

# MANITOBA OPIOID AGONIST THERAPY RECOMMENDED PRACTICE MANUAL

## **1.3** Initiating Opioid Agonist Therapy: Comprehensive Assessment, Diagnosis, Informed Consent & Investigations

# GENERAL CONSIDERATIONS

Before starting opioid agonist therapy (OAT) a thorough intake assessment is critical to safe patient care. This section summarizes key aspects of the initial comprehensive assessment of a patient with opioid use disorder (OUD), as well as key clinical investigations that should be considered in early treatment.

The importance of informed consent and treatment agreements is also discussed. Establishing a mutual understanding of the treatment plan and goals with the patient, as well as behavioural expectations, is essential to safe care. This also lays the foundation of the therapeutic relationship for ongoing treatment.

# THE COMPREHENSIVE ASSESSMENT

## INITIAL ASSESSMENT

The comprehensive patient assessment should address the KEY COMPONENTS listed below.

Assessment should confirm a diagnosis of OUD, consistent with DMS-5 criteria (see **Appendix A**), and explore key safety considerations, *before* starting OAT. With this established, a discussion of treatment options and goals can follow, including review of pharmacotherapy, psychosocial interventions, and harm reduction strategies.

## Set the Stage for the Interview

Addiction medicine care requires a compassionate, non-judgmental, and sensitive approach to gathering information. Building a therapeutic alliance with the patient starts with the initial interview and is important to effective care.

Before delving into questioning, take a moment to help the patient settle into the interview space:

- Welcome the patient and introduce yourself and whomever may be joining for the interview.
- Let them know how long the assessment may take.
- Let them know what to expect and the type questions you will ask (e.g., about their medical history, life circumstances, and the substances they may be using).
- Determine if they would like a support person to join the interview and/or treatment discussion, as appropriate.

The assessment will be affected by the clinical setting, time limitations, and, of course, the patient's readiness to share information. Patients struggling with substance use disorder may feel guarded and reluctant to share certain information about themselves, their family, or their substance use, at least initially. Offer reassurance that the more shared, the better the treatment plan can align with their individualized needs, preferences, and values.

## KEY COMPONENTS: THE COMPREHENSIVE ASSESSMENT

The following areas should be reviewed to determine a diagnosis of OUD and to establish a safe and realistic treatment plan with the patient:

#### **PSYCHOSOCIAL HISTORY**

Review age, housing, family/friends, finances, education, employment, legal issues, illicit activity, supports, stressors, interests, and valued life roles.

#### SUBSTANCE USE & TREATMENT HISTORY

Screen all drug classes. Ask for details if using/used a substance regularly: length of use, pattern of use, amount, route (oral, insufflation, IV, other), access (prescribed and/or illicit), last use, periods of abstinence, cessation symptoms. Screen for behavioural addictions. Review past experience with addiction treatment.

#### MEDICAL HISTORY

Review physical & psychiatric/mental health history, hospitalizations, surgeries, other healthcare providers involved, and the status of current issues or diagnoses.

#### **MEDICATION REVIEW**

Review prescribed medications. Link current meds to active clinical issues. See, "An Approach to Polypharmacy in the Context of OAT" in <u>Managing</u> <u>Polypharmacy, Benzodiazepines, Alcohol, &</u> <u>Polysubstance Use in OAT</u>, for guidance on medication reviews.

#### FOCUSED PHYSICAL & MENTAL STATUS EXAM

Check vitals, heart, lungs, focused pain assessment (as appropriate), focused lab tests.

Special attention should be given to signs of opioid withdrawal, cardiovascular and respiratory status, pupil size, alertness, affect, speech, agitation, skin (injection sites, infection, abscess), malnutrition, jaundice, hepatosplenomegaly.

#### TREATMENT GOALS & PLAN

Identify goals, safety considerations, and plan.

Additionally, substance use and trauma often overlap. It is important to be mindful of adverse childhood experiences and other trauma during the interview. This should also be approached with sensitivity and consideration of the patient's readiness to share, using a person-centered and trauma-informed lens.

Incorporating trauma-informed principles into care is also recommended by the Centre for Addiction and Mental Health (CAMH) guidelines for OUD, including "trauma awareness, choice, collaboration and connection, safety and trustworthiness, skill building, and strengths-based approaches"<sup>1</sup>. Cultivating this care starts with the initial interview.

## Templates & Documentation

Documenting the details of the assessment, diagnoses, and rationale for the treatment approach is critical to quality care. This can be done in narrative form or on templated assessments forms. Templates, either in electronic or paper format, are an effective way to ensure the KEY COMPONENTS of the initial interview are covered. They can prompt you to remember important topics and questions. See **Appendix B** for a template example.

Please note that while templates are useful tools, **quality contemporaneous documentation in the medical record is required**. Details of the patient's specific history, physical, substance use, as well as diagnoses, problem list, and plan/goals must be captured in the medical record.

In general, medical record keeping should align with the CPSM Standards of Practice for <u>Documentation in Patients Records</u> and <u>Maintenance of Patients Records In all Settings</u>, as highlighted in the box below.

## STANDARD OF PRACTICE: DOCUMENTATION IN PATIENT RECORDS<sup>2</sup>

For accuracy and completeness, the Standard for Documentation emphasizes:

- 2.9. In creating an entry, the use of templates or macros carries substantial risk that information not relevant to the specific patient's actual clinical circumstance or the specific encounter may inadvertently be included in the patient record, rendering the entry unreliable or inaccurate. For this reason:
  - 2.9.1. Templates or macros prepopulated with clinical information should be avoided.
  - 2.9.2. Registrants who use templates or macros must review them and ensure that the content accurately and comprehensively reflects the care given.
- 2.10. Registrants must not copy and paste an entry related to a prior visit with a patient unless the copied entry is modified to remove outdated information and include current information which reflects the actual circumstances the visit entry is meant to reflect.

## Substance Use History – Get Details

Templates can also help the clinician complete a detailed review of substance use. Asking patients about each class of drug, and giving examples of specific types, common names, or local slang terminology, will often yield more definitive information about substance use.

While the patient may present for help with opioids, the OAT provider should be aware that polysubstance use is very common. Patients may be using more than one type of drug on a regular basis. It is important to screen all classes of drugs, then focus on gathering details about the substances used regularly. The QUICK REFERENCE below lists commonly used substances that should reviewed in most initial interviews. **Evaluating polysubstance use, including sedating and psychoactive medications, is critical to treatment planning and establishing safeguards during OAT induction and early recovery**.

#### QUICK REFERENCE: DRUG CLASSES FOR SUBSTANCE USE HISTORY

It is best practice to screen for substance use within all drug categories during initial interviews. The list below is not exhaustive but covers commonly used substances. The clinician should acknowledge that polysubstance use is common. If there is a signific history of use, gather more details about the specific substance(s) (e.g., frequency, amount, route, length of use, access, cessation, abstinence).

While not all listed here, using trade names and local slang (acquired over time), or asking patients to described shapes, sizes, or colours of pills, can often help identify what patients are using and improve communication. If patients use unfamiliar terms, ask them to clarify to build mutual understanding.

Opioids	prescribed or illicit sources, e.g., morphine, codeine, hydromorphone, oxycodone, fentanyl, heroin, "down" (typically an illicit combination of fentanyl, heroin, possibly benzodiazepines), diverted methadone or buprenorphine.
Benzodiazepines	prescribed or illicit sources, e.g., alprazolam, lorazepam, diazepam, clonazepam, temazepam, zopiclone.
Alcohol	beer, wine, spirits, home-brew, potable/non-potable.
Stimulants	cocaine powder, crack cocaine, methamphetamine, amphetamines, methylphenidate, MDMA, ecstasy.
Hallucinogens	LSD/acid, psilocybin/magic mushrooms, phencyclidine (PCP)/angel dust, synthetic cathinone/bath salts, ketamine.
Cannabis	commercially acquired or illicit sources, smoked, vaped, oils, edibles.
Over the counter	diphenhydramine, dimenhydrinate, dextromethorphan/cough syrups, sleep aides/acetaminophen or ibuprofen PM.
Nicotine	cigarettes, cigars, vaping.
Other	gabapentinoids, quetiapine, trazodone, muscle relaxants (cyclobenzaprine, baclofen), caffeine, kratom, solvents, steroids.

Additionally, understanding the patient's life circumstances or history around substance use can be a helpful framework to better understand the patient and, ultimately, tailor a recovery plan. When and why did they start using a particular substance? What led to opioid use? What positive benefits did substance(s) have and when did it start affecting their life in a negative way? The answer may not always be clear to the patient but asking will typically offer insights and useful information.

## List of Active Issues & Medication Review

The history and physical completed upon initial assessment should assist in generating an updated **list of active clinical issues/diagnoses** that require management. Ideally, a detailed review of the patient's medication record (e.g., DPIN or E-Chart) must occur in conjunction with the review of active clinical issues. This provides the clinician and patient an opportunity to clarify how medication is being used, and to determine where a particular medication ranks in terms of importance in managing the clinical concerns.

The section, "An Approach to Polypharmacy in the Context of OAT" in <u>Managing Polypharmacy</u>, <u>Benzodiazepines</u>, <u>Alcohol</u>, <u>& Polysubstance Use</u>, provides useful recommendations to support medication reviews. This section's feature box, "MEDICATION REVIEW - KEY QUESTIONS", can be used to explore each medication on the patient's DPIN.

It is important to also note that the absence of prescribed medications on DPIN does not rule out polypharmacy; the patient may be using sedating and/or psychoactive medications from a non-prescribed source.

In collaboration with the patient, identifying the active clinical issues, setting priorities, and making a medication management plan are critical steps of the comprehensive assessment, *particularly in the context of polypharmacy*. These are often the final steps as assessment moves towards treatment planning.

## **DIAGNOSIS & TREATMENT GOALS**

## Diagnosis of OUD

The comprehensive assessment should gather enough information about the patient's substance use, health, and psychosocial status to make a diagnosis of OUD. The clinician needs to develop an understanding of the patient's function and the consequences experienced because of substance use, and identify the strengths and barriers that will impact recovery. Several helpful checklists for DSM-5 OUD criteria (**Appendix A**) are available to help practitioners make a clear diagnosis, as listed in the box below.

Co-occurring conditions can certainly complicate diagnosis. For example, mental health issues, psychiatric disorders, and chronic pain conditions will impact patient function and blur diagnostic lines.

If questions remain regarding definitive diagnosis, further investigations or consultations may be needed to sort out the diagnoses.

A diagnosis of OUD must be confirmed to start OAT. In many circumstances, by the time patients are seeking help for opioid use, they will likely meet at least two to three criteria to diagnose mild OUD, at minimum. Of note, tolerance and withdrawal, in the context of taking opioids solely under appropriate medical supervision, do not qualify as criteria towards diagnosis of OUD. This would be something to consider in a patient prescribed opioids for chronic pain – evaluating if they meet other diagnostic criteria is important to confirm a concurrent diagnosis of OUD.

ONLINE RESOURCES: OUD DIAGNOSTIC CHECKLISTSBritish Columbia Centre on Substance Use (BCCSU)DSM-5 Clinical Diagnostic Criteria for Opioid UseDisorderUniversity of Colorado – IT MATTTRs<sup>TM</sup>DSM-5 Criteria for Diagnosis of Opioid Use DisorderBoston Medical Centre – MassachusettsConsultation Service for Treatment of Addiction<br/>and Pain (MCSTAP)DSM-5 Checklist of Diagnostic Criteria: Opioid Use<br/>Disorder

## Treatment Goals

Identify the goals of treatment in collaboration with the patient. Harm-reduction – improving patient safety and reducing harms through addiction care and/or while on OAT – is paramount. Both provider and patient-driven goals are important to document and revisit periodically.

Cessation of drug use or complete abstinence from non-prescribed substances may be a later goal along the treatment continuum, or it may not be realistic or achievable for some patients, but they can still benefit from harm-reduction and involvement with the OAT program now.

The CAMH describes a comprehensive harm-reduction approach as:

- Outreach services,
- Access to naloxone (naloxone kits),
- Sterile drug consumption equipment,
- Supervised consumption services,
- Education on harm reduction practices,
- Infectious disease testing,
- Access to primary care,
- Vaccinations, and
- Appropriate referrals to other health and social services<sup>1</sup>.

Treatment goal areas to discuss include:

1) **Safety Goals**. This includes safety of self and others so that OAT medications are safely used, stored, and not diverted. Providers and team members must ensure that patients receive adequate education regarding the risks involved with OAT treatment, as care plans are negotiated and adjusted over time.

This education must be provided in a manner that is easy to understand and relevant to the patient's circumstances and literacy level. Handouts that patients can share with family, friends, and roommates, may be especially useful. See **Appendix C**, "A Patient Guide: Avoiding Overdose in the First Two Weeks of OAT", as an example to facilitate this teaching. Treatment agreements will also explicitly address safety considerations for treatment.

- 2) **Substance Use Goals**. Discuss the patient's goals around opioid and other drug and alcohol use. What changes are they ready for? What substances to do they hope to cutback, reduce, stop? This also involves discussion around safe use and harm-reduction teaching, supplies, and provision of naloxone kits and associated education, as above.
- 3) Medication Management Goals. How will current medications be managed for safety? If polypharmacy concerns exist, what can be stopped, reduced, or tapered first? Discuss this collaboratively with the patient for increased engagement with the medication management plan.
- 4) **Other Health Goals**. Discuss the other active issues or diagnoses that require further assessment, work-up, and management, as applicable. What does the patient feel ready to address?
- 5) **Psychosocial Goals**. Consider goals to improve psychosocial function for **pragmatic reasons** (e.g., how will they pay for their medication? How stable is housing?), **safety** (e.g., who will care for the children if they go to a treatment program? How will medication be safely stored?), and for overall **recovery** (e.g., how will they abstain from illicit drug use if their partner is still using? How will they spend their time if not using anymore?).

The OAT provider should give attention to the following needs, as applicable:

- Addressing family or relationship problems or need for supports,
- Housing issues,
- Financial needs,
- Legal concerns,
- Employment or educational needs or skills training,
- Mental health, peer supports, cultural supports, and/or spiritual health.

## INFORMED CONSENT & TREATMENT AGREEMENTS

As with any treatment in the practice of medicine, informed consent prior to starting OAT is essential. The British Columbia Centre on Substance Use (BCCSU) explains that "seeking informed consent to trial an intervention requires disclosing the relevant information that will allow the patient to make a voluntary choice to accept and consent or decline the intervention"<sup>3</sup>.

Individualized treatment plans that incorporate patients' preferences, values, and choice must be balanced with evidence-informed treatment and safety considerations. Treatment agreements can be useful tools to support informed consent and treatment planning. They can also be used to, "delineate expectations, negotiate boundaries, and minimize conflicts between providers and patients with OUD"<sup>4</sup>.

See Appendix D for an example Treatment Agreement & Consent Form.

The BCCSU clinical guideline for OUD also provides examples of treatment agreement and consent forms specific to OAT medications, including methadone, buprenorphine/naloxone, and slow-release oral morphine (see <u>Appendix 8, pages 61-69</u>)<sup>5</sup>. However, these BC resources should be considered within the local provincial context and Manitoba guidelines and standards applied accordingly.

## **Boundaries & Expectations**

**Compassion combined with clear boundaries is often needed to support patients with OUD.** Treatment agreements are also useful tools to help providers role model healthy boundaries and effective communication with patients. They can also foster trust and transparency at the forefront of treatment.

It is important that all patients and prescribers understand their respective expectations and responsibilities when it comes to participating in OAT care. Mutual respect is essential and worth an investment of time and effort. Reviewing and signing a treatment agreement that includes behavioral expectations can assist in clarifying roles and expectations. A clear discussion of boundaries around behavior may be needed so that patients understand that threats or aggression directed at staff, pharmacists, or co-patients, will not be tolerated and may result in discontinuation of care.

**Reviewing agreements should be adapted to meet patients' cognitive abilities, literacy level, and psychosocial needs**. These agreements can be also revisited in early treatment as patients are stabilizing on OAT, ideally when not in withdrawal, more clear-headed, and able to retain information, to ensure mutual understanding of expectations.

Information on urine drug testing parameters, expectations, and management should also be included in treatment agreements, using a patient centered, non-punitive, and non-stigmatizing approach<sup>6</sup>.

## The Circle Of Care

Treatment agreements can also help address confidentiality, circle of care, and circumstances where providers have a duty to report. Upon intake, patients should be made aware of the importance of communicating and collaborating with their other care providers. Discuss openly with the patient the importance of communicating with their circle-of-care providers as needed (e.g., family physician, pharmacist, psychiatrist, counsellors, and other professionals involved).

This requirement for transparency facilitates patient safety for OAT induction and ongoing care and can be outlined in the treatment agreement. If patients decline to participate in treatment because of the need for such communication, OAT induction is not recommended as it puts both the patient and provider at risk and jeopardizes safety. Focusing on harm-reduction education and resources, clarifying treatment expectations, and ensuring patients know where they can access future care then becomes paramount.

The CPSM <u>Standard of Practice for the Duty to Report Self, Colleagues, or Patients</u> provides more information about the ethics and legalities of reporting. The Standard highlights that honesty and compassion are fundamental to the patient-physician relationship and encourages communication with patients around reporting duties and potential breaches as appropriate, to foster a trusting relationship between patient and provider<sup>7</sup>. Please see this Standard for more information around mandatory reporting with patients.

It is also important to note that sharing patient information to their benefit within the circle of care is permissible and still fulfills the duty of confidentiality<sup>7</sup>.

## **INVESTIGATIONS & LABORATORY TESTS**

The following minimum investigations are recommended in early treatment:

- Urine Drug Testing (UDT)
- Sexually Transmitted and Blood Borne Infections (STBBI) screening
- CBC, liver function, renal function, and blood sugar tests
- Urinalysis
- Pregnancy test (as appropriate)

## While the above investigations are ideal, they should not delay access to timely treatment<sup>5</sup>.

Urine testing that identifies the presence of opioids is also ideal prior to initiating OAT, however, if testing cannot be feasibly completed and OAT is indicated, treatment should be initiated promptly regardless.

UDT can then be arranged as soon as it is feasible – not only to help evaluate opioid use, but to inform the polysubstance use history.

Of note, if urine testing *does not* detect opioids upon intake, this does not preclude a patient from starting OAT if clinically indicated. There may be clinical reasons for this, such as recent abstinence, or failure of the test to reliably detect certain opioids.

Consideration must be given to select the type of UDT that will be most effective for the clinical context (e.g., point-of-care, street drug screen, or comprehensive). The benefits and drawbacks of each type of test must be considered along with the clinical context and utility. See the <u>Use of UDT in the Management of OUD</u> for a general approach to testing, including the recommended frequency and important issues to consider when interpreting results.

## Importance of STBBI Screening

It is important to note that OAT providers must offer comprehensive screening for STBBIs to all patients with OUD. This can occur around intake and periodically thereafter based on ongoing risk assessment. Initial screening should include testing for HIV, hepatitis A, B, and C, as well as syphilis, chlamydia, and gonorrhea, including throat and rectal swabs if indicated.

Patients at significant and ongoing risk of infection should be offered STBBI screening every 6 to 12 months. Repeat testing may be customized based on individual risk factors. Please see <u>Prevention, Screening, & Management of HIV & Hepatitis C in Individuals with OUD</u> for further guidance. Again, such testing should not delay access to OAT, and should a patient present for help and then decline OAT, offering STBBI screening is still part of a comprehensive harm reduction approach.

## Other Investigations

Other investigations can be considered as clinically relevant or indicated.

Baseline and monitoring electrocardiograms (ECG) may be warranted and are recommended in the context of methadone (particularly at higher doses), QT prolonging medications, and other risks factors. Further considerations for ECG and clinical management of the QT interval with methadone treatment are discussed in detail in the Maintenance Phase recommendations of this manual.

In the context of new-onset mental health symptoms, standard lab work including thyroid, kidney, and liver function, and any other investigations suggested by a review of systems, can be helpful to rule out if physical health conditions are contributory. Chronic pain conditions may also benefit from further investigations and referral to relevant specialists.

Individuals with substance use disorders may not routinely access healthcare, and may in fact avoid it given past negative or stigmatizing experiences. While OAT may not be offered in conjunction with primary care in some settings, the OAT prescriber could be the one trusted provider who is seen routinely enough to offer basic screening lab work and facilitate a connection with primary care for follow-up, if possible and available.

## ONGOING ASSESSMENT AT REGULAR CLINIC VISITS

Upon routine follow up, the OAT provider should review and document, as applicable:

- The current OAT dose.
- Any signs or symptoms suggestive of need for dose change.
- Current medications, review DPIN or E-Chart, and communication with pharmacy as needed.
- Use of illicit opioids or other drugs, alcohol, prescribed and/or non-prescribed medications, and/or OTC medications.
- Recent urine drug testing as clinically indicated.
- Presence of signs or symptoms of intoxication or withdrawal.
- Presence of any acute stressors or acute medical problems.
- Current psychosocial status/stability (e.g., housing, finances, relationships, legal concerns, productivity, coping, recovery activities, as applicable).
- Appropriateness of change in take-home dosing (carries).
- Any safety concerns including the safe storage of medications or psychosocial stability as above.

The provider should also document the new OAT prescription and any other prescriptions given.

Physicians are encouraged to utilize narrative notes for follow up visits. Careful attention should be paid to ensure documentation on forms or electronic records is patient-specific and detailed. **Quality contemporaneous documentation in the medical record upon follow up is imperative**. Please refer to the earlier box regarding the STANDARD OF PRACTICE: DOCUMENTATION IN PATIENT RECORDS and the importance of accuracy and completeness.

Periodically the OAT provider should also review:

- Common potential side effects (e.g., constipation, sexual difficulties, weight gain).
- Need to consider referral for treatment of chronic health conditions and/or for primary care (e.g., hepatitis C, HIV, pain, mental health).
- If there is a need for ECG, other laboratory tests, or serum levels.
- If more intensive counseling or other treatment support would be appropriate.

## References

- <sup>1.</sup> Centre for Addiction and Mental Health (CAMH). Opioid Agonist Therapy: A Synthesis of Canadian Guidelines for Treating Opioid Use Disorder. CAMH; 2021. Available at: <u>https://www.camh.ca/-/media/files/professionals/canadian-opioid-use-disorder-guideline2021-pdf.pdf</u>
- <sup>2.</sup> College of Physicians & Surgeons of Manitoba. *Standard of Practice: Documentation in Patient Records*. CPSM; 2022.
- <sup>3.</sup> British Columbia Centre on Substance Use (BCCSU). Opioid Use Disorder Practice Update. BCCSU and BC Ministry of Health; 2022. Available at: <u>https://www.bccsu.ca/wp-content/uploads/2022/02/0pioid-Use-Disorder-Practice-Update-February-2022.pdf</u>
- <sup>4.</sup> Korownyk C, Perry D, Ton J, et al. Managing opioid use disorder in primary care: PEER simplified guideline. *Canadian Family Physician*. 2019; 65(5):321-330.
- <sup>5.</sup> Provincial Opioid Use Disorder Treatment Guideline Committee. A Guideline for the Clinical Management of Opioid Use Disorder. British Columbia Centre on Substance Use (BCCSU) and BC Ministry of Health; 2017. Available at: <u>https://www.bccsu.ca/care-guidance-publications/</u>
- <sup>6.</sup> British Columbia Centre on Substance Use (BCCSU). Urine Drug Testing in Patients Prescribed Opioid Agonist Treatment – Breakout Resource. BCCSU, BC Ministry of Health, and Ministry of Mental Health and Addictions; 2021. Available at: <u>https://www.bccsu.ca/wpcontent/uploads/2021/07/Urine-Drug-Testing-Breakout-Resource.pdf</u>
- <sup>7.</sup> College of Physicians & Surgeons of Manitoba. *Standard of Practice: Duty to Report Self, Colleagues, or Patients, Contextual Information and Resources*. CPSM; 2021.

# Appendix A

## DSM-5 CRITERIA<sup>1</sup> FOR OPIOID USE DISORDER

- A. A problematic pattern of opioid use leading to clinically significant impairment or distress, as manifested by **at least two** of the following, occurring within a 12-month period:
  - <sup>1.</sup> Opioids are often taken in larger amounts or over a longer period than was intended.
  - <sup>2.</sup> There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
  - <sup>3.</sup> A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
  - <sup>4.</sup> Craving, or a strong desire or urge to use opioids.
  - <sup>5.</sup> Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
  - <sup>6.</sup> Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
  - <sup>7.</sup> Important social, occupational, or recreational activities are given up or reduced because of opioid use.
  - <sup>8.</sup> Recurrent opioid use in situations in which it is physically hazardous.
  - <sup>9.</sup> Continued opioid use despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance.
  - <sup>10.</sup> Tolerance\*, as defined by either of the following:
    - a) A need for markedly increased amounts of opioids to achieve intoxication or desired effect.
    - b) A markedly diminished effect with continued use of the same amount of an opioid.
  - <sup>11.</sup> Withdrawal\*, as manifested by either of the following:
    - a) The characteristic opioid withdrawal syndrome (refer to Criteria A and B of the criteria set for opioid withdrawal, pages 259-260).
    - b) Opioids (or a closely related substance) are taken to relieve or avoid withdrawal symptoms.

\* **Note:** These criteria are not considered to be met for those individuals taking opioids solely under appropriate medical supervision.

#### Specify current severity

305.50 (F11.10) Mild:	Presence of 2-3 symptoms
304.00 (F11.20) Moderate:	Presence of 4-5 symptoms
304.00 (F11.20) Severe:	Presence of 6 or more symptoms

<sup>&</sup>lt;sup>1</sup> The criteria are reprinted with permission from American Psychiatric Association (2013). *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.). Washington, DC: Author.

# Appendix B

## OAT COMPREHENSIVE ASSESSMENT TEMPLATE

Name: \_\_\_\_\_

DOB: Y/M/D:

Date/Time	Focus	Progress Notes					
	Pre-screen						
	Social History						
	Age						
	Partner						
	Children						
	Main supports						
	Childhood						
		Adverse Childhood Experiences:					
		Other Trauma:					
	Education						
	Job history						
	Last worked						
	Current job						
	Income						
	Medication coverage						
	Driver's licence	Yes No					
	Legal history						
	Current charges						
	Upcoming court dates						
	Substance Use History						
	Cannabis						
	Alcohol						
		Ever in ER or admitted for alcohol withdrawal:					
		Seizures:					
		DT's:					

Cocaine powder		
Crack		
Methamphetamines		
MDMA		
Hallucinogens		
Benzodiazepines		
Opioids		
	Last Use:	
	DOC:	
	Overdoses:	
	Clean Supplies:	
	Naloxone kit:	
Nicotine		
Ketamine		
Solvents		
OTCs		
Previous substance use treatment		
Current treatment involvement		
Self-help groups		
Co-occurring issues	Gambling:	
	Shoplifting:	
	Disordered eating:	
Medical History		
IVDU	Complications of IV use:	
Previous STI panel		
Fertility control		
Other care providers		
Family history		
Current medications		

DPIN/EChart Review					
Allergies					
Hospitalizations					
Surgeries					
Psychiatric history					
Previous suicide					
attempt/ideation Notable on review of					
systems					
Physical Exam					
General appearance					
	BP:	Pulse:	Temp:	Weight:	
	H & N:		Pupils:		
	Chest:				
	CVS:				
	Abdomen:				
	Skin:				
Point of care UDS	IV sites:				
Goals					
Assessment					
Plan					
Additional comments					
Signed					

# Appendix C

## A PATIENT GUIDE: AVOIDING OVERDOSE IN THE FIRST TWO WEEKS OF OPIOID AGONIST THERAPY

This clinic provides opioid agonist therapy (OAT) care *as safely as possible*, but accidental overdoses sometimes happen in the first two weeks of treatment. This is especially important when starting methadone treatment, but many of the same safety ideas should also be applied when starting buprenorphine/naloxone (Suboxone).

The questions and answers below will help you to get through this period safely. Share this information sheet with a friend or family member.

## Why can't my doctor increase my dose more quickly?

When you first start taking methadone or buprenorphine/naloxone, you want to get on the right dose as soon as possible. With buprenorphine/naloxone your doctor may only need a few days to get you to the right dose while making sure you can safely tolerate the medication. With methadone, however, your doctor must increase your dose slowly over several weeks, because your body takes time to adjust to the methadone and (unlike other opiates), methadone builds up slowly in your bloodstream over several days. A dose that may feel like too little on a Monday could put you in hospital by Thursday.

## What can I take to relieve withdrawal and help me sleep until the OAT medication begins to work?

Your doctor may discuss taking certain medications to assist with your symptoms. These medications may include plain Tylenol<sup>®</sup> (acetaminophen) and Advil<sup>®</sup> (ibuprofen). Drinking lots of water is important to stay hydrated. Occasionally, your doctor may prescribe other medications to help with specific symptoms – **only take medications that are approved by your OAT doctor**. If you're on a medication prescribed by another doctor, your OAT doctor needs to approve it because it could interact with the buprenorphine/naloxone or methadone.

Substances that make you relaxed or sleepy can be dangerous. This includes:

- Alcohol, opioids, and benzodiazepines (e.g., Ativan<sup>®</sup>, Valium<sup>®</sup>, Xanax<sup>®</sup>, Restoril<sup>®</sup>, etc.).
- Antihistamines, cold medications, and sleeping pills (such as, but not limited to, Gravol<sup>™</sup>, Benadryl<sup>®</sup>, Nyquil<sup>™</sup>, Benylin<sup>®</sup>, or Tylenol<sup>®</sup> PM, zopilcone).
- Certain types of antidepressants and tranquilizers.

Even certain antibiotics can be dangerous as they block the breakdown of methadone in the body. **Make sure to check all your medications with your OAT doctor**.

## What if I feel like I still need to use other opioids while starting OAT?

If you feel like you need to use other opioids in addition to the OAT medication, particularly while at a lower methadone dose, talk to your doctor about this honestly at every visit. Your doctor understands that your buprenorphine/naloxone or methadone dose may not last 24 hours in early treatment. Knowing that you are using other opioids and how much, will help your doctor to increase your OAT medication dose as needed, while being safe. Your doctor can also help you to determine the safest way to use additional opioids if this is needed. **However, if you can cope with your OAT dose only, that is the safest option**.

## Isn't OAT, especially methadone, supposed to make you sleepy?

No. You are supposed to feel normal on your OAT medication, not high or sleepy. This applies to both buprenorphine/naloxone and methadone. When taken as prescribed by your doctor, OAT medications build up slowly in your system and should not make you feel drowsy. You should take the following precautions to help the clinic staff keep you safe:

- Take your OAT at the same time each day.
- See your doctor or case manager at least once a week for the first two weeks. (Many clinics will require visits that are more frequent.)
- Discuss your OAT treatment with a close friend or family member. If they see that you are drowsy, they must call your OAT doctor or 911.
- Discuss naloxone kits with your doctor and with a close friend or family member. Make sure you and your friend/family know how and when to use naloxone (your doctor or trained clinic staff can teach you this).

## I'm starting methadone...What are some of the symptoms if my dose is too high?

- You may feel sleepy and nod off several times during the day.
- You may be forgetful.
- You may be difficult to wake up from your sleep.
- You may experience slurred speech, stumbling walk, or appear drunk.

If these things are occurring, you must call your doctor immediately and call 911 for help.

# I've been offered a small amount of methadone by a methadone patient at the pharmacy. This can't hurt – I know I need 80 mg?

Above all, don't take any extra methadone! What is safe for your friend could be lethal for you. It may be true that you took 80 mg **once** and were okay. If you had taken 80 mg every day for three or four days, you might have overdosed. Remember, it takes *five or more days* for a certain dose to build up in your blood.

# Appendix D

## OAT TREATMENT AGREEMENT & CONSENT FORM

Adapted with acknowledgment and permission from Manitoba Programs including MOST, HSC, & OCN

The prescribing and dispensing of methadone/Suboxone/Sublocade is regulated by provincial guidance documents, as well as policies unique to this Opioid Agonist Therapy (OAT) Program.

This treatment agreement has been prepared to both inform you about opioid agonist therapy, as well as to document that you agree to the rules/obligations contained in this agreement.

## ACKNOWLEDGEMENTS

## I acknowledge that:

- <sup>1)</sup> Methadone and buprenorphine (Suboxone/Sublocade) are opioids (opioids are drugs like heroin, codeine, morphine, oxycodone, hydromorphone, fentanyl, etc.), and that I will develop a physical dependence on the medication. Sudden decreases in dose or discontinuation of this medication will likely lead to symptoms of opioid withdrawal.
- <sup>2)</sup> I am already physically dependent on at least one opioid, and I am unable to discontinue the use of opioid(s).
- <sup>3)</sup> I have had the opportunity to review and determine whether abstinence-based treatment is appropriate for me.
- <sup>4)</sup> Taking any mood-altering substance with OAT medications can be dangerous. There have been reported deaths caused by the combination of medications with alcohol, opioids, cocaine, barbiturates, and/or tranquillizers.
- <sup>5)</sup> It is important to inform any physician/dentist who is prescribing any other medication(s) that I am taking an OAT medication.
- <sup>6)</sup> My DPIN history (pharmacy record) will be reviewed on admission to prevent potential adverse drug interactions. For safety reasons, my DPIN may be reviewed periodically while I am on the program.
- <sup>7)</sup> I may voluntarily withdraw from the OAT program at any time.
- <sup>8)</sup> Regarding pregnancy, I understand that the newborn baby may experience opioid withdrawal as a result of my methadone/buprenorphine treatment. This withdrawal is usually mild, but if more severe, specialized care may be required for some days after birth. For this reason, I am aware that I may be required to deliver away from my hometown, in a hospital able to provide an elevated level of care.

- <sup>9)</sup> If my treatment team and I decide to switch to Sublocade (buprenorphine extended-release injection), I understand that is not considered safe to receive Sublocade injections while pregnant. My treatment team will rule out pregnancy before administering Sublocade and will require me to use a reliable fertility control method for the duration of my Sublocade treatment.
- <sup>10)</sup> It is unsafe to drive a motor vehicle or operate machinery during the stabilization period after starting methadone/Suboxone/Sublocade and during dose adjustments. My OAT prescriber will advise me when it is safe to drive after starting methadone/Suboxone/Sublocade and during dose adjustments.
- <sup>11)</sup> The common side effects of methadone are sweating, constipation, decreased sexual function, drowsiness, increased weight, and water retention. These are usually mild and can be lessened with help from my OAT prescriber. Methadone can cause serious cardiac arrhythmias (irregular heartbeat), particularly at high doses. Methadone can also cause long-term hormonal changes that may increase risk of osteoporosis. Suboxone/Sublocade has similar but milder side effects.
- <sup>12)</sup> I acknowledge that my OAT prescriber is not my family doctor/primary care provider.
- <sup>13)</sup> Treatment will be tapered and discontinued if my physician determines that it has become medically unsuitable (i.e., the treatment is not effective, or I develop a medical condition that could make further methadone/Suboxone/Sublocade administration unsafe).
- <sup>14)</sup> Treatment may also be tapered and discontinued if my physician determines that continuing treatment poses a risk to the community (i.e., I am selling or giving away my medication).
- <sup>15)</sup> I acknowledge that the cost of my medication (methadone/Suboxone/Sublocade) is my responsibility if I do not have medication coverage in place, for example through EIA, FNIHB, or a private medication insurance plan.

## BEHAVIOR WHILE AT THE CLINIC & PHARMACY

*I understand the following behavior is not acceptable* in the clinic or pharmacy, and may result in the termination of treatment:

- <sup>1)</sup> Any violence or threatened violence directed toward staff or other clients.
- <sup>2)</sup> Disruptive behavior in the clinic or the surrounding vicinity of the clinic.
- <sup>3)</sup> Any illegal activity, which includes selling or distribution of any kind of street drug or substance or prescription drug, in the clinic or the surrounding vicinity of the clinic.
- <sup>4)</sup> Any behavior that disturbs the peace of the clinic or the surrounding vicinity of the clinic.

- <sup>5)</sup> Illegal activity or disruptive or threatening behavior at the pharmacy.
- <sup>6)</sup> Any diverting, selling, or misuse of methadone/Suboxone/Sublocade.

*I agree* to maintain positive, respectful behavior towards other program clients and staff at all times when in the clinic and pharmacy. I understand that threats, racist or sexist remarks, physical violence, theft, property vandalism or mischief, the possession of weapons, and selling, buying, or distributing illicit substances while on clinic property are extremely serious program violations and may result in the termination of my treatment.

#### OBLIGATIONS OF BEING ON THE OAT PROGRAM

## l agree to:

- <sup>1)</sup> Take only one dose of methadone/Suboxone a day unless additional doses are prescribed for use, and to have the ingestion of my dose witnessed on those days that I don't have takehome doses of methadone/Suboxone (carries).
- <sup>2)</sup> Inform any prescribing physician or dentist who may treat me for any medical or psychiatric condition that I am receiving methadone/Suboxone/Sublocade, so that my treatment can be tailored to prevent potentially dangerous interactions with methadone/Suboxone/Sublocade.
- <sup>3)</sup> Provide a urine sample for a drug screen when I receive a prescription for methadone/Suboxone/Sublocade or when I am asked to do so by program staff.
- <sup>4)</sup> Recognize that failure to provide a urine sample will result in my record being marked as a sample assumed to contain drugs other than my prescribed medication(s) and this could reduce the number of carries I receive.
- <sup>5)</sup> Not tamper with my urine sample. To tamper with my urine sample in any way is a serious violation of the program, and it may affect my future status in the program.
- <sup>6)</sup> Keep all my appointments with the OAT prescriber. Repeatedly missing appointments may result in reduction of my carry doses, changes to my prescribed medication(s), and could interfere with the prescriber-patient relationship. The prescriber is not obligated to supply a prescription without an in-person assessment.
- <sup>7)</sup> Have my methadone/Suboxone dose witnessed by my nurse or pharmacist 7 days per week until stability has been determined by the treatment team, unless otherwise directed by the treatment team.
- <sup>8)</sup> To attend the clinic for administration of my Sublocade injection by my doctor or a program nurse (if applicable). In some cases, a program nurse may visit my community (at a nursing station or other medical space) to administer my Sublocade injection there.

## OBLIGATIONS FOR DOSING & SAFETY

## I understand that I will not be given a dose of methadone/Suboxone/Sublocade if:

- <sup>1)</sup> I appear to be intoxicated or under the influence of some other substance. I may be asked to see a physician, nurse, or pharmacist for assessment before receiving my medication. For my own safety, I may be asked to return later to receive my dose or be refused a dose for that day.
- <sup>2)</sup> I arrive late, after my pharmacy's dispensing hours. **NO EXCEPTIONS**!
- <sup>3)</sup> I exhibit threatening or disruptive behavior towards any staff member or another patient at the clinic or pharmacy.
- <sup>4)</sup> I do not show proper identification before receiving methadone/Suboxone/Sublocade, if asked for identification.
- <sup>5)</sup> I miss three or more doses of methadone or miss five or more doses of Suboxone in a row (the dose of medication needs to be lowered after multiple missed doses in a row).
- <sup>6)</sup> I am late for my Sublocade injection, my treatment team will provide me with instructions on how to proceed in order to resume treatment.

*I further understand* that OAT is most effective when combined with psychosocial interventions (participating in activities that can improve my mind, health, and life) and clinic staff will encourage participation in things like:

- Individual or group counselling,
- Peer-support or self-help groups,
- Formalized treatment programs, and/or
- Working on personal goals related to my health, family, work, school, etc.

## **OBLIGATIONS FOR TAKE-HOME DOSES (CARRIES) & SAFETY**

#### I agree that:

- <sup>1)</sup> Methadone and Suboxone are potent medications. A single dose taken by a person who is not used to taking opioids can be fatal, especially if taken by a child. For this reason, I agree to store take-home dose(s) in a locked box, in a location where it is unlikely to be stolen or accidentally taken by another person. For methadone, an ice pack can be included in the box to keep the liquid/juice fresh.
- <sup>2)</sup> The number of take-home doses I receive will be decided by my prescriber, with input from the clinic staff (e.g., OAT nurse, counsellor, and pharmacy staff) as my treatment progresses.

- <sup>3)</sup> I will not give, lend, or sell my take-home dose(s) to anyone.
- <sup>4)</sup> I will consume the methadone/Suboxone on the dates specified on the medication label and in the appropriate manner that is, a full dose is taken within 24 hours.
- <sup>5)</sup> I will return all empty methadone/Suboxone bottles to the pharmacy, on my next day back at the pharmacy after receiving take-home dose(s).
- <sup>6)</sup> Take-home doses will **only** be given if I provide urine screens as requested by my OAT prescriber or nurse.
- <sup>7)</sup> If an appointment is missed and a prescription runs out, I may be asked to attend the clinic in-person before a new prescription is given. Most commonly take-home doses of methadone/Suboxone will also be restricted.

## CIRCLE OF CARE CONSENTS

## *I hereby give my consent for the following:*

- For my OAT prescriber to speak to any other doctors or healthcare professionals involved in my care, regarding my care. I understand this is very important to ensure my safety, especially around medication use.
- For OAT clinic staff to speak to pharmacists or other health care providers to verify my recent methadone/Suboxone dose(s), which I received in another pharmacy or institution, and to communicate appointment information. Nurses, therapists, and other OAT clinic staff follow PHIA (Personal Health Information Act) and clinic policies regarding privacy and may ask for specific signed consents as necessary.
- For OAT clinic staff to review my DPIN (pharmacy prescription record) as deemed necessary by staff. I am aware that a DPIN will be reviewed on upon intake into the program and intermittently while on OAT to prevent potential adverse drug interactions.

## CONFIDENTIALITY

Everything that you tell OAT clinic staff is confidential (private) and protected by PHIA. However, it is important to realize that there are some exceptions to this rule of confidentiality. Under exceptional circumstances clinic staff may have to report something you share to the appropriate authority. This can occur under the following circumstances:

• If we suspect that a child is at risk of emotional or physical harm or neglect – it is the law that we report this information.

- If you become suicidal, homicidal, or are unable to take care of yourself due to a medical or psychiatric condition, you may be held to be assessed by an emergency room physician or psychiatrist against your will.
- If you reveal to staff that you intend to harm another person, we will be obliged to protect that person by notifying the appropriate authority.
- If a court subpoenas your medical chart, we must release it in accordance with the subpoena.
- If it is suspected that you are unable to safely drive an automobile due to a medical condition (which includes intoxication from alcohol or drugs), we are obliged to notify the appropriate authority.
- Certain infections must be reported to the local public health department.

## AGREEMENT & CONSENT

My signature below indicates that I understand and agree to the information contained in this treatment agreement, including my personal responsibilities while participating in treatment. Should I fail to meet the terms of this agreement, I understand that I may be discharged from the Opioid Agonist Therapy (OAT) Program.

I also agree to respect the confidentiality of other clients in the program.

I have had an opportunity to discuss and review this agreement with my OAT prescriber and my questions (if any) have been answered to my satisfaction.

## Client Information & Consent

