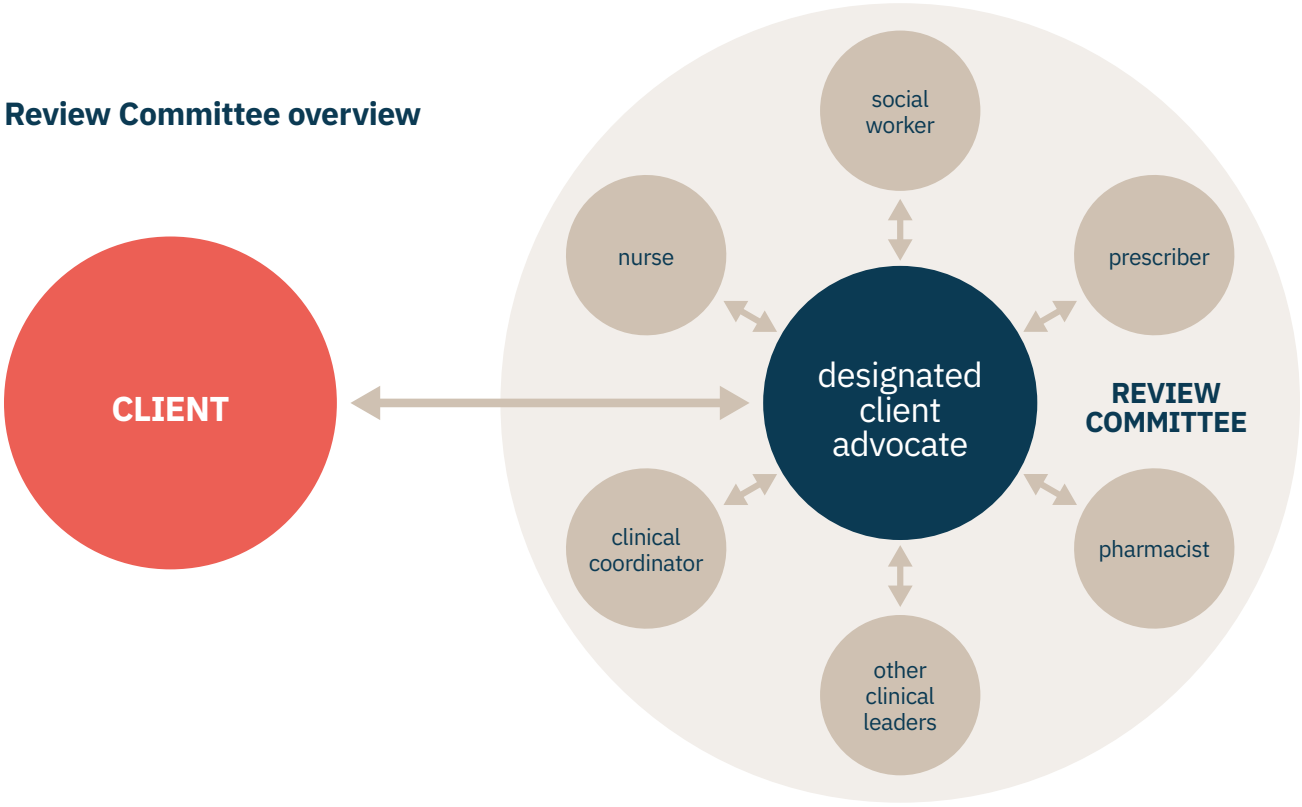
The committee includes but is not limited to the following roles at the clinic:

- Prescriber
- Nurse
- Pharmacist
- Clinical Coordinator
- Social Worker

It is recommended that the team member (prescriber, or advocate) who brought a client case to the Review Committee is responsible for communicating the Committee's decision with the client.

If it is still not recommended that a client receive take-home doses after the committee's review, the prescriber and/or a designated nurse will meet with the client to develop an individualized care plan with the goal of meeting criteria for take-home doses (if deemed appropriate by the client). The committee can always re-evaluate any client who was turned down for take-home doses if/when their circumstances change.

Review Committee overview



Prescribing and dispensing take-home doses

This section provides recommendations for writing and dispensing prescriptions for take-home doses of iOAT. It also provides recommendations for delivery of take-home doses, and outlines actions that can be taken if a client misses their appointment(s).

Writing a prescription for a take-home dose

When writing a prescription for a take-home dose of iOAT, consider including the following instructions for the pharmacy and regulated health professionals who are administering the medication to the client:

1. **Pharmacist:** Dispense 7 days' supply every 7 days
2. **Clinic Nurse:** Provide pharmacy-dispensed doses as take-home doses to client every 7 days
3. First iOAT dose of each day witnessed by a nurse at the clinic

Does treatment with take-home doses require witnessing?

At Crosstown Clinic, clients must be present at the clinic for their first iOAT dose of each day, even if they have been prescribed take-home doses. Their first dose is administered at the clinic under observation by clinical staff. This is known as a witnessed dose. Witnessed doses can be performed by:

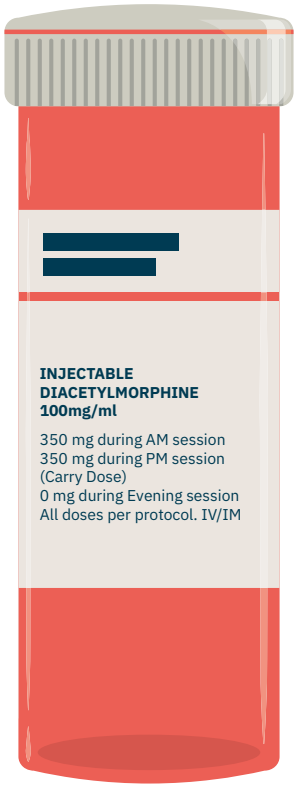
- Pharmacists
- Nurses*
- Other regulated health professionals*

*If witnessed doses are performed by a nurse or other regulated health professional, they should clearly specify this in the "Directions for Use" portion of the prescription.

Witnessed doses should only be performed by staff members who have the appropriate scope, competence, and are responsible for client care.

Most clients will wish to complete their witnessed dose in the morning. The witnessed dose is administered as per normal clinic process for iOAT. This includes a pre-dose and post-dose assessment by the nursing team.

An example prescription of a take-home dose (in this case, the term “Carry Dose” is used) could look like this:



Dispensing a take-home dose

After their witnessed dose post-assessment, the client can collect up to two take-home doses. Labeled, pre-filled, client-specific syringes of hydromorphone or diacetylmorphine are dispensed in a labeled, child-proof container as take-home doses, once per day.

Information on Crosstown’s dispensing procedures is detailed in the documents titled “Dispensing iOAT Carries—Pharmacy Process” and “OAT Database Production Guide”. (Appendix 1, item #4 and #5).

- The times indicated on take-home doses are arbitrary. Clients may choose to take these doses at any time as long as they are three hours apart and taken on the same day
- The dose amounts may differ between the two take-home doses based on the individual client
- Clients may choose which dose to take first
- Nurses can be authorized to provide take-home doses of pharmacy-prepared medication when it is written on a client’s prescription
- If the pharmacy is unable to prepare a dose, it can be prepared by nursing and provided through clinic stock and the exceptional reason documented
- Health professionals should notify the prescriber or pharmacist prior to the next prescription filling/writing if a client experiences an adverse reaction or requires a change in dose

Feedback from clients with lived/living experience:

“Before I throw out a container that holds my medication, I often have to scratch out my personal information to protect my anonymity. I would like to see a future with simple packaging that reduces waste and does not require me to scratch out my personal information.”

Situations that might require delivery (mail) of take-home doses

The delivery of doses may be an operational consideration for homebound client or for clients who are isolating due to illness.

Provision of take-home doses to nurses or pharmacists as part of an outreach or medical support team may also be considered for clients with these supports if in compliance with existing Health Canada regulations.

Providing supplies to help clients administer their doses

Clients at Crosstown Clinic can pick up supplies for their take-home doses from the clinic assistant at the front desk. These supplies often include the following items:

- Needle tips
- Alcohol swabs
- Band-aids
- Tourniquets
- Sharps container
- Naloxone Kit

It is recommended that naloxone training is made available to clients who need it.

Feedback from clients with lived/living experience:

"I live far away from the clinic, so picking up my medication everyday takes up a lot of my time and makes it difficult to keep a job. I would like to see a future where I could pick up my medication at the pharmacy that is close to my house."

Naloxone Kit
(CHÉOS, retrieved November 2022).

What if a client is absent or misses a dose?

If the client arrives after the pharmacy has closed

- If a client arrives to pick up their dose after the pharmacy has closed, pharmacy will deliver the take-home doses to the nursing team
- If the pharmacy is unable to prepare take-home medication, a nurse can be provided through clinic stock (this must be documented)
- If authorized, the nursing team can dispense take-home doses to the client

If the client is absent for more than 96 hours (4 days)

- If a client is absent for more than 96 hours, the client will be put on a missed-days order
- If a client is put on a missed-days order, all their take-home doses will be delivered to the nursing team for witnessed administration in clinic

If the client leaves the clinic after their witnessed dose

- If a client leaves the clinic after their witnessed dose and arrives later to pick up take-home doses, pharmacy may request nursing to do a pre-dose assessment

If the client goes on vacation

- If a client goes on vacation, take-home doses will be put on hold until the client returns and is re-assessed
- If the client is eligible, take-home doses will start two days after they return from vacation

If the client does not look well

- If client does not look well and clinical staff determines that they may not tolerate their doses, pharmacy will deliver take-home doses to nursing for witnessed administration
- Clinical signs indicating a client may not tolerate their doses include intoxication, slurred speech, sedation, dyskinetic movements, or other changes from baseline

Other important notes about missed doses

- Healthcare professional must document and notify the prescriber and pharmacist of any missed doses, partial doses, or dose adjustments by the end of the clinic day
- Clients may be absent for their appointment and miss a dose for various reasons, these reasons should be discussed with the client in follow-up appointments
- Unused doses can not be reused or saved and provided to a client later. Unused doses must be destroyed on-site per clinic protocol in a timely manner

Providing clients with information and support

This section provides some information and support that can be provided to clients who are receiving take-home doses. It is recommended that the healthcare team provides information to their clients when take-home doses are first prescribed.

Information that can be provided to a client

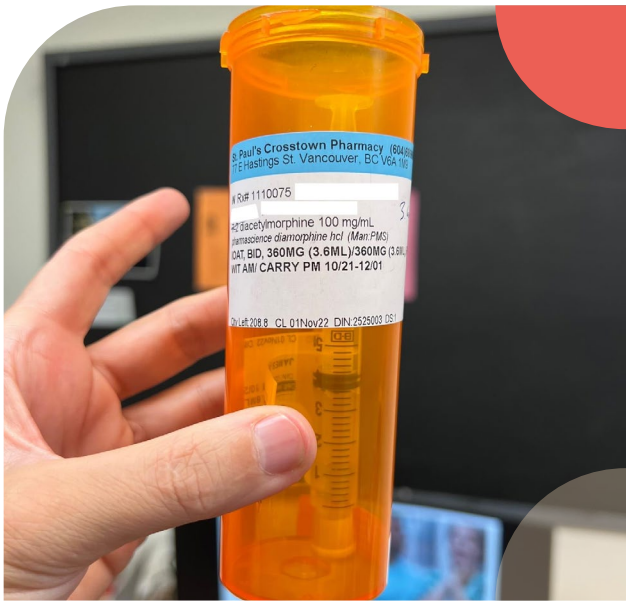
The following is a list of information that clients may find helpful prior to receiving their take-home dose.

Information on take-home iOAT doses

- To review information and procedures related to take-home doses, Crosstown Clinic uses the form titled "Crosstown Clinic iOAT Carries Client Information" (Appendix 1, item #1)
- Once clients fully understand the Client Information form, they are invited to sign an agreement form titled "Crosstown Clinic iOAT Carries Client Agreement" (Appendix 1, item #2)

Information on how to administer medication off-site

- This can include a safety plan strategy for self-administration
- Encouragement for clients to administer their dose at an overdose prevention site
- Encourage clients to administer their dose with a 'buddy'
- Encourage clients to use the LifeGuard app (Appendix 1, item #9) (Only available in British Columbia)
- Provide client with sharps container and instruction on appropriate disposal of container when full



Feedback from clients with lived/living experience:

"I sometimes feel unsafe leaving the clinic with my medication because I am afraid someone might know that I am on [take-home doses] and try to steal it."

"I try to keep [take-home doses] on the down low to reduce negative attention, including stigmatization from the media."

"Coming to [dose pick-up location] can be triggering because there are always people hanging around the area who try to sell me street drugs."

Other support that can be provided to a client

Clients may find it helpful to have support for keeping their medications safe. Clients and prescribers may want to discuss the following:

- Do clients and prescribers have a plan in case of lost, spilled, or stolen doses?
- Does the client have a safe place to store their take-home dose?
- Can the clinic provide the client with a lock box for safe storage?
- Does the client have a place to safely dispose their medication and supplies?
- Does the client live in a shared space?

Monitoring and follow-up

This section provides recommendations on how to monitor a client who is receiving take-home doses and describes situations in which a client may need further monitoring.

Monitoring clients DURING the first two weeks

During the first two weeks of receiving take-home doses, it is recommended that prescribers follow-up with clients once per week with feedback from nurses/pharmacists.

- Monitor for changes in opioid use, alcohol and other (non-opioid) substance use, social instability, and loss, theft, or diversion of carry doses.
- Monitor for changes in clinical presentation.
- Create and document a plan with the client to help mitigate loss, theft, or diversion (e.g., safe dose storage and transportation strategies). Assess need for additional support.
- UDS if clinically indicated. Inability to provide a UDS is not in itself a contraindication to providing carry doses and will be assessed on a case-by-case basis by the prescriber and/or care team.

Monitoring clients AFTER two weeks

After the first two weeks of receiving take-home doses, it is recommended that prescribers follow-up with clients once per month with feedback from nurses/pharmacists. During these follow-up appointments, prescribers should do the following:

- Monitor for changes in opioid use, alcohol and other (non-opioid) substance use, social instability, and loss, theft, or diversion of carry doses.
- Monitor for changes in clinical presentation
- Create and document a plan with the client to help mitigate loss, theft, or diversion (e.g., safe dose storage and transportation strategies). Assess need for additional support.
- UDS if clinically indicated. Inability to provide a UDS is not in itself a contraindication to providing carry doses and will be assessed on a case-by-case basis by the prescriber and/or care team.

Other factors that may need further monitoring

There may be factors specific to individual clients that indicate a need for further monitoring, planning and/or follow-up. Consider the following:

- **Has the client self-reported or are there other indications of changing substance use patterns?**
  - » This could be observed in the Urine Drug Screening test.
- **Has the client missed appointments?**
- **Has the client had any recent incidences of moderate to severe opioid related adverse drug events?**
  - » Has the client needed to use naloxone?
  - » Has the client reported or documented need for supportive medical care due to over or under dosing (including emergency department or hospital admission)?
  - » Does the client have any injuries associated with over or under dosing?
- **Has the client missed any doses?**
  - » Either missed witnessed doses, or not picked up take-home doses.
- **Has the client requested an increase to their previously stable dose?**
- **Has the clients' health status changed?**
  - » Changing health status that may impact dose tolerance or opioid replacement needs.
- **Has the client changed living accommodations?**
  - » This may impact their ability to safely store doses.

Reassessment, hold, or discontinuation

This section describes situations in which the benefits of take-home doses may need to be reassessed. It also provides recommendations for what processes can be taken during this reassessment.

Situations where take-home doses may need to be reassessed

Take-home doses may be reassessed, placed on hold, or discontinued during therapy. The factors that might require reassessment include:

- If the client has a significant change in health status (acute or chronic)
- If the client experiences other destabilizing factors
  - » This could include a change in living or housing situation or other significant change in personal circumstances
- If the client is not attending follow-up appointments with their prescriber
- If there are ongoing incidences of lost, spilled, or stolen syringes and the client is not responsive to supportive mitigation strategies

Process for reassessment of take-home doses

When a member of the client's clinical team identifies any factors that require reassessment take-home doses, it is recommended that they notify the prescriber. It is the prescriber's responsibility to meet with the client to discuss the next steps of their care plan. This discussion can include a decision to continue, hold, or discontinue take-home doses, or development of a plan to help the client regain stability and continue with their take-home dose treatment.

If needed, a Review Committee can be brought together to review the case, support the prescriber with the reassessment. For more information on the Review Committee, see the section of this guidance titled "Making the decision to prescribe take-home doses". Carry doses may be temporarily held until the review process has taken place.

Documenting a care plan

This section provides an outline of the care plan documentation practices done at Crosstown Clinic for take-home doses of iOAT.

Crosstown Clinic, PharmaNet, and the Transaction Medication Update

Crosstown clinic use the Transaction Medication Update (TMU) on PharmaNet for documenting changes to a client's medication. This includes:

- Increases or decreases in doses
- Missed doses
- Use of clinic stock

Detailed guidelines for using the TMU on PharmaNet can be found in the Integrated, interdisciplinary model of opioid agonist treatment (Appendix 1, item 11).

Care providers in other areas will have their own software documentation requirements, processes, and regulations. We recommend that care providers follow their own best practices for documenting care plans.

Documenting an individual care plan

The prescriber and/or a designated nurse will work with the client to update an individualized care plan that includes how take-home doses will support and improve the client's care.

This information will be documented in the following places:

- Electronic Medical Record (EMR)
  - » clinical care (what happened at appointments)
  - » assessment (how clients did at assessments)
  - » care planning UDS results
- OAT database for doses administered and dispensed as take-home doses

Consider uploading the following forms into the EMR:

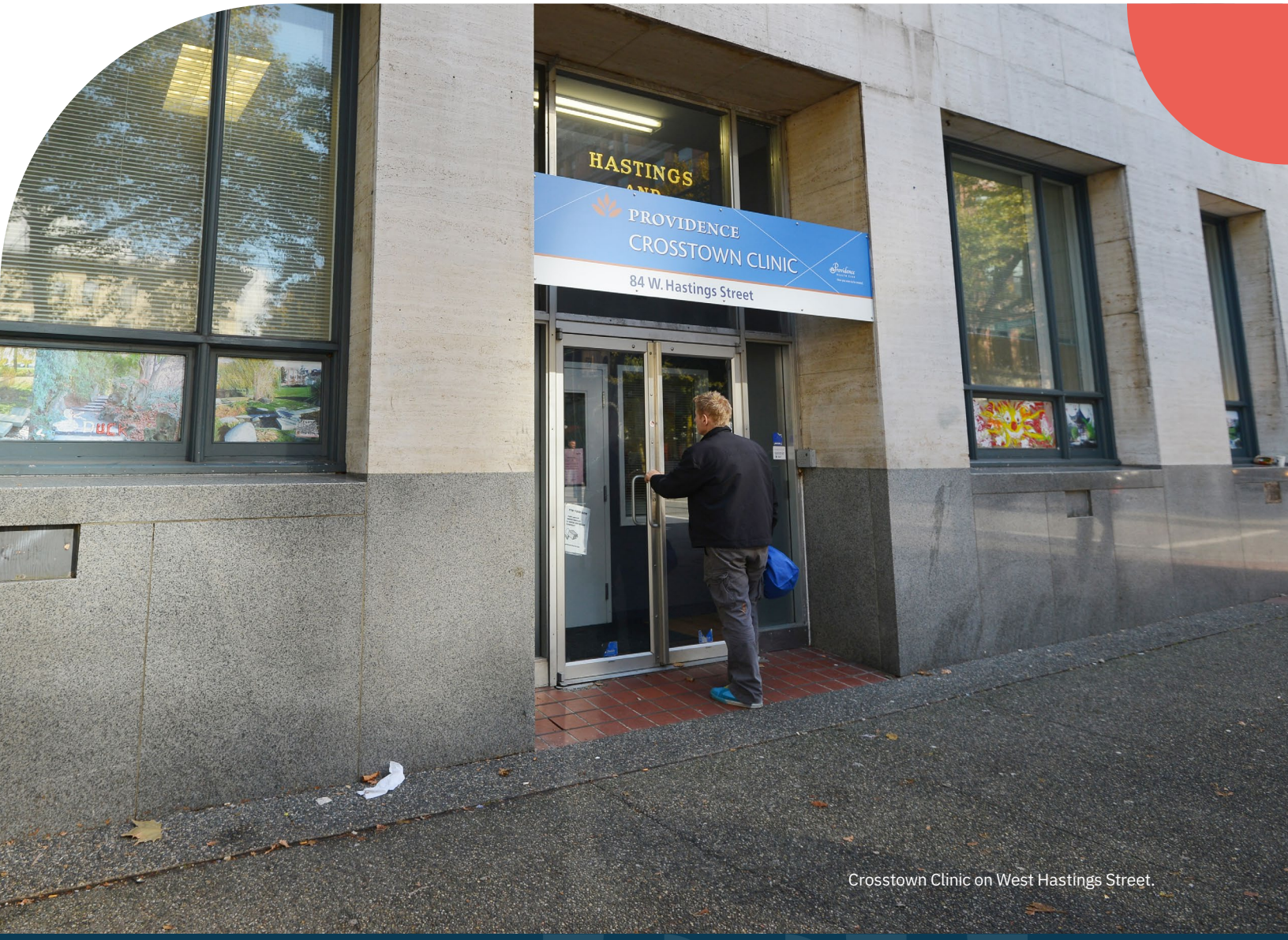
- Client Agreement Form (Appendix 1, item #2)
- Treatment of Outcomes Form (Appendix 1, item #3)
- Nurses should document any changes that are made to pharmacy prepared, client-specific medication by the end of the clinic day or end of their shift

Continuation of care and documentation between sites

Clients may move between sites and clinics for a variety of reasons (for example, clients who are precariously housed and require moving locations). Different sites may have different models of care and different ways of keeping a client's medical record.

To ensure continuation of care, and to support a client effectively, the following communication strategies are recommended:

- Communication between members of the care team (nurses, pharmacy, prescriber, etc.) is required anytime a client transitions between sites, or models of care
- Communication between members of the care team should be documented
- Documentation should be confidentially transferred between the receiving site and pharmacy to facilitate transfer of care
- After assessment and if deemed appropriate, the pharmacist can renew a previous prescription or offer an emergency supply for continuity of care



Crosstown Clinic on West Hastings Street.

Appendix 1: Documents to support clinical programs

The following table contains resources that were mentioned in the previous sections of this document. It also contains other relevant forms and reports that health care providers or organizations may find helpful. To view a document, double click the icon in the "Link" column.

#	Document Name	Description	Link
1	**Crosstown Clinic iOAT Carries Client Information**	Informational form provided to clients at crosstown clients about iOAT take-home doses.	Crosstown Clinic: iOAT Carries (Take-Home) Dosing Client Information
2	**Crosstown Clinic iOAT Carries Client Agreement**	Agreement form for iOAT take-home doses that clients of Crosstown Clinic are asked to sign.	Crosstown Clinic Carry (Take Home) Doses Client Agreement
3	**Treatment Outcomes Profile (TOP) Form**	Simple set of questions that can aid improvements in clinical practice by enhancing assessment and care plan reviews. Completed with client during clinical assessment/eligibility determination.	Treatment Outcomes Profile (TOP) Form
4	**Dispensing iOAT Carries—Pharmacy Process**	Contains information for pharmacies on take-home doses medication preparation, packaging, and dispensing.	Dispensing iOAT Carries Pharmacy Process
5	**OAT Database Carries Function**	Step by step guide for inputting take-home doses into Crosstown Clinic Pharmacy database.	OAT Database Carries Function
6	**Carries Eligibility Form for EMR**	Form for helping clinicians determine a clients eligibility for take-home doses.	Carries Eligibility Form for EMR
7	**Carries Follow-up Template**	Form that provides some guidance on the follow-up assessment of a client receiving take-home doses.	Carries Follow-up Template
8	**iOAT Carry Dose Informational Sheet**	Educational one-pager for healthcare professionals that provides an overview of the benefits of take-home doses.	iOAT Carry Dose Informational Sheet
9	**Lifeguard Phone App**	A phone application used in BC that helps to prevent overdoses in people who use drugs alone.	https://lifeguarddh.com/
10	**Health Canada Controlled Drugs and Substances Act**	One of Canada's Federal drug control laws which provides frameworks for the control of drugs. See Subsection 56(1) for information on exemptions at supervised consumption sites.	https://laws-lois.justice.gc.ca/PDF/C-38.8.pdf
11	**Integrated, interdisciplinary model of opioid agonist treatment (IIMOAT)**	Outlines the responsibilities of the health care professionals involved in the care of people on opioid agonist treatment (OAT) in an interdisciplinary model. Includes details on using PharmaNet and the Transaction Medication Update.	https://www.bccsu.ca/opioid-use-disorder/iimoat/

Appendix 2: Resources of interest

British Columbia Centre on Substance Use, BC Ministry of Health. *A Guideline for the Clinical Management of Opioid Use Disorder.* 2017. http://www.bccsu.ca/care-guidance-publications/

Canadian Research Initiative in Substance Misuse (CRISM). *National Injectable Opioid Agonist Treatment for Opioid Use Disorder Operational Guidance.* 2019. https://crism.ca/projects/ioat-guideline/

Canadian Research Initiative in Substance Misuse (CRISM). *National Injectable Opioid Agonist Treatment for Opioid Use Disorder Clinical Guideline.* 2019. https://crism.ca/projects/ioat-guideline/

Ferri M, Davoli M, Perucci CA. Heroin maintenance for chronic heroin-dependent individuals. *Cochrane Database of Systematic Reviews.* Published online 2011. doi:10.1002/14651858.cd003410.pub4

Figgatt MC, Salazar Z, Day E, Vincent L, Dasgupta N. Take-home dosing experiences among persons receiving methadone maintenance treatment during COVID-19. *J Subst Abuse Treat.* 2021;123. doi:10.1016/j.jsat.2021.108276

Frank D, Mateu-Gelabert P, Perlman DC, Walters SM, Curran L, Guarino H. "It's like 'liquid handcuffs": The effects of take-home dosing policies on Methadone Maintenance Treatment (MMT) patients' lives. *Harm Reduct J.* 2021;18(1). doi:10.1186/s12954-021-00535-y

Hoffman KA, Foot C, Levander XA, et al. Treatment retention, return to use, and recovery support following COVID-19 relaxation of methadone take-home dosing in two rural opioid treatment programs: A mixed methods analysis. *J Subst Abuse Treat.* 2022;141. doi:10.1016/j.jsat.2022.108801

MacDonald S, Oviedo-Joekes E. Injectable opioid agonist therapy. In: Selby P, Rieb L, Lam V, Zhang M, Bertram J, eds. *Opioid Agonist Therapy: A Prescriber's Guide to Treatment.* 3rd ed. Centre for Addition and Mental Health. 2022.

Magel T, Matzinger E, Blawatt S, et al. How injectable opioid agonist treatment (iOAT) care could be improved? service providers and stakeholders' perspectives. *Drugs: Education, Prevention and Policy.* Published online 2023. doi:10.1080/09687637.2023.2176287

Oviedo-Joekes E, Dobischok S, Carvajal J, et al. "I can't see anything but upside": A qualitative study of clients' experiences on North America's first take-home injectable opioid agonist treatment (iOAT) program. Published online 2023. doi:10.21203/rs.3.rs-2570581/v1