MANITOBA METHADONE & BUPRENORPHINE MAINTENANCE

*****

RECOMMENDED PRACTICE

[Revised July 2014]

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PREFACE

In 2007, representatives of AFM, Winnipeg Regional Health Authority (WRHA), and University of Manitoba came together to develop consensus guidelines for the provision of methadone maintenance treatment (MMT) in Manitoba. In 2013, under the jurisdiction of the College of Physicians and Surgeons of Manitoba, five experienced clinicians reviewed and revised the previous recommendations. The results are reported in this publication.

The goal of the publication is not to produce a comprehensive review of MMT, but rather to present a guide for prescribers of methadone/buprenorphine in treating patients diagnosed with opioid use disorder. A framework of usual practices in providing MMT has been developed with a view to establish a structure for the practice of MMT, in this way also giving support to physicians that provide MMT. Another goal is to make information available to physicians that provide other medical care for patients that are on methadone/buprenorphine maintenance. Furthermore, the guide is inspired by the ethic of maintaining high standards of patient care. This can be achieved by increasing the consistency of and access to safe clinical methadone/buprenorphine maintenance treatment. The vision is to contribute to the improvement of patient health and social outcomes.

No manual can replace sound clinical judgment or give an answer to every clinical dilemma. Physicians are encouraged to seek assistance and consultation for any complex or difficult case. Departing from the usual practice, however, requires the patient's record to contain clear documentation, including the rationale for the variation.

This document is based on a review of material from a number of sources including:

- Health Canada Best Practices in MMT (2002)[1]
- Provincial Guidelines of Ontario (revised 2011)[2]
- Consensus of practitioners with experience in MMT

The following physicians have contributed to this manual:

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The College of Physicians & Surgeons of Manitoba is recognized for their support and guidance in this project, and their review of the document.

[1] Health Canada. (2002). Best Practices: Methadone Maintenance Treatment. Ottawa, Ontario: Author.

[2] College of Physicians and Surgeons of Ontario. (2011). *Methadone Maintenance Treatment: Program Standards and Clinical Guideline.* (4th ed.). Toronto, Ontario: Author.

TERMINOLOGY AND DRUG NAMES

1. MMT – Methadone Maintenance Treatment
2. MT – Maintenance Treatment with methadone or buprenorphine
3. Buprenorphine – This drug is marketed under different names and in different combinations including:
   - Subutex – buprenorphine
   - Suboxone®– buprenorphine combined with naloxone
   - Generic Suboxone

The term *opioid addiction/dependence* has been changed to *opioid use disorder* to correlate with the DSM-5[3] definition (American Psychiatric Association, 2013).

[3] American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). Washington, DC: Author.

1. PHYSICIAN LICENSING AND EDUCATION

The current standards for obtaining an exemption to prescribe methadone/buprenorphine for addiction in Manitoba are set out below.

For Methadone

- The Registrar of the College of Physicians & Surgeons of Manitoba reviews individual applications and may make additional recommendations.
- The applicant must take an addiction and methadone training course that stretch over two days. The course may be taken in Ontario or B.C. or as an on-line course provided by the Centre for Addiction and Mental Health (CAMH). Alternatively, a six to eight hours review of assessment and guidelines can be done one-on-one with an experienced MT provider certified in addiction medicine and approved by the College. The review takes place in Winnipeg for doctors who experience timing and travel barriers to an out-of-province course.
- Several supervised shifts in a methadone/buprenorphine clinic, with the minimum of four half days, have to be completed.
- Alternatively, extensive experience in methadone/buprenorphine addiction practice in another province may satisfy College requirements. Discussion with the Registrar should occur.
- Physicians need to be aware of their own experience and should seek consultation or mentorship with complex cases when necessary.
- *Methadone Maintenance Treatment – Program Standards and Guidelines* of the College of Physicians and Surgeons of Ontario[4] is an excellent resource for more detailed descriptions of care issues and references in methadone maintenance treatment. Physicians should consider downloading and reviewing the document.

For Buprenorphine

A physician must have a methadone exemption, and then take a buprenorphine training course. An example of an approved course can be found at www.suboxonecme.ca on the internet. This online course takes six to eight hours to complete. The physician receives a certificate, which is submitted to the College for approval. (There may be a future training course for Suboxone, which will review addiction assessment and management that do not require a methadone exemption.)

[4] College of Physicians and Surgeons of Ontario. (2011). *Methadone Maintenance Treatment: Program Standards and Clinical Guidelines.* (4th ed.). Toronto, Ontario: Author.

2. PHYSICIAN AUDIT AND REVIEW

It is suggested that cases presenting unusual problems or variations from standard practice, be discussed informally or by formal consultation with a colleague experienced in addiction practices. A self-audit or peer review process has been instituted in the past several years under College guidance.

Where concern exists that a physician is prescribing methadone/buprenorphine or any other opiate for addiction in a significant variation from standard practice, the College may decide if a further review, audit or educational process is necessary.

Deaths from methadone/buprenorphine are also reviewed.

3. REGISTRATION OF SERVICES

Registration of Patients in a Methadone/Buprenorphine Program

At present, several clinics in Winnipeg and one AFM clinic in Brandon prescribe methadone/buprenorphine for addiction. Clinics keep records of their active patients.

In some provinces, it is necessary to register patients receiving methadone with the College of Physicians & Surgeons. In Manitoba, patients are not registered with the College. Once an appropriate evaluation is performed and the patient has given informed consent, the physician can initiate methadone/buprenorphine treatment as indicated.

Physicians prescribing methadone/buprenorphine for addiction will be required to submit a brief description of services to the College on a yearly basis.

4. CRITERIA FOR ADMISSION TO MT PROGRAM

Individuals requesting admission to a methadone/buprenorphine maintenance treatment program must meet the DSM-5 criteria for opioid use disorder (see Appendix B: Diagnostic Criteria for Opioid Use Disorder (DSM-5 Criteria), page 54).

4.1 General Considerations

Before initiating MT, patients have to be informed of other treatment options to treat opioid use disorder so that they may make an informed decision about starting MT (see 5. ALTERNATE TREATMENT OPTIONS TO METHADONE/ BUPRENORPHINE, pages 3–5) regarding other treatment options).

Patients should have a significant history of any of the following:

1. opioid use disorder for at least one year or significant biopsychosocial complications from opioid use disorder of less than one year;
2. a history of opioid use disorder and failure of abstinence-based treatment;
3. a history of opioid use disorder and a small likelihood of benefit from non-methadone/buprenorphine treatment;
4. opioid use disorder and pregnancy; and/or
5. opioid use disorder and major medical illness.

Patients may be suitable candidates for MT even if it has been unsuccessful or discontinued in the past.

4.2 Special Situations

- ***Adolescents***

  Adolescents of a younger age (younger than 18) may be considered for MT in special circumstances. In cases where a doctor considers it appropriate to offer an adolescent MT, it is recommended that he or she seek assistance by referral, or by consultation with a physician knowledgeable in addiction medicine. Care options should also be discussed with the patient's family.

- ***Pregnancy***

  MT has been shown to improve both maternal and neonatal outcomes in pregnant opioid-dependent women. Referral to, or guidance from a physician experienced in managing the care of the pregnant opioid-dependent patient is strongly advised. It is recommended that, if willing, unstable pregnant patients be stabilized in hospital (for methadone/buprenorphine initiation if necessary).

  The addiction unit at the Health Sciences Centre and the AFM M.I.N.E. Clinic will assist with rapid access to treatment or stabilization of a pregnant patient and will help the patient access further care if appropriate.

- ***Chronic Pain***

  For people who have chronic pain but who also have lost control of the use of opioid medication, and where other methods fail in returning to stability, MT can sometimes be helpful.

5. ALTERNATE TREATMENT OPTIONS TO METHADONE/ BUPRENORPHINE (ABSTINENCE-BASED TREATMENT)

Methadone maintenance treatment used to be recommended only when other treatment

methods failed. MT is now recognized as effective treatment for opioid use disorder for patients with intravenous use, lifestyle instability, or physical complications; it is appropriate to offer methadone/buprenorphine as the best initial treatment option.

However, physicians may also assess some patients as being appropriate for abstinence-based treatment. Many patients will want to attempt abstinence-based treatment before willingly committing to the long-term, highly structured treatment plan of MT. Physicians and patients should decide together, where resources permit, which treatment plan is most appropriate. Patients wishing to pursue abstinence should consider a long-term residential treatment program (such as a therapeutic community) to follow detoxification.

Physicians and patients need to be aware that long-term abstinence is difficult and relapse rates are high. Patients and their families need to have information about and access to ongoing addiction care or changing to MT if active addiction should recur.

5.1 Withdrawal Management

Careful patient selection with a detailed treatment agreement is necessary. Inpatient or outpatient detoxification can be attempted using a tapering dose of any of the long-acting oral opioids or by stabilizing the patient on methadone or buprenorphine and then tapering the methadone/buprenorphine dose. The taper of methadone/buprenorphine may be done over a one to two week period in an inpatient setting or over 1-6 months in an outpatient setting. Restricted dispensing (often daily dispensing) with regular clinical contact is necessary for those on outpatient treatment plans. Adjuvant medication may make withdrawal symptoms more manageable (see 20. OPIOID DETOXIFICATION/WITHDRAWAL MANAGEMENT, page 47).

Relapse to opioid abuse is common, especially when the patient reaches a lower dose of opioids. Urine drug testing should be performed as appropriate and DPINs (pharmacy dispensing records) should be reviewed intermittently.

Patients who do manage to taper to a low dose of opioids are at particular risk of overdose or death if they relapse, as they are now intolerant of the high doses they have been using.

Opioid tapering needs to involve further addiction care. Some options are suggested below.

5.2 Residential Programs

Long-term (3-12 months) treatment in a therapeutic community should be considered for patients seriously wishing to achieve and maintain abstinence. In Manitoba, the Behavioural Health Foundation will allow patients to be on a tapering dose of methadone/buprenorphine for the first month of their stay.

Shorter residential treatment options are available through AFM and some faith-based organizations, and can be followed up by supportive halfway housing.

5.3 Treatment for Other Addictions

Many opioid-use disorder patients abuse or are dependent on alcohol or other drugs. Detoxification from alcohol, stimulants or benzodiazepines may also need to be organized.

5.4 Outpatient and Day Treatment Programs

Outpatient and day treatment programs are available through AFM. They provide support and addiction counseling, with less disruption of home life. This may be offered to patients with more stability in their lives.

5.5 Support Groups

Support groups such as the AA and NA are available throughout the province and provide ongoing support for addiction recovery.

5.6 Family Counseling

Families may access family counseling through professional organizations or they may seek support through groups such as Alanon and Families Anonymous. Employment Assistance Program (EAP) and organizations such as Blue Cross can provide outpatient addiction counseling for some employed/insured patients.

6. ASSESSMENT

6.1 Assessment for Admission to MT

General

- The physician must confirm the patient has a diagnosis of opioid use disorder.
- The patient must be given adequate information about methadone/buprenorphine and the MT program to give informed consent.
- If appropriate, abstinence-based options should be reviewed with the patient.

Full Assessment

A full assessment consisting of the following procedures should be carried out:

- A medical history of the patient should be noted down.
- A primary caregiver should perform a general physical examination. Special attention should be given to signs of opioid withdrawal, malnutrition, jaundice, hepatosplenomegaly, cardiovascular and respiratory status, pupil size, needle tracks, and abscesses.
- If a clinic chooses not to provide physical examination services, the client should be asked to arrange a physical examination with a primary care provider.
- Drug use and treatment history should be noted down.
- A psychosocial assessment should be carried out. This would include an assessment of housing, employment, financial issues, legal issues, stability and support of family and close friends, and issues regarding childcare.
- Laboratory tests such as the following may have to be performed:
  - urine drug screen;
  - CBC, liver function, creatinine and blood sugar tests;
  - urinalysis;
  - pregnancy test (if appropriate); and
  - with patient consent: HIV tests and Hepatitis ABC tests.

The assessment may be done in narrative form or on a standard assessment sheet (Appendix C: Intake/Initial Assessment for MT (Sample), page 55). The patient should review and sign the required consent forms.

Treatment goals that include the following should be discussed:

1. Goals for safety regarding self and others so that methadone is safely stored, safely used and not diverted must be clarified. (Consider using a patient safety guide in early treatment. See page 12.)
2. Goals around opioid and other drug and alcohol use must be reviewed.
3. Goals must be set to improve psychosocial function and will give attention to the following needs:

- need of counseling or improving coping skills;
- need of addressing family problems;
- educational needs;
- financial needs;
- need of advice on legal problems;
- need of support regarding housing issues; and
- need of support regarding employment issues.

6.2 Assessment at Regular Clinic Visits

The physician should review the following:

1. current methadone/buprenorphine dose;
2. any signs or symptoms suggestive of need for dose change;
3. illicit drug or alcohol use or use of mood-altering drugs (consider review of pharmacy record);
4. current urine drug screen;
5. the presence of signs or symptoms of intoxication or withdrawal;
6. the presence of any acute stressors or acute medical problems; and
7. The appropriateness of change in carries (take-home medicine).

There should be documentation of the new methadone/buprenorphine prescription and any other prescriptions given. Physicians may choose to use a form or make narrative notes (see Appendix C: Intake/Initial Assessment for MT (Sample), page 55).

Periodically the physician should review:

- safety issues regarding the locked box;
- common potential side effects (constipation, sexual difficulties, and weight gain);
- need to consider referral for treatment of chronic health conditions (e.g., Hepatitis C);
- if there is a need for serum methadone/buprenorphine level, ECG, or other laboratory tests;
- if more intensive counseling or other treatment would be appropriate; and
- safety and stability issues concerning housing, family, relationships, and work.

If any of these functions would be delegated, the physician would remain responsible for the clinical decisions.

7. PATIENT INFORMED CONSENT/TREATMENT PLAN

Clinics may develop their own consent form. One sample agreement that addresses multiple areas of concern is shown on the next page.

Methadone/Buprenorphine Treatment Agreement and Consent

The prescribing and dispensing of methadone/buprenorphine is regulated by provincial guidelines, as well as policies unique to the clinic's practice at _____ practice. This contract has been prepared to inform you about methadone/buprenorphine maintenance therapy, as well as to document that you agree to the rules/obligations contained in this agreement.

Acknowledgements

I, _____, acknowledge the following:

1. Methadone/buprenorphine is a combination of opioids (i.e., drugs like heroin, codeine, morphine, Percocet., etc.), and that I will develop a physical dependence on this medication. Sudden decreases in dose or discontinuation of this medication will likely lead to symptoms of opioid withdrawal.
2. I am already physically dependent on at least one form of opioid and I am unable to discontinue the use of opioids.
3. I have had the opportunity to review if abstinence based treatment would be appropriate.
4. Taking any mood-altering substance with methadone/buprenorphine can be potentially dangerous. I am aware of reported deaths caused by the combination of methadone/buprenorphine with alcohol, opioids, cocaine, barbiturates, and/or tranquillizers.
5. It is important to inform any physician/dentist who might prescribe an opioid to me that I am taking methadone/buprenorphine.
6. I may voluntarily withdraw from the treatment program at any time.
7. Regarding pregnancy, I understand that there can be withdrawal symptoms in the baby caused by methadone/buprenorphine and that specialized care may be required for some days after birth.
8. It may be unsafe to drive a motor vehicle or operate machinery during the stabilization period after starting methadone/buprenorphine and during dose adjustments.
9. The common side effects of methadone/buprenorphine are sweating, constipation, decreased sexual function, drowsiness, increased weight, and water retention. These are usually mild and can be lessened with assistance from my doctor. There are also potential problems with sleep apnea or cardiac arrhythmias on higher doses of methadone.
10. I acknowledge that Dr. _____ is not my family doctor.
11. Methadone/buprenorphine treatment will be discontinued or tapered 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 be made worse by methadone/buprenorphine administration or I behave unsafely in the program).
12. I acknowledge that methadone/buprenorphine payment is my responsibility and that a payment plan must be in place prior to initiating maintenance treatment.

Behaviour while in _____Clinic

I understand the following behaviour is unacceptable in the clinic and may result in the termination of treatment:

1. any violence or threatened violence directed toward the staff or other patients;
2. disruptive behaviour in the clinic or the surrounding vicinity of the methadone/buprenorphine clinic;
3. any illegal activity, which includes selling or distribution of any kind of illicit drug in the clinic or the surrounding vicinity of the methadone/buprenorphine clinic; and/or
4. illegal activity or disruptive or threatening behaviour at the pharmacy.

I agree to maintain positive, respectful behaviour towards other program patients and staff at all times when in the clinic. Threats, racist or sexist remarks, physical violence, theft, property vandalism, the possession of weapons, and selling or buying illicit substances while on clinic property are extremely serious program violations and may result in the termination of my treatment and/or police intervention.

Obligations of being in this program

1. I agree to take only one dose of methadone/buprenorphine a day, unless a split dose is prescribed for use, and to have the ingestion of my dose witnessed on those days that I do not have carries (take-home medication).
2. It is important to inform any prescribing physician or dentist who may provide treatment for any medical or psychiatric condition that I am receiving methadone/buprenorphine so that my treatment can be tailored to prevent potentially dangerous interactions. I will report any prescriptions that I receive from other doctors to the addiction clinic staff.
3. I agree to provide a urine sample for a drug screen when I receive a prescription for methadone/buprenorphine. (Occasionally there may be a need to provide a supervised urine sample for testing.)
4. Failure to provide a urine sample may mean that my record will be marked as a sample assumed to contain drugs and that this could reduce my level of carries.
5. I understand that tampering with my urine sample in any way is a serious violation of the program, and that it may affect my future status in the program.
6. I understand that counseling is highly recommended while I am in the program.
7. I agree to keep all my appointments with the physician who is prescribing methadone/buprenorphine for me. Repeatedly missing appointments may result in the reduction of my carry status and could interfere with the doctor-patient relationship. The physician is not obligated to supply a methadone/buprenorphine prescription without an assessment.

I understand that I will not be given a dose of methadone/buprenorphine if I

1. appear to be intoxicated or under the influence of some other substance. (I may be asked to see a physician or a delegate of the physician. For the sake of my own physical safety, I may be asked to wait before receiving my dose, or refused a dose for that day.)

2. arrive late, or after the clinic/pharmacy closes.
3. exhibit threatening or disruptive behaviour towards any staff member or another patient.
4. do not show proper identification before receiving methadone/buprenorphine, if asked for identification.
5. miss three or more consecutive doses of methadone or five consecutive doses of buprenorphine. (The dose of medication needs to be lowered after multiple missed doses.)

Regarding carries (take-home methadone/buprenorphine doses)

1. I am aware that methadone/buprenorphine is a potent medication. **A single dose taken by a person 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 and store it in in a location where it is unlikely to be stolen or accidentally taken by another person.
2. I agree that my physician with input from therapists, nurses, and pharmacy staff will decide the number of take-home doses I receive as I progress in my treatment.
3. I agree not to give, lend, or sell my take-home dose(s) to anyone.
4. I agree that I will consume the methadone/buprenorphine on the dates specified on the medication label and in the appropriate manner, i.e., a full dose taken within every 24 hours.
5. I agree to return all empty methadone bottles at the pharmacy on the day directly after the day I have received take-home dose(s), if I am requested to do so by clinic or pharmacy staff.
6. I agree that take-home doses will ***only*** be given if I leave urine screens according to the schedule arranged with my doctor.
7. If I miss an appointment and a prescription runs out, I will be asked to attend the clinic in person before a new prescription is given. Carries may also be restricted.

Consents

- I allow my methadone/buprenorphine prescribing physician to speak to other doctors or health care professionals about my care.
- I allow the clinic's pharmacist and nursing staff to speak to pharmacists or other health care providers to verify my recent methadone/buprenorphine dose(s) I have received at another pharmacy or institution. (Nurses and other clinic staff follow PHIA and clinic policies regarding privacy and may ask for specific signed consents as necessary.)
- I allow clinic staff to review my DPIN (pharmacy prescription record) as deemed necessary by clinic staff. I am aware that a DPIN will be reviewed on admission to prevent potential adverse drug interactions.
- I allow my methadone/buprenorphine physician to speak to his/her regulatory body (The Registrar of the College of Physicians and Surgeons) to review any aspects of care if deemed necessary.

Confidentiality

Everything I tell the clinic staff is confidential, although it is important to realize that under exceptional circumstances they may be obliged to report something I tell them to the appropriate

authority. This can occur under the following conditions:

- If the clinic staff suspect that a child is at risk of emotional or physical harm or neglect, the law prescribes that they report this information.
- If I become suicidal, homicidal, or are unable to take care of myself due to a psychiatric condition, I might be held to be assessed by a psychiatrist against my will.
- If I reveal to the staff that I intend to harm another person, they will be obliged to protect that person by notifying the appropriate authority.
- If a Court subpoenas my medical chart, the staff must release it in accordance with the subpoena.
- If my behaviours or addiction raises serious concerns about safety for myself or the public, the staff may need to report concerns to an appropriate authority (e.g. notifying Motor Vehicle Branch).

I agree to respect the confidentiality of other patients in the program.

My signature below indicates that I agree to follow the obligations and responsibilities outlined in this agreement. Should I fail to meet the terms of this agreement, I understand that I may be asked to leave the methadone/buprenorphine program. ***I have had an opportunity to discuss and review this agreement with my attending physician and my questions (if any) have been answered to my satisfaction.***

_____	_____	_____
Dated (dd/mm/yyyy)	Patient's name	Patient's signature
_____	_____	_____
Dated (dd/mm/yyyy)	Physician's name	Physician's signature

8. A PATIENT'S GUIDE – AVOIDING OVERDOSE IN THE FIRST TWO WEEKS OF METHADONE TREATMENT

The clinic provides methadone care as safely as possible, but accidental overdoses sometimes happen in the first two weeks of treatment. 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, you want to get on the right dose as soon as possible. However, your doctor has to increase your dose slowly over several weeks, because your body takes time to adjust to methadone, and (unlike other narcotics), 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 methadone begins to work?***

  Only take medications that are approved by your methadone doctor. If you're on a medication prescribed by another doctor, your methadone doctor needs to approve it because it could interact with the methadone.

  Substances that make you relaxed or sleepy can be dangerous. This includes alcohol, opioids, benzodiazepines (Ativan, Valium, Xanax, Restoril, etc.), antihistamines (such as Gravol® or Benadryl), and certain types of antidepressants and tranquilizers.

  Even certain antibiotics can be dangerous as they block the breakdown of methadone in the body. So make sure to check all your medications with your methadone physician.

- ***Isn't methadone supposed to make you sleepy?***

  No. You are supposed to feel normal on methadone, not high or sleepy. Methadone builds up so slowly that it happens only occasionally that someone can feel a bit sleepy during the day, lie down for a nap and not wake up. So please take the following precautions:

  - Take your methadone at the same time each day.
  - See your doctor or case manager at least twice a week for the first two weeks. (Many clinics will require visits that are more frequent.)
  - Discuss your methadone treatment with a close friend or family member. If they see that you`re drowsy, they must call your methadone doctor or an ambulance.

- ***What are some of the symptoms if my methadone 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 or go to Emergency as you may be overdosing.

- ***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! It's probably safe for your friend, but 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 died. Remember, it takes five days for a certain dose to build up in your blood.

9. METHADONE DOSING ISSUES

It has been reported that the most common reason for death or overdose from methadone treatment is overly aggressive prescribing during the first two weeks of treatment. The combination of overestimated tolerance and underestimated accumulation is the main cause. After stabilization, the most common reason for significant complications is drug-drug interactions, typically with sedatives and/or hypnotics. Appropriate doses during each of the phases of methadone treatment are therefore vital.

This section is discussed under the following headings:

NOTE: Buprenorphine is dosed and adjusted quite differently from methadone. For a discussion of buprenorphine dosing, see 23. BUPRENORPHINE/NALOXONE (Suboxone®), page 50.

9.1 The Early Stabilization Phase (0-2 Weeks)

Methadone has a significant risk of morbidity and mortality during the early stabilization phase. Due to its prolonged half-life, serum levels increase for up to five days at the same dose. Thus, a dose that is barely adequate on day one can be toxic by day three to five.

Methadone overdose can have an insidious onset. A patient appearing relatively alert during the day may succumb because of an overdose during a nap or at night. Early signs of toxicity include ataxia, slurred speech, and euphoria. Careful prescribing, patient education and intervention at the first sign of toxicity can reduce the risk of overdose.

The following dosing protocol is therefore suggested:

- The initial dose should be 10-30 mg of methadone per day for at least the first three days. Patients at high-risk for methadone toxicity should start on no more than 10-20 mg.
- During the early stabilization phase for patients new to methadone, doses may be increased by up to 5 mg every 3-5 days, or by 10 mg increments every 7 or more days.
- During the early stabilization phase for patients new to methadone, you may elect to prescribe a single dose increase of 10 mg after 5 days, but all subsequent 10 mg dose increases should occur no sooner than 7 days apart. Alternatively, a 5 mg dose increase may be considered 5 days after a 10 mg dose increase. **Caution surrounding serial 10 mg dose increases is emphasized.**

9.1.1 Patients at High Risk for Methadone Toxicity

An initial dose of 10-20 mg with careful dosage titration is recommended for the high-risk patients described below. The care of these patients frequently warrants telephone consultation with an experienced addiction physician.

- ***Patients recently using benzodiazepine***

  Patients recently abusing benzodiazepine or using the drug for therapeutic purposes are high-risk patients. An exception might be the patient who has been on a small HS dose for at least several months.

- ***Patients using other sedating drugs***

  Patients using antipsychotic and sedating antidepressants are at high risk, particularly if the sedating drug was started or increased within the last two months, or the dose is moderate or high.

- ***Problem drinkers and alcohol-dependent patients***

  Problematic alcohol use can be identified through an alcohol history and laboratory measures (GGT and MCV). All patients should be advised to abstain from alcohol during early stabilization. If the patient is at significant risk for alcohol withdrawal, the patient needs appropriate alcohol detoxification.

- ***Patients who are older (>60 years) and have a respiratory illness***

  This group includes patients with chronic illnesses such as COPD and acute illnesses such as pneumonia.

- ***Patients who are on drugs that inhibit/promote methadone metabolism***

  If a drug that inhibits metabolism is meant for short-term use only, the physician might recommend that the patient finish the course before prescribing methadone. Conversely, patients on medications that promote rapid methadone metabolism should avoid abrupt cessation of the medication.

- ***Patients with lower opioid tolerance***

  Tolerance is difficult to establish from history; therefore, if in doubt, it is safer to initiate methadone at a lower dose. Lowered tolerance might be possible in patients who report non-daily opioid use, daily use of codeine, or daily use of oral opioids at moderate doses. A urine drug screen can be helpful in confirming the patient's self-reported use of opioids. (Urine drug screens may not detect synthetic opioids such as oxycodone and Fentanyl and they do not indicate length or severity of use.)

9.1.2 Reducing Risk during the Early Stabilization Phase

The steps described below can help to reduce risk during the early stabilization phase.

- ***No new prescriptions for sedating drugs***

  Avoid prescribing any new sedating drugs during the early stabilization phase. Patients should also be advised to avoid alcohol and over-the-counter sedating drugs.

- ***General advice to the patient and family***

  Explain to the patient that it takes several weeks to reach the optimal dose of methadone, and that it is dangerous trying to relieve withdrawal symptoms with benzodiazepines, alcohol, opioids, illicit methadone, or other drugs. Advise the patient to limit his or her driving or use of machinery after a dose increase, particularly in the first few hours after dosing. Advise the patient to take the methadone dose in the morning, since the risk of overdose is increased at night. (See the patient's guide on page 12 to give to patients and family).

  During the early stabilization phase, patients and their families (if the patient consents) should be educated about methadone toxicity.

- ***Explaining the risks of diverted methadone***

  Even a single dose of methadone can be fatal to both children and adults. Patients are responsible for the safe storage of their methadone. Physicians must advise patients that it is dangerous and illegal to sell or give methadone to anyone, even in small doses or done with good intentions.

- ***Educating the patient and family members about signs of impending toxicity***

  Whenever feasible (with the patient's consent), a family member or significant other should be educated about the symptoms of overdose or toxicity. Clear instructions should be given to contact their clinic or to go to the emergency department immediately at the first sign of toxicity. A patient information guide may be used for this purpose (see the patient's guide on page 12).

- ***Carries during initial titration***

  No carries should generally be granted during the first two months of treatment (except for Sunday carries). Some programs give weekend carries if the patient shows reliable behaviour; otherwise, daily-witnessed ingestion is arranged.

- ***Missed doses***

  During the early stabilization phase, patients should be on the same dose for three to four consecutive days with no missed dose before a dose increase. If a patient misses three or more doses consecutively, he or she should resume at the initial dose (10-30 mg) for at least three consecutive days.

- ***Negative initial urine drug screen and recent abstinence***

  If patients who report no recent opioid use have a negative initial urine drug screen, methadone should not be initiated unless they have recently been abstinent in a supervised setting (incarceration, inpatient program, etc.). These patients should have a long history of opioid use disorder, strong urges to use methadone and/or a good response to MT in the past. The initial dose should be 5-10 mg, titrated upwards every five or more days in increments of 5 mg or less, with careful assessment of withdrawal symptoms and sedation. Repeat assessment and repeat urine screens may be indicated for some patients with initial negative urine screens.

9.1.3 Summary of Recommendations for Management of the Early Stabilization Phase

- The recommended initial daily dose is 10-30 mg.
- Methadone must be dispensed in a vehicle that does not lend itself to injection (e.g. Tang®) or Methadose™.
- The methadone dose must be consumed under the direct supervision of a regulated health professional.
- Physicians should implement policies to prevent toxicity, including patient education and frequent assessment.

- Avoid prescribing any sedating drugs during the stabilization phase. Advise the patient to avoid alcohol and over-the-counter sedating drugs.

9.1.4 Doses for Patients at Higher Risk for Methadone Toxicity

Consider prescribing a lower dose (10-20 mg) for the following patient groups:

- the elderly, with underlying respiratory disease;
- users of sedating drugs (especially benzodiazepines) or alcohol, or drugs that inhibit methadone metabolism;
- patients with lowered opioid tolerance, e.g. non-daily opioid use, daily use of codeine, or moderate use of oral opioids;
- the recently abstinent with negative initial urine screen (initiate at 5-10 mg);
- patients with low body mass (<50 kg); and
- patients having concurrent acute medical illness. (Consider delay in initiating treatment until illness resolves.)

9.2 The Late Stabilization Phase (2-6 Weeks)

Most patients in the late stabilization phase are taking between 50-80 mg of methadone. During the late stabilization phase, the patient experiences only partial relief or withdrawal symptoms; he or she is only partially tolerant to methadone; and he or she might continue to use opioids. During this period, dose adjustments are usually in the 3-5 mg range every 3-7 days, depending on the severity, onset, and duration of the patient's withdrawal symptoms. Careful assessment of withdrawal symptoms is essential.

The care manager or physician of the patient should see him or her at least weekly to assess and adjust their dose. All dose adjustments require an assessment. Avoid automatic dosage adjustments on the prescription (for example, 'Increase by 5 mg daily'). (A clinic case manager may adjust doses in accordance with written physician instructions.)

9.3 The Maintenance Phase (6 Weeks +)

By this time, most patients have substantially reduced their opiate use, they are largely tolerant to methadone, and experience no withdrawal symptoms for most of the day. They may occasionally ask for dose increases because of episodic subjective withdrawal symptoms, opioid cravings, or a relapse to opioids. During the maintenance phase, or if the dose is 80 mg or higher, dose adjustments are typically between 3 - 5 mg every three to seven days.

Stable Daily Dose

The optimal daily dose of methadone will relieve withdrawal symptoms, block opioid-induced euphoria and reduce drug cravings without sedation or other significant side effects. Urine drug

screens should be negative for opioids most of the time. With experience, physicians can establish the stable dose for the majority of their patients within two to eight weeks of initiating MT. The stable dosage range for most MT patients is 50-120 mg.

9.4 Summary of Recommendations for Dosage Adjustment during the Late Stabilization and Maintenance Phases

- Doses should only be increased after the physician (or case manager with physician consultation) has assessed the patient, and determined that the patient has symptoms of withdrawal, ongoing opioid use, or opioid cravings.
- During the late stabilization phase, doses should be increased by no more than 5-10 mg every three to four days. Extra caution is advised for high-risk patients.
- During the maintenance phase, or if the dose is 80 mg or higher, the dose should be increased by no more than 3-5 mg every three to seven days.
- For most patients, the optimal dose is between 50 and 120 mg. Some patients will stabilize at lower doses.

9.5 Management of Low Maintenance Doses

Low-dose maintenance, below 50 mg.

Some patients stabilize at lower than average doses. Low-maintenance doses are justified for patients for the following groups of patients: those who have no unauthorized opioid use; those who report no significant withdrawal symptoms or cravings for opioids; those who have a history of low-potency opioid use; those who are at high risk for methadone toxicity; and those who are on a tapering protocol.

Doses below 50 mg are generally less effective than higher doses at reducing heroin and other high-potency opioid use and retaining patients in treatment.

9.6 Management of High-maintenance Doses of Methadone

Maintenance doses are above 120 mg.

Some patients who require maintenance doses above 120 mg may have either a higher innate tolerance secondary to long-standing opioid use, or increased metabolism of the methadone secondary to certain conditions or medications (e.g. some HIV medications). Patients on high doses should be granted dosage increases if they consistently report a cluster of withdrawal symptoms that occur at a predictable time at the end of a dosing interval. The cluster should include both physical and psychological symptoms. The physician should assess the patient for other conditions that are commonly confused with withdrawal. Drug craving alone may not be an adequate reason to increase the dose above 120 mg. Doses above 120 mg warrant consideration of trough methadone levels after three to five days of witnessed ingestion.

The three to five days of witnessed ingestion should take place at the same time of day; the trough level is measured 24 hours after the last dose.

Tapering from Higher Doses

The clinician might periodically broach the subject of tapering with the patient on high doses. Clinical experience has found that patients sometimes report feeling more alert and energetic after being tapered from high doses, and some patients are able to decrease their dose by 20-40 mg with relative ease. The dose should be tapered by no more than 5-10% of the dose every one to two weeks. The taper should be held or reversed if the patient reports persistent, uncomfortable withdrawal symptoms.

Risks of Prolonged Q-T Interval

Methadone (at higher doses) causes modest prolongation of the Q-T interval, with a small minority of patients (approximately 2%) crossing a threshold associated with increased risk for arrhythmia (especially torsade de pointes). There is no consensus on ECG screening.

- Some guidelines recommend that ECG screening be done prior to methadone treatment, after one to three months, and annually.
- Patients with a history or physical examination that suggests possible cardiac problems should have an ECG performed.
- An ECG is suggested for patients on a methadone dose higher than 120 mg. It should be repeated at doses of 150 mg, 180 mg, and 200 mg. If the Q-T interval exceeds 450 msec (men) or 470 msec (women), decreasing the methadone dose and avoiding other medication that affects the Q-T interval should be considered. Buprenorphine may be considered in select patients.
- If the Q-T interval exceeds 500 msec, cardiology consultation and decreasing the methadone dose are suggested.
- Other factors that may increase risk are cocaine and alcohol intoxication, electrolyte abnormalities, and a structural heart disease.
- Risks (specifically risk of arrhythmias) and benefits of high dose treatment should be reviewed with the patient.

Consideration of Dose Tapering in Older Patients

Metabolic, cardiac, respiratory, and cognitive functions change with aging. Physicians should review the situation of older patients to establish if a slow taper to a lower dose would be beneficial.

Summary of Recommendations for Management of Patients on Doses Higher than 120 mg.

- Only grant dosage increases if the patient reports a cluster of withdrawal symptoms toward the end of a dosing interval and/or ongoing opioid use. Drug craving alone is not an adequate reason to increase the dose.
- If the patient continues to report withdrawal symptoms despite a high dose, the physician should systematically look for causes of opioid withdrawal and common conditions that are easily confused with withdrawal.
- Consider need for trough levels for doses over 120 mg.
- A consultation should be considered if the physician has continuing difficulty in stabilizing the patient's dose above 150 mg.
- A cardiogram should be obtained of all patients at doses higher than 120 mg, and repeated as the patient approaches 150-200 mg. Patients with a Q-Tc interval of 470 msec or above should be carefully reviewed to see if tapering methadone to a lower dose would be helpful.

9.7 Split Doses of Methadone

Split dosing consisting of two or more doses per day is an alternate way of providing methadone to patients. Some clinics may not be able to provide split dosing. Split dosing is not often necessary and it is not recommended for any patient who does not meet the criteria of clinical stability or who are not eligible for "carry" doses. There are three indications for split dosing:

1. *Chronic pain sufferers:* Split dosing can be used for clinically stable patients who suffer from chronic pain when non-narcotic pain medications have been ineffective. In certain situations, temporary split dosing may benefit clinically stable patients who suffer from acute pain. However, once the pain is resolved, single dosing should be resumed.
2. *Rapid metabolizers*: Split doses are also used for patients who have demonstrated rapid metabolism of their once daily methadone/buprenorphine dose or who are on medications that have been shown to induce rapid metabolism of methadone/buprenorphine (i.e., certain HIV medications). A consultation with an experienced MMT provider should be considered in these circumstances.
3. *Pregnant patients*: These patients may report withdrawal symptoms in the evening or night hours. A small portion of the dose may be given in the evening to see if symptoms improve.

How to Assess for Rapid Metabolism of Methadone

1. Arrange for three to five consecutive days of observed ingestion of methadone.
2. Draw a trough level (just before ingestion) and a peak level (four hours post dose).
3. If the peak level is more than twice the trough level, the patient is exhibiting rapid metabolism.

9.8 Missed Doses and Loss of Tolerance to Methadone

Missed doses may indicate a variety of problems, including relapse to alcohol or other drug use. Pharmacists should report missed doses to the prescribing physician or the clinic in a timely manner (preferably the same day).

- ***One or two days missed***

  Patients who have missed their methadone dose(s) for one or two days can be given their usual prescribed dose, provided they are not intoxicated.

- ***Three consecutive days missed***

  Patients who have not picked up their dose for three days or more should not be medicated until the prescribing physician or case manager has reassessed them. The remainder of their prescription should also be cancelled. A clinically significant loss of tolerance to opioids may occur within as little as three days without methadone. For this reason, the physician should reduce the methadone dose because the usual dose carries a risk of toxicity.

  If the usual dose is 30 mg or less, the prescribing physician may direct that the prescription be continued at the same dose after the patient has been assessed. For doses larger than 30 mg, the common practice after three missed days is to restart the patient at 50% of his or her usual maintenance dose. Usually the reduced dose should be no less than the initial dose of 10-30 mg. After tolerance to the reduced dose has been demonstrated, the dose can be rapidly increased (by no more than 10 mg per day) if daily supervision occurs. Slower dose escalation is suggested for patients with an unstable clinical picture or concurrent benzodiazepine use. The patient should be assessed at least every two to three days during this titration.

- ***Four or more days missed***

  After missing four or more days of methadone, the most prudent course of action is to restart methadone at 30 mg or less. After assessing the patient's response to this new dose, the dose can be increased quickly (10 mg every 3 days) toward the previous stable dose, with reassessment by the physician or case manager every two to three days.

9.9 Vomited Doses and Guidelines for Replacement Doses of Methadone

Vomited methadone doses are not replaced, neither in full or in part, unless a health professional or staff member directly observes emesis. It is impossible to empty the gut completely, even with violent emesis. Repeated dose replacement involves the risk of unexpected overdose. Underlying causes of the vomiting should be addressed. After a replacement dose, patient should be observed for 30 minutes.

Guidelines for replacement doses

1. One may choose not to replace the vomited dose.
2. If emesis occurs less than 15 minutes after consumption, consider replacing 50-75% of the full dose. If the dose is in the high range above 120 mg, consider replacing only 50% of the full dose.
3. If emesis occurs at between 15 and 30 minutes after consumption, consider replacing 25-50% of the full dose.
4. If emesis occurs at more than 30 minutes after consumption, do not replace the dose.

In the case of MMT patients who are pregnant, the physician may decide to prescribe a replacement dose even if the pharmacy or clinic staff have not observed emesis. It is very important that pregnant MMT patients do not go into withdrawal. It may be necessary to arrange observation of the patient for some hours. Pregnant patients with significant nausea and vomiting can choose to sit quietly at the clinic or pharmacy after their methadone dose, both to decrease the risk of vomiting and to have it observed if it occurs.

9.10 Intoxicated Patients/Withholding Doses

Patients may appear intoxicated from alcohol or drugs. Concurrent use of sedatives such as benzodiazepines greatly increases the risk of methadone/buprenorphine toxicity. Intoxicated patients should not be medicated with methadone/buprenorphine until they have been reassessed by the physician or case manager and found to be unimpaired. If a patient is found to be impaired after methadone/buprenorphine ingestion, consideration should be given to clinic or emergency room observation.

9.11 Methadone Tapering

Tapering is most likely to be successful if the patient

- has been abstinent from illicit substances for a substantial period;
- does not have current, untreated psychiatric co-morbidity; and
- has strong social support and counseling.

Full discussion about the patient's motivations, strength and current problems should occur. The taper should be slow, usually no more than 5-10% of a dose per week. The taper should be slower

at lower doses, particular below 20 mg, to concur with withdrawal symptoms becoming more pronounced. The patient should play a major role in deciding the rate of the taper. The taper should be accompanied by counseling and regular office visits.

Methadone tapering can precipitate significant withdrawal symptoms, particularly at doses below 20 to 30 mg. The taper should be halted or reversed if the patient relapses to drug use, or if he or she experiences severe withdrawal symptoms, cravings, or clinical instability. For more details of managing withdrawal, see 19. Withdrawing from Maintenance Treatment, pages 43-46.

9.12 Management of Wrong Dose/Overdose

On occasion, a dosing error of methadone may occur at the clinic or pharmacy, or a severely sedated patient may attend the clinic. If the dose that has been given is significantly higher than usual (10% higher than the usual dose), the clinic staff must notify a clinic physician. The clinic staff should ask the patient to remain for observation for two to four hours. For high dose ingestions or if the patient shows any signs of sedation, the following steps should be followed:

- The clinic staff should recommend and help to arrange transfer to an emergency department and provide appropriate information to the receiving institution.
- Consider the need for involuntary transfer to a hospital if the nurse or physician has significant concerns.
- Consideration should be given as to whether Narcan® should be available in the clinic setting to be given as an IM injection if the physician should order it. (Note: Other health staff must be available to assist and to detain the patient, as a patient in a condition of near unconsciousness may wake up and become agitated or angry.)

The risk of toxicity is also affected by other factors, such as the stage of treatment, age of the patient and health issues. Patients in the early the stage of treatment, the elderly and patients with respiratory illness are more prone to toxicity. Even a small “extra” dose of 20 mg of methadone might cause harm in such patients.

If the patient is referred to the emergency department, the methadone physician or nurse should speak to the ER staff and advise them that

- the patient should be observed for a minimum of 10 hours; and
- the patient should not be discharged if he or she is showing any signs of lethargy or sedation.

10. PRESCRIPTIONS & PHARMACY ISSUES

1. Methadone/buprenorphine prescriptions must be written on a duplicate prescription (except in a hospital setting).
2. The dose must be written numerically and in words. The prescription must be legible and

clear, also with regard to the dose prescribed.

3. Methadone syrup is dispensed as 10 mg/ml liquid usually diluted with Tang® or juice. An exception may be made for patients stabilized for a significant amount of time; they may be eligible for tablets or capsules at the discretion of the physician.
   In late 2014, Manitoba Health decided to change from methadone compounded by pharmacists, to a preparation called "Methadose™", which comes pre-mixed at 10 mg/ml. Pharmacies will most likely label doses in millilitres, e.g., an 80 mg dose would be labelled Methadose™ 8 ml. Patients who travel out of province with short term prescriptions should be certain their correct dose is confirmed by the pharmacist, who may see the majority of prescriptions written in millilitres.
4. The prescription must clearly state the first day and the last day of the period covered by the prescription. No doses are to be given beyond the last day without consultation between the pharmacist and the prescribing physician.
5. The prescription (or an accompanying pharmacy agreement) must clearly describe carried doses and which doses are to be taken by witnessed ingestion.
6. A new prescription must be written for any change from a previously stable dose.
7. The practice of having pre-signed blank prescriptions in the clinic is unacceptable.
8. The physician copy of the duplicate prescription must be retained and must be identical to the copy issued to the patient.
9. Any new prescription cancels the previous prescription. If the patient is changing pharmacies, the previous prescription should be cancelled.
10. The patient is at risk when methadone/buprenorphine is dispensed at two or more pharmacies, and this should be done only if no alternative exists. The patient could potentially receive two doses on one day, or the pharmacist could be unaware of missed doses.
11. The prescribing physician (or clinic) must have a clear agreement with the pharmacist concerning spoiled, lost, and missed doses. (See the sample instruction letter of the methadone/buprenorphine clinic in Appendix E: 65Letter to Pharmacy (Sample), page 65.)

11. URINE DRUG SCREENING

Results of urine drug screens can be used as an aid in verifying the patient's self-reporting of substance use, assessing compliance with methadone/buprenorphine, and assessing response to treatment. Results of the urine drug screens require clinical interpretation by a physician. Patients not willing to comply with urine testing as directed, will not receive carries except in exceptional circumstances and may be discharged from the program.

- ***Urine Collection***

  If tampering is suspected, the physician should be notified. Whenever possible, a second sample should be collected the same day. In select difficult cases, direct observation may be appropriate.

- ***Frequency of Urine Testing***

  At least one urine drug screen must be documented prior to initiation on methadone/buprenorphine; thereafter, urine testing can be done to a fixed or random schedule. Screening should be continued during the maintenance phase, particularly during the acquisition of carry privileges to confirm sustained abstinence. Frequency of urine collection should be increased in the event of a lapse, relapse, or signs of clinical instability. A patient admitting to problematic drug use should still be ordered to have a urine drug screen to see if he or she is using more or less drugs than stated.

  For stable patients and all those receiving carries, urine drug screens should be done every three months at a minimum. Some clinics order ongoing frequent urine drug screens (1-2 times a week). The methadone physician should ensure that frequent urine tests do not interfere with a stable patient's family responsibilities, work, or with other obligations.

Urine Toxicology

It is important to detect substances that may interact dangerously with methadone/buprenorphine or that are associated with significant lifestyle instability. It is important to check for methadone/ buprenorphine (or metabolites) to be sure the client is taking methadone/buprenorphine.

The physician must carry out and review a urine drug screen before initiating methadone treatment. If the urine drug screen is negative for opioids, the physician must write an explanatory note to motivate the need for methadone treatment.

Two types of testing are available:

1. *Point of care (immunoassay) testing*.
2. *Gas chromatography testing:* This test is more expensive. It carried out at a major laboratory site, and it may take one to two weeks to receive results. This test can identify specific opioids, illicit drugs, and other drugs such as gabapentin or Gravol®, which may also be abused.

Most often, immunoassay tests are done. Gas chromatography testing can be ordered in unusual situations or in cases where patient history does not match urine immunoassay results.

- At a minimum, tests for cocaine, benzodiazepines, amphetamines, opioids and methadone/buprenorphine should be requested.
- Oxycodone is currently a frequent drug of abuse and can be detected by a specific screening test.
- Synthetic and semi-synthetic opioids like oxycodone, Fentanyl, and methadone/buprenorphine are unlikely to be detected unless a specific screening test is used.
- Many, but not all clinics choose to test for marijuana and consider restrictions of carry privileges as the clinic staff might feel to be appropriate.

- Urine tests that are positive for cocaine, benzodiazepines, or opiates suggest significant lifestyle risks; carries should be restricted if these tests are positive.

Continued illicit drug use, as determined by urine drug testing, is not in itself an indication to withdraw a patient from MMT. Overall risks and benefits of MMT need to be reviewed on an individual basis rather than withdrawing a patient using illicit drugs from MMT.

12. CARRY POLICY

Take-home doses as part of contingency management, are effective in reducing substance use and retaining patients in treatment. Patients value take-home doses very highly. Treatment retention rates are lower in clinics with restrictive carry policies.

However, methadone/buprenorphine diversion is common, and most methadone/buprenorphine related deaths are due to diverted methadone/buprenorphine. Therefore, patients must be assessed for stability before receiving carries.

The impact of restrictive take-home policies on mortality is not known. While a restrictive take-home policy would likely reduce deaths from methadone/buprenorphine diversion, its impact on overall mortality is unclear. Currently, only 15-20% of opioid dependent patients are on methadone/buprenorphine treatment in Canada, and restrictive policies are cited as one of the factors in dissuading patients to enter treatment. The annual mortality rate of methadone/ buprenorphine patients is one quarter the rate for heroin users, primarily due to fewer deaths from overdose and suicide. The overall mortality rate of heroin users declines sharply with entry into treatment, and climbs again with discharge. Thus, while restrictive policies might reduce diversion, they might also reduce treatment retention and increase mortality by increasing the population of untreated opioid users.

12.1 Safety Considerations

> Prior to initiating carries, it is imperative that physicians advise patients of the potential danger to the opioid naive, particularly children, of consuming methadone/buprenorphine and the need to store the carries in a locked box.

The following three criteria should be assessed prior to initiating carries and/or increasing/decreasing the level of carries.

Clinical Stability

Patients are clinically stable when they demonstrate the social, cognitive and emotional stability necessary to assume responsibility for the care and safeguarding of methadone/buprenorphine

and use it only as prescribed.

Clinical stability can be shown when the following criteria have been demonstrated:

- The patient has eliminated sustained problematic drug or alcohol use and demonstration of mostly negative urine drug screens.
- The patient's methadone/buprenorphine dose is stable.
- The patient is emotionally stable.
- Housing, employment or schooling, and/or a stable support system are in place.
- Adherence to the methadone/buprenorphine treatment agreement and program requirements is demonstrated.

The Length of Time in Methadone/Buprenorphine Treatment

Carries are not recommended during the first two months of treatment (except for Sundays).

Ability to Safely Store Methadone/Buprenorphine in a Locked Box

For patients with unstable living arrangements, such as those living on the street or in hostels without storage facilities, it may not be appropriate to receive carries.

It is recommended that the patient store methadone/buprenorphine carries in a locked box and that it be shown to the physician when carries are initiated. The use of a locked box should be specified in the treatment agreement. The regular pharmacy the patient attends may be informed not to dispense carries unless a locked box is demonstrated by the patient. Safe storage of carries by using a locked box should be assessed periodically by the physician and pharmacist.

12.2 Carry Schedule

In general, after the first two months in treatment, methadone/buprenorphine patients who meet the criteria for clinical stability (see Clinical Stability, page 26) can receive one additional carry per month **each month** to a maximum of six carries per week (one witnessed dose in the pharmacy, six take-away carry doses). The table below sets out the criteria.

TABLE 1: Carry Schedule

Criteria	# of Carries

Meets stability criteria and – has been on methadone/buprenorphine for at least 2 months	1 (plus Sunday)
Meets stability criteria and – has been on methadone/buprenorphine for the past 3 months	2 (plus Sunday)
Meets stability criteria and – has been on methadone/buprenorphine for the past 4 months	3 (plus Sunday)
Meets stability criteria and – has been on methadone/buprenorphine for the past 5 months	4 (plus Sunday)
Meets stability criteria and – has been on methadone/buprenorphine for the past 6 months	5 (plus Sunday)

Patients who have occasional non-problematic drug use may be appropriate to receive carries, provided the physician determines that they are clinically stable and are able to store their medication safely. However, the number and progression of carries on their schedule would be reduced. Physicians should clearly document these exceptions. Overall life stability and responsible attitudes are just as important to consider, as well as drug screen results.

When a patient demonstrates risky behaviour (see 12.4 Managing Relapse, page 28), the prescribing physician must reassess the progression of carries and/or level of carries. **The decision to give carries must take into consideration both patient safety and public safety.** Some clinics may choose to adopt a slower and more cautious rate of allowing carries.

12.3 Reassessment and/or Reduction of Carry Privileges

A reassessment and possible reduction of a patient's carry privileges should be undertaken when any of the criteria for clinical stability are not met. Examples are mental health problems or legal incarceration.

Patients who consume carries early, report lost or stolen carries, or frequently vomit carries, should have their level of carries reassessed.

12.4 Managing Relapse

A relapse is defined as a return to sustained problematic drug use, along with loss of clinical stability. A relapse to mood altering substances indicates reduced stability in the patient; consequently, the level of carries must be reduced. Physicians may consider not reducing the level of carries following a single episode of drug use (a slip or lapse) if the episode appears to be over and the patient does not demonstrate other signs of instability. Physicians may increase the frequency of clinical re-

assessments (i.e., office visits, urine drug screens) until stability is re-established.

12.5 Proposed schedule for carries during a sustained relapse

- Patients who demonstrate continued sustained use and/or clinical instability should have all carries discontinued.
- Reduce a minimum of one carry per week for each positive urine sample (typically tested once per week), if the patient remains clinically stable.
- Reset carries to the previous level at a rate no greater than an increase of one carry per week for each negative urine sample (typically tested once per week), if the patient is otherwise stable and meets the criteria.

12.6 Complete Forfeit of Carries

All carry privileges should be removed for the following reasons:

- The patient has diverted his or her methadone/buprenorphine.
- The patient has tampered with his or her urine sample.
- The patient has ingested his carries early and run out of methadone.

Physicians should be aware that the risk of overdose could be increased with resumption of daily dispensing at the pharmacy if the methadone/buprenorphine carries have not been consumed as directed. All carries must be abruptly removed. It may be appropriate to reduce the daily-dispensed dose to 50-75% of the original dose. If the methadone/buprenorphine dose is reduced, the patient should be assessed regularly for signs and/or symptoms of withdrawal and appropriate dose increases should then be made.

12.7 Measures to Reduce Risk of Diversion

Patients may be asked to return empty labelled carry bottles on each visit to the doctor or pharmacy, or they may be randomly asked to show unused carry bottles to the doctor.

12.8 Exceptions to the Carry Schedule

All exceptions to the carry schedule must be clearly documented.

12.9 Carries and Benzodiazepines and Other Mood-altering Prescription Medications

The risk of abusing benzodiazepines, prescription opioids, and other potential drugs of abuse is increased in a patient who has already demonstrated a history of substance abuse and/or dependency. Benzodiazepines and other potential drugs of abuse should only be used as a last resort and only after less addictive medications have been used to treat the same condition. Patients being prescribed medications with abuse potential may receive more than one carry per week if the following conditions are met:

1. The patient meets the criteria for clinical stability.
2. The prescribing physician has made a specific medical diagnosis that warrants the use of the medication. A second opinion (formal or informal) should be sought from a physician knowledgeable in addiction medicine to support the use of the medication. He or she should document his or her opinion.
3. The medication should be dispensed with the methadone/buprenorphine in a controlled fashion. The methadone/buprenorphine prescriber should communicate with other physicians involved in the patient's care to establish which provider will prescribe the medication.
4. Early refills should not be granted, and lost or stolen medication should not be replaced.
5. The patient's condition that warrants the prescription should be reassessed on a regular basis.
6. A taper of the medication may periodically be attempted. For example, with benzodiazepines, a taper schedule may be established at the outset to ensure a gradual decrease of ingestion. If the patient is found to be destabilized with the taper, it will be reasonable to maintain the medication as prescribed in a controlled manner and at a reasonable dose. Evidence of misuse should result in tapering the medication.
7. Patients continuing to use benzodiazepines generally should not receive full carries.
8. Also, see sections 15. METHADONE/BUPRENORPHINE AND PAIN, pages 33 ff., and 16. USE OF BENZODIAZEPINES AND OTHER PRESCRIBED MEDICATION, pages 35 ff.

12.10 Carries and Medical Disability

A physician may decide to initiate or increase carries to a patient who would otherwise not qualify for carries, when such a patient suffers from a medical condition that significantly interferes with his or her ability to attend the pharmacy. In these cases, every effort should be made to ensure that a health care professional trained to identify signs and symptoms of methadone/buprenorphine toxicity supervises the consumption of methadone/buprenorphine. For medical conditions of a temporary nature, the requirement for carries should be reassessed once the patient's ability to attend the pharmacy is thought to have returned.

It should be recognized that the medical condition that necessitates carries might involve pain and clinical conditions that trigger increased substance abuse. The physician must carefully decide

whether the benefits of carries for the patient outweigh the risk of further destabilizing the patient.

Direct delivery of methadone/buprenorphine to the patient's address is rarely indicated and should only be done in exceptional medical/social circumstances.

12.11 Compassionate Basis

Patients who have not satisfied all of the criteria for carries may be provided carries on a short-term compassionate basis in cases of personal or family crises or bereavement. The minimum requirement in these circumstances is demonstration of a locked box.

12.12 Job or Vacation

Patients who are deemed appropriate for a large number of carries (four to six carries, attending the pharmacy once or twice weekly), may be granted an increased number of carries for reasons such as travel and employment opportunities. Patients may be asked to provide the clinic with verification of their travel plans (e.g., plane ticket, letter from work). A maximum of two to four weeks of vacation carries is recommended.

13. EXTENDED METHADONE/BUPRENORPHINE MAINTENANCE (FOR LONG-TERM STABLE CLIENTS)

*Not all clinics have the capacity to offer this option.

Extended methadone/buprenorphine maintenance is the next phase of methadone/buprenorphine treatment for stable, socially rehabilitated patients and allows flexibility that is more general, e.g., in the event of business opportunities and personal travel. Patients must meet the criteria indicated by the following outline to progress to the next phase:

A. Two consecutive years of biopsychosocial stability in a methadone/buprenorphine maintenance program
   - Employment or other socially productive activity
   - Absence of criminality
   - Absence of drug and alcohol abuse

B. Reliability and honesty in keeping appointments and interaction with clinic staff

C. Ability to store the medication safely

The physician can see these patients every one to three months. At each visit, a urine drug screen is done, and a one-, two- or three-month prescription is given for methadone/buprenorphine (in tablet form). If any concern about stability arises, then more frequent urine drug screens should be done and carries should be reassessed.

The methadone/buprenorphine is dispensed Q2 weeks or monthly and a witnessed dose under supervision at the pharmacy or at the clinic must be taken at the time of dispensing. Tablets may be given as an alternative to liquid methadone.

Unstable or noncompliant patients with behaviour such as indicated below are to be referred back to the standard protocols of the clinic for increased structure and supervision:

1. positive urine drug screens;
2. criminality;
3. significant emotional or psychiatric instability; and
4. loss of employment.

Some patients with long-term stability may choose to attempt a taper of methadone/buprenorphine at first. It might happen that a patient succumbs briefly to opioid use, but returns to stable behaviour and stable methadone/buprenorphine dosing. Such a patient could be considered as a candidate for extended methadone/buprenorphine maintenance after a further six months of sustained stability.

14. COUNSELING

Regular counseling, when added to methadone/buprenorphine maintenance, is associated with decreased drug use. Access to counseling should be an integral part of methadone/buprenorphine maintenance treatment. Counseling can be structured around the following areas:

- securing basic necessities, such as housing, food, clothing;
- legal issues;
- life skills;
- coping with stress;
- identification and treatment of concurrent mental illness;
- issues of abuse, including physical, sexual, emotional abuse;
- parenting and family counseling;
- education about harm reduction; and
- stopping drug use and preventing relapse.

Therapeutic approaches are most successful when there is a strong therapeutic alliance between the therapist and the patient. This involves the physician creating a non-judgmental, collaborative environment in which the patient feels safe to discuss his or her feelings and concerns. Particularly where there are complex psychosocial problems, the physician will need to draw on the support of formal and informal resources. He or she will have to realize the limits of what they can personally

provide in their role. If appropriately educated and supported, the family can be a valuable resource for the clinician and patient. The physician and clinic staff can also play a valuable role in encouraging and facilitating access to support and services, such as relapse prevention programs in the community.

15. METHADONE/BUPRENORPHINE AND PAIN

15.1 General considerations

The following considerations are suggested for treatment of acute and chronic pain in methadone/buprenorphine maintained patients. They apply to those who are somewhat stable on methadone/buprenorphine; that is, patients who have been on the medication for at least three months. **Liaison between other prescribers and the methadone/buprenorphine prescriber should occur.**

Pentazocine (Talwin), Nalbuphine (Nubain), and buprenorphine are partial opiate antagonists. If administered to people maintained on methadone, they cause severe opiate withdrawal. They should not be used in this population.

Methadone/buprenorphine is a combination of two potent opioids, which have the potency of morphine at the very least when both are taken orally. Their usefulness in opioid use disorder relates to their long half-life, which results in very significant reduction of opiate craving with once daily dosing. Despite their usefulness in diminishing opiate craving with once daily dosing, their analgesic effects are of much shorter duration. For analgesia, methadone/buprenorphine is often used with T.I.D. dosing. Effectively, once daily stable dosing of methadone/buprenorphine is non-analgesic.

When patients with addiction also complain of pain, they need thorough and objective assessment of their pain. It is a matter of clinical judgment as to the most appropriate treatment of individual patients. Assessment and judgement involve the following issues:

1. the objective assessment of a subjective phenomenon (pain);
2. the question whether the pain presentation of the patient who suffers from opiate use disorder is in fact drug-seeking or a genuine request for relief of real pain; and
3. the appropriate dose of opiate or other analgesics or adjuncts for a methadone/buprenorphine maintained patient.

Issues 1 and 2 above are best dealt with by a thorough assessment that is as objective as possible about the physical lesion and its correlated pain. This is a matter of clinical judgement and includes making one's best assessment for the appropriate treatment for similar physical lesions in most other patients.

Use of NSAIDs and Tylenol for methadone/buprenorphine maintained patients should be no

different from the use of these medications for non-methadone/buprenorphine maintained patients.

15.2 Methadone/Buprenorphine and Acute Pain

Patients on long-term methadone/buprenorphine therapy may have a lower pain threshold, and are tolerant to the analgesic effects of other opioids. There is no evidence that opioid use for acute pain increases the risk of relapse. Indeed, some have argued that treatment of acute pain can cause relapse by increasing stress and increasing the rise of self-medication.

Management of Methadone/Buprenorphine Patients with Acute Pain

- Use non-opioid alternatives along with or instead of the additional opioid.
- Patients on stable doses of methadone/buprenorphine often require higher or more frequent opioid doses for acute pain than other patients. Initiate treatment at doses usually used to treat patients with a similar condition. Titrate upwards, if necessary.
- The opioid should be dispensed along with the methadone/buprenorphine (i.e., daily, if the patient has no methadone/buprenorphine carries).
- The prescribing physician should avoid prescribing opioid agonist-antagonists.
- Acetaminophen opioid combinations are preferred for injection drug users.
- Where possible, the physician should avoid prescribing short-acting opioids with a higher dependence liability, such as oxycodone or hydromorphone.
- Alternatively, a 10-15 mg increase in methadone/buprenorphine dose may be considered as a temporary split dose. The dose should be reduced after the acute pain has resolved.
- For constant pain, scheduled use is preferred to PRN (as needed) use.
- The physician should address any patient concerns about inadequate pain control, and the risk of relapse.
- The physician should be alert for signs of relapse such as continued use of short-acting opioids long after the pain should have resolved, excessive use, and unwillingness to share information with the prescribing physician.
- Opioids should generally not be given for more than two weeks for acute pain, and a re-evaluation of the patient's pain should be made with the appropriate referrals. Avoid prescribing the opioid the patient was originally abusing.

15.3 Chronic Pain

1. MMT is used for the treatment of opioid use disorder and not for the treatment of pain. The protocol for methadone/buprenorphine used for treating chronic pain may be different from the protocol used for treating opioid use disorder. If a patient appears to have chronic pain issues, consultation should be sought. The ideal is to consult a physician with skills and experience in managing these dual diagnosis patients, i.e., addiction and chronic pain, or a physician who deals specifically with chronic pain.

2. Methadone/buprenorphine use in chronic pain is an evolving area; indeed, the medication is used more frequently in individuals with chronic pain. It is important to understand that it may be impossible to determine the difference between addiction and chronic pain. In such cases, consultation should be sought, and if there is any doubt, the patient should be managed with controls appropriate for the most problematic diagnosis.
3. Sometimes, patients on MMT may need additional opiates to control chronic pain. Thorough discussion should occur between the methadone/buprenorphine prescriber and the family physician before long-term prescribing of additional opioid medication is begun. Because of opioid tolerance, the dose of opioid analgesia may need to be higher than in non-methadone/buprenorphine maintained patients with similar pain. The physician may decide that some restriction of carries is necessary to provide supervision and structure when prescribing additional opioids.

16. USE OF BENZODIAZEPINES AND OTHER PRESCRIBED MEDICATION

General

1. The patient's consent to be in the MMT program includes consent for the MMT physician to review all medication and communicate as necessary with other physicians prescribing medication.
2. The methadone/buprenorphine prescriber may decide to discontinue methadone/buprenorphine treatment
   - if the methadone/buprenorphine prescriber/treatment team feels that other prescribed substances are interfering with the methadone/buprenorphine treatment; and
   - a safe and satisfactory resolution cannot be reached after consulting with the prescribing physician or physicians.

Opioids

1. Short-term use (usually less than two weeks) of other opioids for acute pain may be appropriate, but may require more careful monitoring.
2. Supplementation of methadone/buprenorphine with other opioids for the treatment of chronic pain should be done cautiously. (See Management of Methadone/Buprenorphine Patients with Acute Pain, page 34.)

Benzodiazepines

1. Benzodiazepines are CNS depressants and have a high potential for addiction; therefore, they should be prescribed and dispensed with caution for patients on MMT.

2. For any patient who is on MMT and who is receiving prescribed benzodiazepines, daily-observed methadone/buprenorphine dosing should be considered if there is reason to believe the patient is at risk.
3. For the majority of patients, long-term use of benzodiazepines is not recommended. If such treatment is considered for patients who have a concurrent major mental disorder, it is recommended that a psychiatric colleague with expertise in the diagnosis and treatment of addictions be consulted. Wherever possible, alternate medications or behavioural therapy should be considered before prescribing benzodiazepines or other CNS depressants.

Other Medications

1. Psychostimulant medications for the treatment of conditions such as Attention-Deficit/ Hyperactivity Disorder (ADHD) or narcolepsy must be used with particular caution for patients on MMT. Prior consultation with a psychiatrist with expertise in the diagnosis and treatment of addictions is recommended.
2. Sedative antidepressants (e.g. trazodone, amitriptyline) should be started at low doses.
3. The prescriber of psychoactive or other potentially interactive substances should be encouraged to limit the amounts and frequency of dispensing to coincide with methadone/buprenorphine dispensing. PRN doses should be limited.

17. SPECIAL HEALTH PROBLEMS

17.1 Pregnant Patients with Opioid Use Disorder

Methadone/Buprenorphine Maintenance in Pregnancy

Methadone (or buprenorphine) maintenance is the treatment of choice for opioid use disorder during pregnancy, as opioid withdrawal can result in premature labour or fetal stress. The dose of methadone/buprenorphine may have to be increased (or split) during the second half of the pregnancy. It is necessary to follow up pregnant clients regularly to review the dosage. After childbirth, the dose may also have to be adjusted downward.

Opioid Withdrawal/Taper of Methadone/Buprenorphine in Pregnancy

Most women with opioid use disorder cannot remain opioid-free during their pregnancy. If a patient insists on attempting abstinence, it should be done in the second trimester. A gradual methadone/buprenorphine taper is best, with the patient having close follow-up consultations with and support by both her addictions physician and obstetrician. The extended post-partum period is a time of significant risk of relapse.

Analgesia

Analgesia during labour and in the postpartum period should be provided as usual. The methadone or buprenorphine dose merely prevents opioid withdrawal symptoms and does not provide any significant analgesia. Most opioid dependent patients develop a high tolerance to opiates. Epidural analgesia should be effective in the usual way.

Breastfeeding

Methadone and buprenorphine maintenance is not a contraindication to breastfeeding. Although small amounts of methadone/buprenorphine enter the breast milk, the possible effects of the medication in the milk does not outweigh the benefits of breastfeeding.

Confidentiality

Please remember that although family members may be visiting, they may not be aware that the mother is on methadone or buprenorphine. This treatment should not be discussed with the family without the woman's specific permission.

Neonatal Withdrawal

The infant should be monitored for withdrawal symptoms for a minimum of five days. Methadone and buprenorphine are long acting and onset of withdrawal symptoms may be delayed. The pregnant patient, where possible, should meet with a neonatologist before delivery to discuss and prepare for best care of the newborn infant.

Neonatologists follow a withdrawal scoring system and treat infants, if necessary, with morphine. Some neonatologists use phenobarbital; however, the sedating effects of this drug may lead to lethargy or poor feeding.

Suboxone® in Pregnancy

It is recommended that pregnant patients change to Subutex (buprenorphine) to avoid the naloxone component. This requires contact with the manufacturer for special release. However, some women stay on Suboxone® for their pregnancy when alternate arrangements are difficult.

17.2 Patients with Hepatitis C

Methadone/buprenorphine maintenance physicians should be well informed about Hepatitis C and the available treatment, but generally, care is provided by the patient's own physician or by specialty clinics. In some populations, over 80% of IV drug users are positive for Hepatitis C.

Currently, anti-Hepatitis C antibody serology is the screening test and hepatitis C RNA polymerase chain reaction is the confirmatory test. Some patients with negative test results have ongoing risk factors for acquiring Hepatitis C; it may be appropriate to offer yearly testing to such clients.

Management

The management tasks of the physician comprise the following:

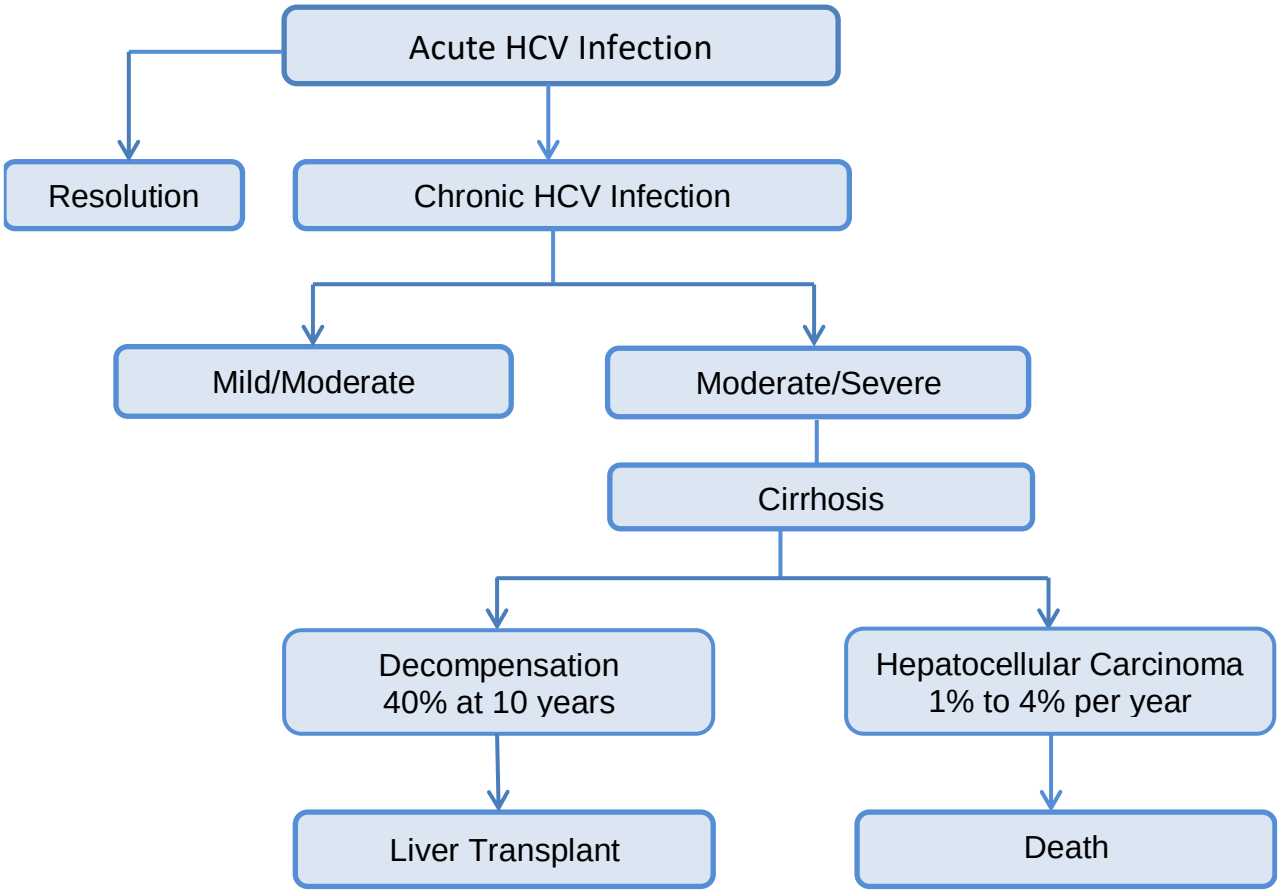
- Advise against alcohol consumption.
- Arrange for all patients to be vaccinated against Hepatitis A and Hepatitis B.
- Discuss an appropriate diet.
- Educate patients about the natural progression of the disease. 15-30% of all patients infected will spontaneously clear the virus. Of the patients who do not clear the virus, 70-85% will have a mild symptoms and a moderate form of the disease. 15-30% will eventually develop cirrhosis. There is a 5% risk of hepatocellular cancer in those patients who develop cirrhosis.
- Discuss Hepatitis C treatment/referral for those patients exhibiting stability on MMT. There is a strong possibility of cure with modern treatment.

Treatment

Methadone/buprenorphine maintenance is not a contraindication to treatment of Hepatitis C.

- Patients on methadone/buprenorphine should be referred for Hepatitis C treatment when they are in stable recovery.
- Methadone/buprenorphine maintenance physicians must be aware that significant psychiatric symptoms may occur from the anti-viral treatment.
- New treatment outcomes using anti-viral drugs have significant success rates depending on the virus genotype.
- When treatment is successful, there is a decrease in the risk of cirrhosis and liver cancer, and improvement in general well-being.

Spectrum of Hepatitis C Disease



17.3 Patients with HIV

Management

Most management occurs at HIV specialty clinics and include the following tasks:

- Educate patients about precautions with regarding relationships and shared needles.
- Educate patients about the natural disease progression.
- Immunize all patients against Hepatitis A and B.
- Immunize all patients with tetanus toxoid, pneumococcal vaccine and influenza vaccine.
- Consider testing for TB and syphilis.
- Monitor CD4 count and viral load.
- Consider referral to an infectious disease specialist for assessment and a treatment plan.
- Give special attention to pregnant women with HIV/AIDS and consider treatment with

antiretroviral agents.
As of June 2004, the research from NIH still supports the Pediatric AIDS Clinical Trial Group Protocol 076 Study, which indicated that about 8% of women treated with AZT during pregnancy and delivery transmitted HIV to their infants as opposed to 25% untreated. It is unclear to date what the long-term health ramifications are for children who received AZT in utero and at birth.

- Physicians should inform patients that all street drugs are dangerous and are likely to interact adversely with antiretroviral medication.
- Methadone doses may need some adjustment, either up or down, as soon as the patient is on antiretroviral medication or if the medication is changed. The reason is that many antiviral medications affect methadone metabolism. Buprenorphine dosing is less likely to be affected.

17.4 Co-occurring Mental Health Issues

- Many opioid dependent patients meet criteria for an Axis I psychiatric disorder, unrelated to drug use or withdrawal. Disorders such as depression, anxiety, bipolar disease, eating disorders, and PTSD (Posttraumatic Stress Disorder) are common.
- It may be difficult to determine whether a psychiatric disorder is the primary condition or whether it is secondary to drug abuse. Re-assessment during ongoing treatment is important.
- Amphetamine and cocaine use can cause psychosis and paranoia. This usually subsides quickly when the drugs are no longer used. Occasionally, this reaction may be prolonged and difficult to manage, and hospital admission may be necessary.
- Depression, anxiety, and insomnia are common and often persist for some time after substance withdrawal.
- Patients with substance use disorder have a significantly higher incidence of trauma histories and of personality disorders (Axis II). They may benefit from psychotherapy.
- Consultation with a psychiatrist with addiction experience may be helpful.
- Many patients have a history of significant abuse or trauma in their lives; some patients may wish to seek counseling for these issues.

18. INCARCERATION ISSUES – MMT IN CORRECTIONAL FACILITIES

18.1 Introduction

Methadone/buprenorphine treatment in correctional settings involves unique issues. There is a significant prevalence of intravenous opioid use within correctional facilities often accompanied by high-risk behaviour. The prevalence of HIV and viral hepatitis is high in the prison population and needle sharing is prevalent. Incarcerated opioid dependent individuals should be offered ongoing

methadone/buprenorphine maintenance.

- ***Federal Corrections Facilities***

  Federal custody institutions house persons serving sentences of two years or more, with most lengths of stay in federal prisons exceeding three years. The Correctional Service of Canada offers a comprehensive methadone maintenance treatment program with extensive assessment of mental health, substance use disorder, and medical and risk behaviour. Patients are screened regarding need and suitability for this treatment program. Methadone induction is available whenever appropriate and inmates arriving in the Methadone Maintenance Program are continued in the program. Counseling is available and strongly encouraged.

- ***Provincial Correctional Facilities***

  Prescriptions for methadone/buprenorphine may be written by correctional services medical staff or by the inmate's community methadone/buprenorphine provider. In this case, clear communication must occur as necessary between the nursing/medical staff of the correctional centre and the staff of the community methadone/buprenorphine clinic.

In Manitoba, the doctors in correctional services do <u>not</u> have methadone or buprenorphine exemptions. Prescriptions therefore need to be handled by their clinic.

The following suggestions apply to provincial correctional facilities in particular.

18.2 Dosing on Admission

1. Staff of the correctional facility should contact, as soon as possible, the community methadone/buprenorphine clinic and the patient's pharmacy to determine:
   - the usual dose of methadone/buprenorphine;
   - date of last dose received; and
   - three consecutive doses of methadone have not been missed; or that five consecutive doses of buprenorphine have not been not missed.

     If these doses have been missed, the patient cannot resume his or her previous dose of medication. Corrections staff may decline to provide ongoing methadone/buprenorphine at any dose in these circumstances.
2. Physicians providing MMT care must use their clinical judgement to determine the appropriate dose:
   - Patients who have frequent witnessed ingestion can generally stay on their regular dose.
   - Patients on very high doses or patients who may have been diverting methadone/buprenorphine may be placed on 50-75% of their regular dose (with reassessment for sedation or withdrawal).

3. Benzodiazepines and sedating sleep aids should generally be withheld.
4. If the patient appears intoxicated or sedated by the nurse's assessment, the methadone/buprenorphine should not be given until communication occurs with the physician.
5. Methadone/buprenorphine brought in by any inmate should be discarded. If it is a transfer, it may be allowed, but if tampering has occurred, it should also be discarded.

Dose adjustments are not usually made while the patient is in a correctional facility. Facility staff can communicate with the methadone/buprenorphine provider if they feel dose adjustments may be necessary.

18.3 Observed Administration

1. Traditional lack of access to maintenance treatment in correctional facilities has created a situation where demand usually exceeds supply.
2. For this reason, attention to dispensing issues is of paramount importance so that methadone or buprenorphine is not diverted.
3. It frequently happens that maintenance patients are under considerable pressure from other inmates to divert their medication. Adequate steps to protect the patients from other inmates are critical to ensure safety within the institution.
4. A suggested process for administration is described below:
   - Each inmate should be properly identified before methadone/buprenorphine is dispensed for him or her.
   - Check the name, date, and dose on the label of the methadone/buprenorphine bottle.
   - Verify that the inmate has completely swallowed the dose of methadone, or the tablet of buprenorphine has been dissolved.
   - Records should be kept that specify the dose administered.
   - All inmates receiving methadone/buprenorphine should be isolated from other inmates post-ingestion for a period to reduce risk of diversion.
   - Methadone and buprenorphine cannot be left unattended. It is advisable to secure them in a locked refrigerator or safe. The drug storage area should not be accessible to inmates or non-medical staff.

18.4 Accidental overdose of methadone/buprenorphine

Facilities should make sure that protocols to treat acute opioid overdose are available to all health care staff. If there are no facilities and/or staff to treat and observe a patient who has overdosed on methadone/buprenorphine for at least 24 hours, the patient should be transferred to another suitable facility. It is recommended that naloxone (Narcan®) be available in all correctional facility pharmacies.

18.5 Initiating Inmates while in a Correctional Facility

- Federal facilities have an assessment process to determine if an inmate is suitable for maintenance treatment.
- Provincial facilities generally cannot consider inmates for initiation of MMT. However, pregnant inmates with opioid addiction require urgent attention and should be referred for assessment as soon as possible, and should be considered as candidates for maintenance therapy even while in custody.

18.6 Treatment Planning for Release

Patients with opioid use disorder are at highest risk of overdose after release from a correctional facility if an appropriate release plan is not made. If the release date is known, an appointment should be scheduled with a representative of the community treatment program to coincide with the release date. Carries should not be provided to the inmate at the time of release.

Sometimes inmates are released from custody directly from Court without the correctional facility having prior knowledge of the release. The following advice is therefore appropriate:

> In order to be prepared in the event that a patient is released from custody directly from Court without the correctional facility having prior knowledge of the release, patients should be given the telephone number of the nursing station and the methadone/buprenorphine program. They should take this contact information with them should they be attending Court. Patients should be further advised to contact the nursing station and the methadone program if they are released directly from Court without the benefit of a release plan.

19. WITHDRAWING FROM MAINTENANCE TREATMENT

Withdrawal from a program may occur under the following circumstances:

- ***Voluntary tapering***

  The patient and physician agree many treatment goals have been achieved and a trial of tapering is reasonable (see 19.1 Voluntary Tapering Process below.)

- ***Voluntary tapering before treatment goals are reached***

  The patient wishes to taper off methadone/buprenorphine, but the physician is concerned that treatment goals have not been achieved or that the patient continues to be at high risk for return to opioid abuse (see 19.2 Voluntary Tapering before Treatment Goals are achieved, page 46).

- ***Involuntary tapering***

  The physician feels significant reasons are present such that ongoing methadone/buprenorphine maintenance is no longer safe or appropriate (see 19.3 Involuntary Tapering, page 46).

19.1 Voluntary Tapering Process

19.1.1 General Considerations

> Patients who continue to benefit from methadone/buprenorphine and do not wish to wean should not be pressured to do so.

Patients frequently request more rapid tapering, and it is important that physicians explain the dangers of rapid tapering. Tapered dosage should be undertaken as a trial of weaning. Patients who relapse to opiates or decompensate in other aspects of their lives during or after the trial of weaning should be offered re-entry to treatment and be re-stabilized. Patients should not be penalized for unsuccessful weaning.

19.1.2 Tapering Methadone/Buprenorphine after Treatment Goals have been achieved

> Optimum benefits from MMT are not realized for at least a year.

Generally, patients who have been in the program for two or three years will have better outcomes when tapered from methadone/buprenorphine than those who taper at less than two years of treatment. In order to reduce the risk of relapse, patients should be encouraged to stay in maintenance treatment until identified treatment goals have been met, although the ultimate decision to wean lies with the patient. Patients will have a reduced risk of relapse while in the program and follow weaning if they have achieved the following:

- long-term abstinence from opioids and other mood-altering drugs;
- stable mental and physical health;
- stable housing;
- stable source of income;
- development of supportive relationships with non-drug users;

- development of non-chemical coping skills; and
- confidence and motivation to wean from methadone/buprenorphine.

19.1.3 Assessing Readiness

A patient's readiness to taper should be assessed by taking the following steps:

- Explore the motivation for the request (finances, family pressures, and client's misconception of the need to withdraw due to pending incarceration).
- Review the history of attempts at withdrawal.
- Determine if the following positive factors are present:
  - abstinence from other proscribed substances;
  - personal, financial, and social stability;
  - no inappropriate involvement with other drug users;
  - stable mental and physical health; and
  - a relapse prevention plan.

19.1.4 Education and Preparation

Educating and preparing the patient is essential in the tapering process and comprises the following:

- Discuss methadone/buprenorphine as a medication vs. an addictive drug.
- Discuss the benefits of long-term substitution therapy.
- Prepare the patient for potential difficulties associated with taper, namely craving, anxiety, impatience, and withdrawal symptoms.
- Assure the patient that returning to the previous dosage is possible.
- Offer supportive resources during process and decide if counseling or support groups would be helpful.
- Tailor withdrawal according to the patient's request; however, it is recommended that the dose is lowered no more than 5-10% of the total dosage weekly, and then slower when tapering has reached a level < 30 mg of methadone. Many patients prefer a slow taper that may take six to twelve months.
- Re-evaluate carries.
- Schedule follow-up appointments and screen for a relapse.
- Review and update the treatment plan.
- Document the process, assessment and all relevant aspects appropriately.
- Consider increased frequency of urine drug screens.

19.1.5 Dose Adjustment

- The duration and amount of dosage reduction during voluntary withdrawal can be individualized.
- Experience has shown that a reduction of no greater than 5-10% per week and then slower when tapering has reached a < 30 mg of methadone avoids significant withdrawal symptoms. Voluntary withdrawal can be suspended at any time. Titration back to stable

dosage should take place gradually.

- Some patients tapering off buprenorphine may find the final step-down of 1 mg difficult. It is possible to use the BuTrans® (buprenorphine transdermal patch) as a final step-down.

19.2 Voluntary Tapering before Treatment Goals are achieved

Some patients choose to taper methadone/buprenorphine despite its benefits. In the opinion of the physician and counseling team, tapering in these cases may put the patient at high risk of relapse. The health care provider should explore options together with the patient in an attempt to understand his or her motivation for tapering and to clarify any misconceptions. The physician may recommend the continuation of maintenance therapy. However, if the patient still insists on withdrawing from methadone or buprenorphine, the patient and physician should prepare a plan for a *trial of weaning*, taking into consideration the relevant risks. Patients who relapse to opioids and become unstable, or who alter their decision to wean at any point during the process should be encouraged to continue maintenance therapy and return to a stabilizing dose.

19.3 Involuntary Tapering

Involuntary tapering is presented when the physician feels significant reasons are present to such an extent that ongoing methadone/buprenorphine maintenance is no longer appropriate.

19.3.1 Reasons to Discontinue Maintenance Therapy

Appropriate reasons to discontinue maintenance therapy are the following:

1. Evidence of failure to ingest prescribed methadone/buprenorphine doses constitutes sufficient grounds for immediate cessation of maintenance therapy. Alternatively, a behaviour contract and increased supervision may be considered.
2. Physical or verbal threats to anyone involved in the patients MMT treatment constitutes sufficient grounds for immediate cessation of MMT. In some cases, there may be a trial of weaning or a behaviour contract.
3. Evidence of diversion of prescribed methadone/buprenorphine doses constitutes sufficient grounds for immediate cessation of MMT. Alternatively, increased control and supervision may be considered.
4. Ongoing disruptive behaviour or repeated failure to attend appointments constitutes sufficient grounds for cessation of MMT.
5. Continued use of proscribed substances may result in cessation of maintenance therapy: a risk-benefit assessment should determine whether treatment should be continued.

19.3.2 Process of Tapering

1. Provide the patient, if appropriate and possible, with an option of transferring to another methadone/buprenorphine prescriber.

2. Document the reasons and plan; inform the patient of the details of the tapering schedule.
3. Patients exhibiting verbally abusive or threatening behaviour may have their methadone/buprenorphine rapidly tapered or discontinued, if the physician has concerns regarding safety of clinic staff, pharmacy staff, or other patients.
4. Consider the need to observe one dose in a clinic setting in case the patient has not regularly been ingesting the prescribed dose.
5. A typical schedule for involuntary tapering is the following: a 5-10% reduction of the daily dose per day.
6. All doses during involuntary tapering must be daily-observed doses, with no carries allowed (some clinics may assess the safety for Sunday carries if the pharmacy is not available).

19.3.3 Possible Resumption of Maintenance Therapy

Patients who are involuntarily withdrawn can be considered for resumption of maintenance therapy at a future date. This is a decision of the prescriber or treatment team, based on the situation at the time of involuntary tapering and the situation when the patient reapplies for treatment. Physicians are not obligated to resume treating patients who have been involuntarily withdrawn if significant safety or behavioural problems are still present.

20. OPIOID DETOXIFICATION/WITHDRAWAL MANAGEMENT

20.1 Two settings of detoxification

Planned detoxification usually happens in one of the following two settings:

1. outpatient tapering in 30-150 days of methadone/buprenorphine (or other opioid in certain circumstances); and
2. rapid inpatient tapering in 7-20 days.
   The latter is usually done to prepare the patient for further treatment, e.g., pursuing abstinence in a residential program. Occasionally it is done for other health, social, travel, or treatment purposes. The risk of relapse is high after discharge and the patient is at exceptional risk of overdose if he or she relapses to using past high doses of opioids; therefore, follow-up support and treatment plans should be in place.

The following drugs may be used for symptom management in either the inpatient or the outpatient setting:

1. NSAID or acetaminophen for myalgia and headaches;
2. Loperamide for diarrhea;
3. Gravol® for nausea (discuss maximum dose with patient);
4. Trazodone or Seroquel 50-100 mg HS for insomnia;
5. Clonidine (see 20.2.3 Use of Clonidine, page 48);
6. Methadone/buprenorphine or other long-acting opioid medication;

7. benzodiazepines for anxiety or treating insomnia (only short-term use of benzodiazepines is recommended).

20.2 Methadone/Buprenorphine in Withdrawal Management – Inpatient Setting

20.2.1 Dose of Methadone/Buprenorphine in an Inpatient Setting

The patient may be converted to methadone/buprenorphine, which is then tapered to zero over approximately ten days. This gives a smoother detoxification and the patient avoids receiving their drug of choice. The first two days are used to achieve a starting dose of methadone/buprenorphine, which gives the patient some comfort and stability as the taper begins.

The initial methadone dose can be ordered according to the following schedule:

- *Day 1 & 2*: The dose is 10 mg po Q6H prn methadone for withdrawal symptoms to a maximum dose of 40 mg in 24 hours. This allows the physician to have a baseline-starting dose of methadone (usually 20-30 mg of methadone per day).
- *Day 3 onward*: Taper methadone by 10% per day. It can be helpful to drop more rapidly at the beginning and more slowly at the end of the taper. Because of withdrawal symptoms and sleep disturbance, the patient may find it more comfortable to receive the methadone in a BID-dosing format.

20.2.2 Useful Considerations in Withdrawal Management

The patient can be assisted during withdrawal by considering the following:

- If experienced staff can address patient anxiety and distress, with counseling or group support, tapering off opioids is generally less stressful.
- The treatment team will have to decide if any restrictions of visitors or off-ward passes are allowed, as some patients may attempt to access more opioid medication.
- Alternatively, the patient may be placed on a step-down of a long acting opioid at BID or TID dosing, with a taper to zero over approximately ten days.
- Physicians experienced with buprenorphine may also use this medication for the taper.

20.2.3 Use of Clonidine

Clonidine decreases some of the symptoms of opioid withdrawal. Common side effects of this medication are hypotension and sedation; rebound hypertension can occur if it is abruptly discontinued after high-dose use. Clonidine is therefore contraindicated

- to patients who are pregnant;
- to patients who are on antihypertensive medication due to a heart disease; and
- to patients with BP < 90/60.

Precautions are the following:

- Warn the patient of postural dizziness and drowsiness. Review driving safety for outpatients.
- If the patient is on an extended prescription, it should be tapered to avoid rebound hypertension.

The dosing schedule for clonidine is the following:

- Inpatient clonidine dosing
  - Check BP each dose; hold if BP < 90/60.
  - Start at .1-.2 mg TID; the dose may be increased to .3 mg TID, if helpful.
- Outpatient clonidine dosing
  - .05-.1 mg BID to start; the dose may be increased to .2 mg TID, if helpful.

21. TRANSFER OF CARE

It is a standard of care for all physicians to communicate significant medical history to the receiving physician when transfer of care occurs. This should include the methadone/buprenorphine dose and the date of the last dose given. Failure to communicate may well result in duplicate or missed doses, an inadequate treatment plan, and overall substandard care, because the new prescriber is not in possession of collateral and important information.

The new methadone/buprenorphine prescriber should perform an updated comprehensive biopsychosocial assessment and physical examination, together with appropriate laboratory investigations.

22. PRESCRIBING FOR HOSPITAL INPATIENTS

Methadone or buprenorphine should continue during hospitalization unless contraindicated for clear medical reasons.

22.1 Methadone

1. An exemption specific to inpatient treatment, granted by the Office of Controlled Substances, Health Canada, to prescribe methadone for the treatment of opioid use disorder, allows licensed physicians (not residents) to order methadone for hospital patients.
2. Hospital pharmacies can supply the one page exemption form to physicians to fill out. WRHA hospitals can also provide information regarding safety issues and methadone to physicians and ward staff.

3. Prescribing of methadone is for the term of the patient's admission only.
4. Carried doses are not generally permitted, except in consultation with the community MMT prescriber. One or two doses of methadone may be given at discharge if the patient cannot immediately attend the clinic.
5. The physician providing methadone during hospitalization should inform the community MMT provider of any changes in dosage or other relevant information such as short-term opioid analgesics, psychoactive or potentially interacting medications prior to discharge from hospital.

22.2 Buprenorphine

1. The attending physician may order buprenorphine at the same dose, or a lower dose, than the patient received in the community. Dose increases need documented discussion with a methadone/buprenorphine prescriber.
2. One or two days of carries may be given if the patient is discharged on a weekend.
3. Communication with the clinic should occur.

23. BUPRENORPHINE/NALOXONE (SUBOXONE®)

CAMH (Centre for Addiction and Mental Health) has published an excellent, detailed review, *Buprenorphine/Naloxone for Opioid Dependence – Clinical Practice Guideline*.[5] Physicians who wish to use the medication can download this publication from the internet. Key points of Suboxone® are reviewed below:

1. *Complete assessment*: The patient must have a complete assessment (including a urine drug screen and blood work) to establish a diagnosis of moderate to severe opioid use disorder. Exercise caution if liver enzymes are elevated, as some cases of significant liver dysfunction have been reported after Suboxone® usage.
2. *Pregnancy*: Pregnant patients should be treated with buprenorphine (without naloxone) or methadone, as the safety of the combination product has not yet been established. However, many patients have continued to stay on Suboxone® for the duration of their pregnancies.
3. *Education of the patient about induction*: The patient must be in moderate opioid withdrawal (COWS scale 13-24) or precipitated withdrawal may occur. See the induction algorithm in *Appendix A: Sample Buprenorphine/Naloxone* Induction Algorithm (Diagram), page 53. A stable dose can be reached within a week (usually in 8-16 mg range).
4. *Methadone exemption and Suboxone® training*: The use/monitoring of Suboxone® is under provincial College jurisdiction and can vary from province to province. In Manitoba, the

[5] Handford, C. (2011). *Buprenorphine/Naloxone for Opioid Dependence: Clinical Practice* Guideline. Principal author, Curtis Handford; co-authors, Meldon Kahan ... [et al.]; collaborating authors, Michael D. Lester ... [et al.]; contributors, Alice Ordean. Toronto, Ontario: CAMH.

prescriber must have a methadone exemption and must have submitted a certificate of Suboxone® training to the College.

5. *Carries*: Concerning carries, in Manitoba, it is expected that as the person demonstrates a stable life style and provides urine tests that indicate no problematic drug use, carries will be gradually increased in a similar way as methadone. Very stable patients may receive up to two weeks of carries. Health Canada states all doses (except weekends) are to be observed for the first two months. If the practitioner wishes to grant carries before such a time, the modified grant should be justified in the clinical record.
6. *Pharmacare for Suboxone®*: To obtain pharmacare coverage for Suboxone® in Manitoba, the practitioner must write to:

   The Provincial Drug Review Committee
   Corporate & Provincial Program Support
   1014-300 Carlton Street
   Winnipeg, Manitoba R3G 3M9
   Fax 204-942-2030

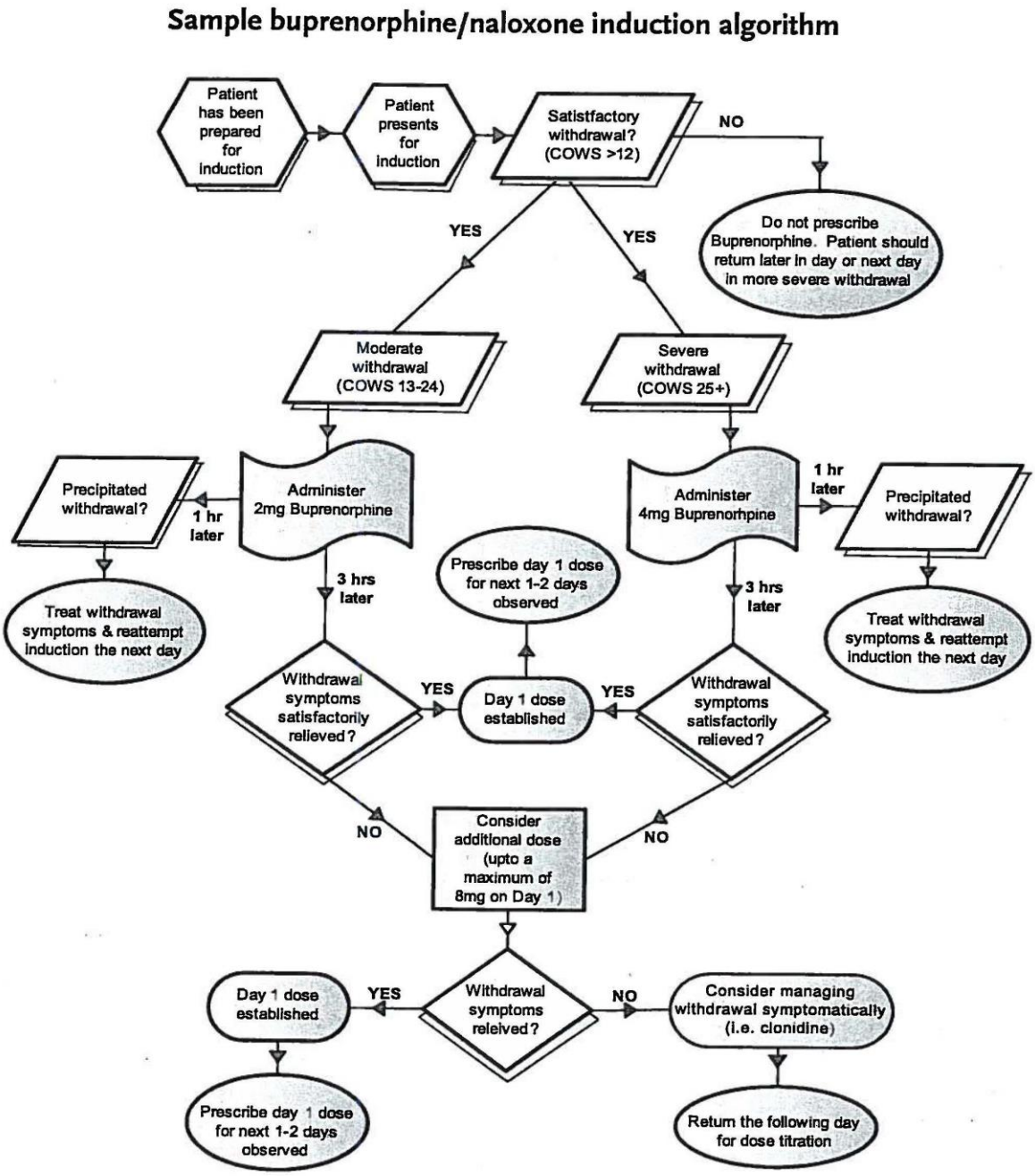
   A detailed motivation must be given why the patient might benefit from Suboxone® rather than methadone. A reply is usually received in three to six weeks. Urgent cases can be discussed by phoning the EDS line at 204-786-7318. Permission has to be renewed annually by a follow-up letter.

7. *NIHB coverage for Suboxone®*: Provision is also made to obtain NIHB (Non-Insured Health Benefits) coverage for Suboxone®. As of September 15, 2015, NIHB will cover patients for Suboxone® therapy if their practitioner feels Suboxone® is a better choice than methadone to treat their opioid use disorder. Medical transportation may be provided for the first two months of therapy. It is not certain that NIHB will cover ongoing transportation if needed for witnessed dosing because of safety concerns.
8. *Missed doses of Suboxone®*: If patients miss doses for more than five days, they must have a dose reduction, usually to 4 mg. They must also attend their practitioner for further dose adjustments and assessment of stability.
9. *Tapering off Suboxone®*: Once the patient has achieved stability for several months, a trial of tapering (2 mg every one or two weeks) may be attempted. If instability occurs, the patient should be re-stabilized on an appropriate dose of Suboxone®. Lower than 4 mg, some patients prefer a decrease of 1 mg every one to two weeks. If it is hard for the patient to discontinue the 1 mg dose, some clinicians have used the BuTrans® pain patch (1 week with BuTrans® 10, one week with BuTrans® 5) as a gentler transition step. The patient must pay for the patches and find a pharmacy willing to sell single patches.

APPENDICES

Clinics may choose to develop their own forms for assessment, physician orders, consent, and treatment agreements.

Appendix A: Sample Buprenorphine/Naloxone Induction Algorithm (Diagram)[6]



[6] This diagram is reprinted with permission from Handford, C. (2012). *Buprenorphine/Naloxone for Opioid Dependence: Clinical Practice* Guideline. Principal author, Curtis Handford; co-authors, Meldon Kahan ... [et al.]; collaborating authors, Michael D. Lester ... [et al.]; contributors, Alice Ordean. Toronto, Ontario: CAMH.

Appendix B: Diagnostic Criteria for Opioid Use Disorder (DSM-5 Criteria)

The following criteria[7] apply 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:

1. Opioids are often taken in larger amounts or over a longer period than was intended.
2. There is a persistent desire or unsuccessful efforts to cut down or control opioid use.
3. A great deal of time is spent in activities necessary to obtain the opioid, use the opioid, or recover from its effects.
4. Craving, or a strong desire or urge to use opioids.
5. Recurrent opioid use resulting in a failure to fulfill major role obligations at work, school, or home.
6. Continued opioid use despite having persistent or recurrent social or interpersonal problems caused or exacerbated by the effects of opioids.
7. Important social, occupational, or recreational activities are given up or reduced because of opioid use.
8. Recurrent opioid use in situations in which it is physically hazardous.
9. 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.
10. 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.

    Note: This criterion is not considered to be met for those taking opioids solely under appropriate medical supervision.
11. 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: This criterion is 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.

[7] The criteria are reprinted with permission from American Psychiatric Association. (2013). *Diagnostic and Statistical Manual of Mental Disorders* (5th ed.). Washington, DC: Author.

Appendix C: Intake/Initial Assessment for MT (Sample)

Health Assessment & Treatment Planning Form				
Name:			DOB:	
Allergies & Alerts			PHIN	
			MHSC:	
# 1 Care Provider & other MDs			Last Pap:	
			Recent Lab Work Done	____No ____Yes
Substance Use and Abuse History		**IVDU**	___NO ___YES	
Substance	**First Use**	**Past History** Pattern, Dose, Frequency	**Present History** Current Pattern, Dose, Frequency	**Last Use Date**
ETOH				
Cannabis				
Cocaine/Crack				
Opiates				
Tranquilizers				
Amphetamines				
Smoker				
Other				
Substance Abuse Tx Hx:				
12 Step Groups:				
Psychiatric History:				
Medications:				
Pm Hx:				
Hospitalizations & Surgeries:				
Seizure:	____No ____Yes			
DT:	____No ____Yes			
HIV Testing				
Hepatitis Testing				
Name:			DOB:	

Family History:	
Social History:	

Review of Systems:		**Examination:**	
SYSTEM	**SYMPT.**	**Normal**	**ABNORMAL**
General Appearance Groomed, Dressed, Odor			
CNS Alert, Oriented			
CVS			
Resp Cough, Wheeze			
GI N&V, Diarrhea, Appetite, Constipation, Liver Border			LMP
GU			
MS			
IS Skin Integrity, Infection, Track Marks			
Psychosocial Coping, Craving, Mood/ Affect, Esteem, Spirit, Sleep			

Diagnosis:

Plan:
__Admission Blood Work Required __Hepatitis & HIV Screens Required __Standing Orders Permitted

Signature:		Date:	

SAMPLE	**ADDICTION MEDICINE: REGULAR CLINIC VISITS** CLINICAL NOTES	

NAME:			**DATE**:	
CURRENT METHADONE/BUPRENORPHINE DOSE:			**CURRENT CARRIES**:	
SUPERVISED URINE DRUG SCREEN RESULTS:			METHADONE/BUPRENORPHINE	
			OPIATES	
			COCAINE	
			BENZODIAZEPINES	

PATIENT'S STATED DRUG USE SINCE THE LAST VISIT:			
Opiates:	No	Yes	
Cocaine:	No	Yes	
THC:	No	Yes	
Benzodiazepines:	No	Yes	
Alcohol:	No	Yes	
Any IV Use:	No	Yes	
Other:	No	Yes	

Any signs/symptoms of sedation	No		Yes
Any signs/symptoms of withdrawal	No		Yes

Social successes/stressors:
Medical problems:
Any safety issues regarding carries:

PLAN:	
Methadone/buprenorphine dose	
Number of carries	
Other Prescriptions	
Counseling or other treatment	
Next Appointment:	
REASON:	

Appendix D: Methadone/Buprenorphine Treatment Agreement and Consent (Sample)

Prescribing and dispensing methadone/buprenorphine is regulated by provincial guidelines, as well as policies unique to the clinic's practice at _____ practice. This contract has been prepared to inform you about methadone/buprenorphine maintenance therapy, as well as to document that you agree to the rules/obligations contained in this agreement.

Acknowledgements

I, _____, acknowledge the following:

1. Methadone/buprenorphine are opioids (i.e., drugs like heroin, codeine, morphine, Percocet, etc.), and I will develop a physical dependence on this medication. Sudden decreases in dose or discontinuation of this medication will likely lead to symptoms of opioid withdrawal.
2. I am already physically dependent on at least one form of opioid and I am unable to discontinue the use of opioids.
3. I have had the opportunity to review if abstinence based treatment would be appropriate.
4. Taking any mood-altering substance with methadone/buprenorphine can be potentially dangerous. I am aware of reported deaths caused by the combination of methadone/buprenorphine with alcohol, opioids, cocaine, barbiturates, and/or tranquillizers.
5. It is important to inform any physician/dentist who might prescribe an opioid to me that I am taking methadone/buprenorphine.
6. I may voluntarily withdraw from the treatment program at any time.
7. Regarding pregnancy, I understand that there can be withdrawal symptoms in the baby caused by methadone/buprenorphine and that specialized care may be required for some days after birth.
8. It may be unsafe to drive a motor vehicle or operate machinery during the stabilization period after starting methadone/buprenorphine and during dose adjustments.
9. The common side effects of methadone/buprenorphine are sweating, constipation, decreased sexual function, drowsiness, increased weight, and water retention. These are usually mild and can be lessened with assistance from my doctor. There are also potential problems with sleep apnea or cardiac arrhythmias on higher doses of methadone.
10. I acknowledge that Dr. _____ is not my family doctor.
11. Methadone/buprenorphine treatment will be discontinued or tapered 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 be made worse by methadone/buprenorphine administration or I behave unsafely in the program).
12. I acknowledge that methadone/buprenorphine payment is my responsibility and that a payment plan must be in place prior to initiating maintenance treatment.

Behaviour while in the _____Clinic

I understand the following behaviour is unacceptable in the clinic and may result in the termination of treatment:

1. any violence or threatened violence directed toward the staff or other patients;
2. disruptive behaviour in the clinic or the surrounding vicinity of the methadone/buprenorphine clinic;
3. any illegal activity, which includes selling or distribution of any kind of illicit drug in the clinic or the surrounding vicinity of the methadone/buprenorphine clinic; and/or
4. Illegal activity or disruptive or threatening behaviour at the pharmacy.

I agree to maintain positive, respectful behaviour towards other program patients and staff at all times when in the clinic. Threats, racist or sexist remarks, physical violence, theft, property vandalism, the possession of weapons, and selling or buying illicit substances while on clinic property are extremely serious program violations and may result in the termination of my treatment and/or police intervention.

Obligations of being on this program

1. I agree to take only one dose of methadone/buprenorphine a day unless a split dose is prescribed for use, and to have the ingestion of my dose witnessed on those days that I do not have carries (take-home medication).
2. It is important to inform any prescribing physician or dentist who may provide treatment for any medical or psychiatric condition that I am receiving methadone/buprenorphine so that my treatment can be tailored to prevent potentially dangerous interactions. I will report any prescriptions that I receive from other doctors to the addiction clinic staff.
3. I agree to provide a urine sample for a drug screen when I receive a prescription methadone/buprenorphine. (Occasionally there may be a need to provide a supervised urine sample for testing.)
4. Failure to provide a urine sample may mean that my record will be marked as a sample assumed to contain drugs and that this could reduce my level of carries.
5. I understand that tampering with my urine sample in any way is a serious violation of the program, and that it may affect my future status in the program.
6. I understand that counseling is highly recommended while I am in the program.
7. I agree to keep all my appointments with the physician who is prescribing methadone/buprenorphine for me. Repeatedly missing appointments may result in the reduction of my carry status and could interfere with the doctor-patient relationship. The physician is not obligated to supply a methadone/buprenorphine prescription without an assessment.

I understand that I will not be given a dose of methadone/buprenorphine if I

1. appear to be intoxicated or under the influence of some other substance. (I may be asked to see a physician or a delegate of the physician. For the sake of my own physical safety, I may be asked to wait before receiving my dose, or refused a dose for that day.)

2. arrive late, or after the clinic/pharmacy closes.
3. exhibit threatening or disruptive behaviour towards any staff member or another patient.
4. do not show proper identification before receiving methadone/buprenorphine, if asked for identification.
5. miss three or more consecutive doses of methadone or five consecutive doses of buprenorphine. (The dose of medication needs to be lowered after multiple missed doses.)

Regarding carries (take-home methadone/buprenorphine doses)

1. I am aware that methadone/buprenorphine is potent a medication. **A single dose taken by a person 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 and store it in a location where it is unlikely to be stolen or accidentally taken by another person.
2. I agree that my physician with input from therapists, nurses, and pharmacy staff will decide the number of take-home dose I receive as I progress in my treatment.
3. I agree not to give, lend, or sell my take-home dose(s) to anyone.
4. I agree that I will consume the methadone/buprenorphine on the dates specified on the medication label and in the appropriate manner, i.e., a full dose taken within every 24 hours.
5. I agree to return all empty methadone bottles at the pharmacy on the day directly after the day I have received take-home dose(s), if I am requested to do so by clinic or pharmacy staff.
6. I agree that take-home doses will ***only*** be given if I leave urine screens according to the schedule arranged with my doctor.
7. If an appointment is missed and a prescription runs out, I will be asked to attend the clinic in person before a new prescription is given. Carries may also be restricted.

Consents

- I allow my methadone/buprenorphine prescribing physician to speak to other doctors or health care professionals about my care.
- I allow the clinic's pharmacist and nursing staff to speak to pharmacists or other health care providers to verify my recent methadone/buprenorphine dose(s) I have received at another pharmacy or institution. (Nurses and other clinic staff follow PHIA and clinic policies regarding privacy and may ask for specific signed consents as necessary.)
- I allow clinic staff to review my DPIN (pharmacy prescription record) as deemed necessary by clinic staff. I am aware that my DPIN will be reviewed on admission to prevent potential adverse drug interactions.
- I allow my methadone/buprenorphine physician to speak to his/her regulatory body (Registrar of the College of Physicians and Surgeons) to review any aspects of care if deemed necessary.

Confidentiality

Everything I tell the clinic staff is confidential, although it is important to realize that under exceptional circumstances they may be obliged to report something I tell them to the appropriate

authority. This can occur under the following conditions:

- If the clinic staff suspect that a child is at risk of emotional or physical harm or neglect, the law prescribes that they report this information.
- If I become suicidal, homicidal, or are unable to take care of myself due to a psychiatric condition, I might be held to be assessed by a psychiatrist against my will.
- If I reveal to the staff that I intend to harm another person, they will be obliged to protect that person by notifying the appropriate authority.
- If a Court subpoenas my medical chart, the staff must release it in accordance with the subpoena.
- If my behaviours or addiction raises serious concerns about safety for myself or the public, the staff may need to report concerns to an appropriate authority (e.g. notifying Motor Vehicle Branch).

I agree to respect the confidentiality of other patients in the program.

My signature below indicates that I agree to follow the obligations and responsibilities outlined in this agreement. Should I fail to meet the terms of this agreement, I understand that I may be asked to leave the methadone/buprenorphine program. ***I have had an opportunity to discuss and review this agreement with my attending physician and my questions (if any) have been answered to my satisfaction.***

_____	_____	_____
Dated (dd/mm/yyyy)	Patient's Name	Patient's Signature
_____	_____	_____
Dated (dd/mm/yyyy)	Physician's Name	Physician's Signature

Appendix E: Pharmacy Agreements

Satellite Pharmacy Agreement

Intent of Agreement:

An integrated, comprehensive approach to an effective, accessible methadone/buprenorphine maintenance program includes involvement from a wider community. This approach focuses on client engagement and retention and a defined Program Team supports the endeavour. Community pharmacies are designated as members of the Program Team along with nurses, counselors, physicians and other community-based resources. Involvement of a wider community fosters the development of working referral networks and inter-agency protocols, agreements and service contracts.

Name of Client:			
Pharmacy:			
Pharmacy Address:			
Pharmacy Telephone No.:		Fax No.:	
Program Contact:		Tell no:	
Commencing Date:			

Terms of Agreement for Client Pharmacy and Methadone Clinic Staff

1. The pharmacist agrees to provide methadone/buprenorphine for the client at the dosage set by the program physician.
2. The pharmacist (or designate) agrees to provide an area of privacy to witness the consumption of methadone/buprenorphine.
3. The client agrees to take methadone/buprenorphine in the presence of a designated pharmacy staff at these mutually agreed upon times:

DAY	MON.	TUES.	WED.	THURS.	FRI.	SAT	SUN.
Time							
Drink (D)							
Carry (C)							

4. The pharmacist agrees that methadone/buprenorphine is to be withheld if either of the following occur:
   a) The client presents under the influence of drugs or alcohol.
   b) The client has missed three (3) consecutive days of methadone/buprenorphine consumption. The pharmacist agrees to contact the Program Team if either of the above occurs.
5. The client agrees to attend the pharmacy in a sober state, and is aware that methadone/buprenorphine will be withheld if he or she appears intoxicated.
6. The client agrees that *ANY* request for "take away" doses beyond the stated schedule will be arranged with his or her program nurse at least 24 hours in advance. Any changes to the dosing schedule will be faxed to the pharmacist via the "Carry Authorization Form".

7. The client agrees to schedule and attend an appointment with the Program staff to renew their methadone/buprenorphine prescription. It is the sole responsibility of the client to be aware of their prescription expiration date.
8. Other conditions

_____	_____
Client Signature	Date
_____	_____
Pharmacist Signature	Date
_____	_____
m.i.n.e. Staff Signature	Date

Letter to Pharmacy (Sample)

(Clinic letterhead)

Dear Pharmacist:

Our patient has chosen your pharmacy for Methadone/Buprenorphine Maintenance Treatment. We encourage an active communication between the pharmacist and physician for proper care of our patients. The following clinic policies must be adhered to so that patient safety is maximized. You may contact the clinic at _____.

Clinic policies:

1. Patients are required to take their methadone or buprenorphine in front of the pharmacist. Ask the patient to speak after they have drunk the liquid or taken the tablet to ensure that it is swallowed or that the tablet is dissolved.
2. We need to be informed of any diversion.
3. We need to be informed of any missed methadone/buprenorphine doses by the patient. Please call _____ to leave a message regarding this matter.
4. If three or more doses of methadone, or five or more days of buprenorphine are missed in a row, the dose must be withheld from the patient to prevent an overdose. The patient must be reassessed at our clinic before methadone/buprenorphine is restarted. Please call to inform us.
5. If there is any evidence of intoxication or sedation (slurred speech, stumbling gait, disorientation) the methadone/buprenorphine dose must be withheld from the patient to prevent an overdose. The patient must be reassessed at the clinic before methadone/ buprenorphine is restarted. Please call to inform us.
6. Carries should be dispensed in childproof bottles. Patients should be told by the pharmacist to keep the bottles in a locked box. (The clinic has already discussed this issue with the patient.)
7. Our prescription must be strictly adhered to with no extra doses, increases or decreases in doses, or changes to carries without consulting the physician.
8. If the patient is observed by the pharmacist to vomit their methadone/buprenorphine within half an hour of their dosage, then please notify the physician.
9. Carry bottles are to be returned to the pharmacy on a weekly basis.

Appendix F: Manitoba Addiction Resources

An extensive list of resources can be found on the Manitoba Addiction Knowledge Exchange website (www.afm.mb.ca/makeconnections). Services that may be of use to patients with opioid use disorder are listed below:

Methadone Clinics

Addictions Foundation of Manitoba
m.i.n.e. (Methadone Intervention and Needle Exchange Program)
Unit 7-25 Sherbrook St
Winnipeg, MB R3B 2B1
Phone: (204) 944-7070
http://www.afm.mb.ca

Addictions Foundation of Manitoba
m.i.n.e. (Methadone Intervention and Needle Exchange Program)
510 Frederick Street
Brandon, MB R7A 6Z4
Phone: (204) 729 3838
http://www.afm.mb.ca

CARI Clinic
641 Broadway Avenue
Winnipeg, MB R3C 0X2
Phone: (204) 784-2840
https://afm.mb.ca/makeconnections/directory-listing/cari-clearview-addiction-rehabilitation-institute-methadone-clinic/

CARI Clinic
893 Main Street
Winnipeg, MB R2W3P2
Phone: (204) 944-1766

OATS Methadone Program (Winnipeg – Turtle Mountain)
968 Main St
Winnipeg, MB R2W 3P5
Phone: (204) 589-3999

OATS Methadone Program (Winnipeg – South Point)
103-1151 Pembina Highway
Winnipeg, MB R3T 2A3
Phone: (204) 504-9772

OATS Methadone Program (Winnipeg –North Point)
1412 ½ Main Street
Winnipeg, MB R2W 3V4

Phone: (204) 505-0560

MBATC (Manitoba Addiction Treatment Centre)
542 Selkirk Avenue
Winnipeg, MB R2W 2M9
Phone: (204) 505-0560
http://www.mbatc.ca

River Point Centre
146 Magnus Avenue
Winnipeg, MB R2W 2B4
Phone: (204) 944 6209

Family Practice Clinics

Some methadone care is provided to a smaller number of patients at the following family practice clinics:

Klinic Community Health Centre
870 Portage Avenue
Winnipeg, MB R3G 0P1
Phone: (204) 784-4090

Nine Circles
705 Broadway
Winnipeg MM R3G 0X2
Phone: (204) 940-6000

Aikins Street Community Health Centre
601 Aikins St
Winnipeg, MB R2W 4J5
Phone: (204) 940-2025

Appendix G: Health Sciences Centre Addiction Services

Addiction Unit at Health Sciences Centre

The address is:

Addiction Unit, Ward GB-2
Health Sciences Centre
820 Sherbrook Street
Winnipeg, MB R3A 1R9

The purpose of admission is

1. to stabilize and arrange further care for pregnant patients; and
2. to assess, stabilize, or detoxify patients that are more complex.

To discuss and arrange possible admission contact: Dr. Marina Reinecke at 204-787-3877.

The Addictions Unit Opioid Assessment Clinic

The purpose of the clinic is

1. to provide outpatient assessment of patients where complex issues of addiction/chronic pain/psychiatric illness may be present;
2. to arrange assessment, fax referral to 204-787-3996, attention Dr. J. Simm or Talia Weisz.

Psychiatric Addiction Services at Health Sciences Centre

- ***CODI Program***

- ***DBT/Addiction Program*** ***Dr. Hynes to fill out as he feels appropriate***

- ***Consultations***

Residential or Intensive Outpatient Treatment Programs

Patients on methadone/Suboxone® are accepted in these programs.

1. Addiction Foundation of Manitoba has men's, women's, and co-ed programs at a variety of locations. Inpatient programs generally take four weeks; there is no cost to the patient.

2. Anchorage (Salvation Army Program) allows two months of residential, co-ed treatment.

3. Behavioural Health Foundation is strongly abstinence-based, but will allow select patients one month to taper off methadone or buprenorphine.

Current contact information for all programs is available on the Manitoba Addiction Knowledge Exchange website. Other potential resources or residential programs can also be found on the website (www.afm.mb.ca/makeconnections).

Appendix H: Index of Medications

REFERENCES

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