



METHADONE MAINTENANCE GUIDELINES

November 2005



THE
COLLEGE
OF
PHYSICIANS
AND
SURGEONS
OF
ONTARIO

These guidelines are in effect as of November, 2005.

This document may be reprinted and distributed in its entirety for non-commercial purposes without permission, but permission must be obtained to edit its content.

The College of Physicians of Ontario
80 College Street, Toronto, Ontario M5G 2E2
Telephone: (416) 967-2661.

Table of Contents

PREFACE 3
 Evidence-based Review 3
 Limitations 4
 Levels of Evidence 4

INTRODUCTION 5
 Effectiveness of Methadone 5
 Conclusion 5
 General Expectations 6

CRITERIA FOR ADMISSION 7
 General Considerations 7

ASSESSMENT 8
 Document the Patient’s History 8
 Focused Physical Examination 8
 Initial Urine and Blood Screening 8
 Explaining Treatment Options 9
 Treatment Agreement (Plan) 9

METHADONE DOSING ISSUES 12
 Safety of Initial Doses of Methadone 12
 Effectiveness and Safety of Different Methadone Dosing Levels 13
 I. Opioid Withdrawal, Tolerance and Overdose 14
 II. Guidelines on Methadone Dosage Adjustment 16
 (i) The early stabilization phase (0–2 weeks) 16
 (ii) The late stabilization phase (2–6 weeks) 21
 (iii) The maintenance phase (6 weeks +) 21
 Management of Low and High Maintenance Doses 22
 Split Doses 24
 Methadone Tapering 25
 Missed Doses and Loss of Tolerance 25
 Vomited Doses 26

URINE DRUG SCREENING 27
 Urine Collection 28
 Frequency of Urine Testing 28
 Urine Toxicology 29

METHADONE MAINTENANCE GUIDELINES

COUNSELLING	29
CARRY POLICY	30
Clinical Stability	31
Length of Time in Treatment	31
Safe Storage	32
CARRY SCHEDULE	32
Reassessment and Reduction of Carry Privileges	33
Managing Relapse	33
Exceptions to Carry Schedule	34
Prescription Issues	37
INVOLUNTARY DISMISSAL FROM CARE	38
METHADONE AND ACUTE PAIN	40
MMT IN A CORRECTIONAL FACILITY	41
Issues Unique to Providing MMT in Correctional Facilities	42
Treatment Planning for Release	43
Reporting to CPSO	44
Observed Administration	45
APPENDIX A Diagnostic Criteria for Substance Dependence	48
APPENDIX B Diagnostic Criteria for Opioid Withdrawal	49
APPENDIX C Suggested Criteria for Methadone Treatment	50
APPENDIX D Opioid Detoxification Protocol	51
APPENDIX E Initial Patient Assessment Form	52
APPENDIX F Sample Methadone Treatment Agreement	57
APPENDIX G Sample Addiction Medicine Clinical Note	62
APPENDIX H A Patient's Guide—Avoiding Overdose	64
APPENDIX I Sample Letter to Pharmacy	65
APPENDIX J Patient Treatment Form	66
APPENDIX K Managing Potential Methadone Overdose	New
REFERENCES AND LITERATURE REVIEW	67
ABOUT THE COLLEGE	72

PREFACE

In 1996, the College of Physicians and Surgeons of Ontario (CPSO; the College) began to administer the provincial methadone program on behalf of the Ministry of Health and Long-Term Care. The mandate of the College's program to improve the quality and accessibility of methadone maintenance treatment in Ontario is achieved in cooperation with the Centre for Addiction and Mental Health (CAMH) and the Ontario College of Pharmacists (OCP). The profile of methadone treatment in Ontario has been enhanced through outreach activities and the recruitment of physicians to prescribe methadone in the treatment of opioid dependence.

The following guidelines are a combination of evidence-based research and clinical consensus for prescribing methadone in the maintenance treatment of opioid dependence. These guidelines are not intended to substitute for sound clinical judgment. In a specific instance where a patient's individual circumstances provide clinical justification for deviating from the guidelines, a physician may do so. However, it is expected that he or she will document any deviation from the guidelines in the patient's medical record indicating the clinical reason(s) for doing so.

The College's guidelines were developed for use by doctors providing methadone maintenance treatment in Ontario. Each province regulates methadone treatment and guidelines may vary between provinces. These guidelines replace the College's October 2001 and August 1996 *Methadone Maintenance Guidelines*, and Health Canada's "*The use of opioids in the treatment of opioid dependence*," published in 1992.

For a comprehensive physician reference, please see *Methadone Maintenance: A Physician's Guide to Treatment*, 2nd Edition, CAMH

Evidence-based Review

A literature review was conducted which focused on the effectiveness and safety of methadone, urine drug screening and take-home doses. The review was conducted using various MedLine search terms such as 'methadone, toxicity, dose, urine drug screen, take-home doses, and cognitive effects.' The search was not restricted to randomized controlled trials but looked at cohort, case control and descriptive studies.

Limitations

- Due to limited time and resources, the College's Methadone Guidelines Working Group did not conduct a systematic review, in which the quality of all relevant studies is rated according to objective criteria. The review relied on systematic reviews, where available.
- It is possible that not all relevant articles were identified (such as NIDA research monographs, articles in German, and older articles).
- Where evidence is limited or inconsistent, the Guidelines Working Group relied on consensus amongst methadone prescribers.

Levels of Evidence

General conclusions were reached for each major topic, accompanied by the level of evidence supporting the conclusion. Sometimes, the levels are accompanied by descriptors such as 'strong', 'weak' or 'inconsistent'. These are based on such factors as the study's sample size and length of follow-up. The levels are based on the rating system developed by McKay and Moore:

- I. Strong evidence from at least one systematic review of multiple well-designed randomized controlled trials.
- II. Strong evidence from at least one properly designed randomized controlled trial of appropriate size.
- III. Evidence from well-designed trials without randomization, pre-post, cohort, time series, or matched case-control series.
- IV. Evidence from well-designed, non-experimental studies from more than one centre or research group.
- V. Opinions of respected authorities, based on clinical evidence, descriptive studies, or reports of expert committees.

The levels of evidence are based on the rating system developed by McKay, H and Moore, A; *An evidence-based resource for pain relief*, 1998: Oxford University Press.

INTRODUCTION

Effectiveness of Methadone

Methadone is a synthetic mu opioid agonist with good oral bioavailability and a long duration of action. It is used in the treatment of opioid dependence because it helps prevent opioid withdrawal symptoms, reduces cravings for opioids, and blocks the euphoric effects of shorter acting opioids.

Methadone Maintenance Treatment (MMT) reduces morbidity and mortality associated with heroin addiction (Level I).^[2-5] One study found that patients were three times as likely to die if not receiving MMT than if they were maintained on treatment.^[6] In addition, studies have shown that MMT can indirectly decrease mortality by decreasing the risk of HIV infection while on MMT.^[7-8] A Cochrane review^[21] of six randomized clinical trials found that methadone was more effective than non-pharmacological treatments with respect to the outcomes of treatment retention (RR = 3.05) and suppression of heroin use (RR = 0.32). The great majority of trials were with heroin users.

MMT has higher retention rates than other treatment modalities (Level I).

For example, in one study^[3] of methadone treatment versus placebo, treatment retention at three years was 2% for the placebo group and 56% for the methadone group. Treatment retention is associated with reductions in drug use and crime.^[1,9]

There is Level I evidence that MMT reduces illicit opioid and other drug use.

For example, in an early trial of methadone versus control, it was found that in addition to having much higher rates of incarceration, the control group was also 92 times more likely to be using heroin on a daily basis.^[14] MMT also reduces other substance use. One large prospective study^[15] of methadone patients found a reduction in the use of cocaine, amphetamines, illegal methadone, sedatives, and marijuana at follow-up. Other factors associated with decreased drug use include counselling, adequate dosing, contingency management strategies such as take-home doses, and harm reduction program orientation.^[5-6,11-13,16-18,20]

Conclusion

Methadone maintenance treatment reduces illicit heroin use and its associated morbidity and mortality. The effectiveness of treatment is enhanced with contingency management and counselling. The benefits of methadone treatment

for prescription opioid users have not been extensively studied. Therefore, physicians should ensure that such patients meet DSM-IV criteria for dependence; are more likely to benefit from methadone treatment than other forms of treatment; and are likely tolerant to opioids.

General Expectations

It is expected that methadone treatment programs and/or physicians providing MMT will:

- Ensure that patients are treated with compassion, respect and dignity regardless of race, creed, age, gender, disabilities, or sexual orientation.
- Retain competent and responsible personnel who will adhere to a strict code of professional ethics including but not limited to the prohibition of fraternization with patients, exploitation of patients, and criminal behaviour.
- Subscribe to the treatment principles contained in these MMT guidelines (2005 edition), which serve as a guide to physicians in making therapeutic treatment decisions.
- Provide patients with accurate and complete information regarding methadone treatment, the nature of available services, and the availability of alternative treatment modalities prior to admission and throughout the treatment process.
- Ensure that discharge from treatment is conducted in accordance with sound and medically acceptable practice. The patient will be assured of due process if the discharge is administrative in nature.
- Provide a safe and clean environment for patients and staff that is conducive to the therapeutic process.
- Remain in compliance with the required federal, provincial and local operating standards and legislation such as *Controlled Drugs and Substances Act*.
- Take all necessary and appropriate measures to maintain individual patient records and information in a confidential and professional manner.
- Strive to maintain good relations with the surrounding community and pursue every reasonable action to encourage responsible patient behaviour and community safety.

CRITERIA FOR ADMISSION

Individuals requesting admission to a methadone maintenance treatment program must meet the DSM-IV criteria for opioid substance dependence. See Appendix A.

General Considerations

Before initiating MMT, inform patients of all other treatment options to treat opioid dependence so they may make an informed decision about starting MMT.

Patients may not receive methadone treatment from more than one treatment facility/doctor at a time. For this reason, prior to initiating treatment, patients should have CPSO approval, or at least a minimum of one urine screen that is negative for methadone and positive for opioids.

Patients may be suitable candidates for MMT even if it was unsuccessful or discontinued in the past.

Adolescents – Those of a younger age (<18) may be considered for MMT in special circumstances. In cases where a doctor considers it appropriate to offer an adolescent MMT, it is recommended that he or she consider seeking assistance by referral, or consultation (formal or informal) with a physician knowledgeable in adolescent addiction medicine. Methadone should always be considered as a last treatment option for adolescents. A trial of medical detox with counselling should be tried first, unless the adolescent is HIV-positive or pregnant.

Pregnancy – MMT 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, pregnant patients be stabilized in hospital. A list of physicians who are experienced in this area is available from the CPSO. Physicians can also contact the Toronto Centre for Substance Use in Pregnancy (T-CUP) at St. Joseph's Health Centre at (416) 530-6860, or the Addiction Clinical Consultation Service (ACCS) at 1-888-720-2227.

The CPSO requires a urine drug screen analysis before MMT is initiated. However, a conditional start may be appropriate if the clinical circumstances warrant it (i.e., recent incarceration or pregnant), and the reasons are documented.

ASSESSMENT

A medical and psychosocial assessment should be completed prior to beginning treatment. The purpose of the assessment is to document the patient's dependence on opioids, evaluate the complications related to drug use and other medical conditions. Psychiatric problems and high-risk behaviour should be assessed to recommend a comprehensive and practical treatment plan. The components of the assessment are as follows:

I. Document the Patient's History

In addition to the standard medical history, the physician should document the diagnosis of opioid dependence using DSM-IV criteria (see Appendix A), the pattern of use of all major drug classes (including tobacco and alcohol), and addiction treatment history and response. High-risk behaviour, such as needle sharing, should be documented. The physician should also review past psychiatric history, current mental status (particularly suicidal ideation), and the patient's social situation (including child custody and the partner's substance use history). A history of chronic or recurrent pain should also be documented.

II. Focused Physical Examination

A focused physical examination should be performed prior to starting a patient on methadone. Special attention should be given to signs of opioid withdrawal; malnutrition; jaundice; hepatosplenomegaly; cardiovascular and respiratory status; pupil size; needle tracks; and abscesses.

III. Initial Urine and Blood Screening

A urine drug screen should be completed and interpreted prior to initiation of MMT. The results should confirm the presence of opioids and identify the patient's primary opioid of abuse. A broad-spectrum initial analysis or an opioid-specific immunoassay will be helpful in most instances. An initial immunoassay screen that is positive for opioids without identifying the specific opioid may be sufficient if there is strong clinical evidence that the patient is opioid dependent (i.e., obvious opioid withdrawal signs along with track marks, corroborating information from a physician, or previous MMT). As a general rule, the validity of the urine screen increases if the sample collection is done under supervision. Methadone may be initiated even if the urine screen is negative, if the patient is HIV-positive, pregnant, or recently incarcerated.

DSM-IV Diagnostic Criteria for Substance Dependence see Appendix A.

If the initial result is inconsistent with the patient's self-reported drug use (for example, it is negative although the patient reported opioid use that day), the patient will require a more thorough assessment to confirm a diagnosis of opioid dependence. This may involve a repeat urine screen or corroboration from the patient's physician. It is important to note that semi-synthetic and synthetic opioids have high false negative rates. Other options should be offered to patients with withdrawal symptoms if methadone is not prescribed on the initial visit (see Appendix D). In addition to urine screening, initial testing should include TB skin testing (if high-risk), an HIV test, Hepatitis B and C serology, liver function tests, and a pregnancy test.

IV. Explaining Treatment Options

After the assessment is completed, the patient should be informed about other treatment options. These may include opioid detoxification (see Appendix D), buprenorphine maintenance therapy, opioid antagonist therapy with naltrexone, mutual support groups (i.e., NA, AA), withdrawal management centres, and residential or non-residential treatment programs. Medical detoxification is rarely successful on its own and should always be combined with intensive counselling and follow-up. Methadone providers are encouraged to consult with addiction specialists if they are unfamiliar with other treatment options, and possibly refer patients to an addiction specialist, if the circumstances require it.

Although MMT is more effective than methadone tapering, the latter may be appropriate for patients who are motivated to abstain and willing to connect with an aftercare program. The taper should be gradual and comfortable, lasting anywhere from two weeks to six months. Patients should have a role in deciding the rate of the taper. When a daily dose of 10–20 mg is reached, the taper may need to be slowed and adjuvant medications may be required (see Appendix D). Patients should be encouraged to attend an aftercare program, and informed of the high risk of overdose if they relapse.

V. Treatment Agreement (Plan)

It is recommended that each physician (or program) use a treatment agreement, which should include the following sections:

1. *Informed consent (signed agreement and/or information sheet)*
2. *General consents*
3. *The physician's obligations to his or her patient*

Prescription drug abuse, such as Oxycontin, is a growing trend for patients entering methadone programs. Oxycodone does not appear on routine immunoassay testing, but can be detected with specific immunoassay dipsticks. These patients often don't exhibit typical withdrawal symptoms or have track marks on the initial visit.

The Ontario Drug and Alcohol Registry of Treatment (DART)
www.dart.on.ca
1 800 565-8603

Metro Addiction Assessment Referral Service (MAARS)
(416) 599-1448

4. *Program rules*

5. *Exceptions to doctor-patient confidentiality*

1. Informed consent

To ensure that patients give informed consent to treatment, sufficient information must be provided prior to initiating MMT, such as:

- The patient has considered the risks and benefits of treatment options other than MMT.
- MMT is generally a long-term (or lifetime) treatment. Many patients find it difficult to discontinue methadone treatment because tapering is associated with an opioid withdrawal syndrome.
- Patients may experience sedation or withdrawal during methadone initiation or dosage adjustment. Physicians should discuss with their patients the safety of driving or operating machinery during these times.
- Side effects from methadone include overdose, sedation, constipation, fatigue, decreased libido, and weight gain.
- Neonates born to women on methadone may undergo withdrawal. Neonatal withdrawal is treatable and has not been shown to cause long-term developmental or physical problems.
- It can be dangerous to combine methadone with alcohol, sedating drugs or drugs that interfere with methadone metabolism. The patient should inform the physician of all drug use, including illicit, prescribed, and over-the-counter drugs.
- For safety reasons, the pharmacist may withhold methadone and contact the physician if the patient appears intoxicated, or has missed doses for three or more days.
- When patients receive a prescription for opioids from another physician, they must inform that physician that they are on methadone. They must also inform the doctor providing methadone that they have received an opioid prescription. Failure to do so is a criminal offence (multiple doctoring).
- MMT is more effective when accompanied by counselling.

Patients are at risk of methadone toxicity after three missed doses due to loss of tolerance.

- **Patients must never allow anyone access to their methadone. Diverted methadone can cause serious harm or death.**
- Patients may choose their own pharmacy.
- Patients may withdraw from MMT at any time.

2. General consents

Patients are required to allow:

- The physician to report to the CPSO the patient's name, date of birth, OHIP number, city of residence, and the date methadone was initiated and completed.
- The exchange of information and communication between the physician and the pharmacist.
- A review of their medical chart by the CPSO or its designate, in order to assess the care provided by the treating physician. Patients have the right to request that their name be obscured for such a review, and if so, this must not have any impact on any decision made respecting the care of the patient.

3. Professional duties

Physicians owe a number of duties to their patients, including to:

- Provide professional, respectful and reliable services to patients.
- Provide back-up coverage for periods when on vacation or otherwise unavailable.
- Provide appropriate notice should they close their methadone practice. Physicians should assist in the transfer of patients to other doctors who prescribe methadone.
- Provide or facilitate patient access to health and social services, such as counselling and primary health care.
- Remain current in practices and standards for MMT and the treatment of opioid dependence.

Provide a copy of the treatment agreement to the patient. Revisit the treatment agreement once the patient is stabilized.

4. Program rules

It is important that the patient receive clear information about the program rules and expectations. Policies on carries, urine screens, appointments, and treatment discontinuation should be specified. See Appendix F for a copy of a sample program or treatment agreement.

5. Exceptions to doctor-patient confidentiality

Physicians should explain under which circumstances they may be required to break doctor-patient confidentiality. See Appendix F for specific examples.

METHADONE DOSING ISSUES

1. Methadone should be dispensed in a vehicle that does not lend itself to injection (e.g., Tang[®]).
2. Methadone/Tang[®] should be consumed under the direct supervision of a regulated health professional.

Safety of Initial Doses of Methadone

Patients are at a high risk of death from methadone overdose in the first two weeks of methadone treatment (Level IV). The mortality rate of patients enrolled in methadone programs was 1.7 per 1,000 in Ontario in the year 2000, with most of the deaths occurring in the first two weeks of treatment.^[1] This figure is similar to the mortality rate of other jurisdictions.^[2–3] The risk of fatal methadone overdose during the first two weeks of treatment is estimated to be 6.7 times higher than that of heroin addicts not in treatment, and 98 times higher than that of patients on maintenance doses of methadone.^[4] The reported death rate of 1.7 per 1,000 is substantially higher than that of other common medications. In a review of mortality from NSAIDs, tricyclic antidepressants and phenytoin, only one study with a mortality rate approaching methadone could be found (elderly rheumatoid arthritis patients taking prednisone and NSAIDs without cytoprotection).^[5]

Deaths have been associated with starting doses in amounts as little as 30–50 mg (Level IV). A single day's maintenance dose of methadone can be lethal to non-tolerant adults.^[6] In one case series of methadone deaths, the mean starting

methadone dose was 50 mg.^[7] The ratio between the maximum recommended initial dose (30 mg) and a potentially fatal single dose is exceedingly narrow compared to other medications.^[9]

Concurrent use of benzodiazepines, alcohol and other sedating drugs substantially increases the risk of methadone overdose death (Level IV). One study found evidence of polydrug use in 92% of methadone-related deaths.^[8] Benzodiazepine use causes a five-fold increase in risk of fatal overdose.^[10] In a report prepared by the Ontario Coroner’s Office, 60% of methadone-related deaths reviewed had benzodiazepines on their toxicology screen, and 30% had alcohol.^[1] Animal studies confirm that benzodiazepines increase the lethality of methadone.^[11] Other risk factors for methadone toxicity include lack of tolerance, respiratory illness, age, and medications that inhibit methadone metabolism (such as quinolone or macrolide antibiotics, fluconazole, and sertraline).^[12–14]

Effectiveness and Safety of Different Methadone Dosing Levels

There is Level I evidence that methadone doses of 60–100 mg are more effective than doses below 60 mg in reducing heroin use and retaining patients in treatment. Two systematic reviews of randomized controlled trials (RCT) and controlled prospective studies have concluded that higher doses (up to 100 mg per day) were more effective than lower doses (below 60 mg) at reducing illicit opioid use.^[17–18] Within that range, one RCT found that doses of 80–100 mg are more effective than doses of 60 mg or less.^[15] There is limited evidence regarding the effectiveness of doses of 120 mg or above compared to doses of 80–100 mg. Controlled trials rarely used doses above 110 mg.^[15–17] One randomized trial found that a fixed dose of 160 mg was no more effective than 80 mg, although both were more effective than 40 mg.^[18]

High doses of methadone are associated with Torsades de Pointes arrhythmias (Level II). Several case series have demonstrated that patients on very high doses of methadone are at risk for Torsades de Pointes caused by prolonged QT intervals. In one case series of 17 patients who had experienced Torsades, the mean methadone dose was 397 +/- 283 mg and the mean QT interval was 615 +/- 77 msec.^[22] Many of the patients had other risk factors for arrhythmias.^[22–24] A QT_c value of more than 500 msec is associated with increased mortality.^[26]

I. Opioid Withdrawal, Tolerance and Overdose

Physicians titrating methadone must be familiar with the clinical features of opioid withdrawal (see Appendix B).

Opioid withdrawal peaks at 2–3 days after the last use. Physical symptoms largely resolve by 5–10 days, although psychological symptoms can continue for weeks or months. Opioid withdrawal symptoms include myalgia, nausea, abdominal cramps, and chills. Psychological symptoms include restlessness, dysphoria, insomnia, anxiety, fatigue, and drug craving. The insomnia and anxiety can be severe and distressing.

Physical signs of opioid withdrawal include restlessness, lacrimation, rhinorrhea, dilated pupils, abdominal tenderness, vomiting, diarrhea, sweating, chills, piloerection, tachycardia, and hypertension. Serious complications of withdrawal include miscarriage, premature labour, suicide, and overdose on relapse due to loss of tolerance.

Tolerance is said to occur when higher doses are required over time to achieve the same effect, and the same dose has less effect over time. Tolerance to the psychoactive effects of opioids develops within days, and is lost within days.

Overdose risk increases with lack of tolerance, high opioid dose, parenteral use, and impaired metabolism due to medications or renal/hepatic insufficiency. Other risk factors include age, cardiorespiratory illness, use before onset of sleep, and concurrent use of sedative classification of drugs. Clinical features include decreased level of consciousness, decreased respiratory rate, bradycardia, and miosis. Long-acting opioids, particularly methadone, can have a gradual, insidious onset of symptoms. Individuals who have taken an opioid overdose appear to be drowsy and “nodding off” (momentarily falling asleep), with slurred, drawling speech, ataxia, and emotional lability.

Assessment of methadone withdrawal

The patient on inadequate doses of methadone will describe a characteristic set of symptoms such as muscle aches; hot flashes; an electric, restless or uncomfortable feeling; nausea; yawning; fatigue; and irritability. The symptoms appear a certain number of hours after the methadone dose, although there may be some variation with the patient’s activity level and other factors. The onset of symptoms is delayed with each dose increase.

The typical reasons for dose increases include:

- (1) Signs and symptoms of withdrawal
- (2) Amount and/or frequency of opioid use not decreasing
- (3) Persistent cravings for opioids
- (4) Failure to achieve a dose that blocks the euphoria of opioids

Alternative explanations should be sought if the patient:

- gives an inconsistent history of withdrawal symptoms;
- has one isolated symptom (such as insomnia or nausea);
- advises the onset of symptoms is not related to the time of the dose; or
- has been taking a stable dose and suddenly complains of withdrawal (see below).

A dose might be considered acceptable if the patient sleeps comfortably at night and only has mild withdrawal symptoms on awakening.

Conditions commonly confused with withdrawal

The clinician should determine why the patient continues to report withdrawal symptoms despite dosage adjustment. Common reasons for ongoing withdrawal include use of medications that speed methadone metabolism (such as phenytoin, chronic alcohol use), continued opioid use, and dose diversion. Physicians should consider discussing a medication review with the pharmacist. The following conditions cause symptoms that are confused with withdrawal.

Pseudonormalization should be suspected if the patient regularly complains some weeks after a dose increase that it is no longer ‘working.’ Patients who are mildly intoxicated on opioids feel more enthusiastic and energetic. As they develop tolerance, they may feel they need a dose increase to recreate this effect, which they view as both desirable and normal.

Insomnia is often the dominant symptom of opioid withdrawal. Other causes should be ruled out if the patient reports insomnia that isn’t accompanied by other withdrawal symptoms and is not relieved by a dose increase. Depression, anxiety, and use of alcohol and cocaine are common causes of insomnia in this population.

A careful sleep history will identify day-night reversal, daytime napping and other causes of nighttime insomnia. Careful instruction in sleep hygiene should be undertaken. Medication should be used only when the patient is on a stable dose and sleep hygiene counselling has failed. Trazodone or other non-benzodiazepine hypnotics are the treatments of choice.

Occasionally patients report sedation several hours after dosing, with withdrawal symptoms and insomnia at night. This can be difficult to sort out. The sedation may simply represent the onset of sleep following a night of insomnia due to

withdrawal. The methadone dose might be too high, causing excessive sleep during the day and inadequate sleep at night. Perhaps the patient has day-night reversal, independent of the methadone dose.

Other conditions: Patients may be anticipating that an increase in their dose will manage symptoms that have little to do with withdrawal. Common examples include depression, anxiety, irritable bowel syndrome, and some forms of chronic pain. The physician should identify these symptoms, explain to the patient the limitations of methadone, and assist the patient in finding an appropriate management strategy.

Clinical criteria for dosage increases

The physician should consider increasing the patient's methadone dose if the patient experiences withdrawal, ongoing opioid use, or cravings. Persistent opioid cravings or opioid use may indicate the need for a dose increase, even in the absence of reported withdrawal symptoms.

One simple way to assess the adequacy of the dose is to ask the patient how long it "lasts" (i.e., the time interval between taking the methadone and the first appearance of withdrawal symptoms). For example, if the patient takes methadone in the morning and experiences the onset of withdrawal symptoms in the early afternoon, further dosage adjustment is needed. The optimal dose is one that is effective throughout the day and night without causing sedation.

II. Guidelines on Methadone Dosage Adjustment

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

(i) 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. The patient may appear relatively alert during the day, succumbing to 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.

Based on this, the following dosing protocol is suggested:

- The initial dose should be 10–30 mg of methadone per day for the first three days. Patients at high-risk for methadone toxicity should be started on no more than 10–20 mg.
- During the early stabilization phase, doses should not be increased by more than 5–15 mg every three to four days. Caution is advised when titrating patients at high-risk for methadone toxicity.

Patients at High-risk for Methadone Toxicity

An initial dose of 10–20 mg, with careful dosage titration, is recommended for the following high-risk patients:

Recent benzodiazepine use. This applies to both abuse and therapeutic use. An exception might be the patient who has been on a small HS dose for at least several months.

Use of other sedating drugs such as antipsychotics and sedating antidepressants, 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, screening questionnaires such as the CAGE, and laboratory measures (GGT and MCV). All patients should be advised to abstain from alcohol during early stabilization. Drinkers at risk for withdrawal on sudden cessation of alcohol should be detoxified before methadone initiation. Assistance from an addiction medicine physician is advised.

Older age (>60 years), respiratory illness including chronic illnesses such as COPD, and acute illnesses such as pneumonia.

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

“Start low—go slow dosing”

Three days represents the average time taken for an individual being dosed daily to reach 87.5% of steady state for a drug with an elimination half-life of 24 hours.

Patients at high-risk for methadone toxicity should be started on a lower methadone dose (10–20 mg).

Sedating drugs should be avoided, if possible, during the early stabilization phase of MMT.

Some drugs that inhibit methadone metabolism:

- Fluconazole
- Quinolone antibiotics
- Erythromycin
- Cimetidine
- Luvox

Overdose can result from sudden cessation of a drug that promotes methadone metabolism (e.g., carbamazepine, phenytoin).

Useful resource for methadone drug interactions:
www.atforum.com
www.drug-interactions.com

Lower opioid tolerance. Tolerance is difficult to establish by history, so, if in doubt, it is safer to initiate on 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 patients' self-reported use of opioids.

Reducing Risk During the Early Stabilization Phase

Avoid prescribing any sedating drugs during the early stabilization phase.

This includes benzodiazepines, non-benzodiazepine hypnotics, antipsychotics, antidepressants, and sedating antihistamines. Even moderate, therapeutic doses of these drugs may increase the risk of overdose if they are initiated at the same time as methadone and the patient is not fully tolerant to their sedating effects. Patients should also be advised to avoid alcohol and over-the-counter sedating drugs.

High-dose benzodiazepine users should be tapered before initiating MMT.

Benzodiazepine abuse and dependence are common in this population. As with opioids, it is difficult to accurately judge a patient's benzodiazepine use and tolerance. Benzodiazepine tapering, while difficult on its own, can be very complicated and potentially unsafe when attempted with methadone initiation.

General advice to the patient and family. Explain to the patient that it takes several weeks to reach the optimal dose of methadone, and it is dangerous to try to relieve withdrawal symptoms with benzodiazepines, 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.

During the early stabilization phase, patients and their families (if the patient consents) should be educated about methadone toxicity. Patients should be assessed twice per week and not be granted any carries.

Explain 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 (see Carry Policy). Physicians must advise patients that it is dangerous to sell or give methadone to anyone, even in small doses, or done with 'good intentions.'

Educate the patient and family members about signs of impending overdose.

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

Intoxication at the pharmacy. At any stage of methadone treatment, the pharmacist should be instructed to alert the physician if the patient appears sedated or intoxicated. Intoxicated patients should not be medicated until assessed by their physician. If signs of intoxication are observed after ingestion of methadone, the patient should be sent to the hospital by ambulance for assessment.

Frequency of visits. Twice-weekly visits during the first two weeks of treatment are recommended, particularly if the patient is at increased risk for methadone toxicity or cannot be stabilized at a low dose. If possible, the visits should be scheduled for two to six hours after the methadone dose. The physician should inquire about sedation and other side effects.

Carries during initial titration. No carries should be granted during the first two months of treatment (including Sunday carries).

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 two or more doses consecutively, he or she should be restarted at the initial dose (10–30 mg) for at least three consecutive days.

Negative initial urine drug screen and recent abstinence. In patients who report no recent opioid use or have a negative initial urine drug screen, methadone should not be initiated unless recently abstinent in a supervised setting (incarceration, inpatient program, etc.). These patients should have a long history of opioid dependence, strong urges to use and/or a good response to MMT 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.

An intoxicated patient should never be medicated with methadone.

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[®]).
- The methadone dose must be consumed under the direct supervision of a regulated health professional.
- Physicians should implement policies to prevent overdose, including patient education and frequent assessment.

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 or drugs that inhibit methadone metabolism.
- Those 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).

Benzodiazepines and Other Sedating Drugs

- Start at a lower methadone dose if history or urine drug screen suggests recent use of benzodiazepines, alcohol or other sedating drugs.
- Avoid prescribing any sedating drugs during the early stabilization phase. Advise the patient to avoid all sedating drugs, including alcohol and over-the-counter antihistamines.
- Taper a patient from high doses of benzodiazepines prior to methadone initiation.

Other Policies to Reduce Risk

Patient education: Explain the risk factors and signs of overdose to patients (and their families, with consent) and advise them to seek immediate medical attention if the patient displays signs of toxicity (see Appendix H). Explain that even a single dose of methadone can be fatal to both children and adults.

Frequency of visits: Assess the patient twice per week for the first two weeks.

Carries: Do not prescribe take-home doses in the first two months of treatment.

Missed doses: Do not increase the dose for several days if the patient misses a dose. Restart the initial dose if the patient misses two doses in a row.

(ii) 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 of withdrawal symptoms, is only partially tolerant to methadone, and often continues to use opioids. During this period, dose adjustments should be made no more frequently than every three to four days. Dose adjustments are usually in the 5–15 mg range, depending on the severity, onset and duration of the patient’s withdrawal symptoms. Careful assessment of withdrawal symptoms is essential.

Patients should be seen at least weekly to assess and adjust their dose. All dose adjustments require a medical assessment by a physician, and the reason for the dosage adjustment should be documented. Avoid automatic dosage adjustments on the prescription (for example—“increase by 5 mg daily”), phone assessments or assessments through non-medical personnel.

(iii) The maintenance phase (6 weeks +)

By this time, most patients have substantially reduced their opiate use, 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 5 and 10 mg every five days to two weeks. The patient should continue to meet with the physician every one to two weeks during the first year, depending on the patient’s clinical stability. The frequency

of visits may be reduced thereafter depending on the clinical stability and recovery needs of the patient.

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. With experience, physicians can establish the stable dose for the majority of their patients within two to eight weeks of initiating MMT. **The stable dosage range for most MMT patients is 50–120 mg.**

A patient on an inadequate dose of methadone will typically describe a characteristic set of symptoms such as muscle aches, hot flashes, restlessness, irritability, dysphoria, nausea, yawning, and fatigue combined with irritability.

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

- Doses should only be increased after the physician has assessed the patient, and determined that the patient has symptoms of withdrawal, ongoing opioid use, or opioid craving.
- During the late stabilization phase, doses should be increased by no more than 5–15 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 5–10 mg every five to 14 days.
- For most patients, the optimal dose is between 50 and 120 mg.

Management of Low and High Maintenance Doses

Low dose maintenance, below 50 mg

Doses below 50 mg are less effective than higher doses at reducing heroin use and retaining patients in treatment. Low maintenance doses are justified for patients who have no unauthorized opioid use; report no significant withdrawal symptoms or cravings for opioids; are at high-risk for methadone toxicity; or are on a tapering protocol.

Maintenance doses, above 120 mg

Some patients that require maintenance doses above 120 mg may have either a higher innate tolerance to opiates secondary to longstanding 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 (see page 15). Drug craving alone is not an adequate reason to increase the dose above 120 mg.

The physician should consider requesting a second opinion if the patient continues to request additional dose increases above 120 mg. The consulting physician should have experience in addiction medicine and methadone treatment. The consultation may be formal or informal and should be documented in the chart.

Although controversial, peak and trough levels might be useful in patients who continue to report withdrawal symptoms despite doses of 120 mg or higher. If the trough level is high, the patient can be reassured that their symptoms are less likely to be due to withdrawal.

The physician should inquire about whether the patient or his or her family has observed cognitive effects that could be attributed to high dose methadone, such as ‘nodding off,’ lethargy, diminished concentration or memory.

High methadone doses may be associated with cognitive impairment on neuropsychological testing (Level III).^[29–35] Caution is advised when titrating patients at risk for cognitive impairment, e.g., those on sedating drugs.

An ECG is suggested for patients on a methadone dose greater than 150 mg. The ECG should be repeated if the patient is at a dose approaching 180–200 mg. They should be referred to a cardiologist and their dose carefully tapered if the QT interval is above 470 msec. The physician should identify and manage risk factors for arrhythmias (e.g., medications that affect the QT interval or affect methadone levels; medications that can trigger arrhythmias, i.e., cocaine or tricyclic antidepressants; electrolyte abnormalities; cardiomyopathy).

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.

The possibility of diversion of high range doses should always be considered.

Summary of Recommendations for Management of Patients on Doses Greater 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.
- A consultation should be considered if the physician has continuing difficulty in stabilizing the patient's dose above 120 mg.
- A cardiogram should be obtained on all patients at doses greater than 150 mg, and repeated as the patient approaches 180–200 mg. Patients with a QT_c interval of 470 msec or above should be referred to a cardiologist and should have their dose carefully reduced. Special caution is required for patients at higher risk for arrhythmias.

Split Doses

Split dosing is an alternative way of providing methadone to patients, consisting of two or more doses per day. It is most commonly used for clinically stable patients who suffer from chronic pain when other non-narcotic pain medications have been ineffective. Physicians should obtain an exemption from Health Canada if they want to prescribe methadone for pain treatment, and refer to the CPSO *Methadone for Pain Guidelines*.

Split doses are also used for patients who have demonstrated "rapid metabolism" of their once daily methadone dose (e.g., during pregnancy) or are on medications that have been shown to induce rapid metabolism of methadone (i.e., certain HIV medications). A consultation with an experienced MMT provider should be considered in these circumstances. Split dosing is NOT recommended for any patient who does not meet the criteria of clinical stability (see page 31), or for those patients who are not otherwise eligible for take home doses. In certain situations, temporary split dosing may benefit clinically stable patients who suffer from acute pain, but once the pain is resolved, single dosing should be resumed. (See Methadone and Acute Pain section).

Methadone Tapering

Tapering is most likely to be successful if the patient has been abstinent from illicit substances for a substantial period of time, does not have current, untreated psychiatric co-morbidity, and has strong social supports and counselling. 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, as withdrawal symptoms become more pronounced. The patient should have a major role in deciding the rate of the taper. The taper should be accompanied by counselling 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 they experience severe withdrawal symptoms, cravings, or clinical instability.

Missed Doses and Loss of Tolerance

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 in a timely fashion. Some pharmacists use a fax form for this purpose.

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 that 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 they have been reassessed by the prescribing physician and the remainder of their prescription should 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 consider reducing 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 greater than 30 mg, common practice after three missed days is to restart the patient at 50% of their 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 is demonstrated, the dose can be rapidly increased (by no more than 10 mg per day). Slower dose escalation is suggested for patients with an unstable clinical picture or concurrent benzodiazepine use. The patient should

As with any period of dose escalation, the treatment team should be particularly vigilant regarding compliance. When patients miss doses and are given their prescribed, scheduled dose increase, they are at risk of overdose.

METHADONE MAINTENANCE GUIDELINES

Often patients who miss doses will be comfortably restabilized on a lower dose of methadone.

As it is impossible to completely empty the gut with even violent emesis, repeated dose replacement can lead to unexpected overdose. The underlying cause needs to be sought.

be assessed every two to three days during this rapid titration. Often the patient is comfortable with a lower maintenance dose.

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 per day) toward the previous stable dose with reassessment by the physician every two to three days.

Vomited Doses

Vomited methadone doses are not replaced, in full or in part, unless a health professional or staff member directly observes emesis. It is impossible to completely empty the gut even with violent emesis. Repeated dose replacement involves the risk of unexpected overdose. Underlying causes of the vomiting should be addressed.

Guidelines for replacement doses

1. 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.
2. If emesis occurs at between 15 and 30 minutes after consumption, consider replacing 25–50% of the full dose.
3. 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 did not observe emesis. It is very important that pregnant MMT patients not go into withdrawal.

Intoxicated patients. Concurrent use of sedatives such as benzodiazepines, greatly increase the risk of methadone toxicity. Intoxicated patients should not be medicated with methadone until they have been reassessed by the physician and found to be unimpaired. If a patient is found to be impaired after methadone ingestion, he or she should be sent to the emergency room for observation.

URINE DRUG SCREENING

Giving take-home doses to methadone patients with drug-free urines is an effective strategy for reducing opioid, cocaine and benzodiazepine use (Level II).

Several randomized trials have demonstrated that patients who receive carries for negative urine drug screens (UDS) will reduce their use of opioids, cocaine and benzodiazepines.^[2–8] In one randomized trial, 56% of the UDS were negative for the methadone patients who received carries based on weekly UDS, compared to 10% whose carries were not dependent on UDS results.^[9] This approach remains effective for up to one year after methadone initiation.^[5] There is little evidence to support routine screening for alcohol. One study found that case managers of patients with severe psychiatric disorders identified alcohol and drug use in 45% and 32% respectively, while weekly urine drug screens detected alcohol and drug use in 4% and 38% respectively.^[10] Other validated detection instruments, such as the CAGE and GGT, are recommended for alcohol detection.

UDS combined with self-reports are more accurate than either method alone (Level III). Self-report and UDS are significantly correlated,^[11] and self-reports combined with UDS give more complete results than either method alone.^[12] Patient self-reports of active substance use are generally very accurate;^[13] however, underreporting of drug use is common in treatment trials.^[14]

The impact of the frequency of UDS on patient outcomes is not known. Frequent UDS testing increases detection rates (Level III), and may reduce substance use in patients early in treatment or who continue to use illicit substances (Level II).^[1,9,12,15–18] There have been no studies examining the impact of ongoing frequent UDS on clinically stable patients whose self-reports and UDS results have consistently been in agreement. A potential concern is that frequent testing will reduce patient satisfaction with treatment and decrease treatment retention. The one-year treatment retention rate in the British Columbia methadone program is only 52%,^[20] and only an estimated 15–20% of illicit opioid users are on methadone treatment in Canada.^[21] Patients identify restrictive practices such as urine drug testing as one reason for their reluctance to engage in methadone treatment,^[22] although other factors are certainly involved.

Urine Testing: A Clinical Guide

Results of urine drug screens can be used as an aid in verifying the patient's self-report of substance use, assessing compliance with methadone, 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, should be carefully assessed with respect to carry privileges.

Urine Collection

Ideally, urine samples should be obtained on a random or fixed schedule under direct observation. If direct observation is not possible or if there is any question about the reliability of testing results, other methods should be employed, such as temperature testing. If tampering is suspected, the physician should be notified and, whenever possible, a second sample should be collected the same day. Laboratory measures, such as those described in Table 1, can be used to increase reliability.

Frequency of Urine Testing

At least **one** urine drug screen must be collected, interpreted, and documented prior to initiation onto methadone. Thereafter, urine testing should be done on a fixed or random schedule. During the stabilization phase, a urine drug screen should be collected at least once weekly. Weekly screening should be continued during the maintenance phase, particularly during the acquisition of carry privileges. After six months of negative weekly UDS, and/or the patient has acquired full carries, urine collection may be biweekly to monthly based on the validity of the patient's self-report, pattern of drug use, and clinical stability. Frequency of urine collection should be increased in the event of a lapse, relapse, or signs of clinical instability, and a reassessment of urine testing frequency should be made at that time.

Urine collection may be on a biweekly or monthly basis for patients who are deemed not appropriate for carries based on ongoing instability, or ongoing problematic drug use. Biweekly testing can also be justified for clinically stable patients with occasional non-problematic drug use who receive no more than one carry per week.

Random urine drug screening, although impractical, is considered the gold standard. Physicians should be aware that patients might alter drug use if the screening is on a fixed schedule.

Urine Toxicology

Enzyme immunoassays typically include opioids, benzodiazepines, cocaine and methadone. Other substances such as amphetamines or cannabis may be included depending on local drug use patterns and clinical judgment. Chromatography will identify specific drugs of abuse, as well as the presence of the methadone metabolite. Tampering should be considered if results indicate absence of methadone metabolite, low specific gravity, low creatinine, high sodium or chloride, or any abnormally low or high urine temperature.

TABLE 1: Immunoassay vs Chromatography

	Advantages	Disadvantages
Immunoassay (EIA)	<ul style="list-style-type: none"> Very sensitive screen for opioids; Detects opioids for 2–4 days 	<ul style="list-style-type: none"> Does not distinguish specific types of opioids; Semi-synthetic and synthetic opioids, such as Oxycodone or Fentanyl, are often missed; Can have false positives for opioids with poppy seeds or quinolone antibiotics.
Chromatography	<ul style="list-style-type: none"> Can identify specific opioids; More specific than EIA; Can distinguish methadone from EDDP. 	<ul style="list-style-type: none"> Detects opioids for 1–2 days; Less sensitive than EIA.

COUNSELLING

Regular counselling, when added to methadone maintenance, is associated with decreased drug use.^[16–19] Access to counselling should be an integral part of methadone maintenance treatment.

Counselling can be structured around the following areas:

- Securing basic necessities, such as housing, food, clothing
- Legal issues
- Life skills
- Coping with stress

The addicted patient’s process of change has been conceptualized as a series of stages that the individual may cycle and recycle until permanent change has occurred. These are:

- precontemplation
- contemplation
- preparation
- action
- maintenance
- relapse

(Prachaska and Di Clementi Transtheoretical Model of Change).

- Identification and treatment of concurrent mental illness
- Issues of abuse – physical, sexual, emotional
- Parenting and family counselling
- Education about harm reduction
- Stopping drug use and preventing relapse

Therapeutic approaches are most successful when there is a strong therapeutic alliance with the therapist. This involves the physician creating a non-judgmental, collaborative environment whereby patients feel safe to discuss their feelings and concerns. Particularly where there are complex psychosocial problems, the physician will need to draw on the support of formal and informal resources and must realize the limits of what he or she can personally provide in his or her role. If appropriately educated and supported, the family can be a valuable resource for the patient and clinician. The physician can also play a valuable role in encouraging and facilitating access to supports and services, such as relapse prevention programs in the community.

CARRY POLICY

Take-home doses are effective in reducing substance use (Level II) and in retaining patients in treatment (Level III). Take-home doses for ‘clean’ urine drug screens have been shown in controlled trials to be effective in reducing substance use.^[1–13] Surveys and observational studies suggest that patients strongly value take-home doses, and treatment retention rates are lower in clinics with restrictive take-home policies.^[14–15]

Methadone diversion is common, and most methadone-related deaths are due to diverted methadone (Level IV). A large UK study found that there is a substantial market for diverted methadone, with many patients selling small amounts of their methadone to pay for other street drugs.^[17] Between 1996 and 2000 in Ontario, 151 of 194 methadone-related deaths were in individuals who took diverted methadone and were not in methadone treatment.^[18] Other studies have had similar results.^[19]

The impact of restrictive take-home policies on mortality is not known. While a restrictive take-home policy would likely reduce deaths from methadone diversion, its impact on overall mortality is unclear. Currently, only 15–20% of opioid

dependent patients are on methadone treatment in Canada, and restrictive policies are cited as one of the factors in dissuading patients to enter treatment.^[22] The annual mortality rate of methadone patients is one quarter the rate for heroin users, due primarily to fewer deaths from overdose and suicide.^[20–23] The overall mortality rate of heroin users declines sharply with entry into treatment, and climbs again with discharge.^[24–26] Thus, while restrictive policies might reduce diversion, they might also reduce treatment retention and increase mortality by increasing the population of untreated opioid users. Further research is needed in this area.

The following three criteria should be assessed prior to initiating carries. These criteria should be re-assessed regularly with regard to continuing carries and/or increasing/decreasing the level of carries.

1. 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 and use it only as prescribed.

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

- Elimination of sustained problematic drug or alcohol use and demonstration of mostly negative urine drug screens.
- The patient’s methadone dose is stable and the patient is emotionally stable.
- Housing, employment, and/or a stable support system is in place.
- Adherence to the methadone treatment agreement, and program requirements (see Appendix F).

2. The Length of Time in Methadone Treatment

Carries are not recommended during the first two months of treatment.

Because some pharmacies may not be open on Sunday to dispense methadone, this may necessitate the use of an alternate pharmacy on Sundays. It is not unreasonable to ask the patient and pharmacist to make arrangements to get that dose from a pharmacy that is open on the weekend. If a pharmacy is found that dispenses methadone on Sunday, and the patient’s regular pharmacy is closed on Sunday, it is advisable to send the patient to the alternate pharmacy on both Saturday and Sunday, so the last dose can be verified by the alternate pharmacy, and communication can be made with the patient’s regular pharmacy.

In order to safely prescribe carry medication, three questions must be answered:

- 1) Is it safe for the patient?
- 2) Is it safe for the public?
- 3) What is the risk of diversion?

Problematic drug use refers to loss of control over substance use, and/or continued use despite harm. This refers to DSM-IV criteria for dependence and abuse. These patients have mostly positive urine drug screens. They often demonstrate social or emotional instability.

The physician should encourage a pharmacy to open at least long enough to provide methadone on Sunday.

Alternatively, patients should be told to show receipts to the Sunday pharmacy for verification of previous methadone ingestion and no missed days. It is recommended that the physician involve the regular dispensing pharmacy in making any accommodations to patients' carries. If alternate arrangements cannot be made and there is not a pharmacy open to dispense methadone, the physician can call the Ontario College of Pharmacists at (416) 962-4861 to get the name of a local pharmacy that dispenses methadone on weekends.

3. Ability to Safely Store Methadone in a Locked Box

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

It is recommended that the patient store methadone 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 using a locked box should be assessed periodically by the physician and pharmacist.

CARRY SCHEDULE

In general, methadone patients who are clinically stable and meet the criteria described above in the Carry Policy section, can receive **each month** after the first two months in treatment, one additional carry per month, to a maximum of six carries per week (one witnessed dose in the pharmacy, six take-away carry doses).

Patients who have occasional non-problematic drug use may be appropriate to receive carries (although the number and progression of carries would be reduced from the schedule) if they are determined by the physician to be clinically stable and able to safely store their medication. Physicians should clearly document these exceptions.

When a patient demonstrates risky behaviour (see Managing Relapse section, which follows), 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.**

Patients that are well known to the physician and stabilized on methadone may qualify for a Sunday carry, even with non-problematic drug use and less frequent urine drug screens, if the patient is otherwise clinically stable (see definition on page 31). Exercise good clinical judgment, along with good documentation of drug use history, and safe storage of carries.

TABLE 2: Carry Schedule

Criteria	# of Carries
Meets carry criteria #1–3 and, – Has been on methadone for at least 2 months	1
Meets carry criteria #1–3 and, – Has been on methadone for the past 3 months	2
Meets carry criteria #1–3 and, – Has been on methadone for the past 4 months	3
Meets carry criteria #1–3 and, – Has been on methadone for the past 5 months	4
Meets carry criteria #1–3 and, – Has been on methadone for the past 6 months	5
Meets carry criteria #1–3 and, – Has been on methadone for the past 7 months	6

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 four criteria for *clinical stability* are not met (see page 31).

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

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 and 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) following a lapse depending on the clinical stability of the patient.

Giving, lending or selling methadone is considered diversion and trafficking in a controlled substance.

Lost or stolen carries should be reported to the police by the physician or staff. It is not required that the patient's name be disclosed, although it is recommended that the patient report the incident and obtain a occurrence reference number from the police.

Proposed schedule for carries during a sustained relapse

- Reduce one carry per week for each positive urine sample (typically tested once per week), if the patient remains clinically stable.
- Patients who demonstrate continued sustained use and/or clinical instability should have all carries discontinued.
- Return 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), provided that the patient is otherwise stable and meets the criteria.

Complete loss of carries

All carry privileges should be removed for the following reasons:

- Patient has diverted their methadone;
- Patient has tampered with his or her urine sample.

Physicians should be aware that the risk of overdose can be increased with sudden daily dispensing at the pharmacy if the methadone carries weren't consumed as directed, and all carries are abruptly removed. It may be appropriate to reduce the daily dispensed dose to 50–75% of the original dose. If the methadone dose is reduced, the patient should be assessed regularly for signs and/or symptoms of withdrawal and appropriate dose increases should then be made.

Measures to reduce risk of diversion: Patients may be asked to return empty labeled carry bottles on each visit to the doctor or pharmacist, or they may be randomly asked to show unused carry bottles to the doctor.

Exceptions to the Carry Schedule

All exceptions to the carry schedule must be clearly documented.

Benzodiazepines and other drugs of abuse

The risk of abuse of 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. A specific medical diagnosis has been made by the prescribing physician which 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, and document the opinion.
3. The medication should be dispensed with the methadone in a controlled fashion (i.e., dispensed weekly, along with the carries). The methadone 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 which 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 and followed gradually. If the patient is found to be destabilized with the taper, then it is reasonable to maintain the medication as prescribed, in a controlled fashion, at a reasonable dose. Evidence of misuse should result in a taper off the medication.

Medical disability

A physician may decide to initiate or increase carries to a patient who otherwise does not qualify if they suffer from a medical condition that significantly interferes with their ability to attend at the pharmacy.

Every effort should be made to ensure in these cases that the consumption of methadone is supervised by a health care professional trained to identify signs and symptoms of methadone toxicity.

For medical conditions of a temporary nature, the requirement for carries should be reassessed once the patient's ability to attend the pharmacy is expected 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.

Physicians must recognize that it is difficult to monitor supplemental and non-prescribed drug use in patients to whom a drug with abuse potential has been prescribed.

Physicians should be aware that abrupt discontinuation of chronic benzodiazepine use might result in seizures if the patient's dose is equivalent to ≥ 50 mg of diazepam.

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.

Physicians should verify the extenuating circumstances and be satisfied that there is no other way to have the patient's dosing observed (i.e., at a local pharmacy).

Additionally, the physician should assess the mental status of the patient to be satisfied that the provision of carries through the crisis period will not compromise the safety of the patient or other persons. The minimum requirement in these circumstances is demonstration of a locked box.

If a person is not eligible for carries as defined in these guidelines, carries **must not** be given to a third party unless the patient is under the care and supervision of a responsible health worker, and appropriate safety measures are in place.

Job or vacation

Patients who have been deemed **appropriate** for a high 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. Physicians can contact the CPSO Methadone Program at (416) 967-2661 for information about the services available in the area to which the patient is travelling.

In certain circumstances, temporary arrangements for pharmacy dispensing can be made with adequate notice to the pharmacist. Patients should provide the physician 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.

Process Considerations

Prior to initiating carries, it is imperative that physicians advise patients of the potential danger to the opioid naïve, particularly children, of consuming methadone and the need to store the carries in a locked box. If practical, a spouse or significant other should be in attendance on initiation of carries.

Prescription Issues

The dose, start and stop dates of the prescription, and the frequency of carries, must be clearly documented both on the prescription and on the patient chart.

Clear documentation of this information will decrease the likelihood that prescriptions will overlap. It will also be essential in the event that another clinician is required to manage the care of the patient. Carbon copy (duplicate) prescriptions kept with the clinical note in the patient's chart can facilitate documentation.

Physicians should indicate on the prescription the start and stop dates, the number of carries to be dispensed per week and/or the days of the week the patient receives carries, and/or the dates the patient is to receive carries. In the event that prescription dates overlap, an explanation should be included to cancel the previous prescriptions (e.g., in cases of change of dose prior to end of previous prescription). Methadone is diluted in a suitable drink (e.g., Tang[®]) to discourage injection. This should also be stated on the prescription.

The patient is at risk when methadone is dispensed at two or more pharmacies, and this should only be done if no alternative exists. This practice increases the possibility that the patient could be inadvertently dosed twice on a single day. Additionally, one pharmacy may not be aware of missed doses that occurred at the other pharmacy. Communication between the physician and pharmacies, as well between the two pharmacies, is very important in this situation (refer to *Methadone Maintenance: A Pharmacist's Guide to Treatment*, CAMH 2005).

In general, the practitioner must weigh the benefits of prescribing a given drug with the risks involved. It should be understood that the presence of any illicit drug or medication in a urine drug screen is indistinguishable from whatever 'prescribed' quantity of drug is present.

SAMPLE Methadone Prescription Form

Valid only at:
(specify pharmacy)

Name	Date	File #				
Rx Methadone _____ mg						
p.o. dispensed daily mixed in orange drink		Dose in words				
Start Date: _____	End Date: _____	Inclusive				
Drink observed in the pharmacy on days circled:						
Mon	Tues	Wed	Thur	Fri	Sat	Sun
The following doses are to be dispensed as take home doses:						
Mon	Tues	Wed	Thur	Fri	Sat	Sun
Special instructions:						
Contact prescriber before filling this prescription if dose is increased by more than 15mg., unless noted above. Hold prescription if more than three consecutive doses are missed, and contact prescriber. Notify the pharmacy if a dose is missed. Fax a copy of this prescription if there are any concerns about this prescription.						
Signature					M.D.	
Print Name						
Prepared by			Date	Dispensed by		

Hearsay is information with no known authority for its truth, and may be passed from no discernable source.

INVOLUNTARY DISMISSAL FROM CARE

While a comprehensive treatment system attempts to provide options and levels of care that are appropriate for the diversity of individuals who are opioid dependent, physicians have the right to determine who they can properly treat, and may discharge or transfer a patient to another program or physician, if deemed necessary. If the physician believes, following a thorough assessment and using all available resources that, in the interest of the patient's safety methadone treatment is not currently appropriate, the physician may appropriately discharge the patient from MMT. The clinical reasoning which led to this decision should be carefully documented.

It is important that information about any patient behaviour that may give rise to discharge from the program come from reliable sources. It is not appropriate to discharge a patient from therapy based on hearsay information or rumour.

Appropriate reasons to terminate methadone treatment may include:

- *Threats:* The patient has made a threat to the safety or well-being of a staff member, another patient, or another person;
- *Disruptive behaviour:* The patient has engaged in ongoing, disruptive behaviour on the methadone program premises;
- *Violent behaviour:* The patient has engaged in violent behaviour towards a staff member, a patient, or another person;
- *Failure to attend physician appointments:* The patient continues to miss appointments, despite repeated attempts to accommodate the physician's and patient's schedules.

The regulations governing medical practice in Ontario provide that it is professional misconduct to discontinue professional services that are needed unless the patient requests the discontinuation, alternate services are arranged, or the patient is given a reasonable opportunity to arrange alternate services.

Recommendations to effectively end the doctor-patient relationship where methadone treatment is being provided are as follows:

1. Provide the patient, where possible, with an option of transferring to another methadone prescriber.
2. Communicate your decision clearly to the patient. This should include the details of a tapering schedule and/or end date of their methadone prescription.
3. Give the patient a reasonable amount of time to find another doctor. This time will vary according to location and circumstances, but should be at least one month.
4. Provide the patient with any reasonable help you can to find another doctor. For example, you can provide the patient with the CPSO Methadone Program phone number, (416) 967-2661, for physician referral.
5. Have the patient sign a notification that makes it clear he or she is aware of the treatment termination. You may choose to send the patient a registered letter, confirming termination with a return receipt requested.
6. Put a copy of this letter and the postal receipt into the patient's medical record along with a terminating entry in the record.

See the CPSO policy *Ending the Physician-Patient Relationship* (www.cpsso.on.ca/Policies/ending.htm) for a sample letter of dismissal.

Patients in methadone treatment who feel that they have been wrongfully dismissed from the treatment program have the option of addressing their concern through the College's complaints process. The potential for dispute will be reduced if the program rules and the circumstances which may give rise to dismissal from the program are made clear at the commencement of treatment (see Appendix F).

For patients with chronic pain, refer to the CPSO's *Methadone for Pain Guidelines*.

METHADONE AND ACUTE PAIN

Patients on long-term methadone therapy 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 under treatment of acute pain can cause relapse by forcing the patient to self-medicate.

In an outpatient setting, the opioid should be dispensed with the methadone (for example, if the patient is on daily dispensing, the additional opioid should be dispensed daily as well). In injection drug users, acetaminophen-opioid combinations are preferred because they are more difficult to inject. If possible, choose opioids with a lower abuse liability (codeine, morphine) over opioids with greater liability such as oxycodone or hydromorphone. Scheduled, rather than PRN dispensing, is preferred for constant pain. The physician may start the patient at a dose that would normally be prescribed for a patient with a similar condition, with upward titration if necessary.

As an alternative to adding an opioid, a temporary increase in the methadone dose of 10–15 mg may be considered as a temporary split dose. The dose should be reduced after the acute pain has resolved.

Management of Methadone Patients with Acute Pain

- Use non-opioid alternatives along with (or instead of) the opioid.
- Patients on stable doses of methadone 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 (i.e., daily, if the patient has no methadone 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 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 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.

For example, a heroin-dependent patient is on methadone dispensed daily. He is otherwise young and healthy, on no medications. He fractures his wrist. The physician prescribes Tylenol #3, two tablets qid for one week, to be dispensed daily with the methadone.

MMT IN FEDERAL OR PROVINCIAL CORRECTIONAL FACILITIES

Introduction

Methadone treatment in correctional settings involves unique issues. The controlled environment, imperatives for security, and the governance of correctional policy may affect the physician’s ability to provide patient-centered care at community standards. The trusting therapeutic relationship between physician and patient must remain the focus of treatment.

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 maintenance or initiation of methadone, as this is the current standard of care.

Issues regarding physician qualifications, assessment, initiation and other areas of MMT common to both community and federal/provincial correctional facilities should be consistent with these guidelines.

Issues Unique to Providing MMT in Correctional Facilities

Dosing on admission

Confirmation must be obtained about whether patients are on a MMT program upon their admission to the correctional facility prior to dispensing the first methadone dose. *The previous provider and/or pharmacy should be contacted to determine the dose and the date/time of the last dose received.*

Often physicians who are working in correctional facilities are not available on the weekend to maintain patients on methadone if incarceration occurs Friday evening, leaving patients at risk for destabilization. For patients who mostly have observed ingestion at the pharmacy with less than or equal to three carries per week, a nurse may assess the patient (vitals, appearance, and level of alertness or withdrawal) to ensure continuity of treatment at the same dose. The nurse should confirm the amount of the last dose, and when it was given at the community pharmacy, making sure that three doses were not missed. The physician may then fax a methadone prescription to the pharmacy at the correctional facility for the same dose, so that methadone can be taken over the weekend, provided three doses were not missed and the patient appears stable.

Ontario Provincial Corrections policy provides for a 30 mg 'holding dose' for those inmates who are known to be on methadone, but where the pharmacy or provider is not available to confirm the current dose.

Physicians have a responsibility to provide MMT care and must use their clinical judgment to determine the appropriate dose (for example, 50–75% of the stated dose if diversion of carries is suspected, or of a high maintenance dose, i.e., the dose is greater than or equal to 150 mg). If the dose is reduced, physicians should reassess the patient regularly for symptoms of withdrawal or sedation, and appropriate dose changes should be made. Benzodiazepines, or sedating sleep aids should be withheld until the physician has done an appropriate assessment of the patient. If the patient appears intoxicated from the nurse's assessment, or three or more doses have been missed, then methadone should not be given until a physician sees the patient. In these circumstances, the patient should be seen within a reasonable amount of time to avoid further discomfort of withdrawal. The Opioid Detoxification Protocol should be followed, as outlined in Appendix D.

Methadone brought with an inmate

Methadone accompanying any inmate should be discarded unless continuity of handling can be proven, such as in a transfer from another facility. Please refer to correctional policies for the discarding of narcotics.

Treatment Planning for Release

Patients are at highest risk of overdose after release from a correctional facility if an appropriate release plan is not made. One of two scenarios is usually encountered in this setting:

Treatment planning—release date known

Often the release date of the inmate is known, and arrangements should therefore be made in advance. An appointment should be scheduled with the community methadone treatment physician, and appropriate clinical information should be sent to this doctor. If there is a gap of time from the date of release to the scheduled appointment with the community physician, it is the responsibility of the physician at the correctional facility to fax a prescription to the community pharmacy to ensure continuity of methadone treatment until the appointment date. It is advisable to end the prescription one day prior to the appointment date to avoid double dosing. **The prescription should never be given to the inmate and carries should never be provided in a release prescription.**

Treatment planning—release date unknown or unexpected

Conversely, inmates are often released from custody directly from Court without the knowledge of the correctional facility. Therefore:

- The patient should not be dosed on the day of a Court appearance.
- In order to be prepared in the event that a patient is released from custody directly from Court without the prior knowledge of the correctional facility, patients should be given the telephone number of the nursing station, and advised to take this contact information with them should they be attending Court. Patients should be further advised to contact the nursing station if they are released directly from Court without the benefit of a release plan.
- The patient should attempt to make an appointment with his or her community methadone treatment physician, and this appointment should be confirmed by the nursing staff. A prescription should be faxed to the community pharmacy to maintain the patient on methadone until the appointment, and the prescription should end one day prior to the appointment date. A release plan should be sent to the community physician conveying all relevant clinical information, including the latest prescription.

If an inmate is released without a community methadone treatment physician, every effort should be made to find a treating physician for the patient by contacting the CPSO Methadone Program at (416) 967-2661. If an inmate is going to a community with no methadone provider, the inmate will require a slow withdrawal from methadone prior to release from the facility. This should be done only as a last resort and with the inmate's informed consent.

If assistance is required by the facility in finding a local pharmacy that dispenses methadone, contact the Ontario College of Pharmacists at (416) 962-4861. The pharmacy should be contacted and, if possible, the prescription should be faxed directly to the pharmacy rather than being provided to the inmate.

Reporting to the CPSO

The CPSO requires physicians at correctional facilities to submit to the CPSO a patient treatment form when MMT is initiated upon incarceration and when patients are released from the correctional facility. (See Appendix J). It is not necessary to submit this form when patients are moving from one institution to another. In cases of intermittent sentencing or in very short sentences (less than 30 days) other procedures may be more practical. An example would be an inmate serving weekends only. In these instances, the community physician may agree to continue the prescription rather than to transfer care to the correctional facility's physician.

Treatment agreement

Treatment agreements should be signed and medical records obtained from previous providers. Information obtained while completing a treatment agreement and taking a medical history should be kept as part of the medical file. Patient confidentiality must be strictly observed.

Urine toxicology screening

It is essential that urine toxicology screening used in MMT in correctional facilities is clearly a part of the medical record and not available to security or administration for any reason. Frequency of urine testing while a patient is incarcerated can vary and may be done less frequently than the guidelines specify. However, it is required that a urine drug screen be done minimally every two to four weeks.

Approach to treatment

Inmates may have difficulties involving trust. A treating physician's primary concern should be for the patient's medical care and every effort should be made to foster a trusting relationship. It must be clear that the interests of the patient are the priority of the physician. A multidisciplinary approach to the provision of MMT is essential in this setting and should include clinical staff, substance abuse counsellors, and parole officers.

Confidentiality is extremely important in the correctional system, as in all medical interactions. Conflicts are often avoidable when the structure of the treatment is conveyed to both inmates and staff. Program rules and expectations should be in writing and verbally described to each inmate. Dispensing times should be clearly defined. Expectations regarding provision of urine samples, appointments with the physician, and general behaviour should be clearly described at the onset of treatment. Inmates who arrive late for dispensing, or who vomit doses should not have them replaced unless extraordinary circumstances exist.

Observed Administration

Traditional lack of access to MMT in correctional facilities has created a situation where demand usually exceeds supply. For this reason, attention to dispensing issues is of paramount importance so that methadone is not diverted.

1. Each inmate must be properly identified prior to dispensing methadone. This should include asking the inmate's name and birth date, and comparing the unit card photograph.
2. Check the name, date, and dose on the label of the methadone bottle.
3. Verify that the inmate has completely swallowed the dose, so there can be no regurgitation or oral diversion.
4. Records should be kept that specify the dose administered.
5. All inmates receiving methadone should be isolated from other inmates to reduce risk of diversion. The following protocol is recommended to reduce risk of diversion:

It is not uncommon for methadone maintenance patients to be 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.

METHADONE MAINTENANCE GUIDELINES

- drink 8 oz of water first;
 - inspect mouth;
 - drink methadone observed by nurse;
 - re-inspect mouth;
 - drink 8 oz of water again;
 - under the observation of guards, sit for 20 minutes in segregation, with no access to bathrooms during the observation period.
6. Methadone cannot be left unattended unless it is secured either in a locked refrigerator or safe. The drug storage area should not be accessible to inmates or non-medical staff.

Accidental overdose of methadone

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

Initiating inmates in a methadone program while in a correctional facility

If an inmate is not receiving methadone at the time of incarceration, the following conditions should be met:

1. The inmate must meet or have met in the past the DSM-IV diagnostic criteria for opioid substance dependence.
2. A urine drug screen must be interpreted and a complete assessment performed prior to initiation.
3. The usual reporting procedure to the CPSO must be followed.
4. Inmates not currently using opioids, but where their documented history clearly shows a pattern of long-term opioid dependence continuing until the time of incarceration, should be considered for initiation on methadone while in the correctional facility. (See page 19, negative initial UDS and recent abstinence).
5. Pregnant inmates currently using opioids must be offered MMT while incarcerated. Patients with HIV infection, or hepatitis B or C should be made a high priority for being offered methadone treatment while incarcerated.

Involuntary discharge

As a last resort, when the risks of providing methadone outweigh the benefits, a patient may be considered for involuntary discharge from MMT. Involuntary discharge from MMT should not be used for behavioural management. Patient retention is a major goal of MMT and it is essential that the correctional systems MMT program strive for this.

Carries

Carries should not be given to inmates upon release from the facility.

Weekend pass

In the event of a weekend pass, arrangements must be made for pick-up at a community pharmacy.

Reprinted with permission from the Diagnostic and Statistical Manual of Mental Disorders, Text Revision, Copyright 2000, American Psychiatric Association.

APPENDIX A

Diagnostic Criteria for Substance Dependence

A maladaptive pattern of substance use, leading to clinically significant impairment or distress, as manifested by three (or more) of the following, occurring at any time in the same 12-month period:

1. Tolerance, as defined by either of the following:
 - a) the need for markedly increased amounts of the substance to achieve intoxication or the desired effect;
 - b) markedly diminished effect with continued use of the same amount of the substance.
2. Withdrawal, as manifested by either of the following:
 - a) the characteristic withdrawal syndrome for the substance (refer to Criteria A and B of the criteria sets for withdrawal from the specific substances);
 - b) the same (or a closely related) substance is taken to relieve (or avoid) withdrawal symptoms.
3. The substance is often taken in larger amounts or over a longer period than was intended.
4. There is a persistent desire or unsuccessful efforts to cut down or control substance use.
5. A great deal of time is spent in activities necessary to obtain the substance (e.g., visiting multiple doctors or driving long distances), use the substance (e.g., chain smoking), or recover from its effects.
6. Important social, occupational or recreational activities are given up or reduced because of substance use.
7. The substance use is continued despite knowledge of having a persistent or recurrent physical or psychological problem that is likely to have been caused or exacerbated by the substance (e.g., current cocaine use despite recognition of cocaine-induced depression, or continued drinking despite recognition that an ulcer was worsened by alcohol consumption).

Specify if:

With Physiological Dependence: evidence of tolerance or withdrawal (i.e., either Item 1 or 2 is present).

Without Physiological Dependence: no evidence of tolerance or withdrawal (i.e., neither Item 1 nor 2 is present).

APPENDIX B

Diagnostic Criteria for Opioid Withdrawal

A. Either of the following:

- cessation of (or reduction in) opioid use that has been heavy and prolonged (several weeks or longer)
- administration of an opioid antagonist after a period of opioid use

B. Three (or more) of the following: developing within minutes to several days after Criterion A:

- dysphoric mood
- nausea or vomiting
- muscle aches
- lacrimation or rhinorrhea
- papillary dilation, piloerection or sweating
- diarrhea
- yawning
- fever
- insomnia

C. The symptoms in Criterion B cause clinically significant distress or impairment in social, occupational or other important areas of functioning.

D. The symptoms are not due to a general medical condition and are not better accounted for by another mental disorder.

APPENDIX C

Suggested Criteria for Methadone Treatment

1. Opioid use (track marks and a urine drug screen that is positive for opioids).
2. Physical dependence, as evidenced by symptoms or signs of opioid withdrawal.
3. Psychological dependence:
 - Regular daily use;
 - Social consequences: financial and legal difficulties; difficulties with employment and relationships;
 - Physical consequences such as hepatitis C;
 - Inability to discontinue use;
 - Neglect of major social responsibilities due to drug use;
 - Preoccupation with the drug: acquiring it, using it, recovering from its effect.
4. Small likelihood of benefit from non-methadone treatment:
 - Past history of treatment failures;
 - Opioid dependence for at least one year.
5. Agreement to terms and conditions of the treatment program.

APPENDIX D

Opioid Detoxification Protocol

Outpatient dosing:

Clonidine 0.1 mg PO bid to tid

- May increase to 0.2 mg bid to tid after first day;
- Continue bid to tid for 3–5 days then PRN for 3–5 more days.

Inpatient dosing:

- Check BP prior to each dose;
- Hold if BP < 90/60 or marked postural drop;
- May increase to 0.3 mg bid to tid.

Additional treatment options:

- NSAID or acetaminophen for myalgia;
- Loperamide for diarrhea;
- Gravol or other antinauseant;
- Trazodone 50–100 mg HS for insomnia.

Precautions:

- Don't prescribe clonidine if BP < 90/60, patient pregnant, on antihypertensives or has heart disease.
- Warn patients about postural symptoms and drowsiness. Postural symptoms are dose-related, so be cautious with higher doses.
- Warn about mixing with opioids, or having prolonged hot bath (both can cause hypotension).
- Don't prescribe for longer than 2 weeks (rebound hypertension).
- Warn patients they're at risk for overdose if they relapse to their usual dose; always combine clonidine protocol with a documented treatment plan.
- A follow-up with patient should be made in 3–5 days and patient should be assessed for an aftercare program.

APPENDIX E
Initial Patient Assessment Form

ABOUT YOURSELF:

Please complete the following questionnaire as accurately and honestly as possible so that we can determine what kind of treatment would serve you best.

NAME _____
(first) (last)

DATE _____

HEALTH CARD # _____ VERSION CODE: _____

DATE OF BIRTH _____
(year/month/day)

ADDRESS _____ APT # _____

CITY _____ POSTAL CODE _____

PHONE day () _____ evening () _____

CONTACT IN CASE OF EMERGENCY (state relationship)

CONTACT'S PHONE () _____

WHO REFERRED YOU HERE ? _____

GENDER: male female

DRUG HISTORY:

DRUG	AMOUNT USED	HOW LONG DAILY USER	ROUTE TAKEN	FIRST USED	LAST USED
Heroin	_____	_____	_____	_____	_____
Other Narcotics	_____	_____	_____	_____	_____
Cocaine	_____	_____	_____	_____	_____
Barbiturates (Fiorinal)	_____	_____	_____	_____	_____
Amphetamines	_____	_____	_____	_____	_____
Alcohol	_____	_____	_____	_____	_____
Cannabis (Pot, Hash)	_____	_____	_____	_____	_____
Cigarettes (packs per day)	_____	_____	_____	_____	_____
Benzodiazepines (Valium, Ativan)	_____	_____	_____	_____	_____

PRESCRIPTION MEDICATIONS:

(Any medications you regularly take or are prescribed, amount and frequency): none or, give details: _____

Are you now or have you ever been prescribed narcotics (e.g., Tylenol #3, Percodan, Percocet, Dilaudid, Talwin, morphine) for an extended period of time (e.g., for more than four weeks?)

yes no narcotic name _____

Amount prescribed _____ For how long? _____
(per week/month) (weeks/months/years)

For what reason was it prescribed? _____

If it has been discontinued, when and why? _____

DRUG ALLERGIES: none or, give details: _____

(any medications you can't take, and WHY NOT?) _____

PAST MEDICAL HISTORY: (circle and give year)

hepatitis A..... neg/pos/never tested/don't know

hepatitis B..... neg/pos/immune/vaccinated/carrier/never tested/don't know

hepatitis C..... neg/pos/never tested/don't know

HIV..... neg/pos (_____)/never tested/don't know
date of last test

Tuberculosis skin test..... neg/pos (_____)/never tested/don't know
date of last test

For the above questions, where was the test done, and where are the results now?

Year of first i.v. drug use . . (_____)/never migraines yes/no

History of needle sharing . . yes/no back problems yes/no
(including cotton, spoons, filters, etc.)

overdoses yes/no ulcers yes/no

asthma yes/no heart problems yes/no

seizures yes/no car accidents yes/no

operations yes/no other: _____

(give year and type): _____

Name and address of your family doctor: _____

Is your doctor aware of your drug problem? yes no

METHADONE MAINTENANCE GUIDELINES

WOMEN ONLY:

1. When was the first day of your last menstrual period ? _____
2. Current method of contraception ? The Pill/condoms/other: _____
3. Is there any chance you might be pregnant ? yes no

EMOTIONAL HEALTH:

Have you ever been treated by a family doctor or psychiatrist for:

anxiety? yes no

depression? yes no

Have been admitted to a psychiatric facility? yes no

Received treatment for any other emotional problems? yes no

Were you abused? (mentally, sexually or physically?) yes no

Have you ever attempted suicide? yes no

Are you currently depressed or suicidal? yes no

FAMILY HISTORY:

(Any family history of medical problems like alcohol or drug abuse, depression, heart disease etc.)

mother: _____ father: _____
(age) (age)

brothers, sisters, others _____

DRUG TREATMENT PROGRAMS:

(Including attempts at detox), program name, when, how long did you stay clean/ why failed?

1. _____
2. _____
3. _____

SOCIAL HISTORY:

Are you: married/single/separated/divorced/common-law/widowed

Children? _____ Whose custody are the children in? _____

Who lives in your household? _____

Do they abuse alcohol/drugs? yes no

Are the people close to you aware of your drug problem? yes no

Usual occupation: _____ Are you currently employed ? yes no

Last job held: _____ From when _____ to _____

Highest level of education: _____

Are you receiving: welfare/FBA/pension/UI/none/other?

Do you drive a car? yes no

LEGAL STATUS:

1. Are you currently on probation or parole? yes no
if yes, until when ? _____
2. Is treatment a condition of your probation? yes no
if yes, when ? _____
3. Do you have any Court dates pending? yes no
if yes, when ? _____
4. Do you have previous convictions? yes no
if yes, for what ? _____
5. Have you been incarcerated? yes no
if yes, for what ? _____
6. How long have you been in jail for in total? _____
7. Have you been charged with impaired driving? yes no
8. Have you been charged with a crime that included a weapon or violence?
 yes no

About your addiction:

In the last 12 months:

Do you need more and more of the drug you are using to get the same effect?
 yes no

Describe what symptoms you experience if you suddenly stop taking the drug:

Do you frequently take more drugs than you planned, or use it for longer than you planned to? yes no

Have you had many unsuccessful attempts to cut down on your drug use? yes no

Do you spend a lot of your day getting, using, and recovering from the effects of drugs? yes no

Have you given up work, social or other things you used to do because of your drug use? yes no

Do you keep taking drugs, despite the harm and problems it is causing you? yes no

Why have you come for treatment at this time? _____

What type of treatment do you feel that you need? _____

What are your goals for treatment? _____

APPENDIX F

Sample Methadone Treatment Agreement

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

Acknowledgments:

I acknowledge that:

1. Methadone is an opioid (opioids are drugs like heroin, codeine, morphine, Percocet, etc.), and that I will develop a physical dependence to 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'm unable to discontinue the use of opioids.
3. I have tried to the best of my ability other possible treatments for opioid dependence, and these attempts have been unsuccessful.
4. Taking any mood altering substance with methadone can be potentially dangerous. There have been reported deaths caused by the combination of methadone with alcohol, opioids, cocaine, barbiturates, and/or tranquilizers.
5. I may voluntarily withdraw from the methadone treatment program at any time.
6. It is important to inform my physician/dentist who is prescribing an opioid that I am taking methadone. I understand that a failure to do so is considered double doctoring, which is a criminal offence.
7. Regarding pregnancy, I understand that there can be effects on the developing fetus caused by methadone, and that specialized care will be required to reduce any harm to my fetus if I am or become pregnant while on methadone.
8. It is unsafe to drive a motor vehicle or operate machinery during the stabilization period after starting methadone and during dose adjustments.
9. Poppy seeds and certain over-the-counter medication may result in a positive drug urine screen.

METHADONE MAINTENANCE GUIDELINES

10. The common side effects of methadone are sweating, constipation, decreased sexual function, drowsiness, increased weight, and water retention. These are usually mild and can be lessened with assistance from my doctor. There are no known serious long-term effects from taking methadone.
11. I acknowledge that Dr. _____ is not my family doctor.
12. Methadone 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 administration).

Behaviour while in our clinic

I understand the following behaviour is not acceptable 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 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 clinic.
4. Any behaviour that disturbs the peace of the clinic or the surrounding vicinity of the methadone clinic.

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 or mischief, 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.

Obligations of being on this program:

1. I agree to take only one dose of methadone a day, and to have the ingestion of my dose witnessed on those days that I don't have carries (take home methadone).
2. It is important to inform any prescribing physician or dentist who may treat me for any medical or psychiatric condition that I am receiving methadone, so my treatment can be tailored to prevent potentially dangerous interactions with methadone. I will bring any prescriptions and/or medication bottles that I receive from other doctors to appointments with Dr._____.

3. I agree to provide a supervised urine sample for a drug screen when I receive a prescription for methadone.
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 it may affect my future status in the program.
6. I understand that counselling is highly recommended while I am in the program.
7. I agree to keep all my appointments with the physician who is prescribing methadone 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 fax a methadone prescription without an assessment.

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

1. Appear to be intoxicated or under the influence of some other substance. I may be asked to see a 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, after the clinic/pharmacy hours.
3. Exhibit threatening or disruptive behaviour towards any staff member or another patient.
4. Do not show proper identification before receiving methadone, if asked for identification.
5. Miss more than three doses of methadone in a row.

Regarding carries (take-home methadone doses):

1. Methadone 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, in a location where it is unlikely to be stolen or accidentally taken by another person. An ice pack can be included in the box to keep the orange juice fresh.
2. I agree that the number of take-home dose(s) I receive will be decided by my physician, with input from therapists, nurses and pharmacy staff, as I progress in my treatment.
3. I agree not to give, lend or sell my take-home dose(s) to anyone.

METHADONE MAINTENANCE GUIDELINES

4. I agree that I will consume the methadone on the dates specified on the medication label and in the appropriate manner—that is, a full dose is taken within 24 hours.
5. I agree to return all empty methadone bottles on my next day back at the pharmacy after receiving take-home dose(s).
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. I understand that if an appointment is missed and a prescription is sent to my community pharmacy directly, my prescription may not include my take-home dose(s).

Consents

- I allow my physician to report to the College of Physicians and Surgeons of Ontario (CPSO) my name, date of birth, OHIP number, city of residence, and the date methadone was initiated. The CPSO will keep this information confidential. This is done to prevent double doctoring.
- I allow the CPSO or its designate permission to review my medical chart. This is done to assess the care provided by my physician and is not meant to judge my recovery.
- I allow my methadone 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 dose(s), which I received in another pharmacy or institution.

Confidentiality

Everything that you tell the clinic staff is confidential, although it is important to realize that under exceptional circumstances we can be obliged to report something you tell us to the appropriate authority. This can occur under the following conditions:

- If we suspect that a child is at risk of emotional or physical harm or neglect, under the *Child and Family Services Act*, it is the law that we report this information.
- If you become suicidal, homicidal, or are unable to take care of yourself due to a psychiatric condition, you might be held to be assessed by a psychiatrist against your will.

- If you reveal to the staff that you intend to harm another person, we will be obliged to protect that person by notifying the appropriate authority.
- If a Court subpoenas your medical chart, we must release it in accordance with the subpoena.
- If it is suspected that you are unable to drive an automobile due to a medical condition (which includes intoxication from alcohol or drugs), we are obliged to notify the Ministry of Transportation of this.
- Certain infections must be reported to the local public health department, e.g., tuberculosis, HIV.

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 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 G

Sample Addiction Medicine Clinical Note

NAME: _____ **DATE:** _____ **TIME:** _____

1. **CURRENT METHADONE DOSE:** _____ mg **NUMBER OF CARRIES:** _____

2. **SUPERVISED URINE DRUG SCREEN RESULTS:** METHADONE _____
 OPIOIDS _____
 COCAINE _____
 BENZODIAZEPINES _____

3. **PATIENT'S STATED DRUG/ALCOHOL USE SINCE THE LAST VISIT:**

	No	Yes	<u>Days/week</u>	<u>Amt/gms/wk</u>	<u>Est. Cost/wk</u>		
Opioids:			1 2 3 4 5 6 7	Powder	gms/wk	\$	/wk
			1 2 3 4 5 6 7	IV		\$	/wk
			Heroin Other				
Cocaine:			1 2 3 4 5 6 7	Crack	gms/wk	\$	/wk
			1 2 3 4 5 6 7	Powder			
			1 2 3 4 5 6 7	IV			
THC:			1 2 3 4 5 6 7	Marijuana	gms/wk	\$	/wk
			1 2 3 4 5 6 7	Hashish			
Benzodiazepines:			1 2 3 4 5 6 7	Rx Pos	gms /wk	\$	/wk
			Valium Other	Rx Neg			
Alcohol:			1 2 3 4 5 6 7	Beer _____	amt/wk	\$	/wk
			1 2 3 4 5 6 7	Wine _____			
			1 2 3 4 5 6 7	Spirits _____			
Other:			1 2 3 4 5 6 7		gms/wk	\$	/wk

4. Appearance	Alert	Intoxicated
Any reported sedation on methadone	No	Yes
Any withdrawal with methadone	No	Yes – Timing of withdrawal _____
Signs & symptoms of intoxication and/or sedation	No	Yes
Speech	Normal	Abnormal
Eye contact/movements	Normal	Abnormal
Gait	Normal	Abnormal
Behaviour	Normal	Abnormal
Needle use	None	Yes
High-risk behaviours	No	Yes
Safer drug use discuss	No	Yes
Safer sex discussed	No	Yes

Opioid Cravings: None Mild Moderate Severe

Opioid Withdrawal: None Mild Moderate Severe

Drug Withdrawal Symptoms: None Muscle Aches Dysphoria Diarrhea Insomnia Malaise Dilated Pupils Sweats Irritability Nausea/Vomiting Fatigue Rhinorrhea Sneezing/Yawning Piloerection Hot Flashes Anxiety Abdominal Cramping

Triggers or/and General Stressors: _____

5. ACUTE MEDICAL PROBLEMS: none yes: _____

6. PSYCHOLOGICAL PROBLEMS DISCUSSED:

Mood	Normal	Other _____
Anxiety	Absent	Present _____
Sleep	Normal	Hypersomnia Insomnia _____
Concentration	Normal	Other _____
Energy	Normal	Other _____
Appetite	Normal	Other _____
Weight	Stable	Loss Gain _____
Hallucinations	Denies	Other Not Assessed _____
Suicidal Ideation	Absent	Present Not Assessed _____

7. CARRY SAFETY ISSUES DISCUSSED:

Patient clinically stable	<input type="checkbox"/> yes <input type="checkbox"/> no	Keeps carries locked up	<input type="checkbox"/> yes <input type="checkbox"/> no
Methadone safety & security issues discussed	<input type="checkbox"/> yes <input type="checkbox"/> no	Safe with carries	<input type="checkbox"/> yes <input type="checkbox"/> no
Has Locked Box	<input type="checkbox"/> yes <input type="checkbox"/> no	Stable housing & safe environment	<input type="checkbox"/> yes <input type="checkbox"/> no

8. COUNSELLING/CLINICAL NOTE: _____

9. CARRY PRIVILEGES ASSESSED: SAME AS LAST VISIT INCREASED DECREASED

10. PATIENT REQUESTS: INCREASE IN DOSE DECREASE IN DOSE NO CHANGE IN DOSE

11. METHADONE MAINTENANCE THERAPY:

METHADONE: _____ mg PO OD NEW & RENEWED MEDICATIONS: _____

FROM _____ TO _____

CARRIES: M T W T F S S

CARRY X ____ / WK

12. PRESCRIPTION EXTENSION: DATE: FROM _____ TO _____ (NO CARRY)

REASON: _____

APPENDIX H

A Patient's Guide—Avoiding Overdose in the First Two Weeks of Methadone Treatment

Methadone is a very safe drug, but accidental overdoses sometimes happen in the first two weeks of treatment. The questions and answers below will help you 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 methadone, you want to get on the right dose as soon as possible. But 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 prescribed 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 methadone.

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

Even certain antibiotics can be dangerous, by blocking the breakdown of methadone in the body. So make sure to check all 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 someone can feel a bit sleepy during the day, lie down for a nap and not wake up. So please take the following precautions:

- Only take your methadone in the morning.
- See your doctor twice a week for the first two weeks.
- 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. 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.

APPENDIX I

Sample Letter to Pharmacy

(On clinic letterhead)

Dear Pharmacist,

Our patient has chosen your pharmacy for Methadone 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 page me at _____.

PLEASE DO NOT GIVE THE PAGE NUMBER TO THE PATIENT.

Clinic policies

1. Patients are required to drink methadone dispensed in orange juice or orange juice substitute in front of the pharmacist. Ask the patient to speak after their drink to ensure that it is being swallowed.
2. We need to be informed of any diversion.
3. We need to be informed of any missed methadone doses by the patient. Please call _____ to leave a message regarding this.
4. If three or more doses are missed in a row, **the methadone dose must be withheld** from the patient to prevent an overdose. The patient must be reassessed at our clinic before methadone is restarted. Please call to inform us.
5. If there is any evidence of intoxication or sedation (slurred speech, stumbling gait, disorientation) **the methadone dose must be withheld** from the patient to prevent an overdose. The patient must be reassessed at the clinic before methadone 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. We have already discussed this 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 was observed by the pharmacist to vomit their methadone 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 J

Patient Treatment Form

Please use this form to report **both** initiation and cessation of treatment for each patient in treatment.

PATIENT (please print):

Last Name: _____

First/Middle Names: _____

City of Residence in Ontario: _____

Gender: Male Female Date of birth: MM ____ DD ____ YY ____

Health Card: Ontario or Other Province: _____

Health Card No.: _____

I have discussed the following with my methadone prescriber and give consent:

The College of Physicians and Surgeons of Ontario will maintain the information contained in this form in a database, and will respect the confidentiality of this personal and health information.

The use of information on this form will also be used for statistical purposes.

Patient Signature: _____ Date: _____

DETAILS OF INITIATION:

Methadone Tx under your care is to start: MM ____ DD ____ YY ____

New to methadone Transfer (by physician/self-referred)

If transferring, name of previous methadone Tx provider: _____

and date of last dose: MM ____ DD ____ YY ____

PHYSICIAN: Name (please print): _____

Signature: _____ Date: _____

Methadone Treatment Practice: Community Correctional

Treatment Site: _____

Tel: _____ Fax: _____

DETAILS OF CESSATION:

Date of the last methadone dose under your care: MM ____ DD ____ YY ____

Patient stopped returning for treatment

Taper initiated by you/patient-initiated taper

Transfer If yes, Name of methadone Tx provider: _____

Other reason for methadone Tx cessation: _____

PHYSICIAN:

Signature: _____ Date: _____

FAX to: (416) 967-2635 **or Mail to:** College of Physicians and Surgeons of Ontario
80 College Street, Toronto, ON, M5G 2E2
Tel: (416) 967-2661 Toll-free (800) 268-7096, Ext. 661

APPENDIX K

Managing Potential Methadone Overdose

The Methadone Maintenance Treatment Guidelines, published in November 2005, are revised to include advice to assist physicians who prescribe methadone in the event of a potential methadone overdose. This information, (documents which comprise **Appendix K**), was developed in partnership with the Centre for Addiction and Mental Health and/or is included in response to recommendations from coroners' inquests that occurred after the release of the MMT guidelines, and was approved by the College's Methadone Committee at its July 24, 2007 meeting.

Appendix K includes documents to assist physicians in handling a potential methadone overdose. These materials are also intended to provide advice to patients and emergency room staff, and ensure that physicians who prescribe methadone have taken the necessary steps to avoid an adverse outcome in a methadone overdose scenario.

Appendix K – List of Documents

- Patient information sheet on methadone overdose
- Against medical advice – release form to be signed by patient/parent/legal guardian
- Emergency Department management of methadone overdose
- Methadone overdose protocol for the ambulatory patient
- [Form 1](#)
- [Form 42](#)

APPENDIX K

Patient Information Sheet on Methadone Overdose

Methadone overdose (receiving a larger dose of methadone than intended) is a serious medical emergency.

Methadone is a long-acting medication and can stay in your body for many hours.

Even if you have been on methadone for a long time, taking more methadone than your body is used to can be dangerous. Even what may seem like a small dose increase can be dangerous.

If you are new to methadone or have not been taking your regular dose, even for a few days, **you are at increased risk of overdose.**

Taking too much methadone can result in difficulty breathing (slow or shallow breathing), drowsiness, small pupils, and, in some cases, coma and death.

For this reason, your nurse, pharmacist or physician has deemed that **IT IS ESSENTIAL THAT YOU GO TO THE EMERGENCY DEPARTMENT** to be observed for a minimum of 10 hours, and maybe longer, depending on your symptoms.

There is good treatment available in the emergency department that can reverse the effects that you may get from taking too much methadone.

**APPENDIX K
Against Medical Advice**

Date: _____

I, _____, acknowledge that

_____ explained my condition to me and advised me of the potential risks and/or complications which could or would arise from refusal of medical care. I have also been advised that other unknown risks and/or complications are possible. Being aware that there are known and unknown potential risks and/or complications, it is still my desire to refuse the advised medical care.

I do hereby release _____ and CAMH from all liability resulting from any adverse medical condition(s) caused by my refusal of the recommended medical care.

Signature of Patient/Parent/Legal Guardian:

Date _____

Witness _____

If witness acted as translator, check here _____

Name of translator _____

APPENDIX K

Emergency Department Management of Methadone Overdose

Fax to Emergency Dept. and also give one copy to patient to carry to Emergency Dept. Call Emergency Dept. prior to faxing information sheet.

Clinical features: Methadone acts for at least 24 hours, much longer than other opioids. Symptoms begin up to 10 hours after the overdose. Early symptoms include nodding off, drowsiness, slurred speech, emotionally labile. Respiratory depression occurs later.

Monitoring: Check frequently for vital signs, O₂ sat, and a brief conversation to assess alertness. ECG & cardiac monitoring recommended to check for prolonged QT interval and ventricular arrhythmias.

Intubation: Avoids risks of naloxone-induced withdrawal. Intubation necessary if:

- RR < 12; hypercapnea; persistent desaturation despite supplemental oxygen
- Patient fails to respond to naloxone within 2 min

Naloxone dosing:

- If the patient has respiratory depression, give 2.0 mg naloxone iv.
- If no respiratory depression, give 0.01 mg/kg body weight to avoid precipitating withdrawal.
- If no response after initial dose, repeat naloxone 2–4 mg every 2–3 min. If no response after 10–20 mg naloxone, search for other causes of the coma.
- If patient responds to naloxone, infuse at 2/3 the effective dose per hour.
- Give a bolus of ½ the effective dose 15–20 min after starting infusion.
- Titrate dose to avoid withdrawal, while maintaining adequate non-assisted respirations.

Precautions: Ventricular dysrhythmias and cardiac arrest can occur with naloxone-induced withdrawal, especially if patients are withdrawing from other substances. Patient may become agitated and leave AMA. Intubation avoids these risks.

Time intervals for monitoring suspected methadone overdose:

- Observe for at least 10 hours post overdose
- Discharge if completely asymptomatic during that time
- If symptomatic at any time during the 10 hours, observe for at least **24 hours** post OD
- If intubated or on naloxone, continue for at least **24 hours** post OD
- Monitor for at least **6 hours** after naloxone or intubation DC'd

Discharge warnings: Don't take any methadone, alcohol or sedating drugs until you see methadone MD the next day. Have family member observe you overnight. Call ambulance if more drowsy, difficult to arouse or snoring much more loudly than usual.

For further management advice, call the **Ontario Poison Centre (416) 813-5900 (local) or 1-800-268-9017**

Centre for Addiction and Mental Health, CAMH, 2007.

APPENDIX K

Methadone Overdose Protocol for the Ambulatory Patient

Note: This protocol does NOT extend to patients who are obtunded or unconscious at presentation.

Patients who have had an overdose of methadone, either inadvertently (e.g., dispensing error) or intentional (e.g., consuming multiple take home doses at one sitting) should receive the following measures:

1. If the additional dose that the patient has received is above and beyond what would be considered a “reasonable” dose increase at his or her stage of treatment, the patient should be counseled on the dangers of methadone overdose and advised to go to the Emergency Department.

Definition of a “reasonable” dose increase:

Please refer to the “Methadone Dosing Issues” section starting on page 12 of the ***Methadone Maintenance Guidelines*** (www.cpso.on.ca under ***Publications***). Reasonable dose increases are usually in the range of 10 to 15 mg increments every three to five days. For example, if a patient has consistently been on 50 mg/d for several weeks and then receives 65 mg by mistake, this would be considered within the range of a “reasonable” dose increase for that patient. However, if the patient had just been increased to 50 mg the day before and then received 65 mg, this would not be considered a reasonable increase as per the CPSO guidelines.

Also, interpret what would constitute a reasonable dose increase in the context of the patient and other substances and medications that they have ingested (e.g., benzodiazepines, methadone inhibitors and inducers, etc. – a list of drug interactions is available at www.drug-interactions.com). Additive effects of sedating drugs and drug interactions may play an important role in determining what a reasonable dose increase is.

2. If you are uncertain, call the Ontario Poison Information Centre at 1-800-268-9017.
3. The patient should be advised on the risks of methadone overdose, including respiratory depression and death, and given the accompanying patient information sheet on the risks of methadone overdose, as well as a copy of the accompanying information sheet for the emergency department.
4. It is reasonable to send the patient by ambulance to the emergency department but use your clinical judgment.

5. The information sheet for the emergency department should be faxed to the emergency department (ED). Ask to speak with the attending ED physician directly to convey your concern. Advise them that the patient should be observed for a minimum of 10 hours and then discharged only if they have not displayed any signs of lethargy or sedation during that time.

What to do if the patient refuses to go the emergency department:

1. If the patient refuses to go the emergency department, then it is appropriate to fill out a Form 1, which allows an involuntary assessment of the patient. A Form 1 is included for your use. In most instances, it would be appropriate to fill out a Form 1 on a methadone maintenance patient who has had an overdose of methadone and who refuses to go to the emergency department, even if they are alert and coherent, as they have a mental health diagnosis and are also at risk for bodily harm.
2. If the patient refuses to go to the emergency department and a clinical decision is made to not fill out a Form 1 (e.g., no physician available onsite or you are speaking to the patient by phone and have not assessed the patient in the preceding week as required by a Form 1), then it is reasonable to send an ambulance or police to the patient's home. In the event that you feel that it is absolutely not possible to fill out a Form 1 or send the police or ambulance to a patient, the patient should be re-instructed about the dangers of methadone overdose. If possible, give the accompanying patient information sheet, and ask the patient to sign the accompanying "AMA or Against Medical Advice" form.
3. Emphasize to the patient and (if available) his or her partner or family member that the patient is at risk of respiratory depression (slow breathing) and death and may be most at risk during sleep. Advise them not to use any other substances or medications.
4. Most patients will start to exhibit signs and symptoms of overdose (e.g., sleepiness, sedation) by five hours, although some patients may not exhibit symptoms until 10 hours have passed.

REFERENCES AND LITERATURE REVIEW

Effectiveness of Methadone

1. Farrell, M, et al, Methadone maintenance treatment in opiate dependence: a review. *BMJ*, 1994. 309(6960): p. 997–1001.
2. Strain, EC, et al, Dose-response effects of methadone in the treatment of opioid dependence. *Ann Intern Med*, 1993. 119(1): p. 23–7.
3. Newman, RG, and Whitehill, WB, Double-blind comparison of methadone and placebo maintenance treatments of narcotic addicts in Hong Kong. *Lancet*, 1979. 2(8141): p. 485–8.
4. Dole, VP, et al, Methadone treatment of randomly selected criminal addicts. *N Engl J Med*, 1969. 280(25): p. 1372–5.
5. Gunne, LM, and Gronbladh, L, The Swedish methadone maintenance program: a controlled study. *Drug Alcohol Depend*, 1981. 7(3): p. 249–56.
6. Caplehorn, JR, et al, Retention in methadone maintenance and heroin addicts' risk of death. *Addiction*, 1994. 89(2): p. 203–9.
7. Ball, JC, et al, Reducing the risk of AIDS through methadone maintenance treatment. *J Health Soc Behav*, 1988. 29(3): p. 214–26.
8. Caplehorn, JR, and Ross, MW, Methadone maintenance and the likelihood of risky needle-sharing. *Int J Addict*, 1995. 30(6): p. 685–98.
9. Zhang, Z, Friedmann, PD, and Gerstein, DR, Does retention matter? Treatment duration and improvement in drug use. *Addiction*, 2003. 98(5): p. 673–84.
10. Zanis, DA, and Woody, GE, One-year mortality rates following methadone treatment discharge. *Drug Alcohol Depend*, 1998. 52(3): p. 257–60.
11. Caplehorn, JR, Lumley, TS, and Irwig, L, Staff attitudes and retention of patients in methadone maintenance programs. *Drug Alcohol Depend*, 1998. 52(1): p. 57–61.
12. Ball JC, et al, The effectiveness of methadone maintenance treatment: patients, programs, services, and outcome. 1991.
13. Villano, CL, et al, Improving treatment engagement and outcomes for cocaine-using methadone patients. *Am J Drug Alcohol Abuse*, 2002. 28(2): p. 213–30.
14. Dole, VP, and Joseph, H, Long-term outcome of patients treated with methadone maintenance. *Ann N Y Acad Sci*, 1978. 311: p. 181–9.
15. Fairbank, JA, Duntzman, GH, and Condelli, WS, Do methadone patients substitute other drugs for heroin? Predicting substance use at 1-year follow-up. *Am J Drug Alcohol Abuse*, 1993. 19(4): p. 465–74.
16. McLellan, AT, et al, The effects of psychosocial services in substance abuse treatment. *JAMA*, 1993. 269(15): p. 1953–9.
17. Kraft, MK, et al, Are supplementary services provided during methadone maintenance really cost-effective? *Am J Psychiatry*, 1997. 154(9): p. 1214–9.
18. Kletter, E, Counselling as an intervention for the cocaine-abusing methadone maintenance patient. *J Psychoactive Drugs*, 2003. 35(2): p. 271–7.
19. Rawson, RA, et al, A comparison of contingency management and cognitive-behavioral approaches during methadone maintenance treatment for cocaine dependence. *Archives of General Psychiatry*, 2002. 59(9): p. 817–24.
20. Stitzer, ML, Iguchi, MY, and Felch, LJ, Contingent take-home incentive: effects on drug use of methadone maintenance patients. *J Consulting Clinical Psychology*, 1992. 60(6): p. 927–34.
21. Mattick, RP, et al, Methadone maintenance therapy versus no opioid replacement therapy for opioid dependence. *Cochrane Database Syst Rev*, 2003(2): p. CD002209.
22. Mattick, RP, et al, Buprenorphine maintenance versus placebo or methadone maintenance for opioid dependence. *Cochrane Database Syst Rev*, 2003(2): p. CD002207.
23. Pirnay, S, et al, A critical review of the causes of death among post-mortem toxicological investigations: analysis of 34 buprenorphine-associated and 35 methadone-associated deaths. *Addiction*, 2004. 99(8): p. 978–88.
24. Ritter, AJ, et al, A randomized trial comparing levo-alpha acetylmethadol with methadone maintenance for patients in primary care settings in Australia. *Addiction*, 2003. 98(11): p. 1605–13.

Methadone Dosing

1. Cairns, J, Methadone-related deaths in Ontario. 2000, Ontario Coroner's Office: Toronto.
2. Caplehorn, JR, Deaths in the first two weeks of maintenance treatment in NSW in 1994: Identifying cases of iatrogenic methadone toxicity. *Drug and Alcohol Review*, 1998. 17: p. 9–17.
3. Buster, MC, van Brussel, GH, and van den Brink, W, An increase in overdose mortality during the first 2 weeks after entering or re-entering methadone treatment in Amsterdam. *Addiction*, 2002. 97(8): p. 993–1001.
4. Caplehorn, JR, and Drummer, OH, Mortality associated with New South Wales methadone programs in 1994: lives lost and saved. *Med J Aust*, 1999. 170(3): p. 104–9.
5. Fries, JF, et al, Nonsteroidal anti-inflammatory drug-associated gastropathy: incidence and risk factor models. *Am J Med*, 1991. 91(3): p. 213–22.
6. Harding-Pink, D, Methadone: one person's maintenance dose is another's poison. *Lancet*, 1993. 341(8846): p. 665–6.
7. Drummer, OH, and Opeskin, K, Methadone toxicity causing death in ten subjects starting on a methadone maintenance program. *Am J Forensic Med Pathol*, 1992. 13(4): p. 346–50.
8. Zador, D, and Sunjic, S, Deaths in methadone maintenance treatment in New South Wales, Australia 1990–1995. *Addiction*, 2000. 95(1): p. 77–84.
9. Repchinsky, C, ed. *Compendium of Pharmaceutical and Specialties: The Canadian drug reference for health professionals*. 2003, Canadian Pharmacists Association: Ottawa.
10. Caplehorn, JR, and Drummer, OH, Fatal methadone toxicity: signs and circumstances, and the role of benzodiazepines. *Aust N Z J Public Health*, 2002. 26(4): p. 358–62; discussion 362–3.
11. Borron, SW, et al, Flunitrazepam variably alters morphine, buprenorphine, and methadone lethality in the rat. *Hum Exp Toxicol*, 2002. 21(11): p. 599–605.
12. Tarumi, Y, Pereira, J, and Watanabe, S, Methadone and fluconazole: respiratory depression by drug interaction. *J Pain Symptom Manage*, 2002. 23(2): p. 148–53.
13. Herrlin, K, et al, Methadone, ciprofloxacin, and adverse drug reactions. *Lancet*, 2000. 356(9247): p. 2069–70.
14. Hamilton, SP, et al, The effect of sertraline on methadone plasma levels in methadone-maintenance patients. *Am J Addict*, 2000. 9(1): p. 63–9.
15. Strain, EC, et al, Moderate vs high-dose methadone in the treatment of opioid dependence: a randomized trial [see comments]. *JAMA*, 1999. 281(11): p. 1000–5.
16. Farre, M, et al, Retention rate and illicit opioid use during methadone maintenance interventions: a meta-analysis. *Drug Alcohol Depend*, 2002. 65(3): p. 283–90.
17. Faggiano, F, et al, Methadone maintenance at different dosages for opioid dependence. *Cochrane Database Syst Rev*, 2003(3): p. CD002208.
18. Goldstein, A, and Judson, BA, Efficacy and side effects of three widely different methadone doses. *Proc Natl Conf Methadone Treat*, 1973. 1: p. 21–44.
19. Maxwell, S, and Shinderman, MS, Optimizing long-term response to methadone maintenance treatment: a 152-week follow-up using higher-dose methadone. *J Addict Dis*, 2002. 21(3): p. 1–12.
20. Maxwell, S, and Shinderman, MS, Optimizing response to methadone maintenance treatment: use of higher-dose methadone. *J Psychoactive Drugs*, 1999. 31(2): p. 95–102.
21. Leavitt, SB, et al, When “enough” is not enough: new perspectives on optimal methadone maintenance dose. *Mt Sinai J Med*, 2000. 67(5–6): p. 404–11.
22. Krantz, MJ, et al, Torsade de pointes associated with very high-dose methadone. *Ann Intern Med*, 2002. 137(6): p. 501–4.
23. Walker, PW, Klein, D, and Kasza, L, High dose methadone and ventricular arrhythmias: a report of three cases. *Pain*, 2003. 103(3): p. 321–4.
24. Krantz, MJ, et al, Dose-related effects of methadone on QT prolongation in a series of patients with torsade de pointes. *Pharmacotherapy*, 2003. 23(6): p. 802–5.
25. Maremmani, I, et al, QTc interval prolongation in patients on long-term methadone maintenance therapy. *Eur Addict Res*, 2005. 11(1): p. 44–9.
26. Moss, AJ, Measurement of the QT interval and the risk associated with QTc interval prolongation: a review. *Am J Cardiol*, 1993. 72(6): p. 23B–25B.
27. Vodooz, JF, Jaquier, F, and Lamy, O, [Torsade de pointes: a severe and unknown adverse effect in a patient taking methadone]. *Schweiz Rundsch Med Prax*, 2003. 92(41): p. 1748–50.

28. Krook, AL, Waal, H, and Hansteen, V, [Routine ECG in methadone-assisted rehabilitation is wrong prioritization]. *Tidsskr Nor Lægeforen*, 2004. 124(22): p. 2940–1.
29. Darke, S, et al, Cognitive impairment among methadone maintenance patients. *Addiction*, 2000. 95(5): p. 687–95.
30. Mintzer, MZ, and Stitzer, ML, Cognitive impairment in methadone maintenance patients. *Drug Alcohol Depend*, 2002. 67(1): p. 41–51.
31. Staak, M, et al, [Empirical studies of automobile driving fitness of patients treated with methadone-substitution]. *Blutalkohol*, 1993. 30(6): p. 321–33.
32. Curran, HV, et al, Effects of methadone on cognition, mood and craving in detoxifying opiate addicts: a dose-response study. *Psychopharmacology (Berl)*, 2001. 154(2): p. 153–60.
33. Curran, HV, et al, Additional methadone increases craving for heroin: a double-blind, placebo-controlled study of chronic opiate users receiving methadone substitution treatment. *Addiction*, 1999. 94(5): p. 665–74.
34. Lyvers, M, and Yakimoff, M, Neuropsychological correlates of opioid dependence and withdrawal. *Addict Behav*, 2003. 28(3): p. 605–11.
35. Dyer, KR, et al, The relationship between mood state and plasma methadone concentration in maintenance patients. *J Clin Psychopharmacol*, 2001. 21(1): p. 78–84.
36. Eap, CB, Buclin, T, and Baumann, P, Interindividual variability of the clinical pharmacokinetics of methadone: implications for the treatment of opioid dependence. *Clin Pharmacokinet*, 2002. 41(14): p. 1153–93.
37. Tennant, FS, et al, Methadone plasma levels and persistent drug abuse in high dose maintenance patients. *NIDA Res Monograph*, 1984. 49: p. 262–8.
38. Tennant, F, and Shannon, J, Cocaine abuse in methadone maintenance patients is associated with low serum methadone concentrations. *J Addict Dis*, 1995. 14(1): p. 67–74.
39. Bell, J, et al, Serum levels of methadone in maintenance clients who persist in illicit drug use. *Br J Addict*, 1990. 85(12): p. 1599–602.
40. Torrens, M, et al, Plasma methadone concentrations as an indicator of opioid withdrawal symptoms and heroin use in a methadone maintenance program. *Drug Alcohol Depend*, 1998. 52(3): p. 193–200.
41. Borg, L, et al, Availability of reliable serum methadone determination for management of symptomatic patients. *J Addict Dis*, 1995. 14(3): p. 83–96.
42. Drozdick, J, III, et al, Methadone trough levels in pregnancy. *Am J Obstet Gynecol*, 2002. 187(5): p. 1184–8.

Urine Drug Screens

1. Compton, PA, et al, Urine toxicology as an outcome measure in drug abuse clinical trials: must every sample be analyzed? *J Addict Dis*, 1996. 15(2): p. 85–92.
2. Chutuape, MA, Silverman, K, and Stitzer, ML, Use of methadone take-home contingencies with persistent opiate and cocaine abusers. *J Subst Abuse Treat*, 1999. 16(1): p. 23–30.
3. Chutuape, MA, Silverman, K, and Stitzer, ML, Contingent reinforcement sustains post-detoxification abstinence from multiple drugs: a preliminary study with methadone patients. *Drug Alcohol Depend*, 1999. 54(1): p. 69–81.
4. Iguchi, MY, et al, Contingency management in methadone maintenance: effects of reinforcing and aversive consequences on illicit polydrug use. *Drug Alcohol Depend*, 1988. 22(1–2): p. 1–7.
5. Preston, KL, Umbricht, A, and Epstein, DH, Abstinence reinforcement maintenance contingency and one-year follow-up. *Drug Alcohol Depend*, 2002. 67(2): p. 125–37.
6. Schmitz, JM, et al, Medication take-home doses and contingency management. *Exp Clin Psychopharmacol*, 1998. 6(2): p. 162–8.
7. Stitzer, ML, Iguchi, MY, and Felch, LJ, Contingent take-home incentive: effects on drug use of methadone maintenance patients. *J Consult Clin Psychol*, 1992. 60(6): p. 927–34.
8. Stitzer, ML, et al, Contingent reinforcement for benzodiazepine-free urines: evaluation of a drug abuse treatment intervention. *J Appl Behav Anal*, 1982. 15(4): p. 493–503.
9. Chutuape, MA, Silverman, K, and Stitzer, ML, Effects of urine testing frequency on outcome in a methadone take-home contingency program. *Drug Alcohol Depend*, 2001. 62(1): p. 69–76.
10. Ries, RK, et al, Use of case manager ratings and weekly urine toxicology tests among outpatients with dual diagnoses. *Psychiatr Serv*, 2002. 53(6): p. 764–6.

11. Preston, KL, et al, Comparison of self-reported drug use with quantitative and qualitative urinalysis for assessment of drug use in treatment studies. *NIDA Res Monogr*, 1997. 167: p. 130–45.
12. Perrone, J, et al, Drug screening versus history in detection of substance use in ED psychiatric patients. *Am J Emerg Med*, 2001. 19(1): p. 49–51.
13. Downey, KK, Helmus, TC, and Schuster, CR, Contingency management for accurate predictions of urinalysis test results and lack of correspondence with self-reported drug use among polydrug abusers. *Psychol Addict Behav*, 2000. 14(1): p. 69–72.
14. Myrick, H, et al, Clinical characteristics of under-reporters on urine drug screens in a cocaine treatment study. *Am J Addict*, 2002. 11(4): p. 255–61.
15. Crosby, RD, Carlson, GA, and Specker, SM, Simulation of drug use and urine screening patterns. *J Addict Dis*, 2003. 22(3): p. 89–98.
16. Goldstein, A, and Brown, BW, Urine testing in methadone maintenance treatment: applications and limitations. *J Subst Abuse Treat*, 2003. 25(2): p. 61–3.
17. Delucchi, KL, et al, Urine toxicology samples in cocaine treatment trials: how many need to be tested? *J Addict Dis*, 2002. 21(2): p. 17–26.
18. Wasserman, DA, et al, Detection of illicit opioid and cocaine use in methadone maintenance treatment. *Am J Drug Alcohol Abuse*, 1999. 25(3): p. 561–71.
19. Joe, GW, Simpson, DD, and Sells, SB, Treatment process and relapse to opioid use during methadone maintenance. *Am J Drug Alcohol Abuse*, 1994. 20(2): p. 173–97.
20. Anderson, JF, and Warren, LD, Client retention in the British Columbia Methadone Program, 1996–1999. *Can J Public Health*, 2004. 95(2): p. 104–9.
21. Fischer, B, Prescriptions, power and politics: the turbulent history of methadone maintenance in Canada. *J Public Health Policy*, 2000. 21(2): p. 187–210.
22. Fischer, B, et al, Canadian illicit opiate users' views on methadone and other opiate prescription treatment: an exploratory qualitative study. *Subst Use Misuse*, 2002. 37(4): p. 495–522.

Carry Policy

1. Chutuape, MA, Silverman, K, and Stitzer, ML, Use of methadone take-home contingencies with persistent opiate and cocaine abusers. *J Subst Abuse Treat*, 1999; 16(1): p. 23–30.
2. Chutuape, MA, Silverman, K, and Stitzer, ML, Contingent reinforcement sustains post-detoxification abstinence from multiple drugs: a preliminary study with methadone patients. *Drug Alcohol Depend*, 1999; 54(1): p. 69–81.
3. Iguchi, MY, et al, Contingency management in methadone maintenance: effects of reinforcing and aversive consequences on illicit polydrug use. *Drug Alcohol Depend*, 1988; 22(1–2): p. 1–7.
4. Preston, KL, Umbricht, A, and Epstein, DH, Abstinence reinforcement maintenance contingency and one-year follow-up. *Drug Alcohol Depend*, 2002; 67(2): p. 125–37.
5. Schmitz, JM, Rhoades, HM, Elk, R, et al, Medication take-home doses and contingency management. *Exp Clin Psychopharmacol*, 1998; 6(2): p. 162–8.
6. Stitzer, ML, Iguchi, MY, and Felch, UJ, Contingent take-home incentive: effects on drug use of methadone maintenance patients. *J Consult Clin Psychol*, 1992; 60(6): p. 927–34.
7. Chutuape, MA, Silverman, K, and Stitzer, ML, Effects of urine testing frequency on outcome in a methadone take-home contingency program. *Drug Alcohol Depend*, 2001; 62(1): p. 69–76.
8. Perrone, J, et al, Drug screening versus history in detection of substance use in ED psychiatric patients. *Am J Emerg Med*, 2001; 19(1): p. 49–51.
9. Downey, KK, Helmus, TC, and Schuster, CR, Contingency management for accurate predictions of urinalysis test results and lack of correspondence with self-reported drug use among polydrug abusers. *Psychol Addict Behav*, 2000; 14(1): p. 69–72.
10. Crosby, RD, Carlson, GA, and Specker, SM, Simulation of drug use and urine screening patterns. *J Addict Dis*, 2003; 22(3): p. 89–98.
11. Goldstein, A, and Brown, BW, Urine testing in methadone maintenance treatment: applications and limitations. *J Subst Abuse Treat*, 2003; 25(2): p. 61–3.
12. Joe, GW, Simpson, DD, and Hubbard, RL, Treatment predictors of tenure in methadone maintenance. *J Subst Abuse*, 1991; 3(1): p. 73–84.
13. Joe, GW, Simpson, DD, and Sells, SB, Treatment process and relapse to opioid use during methadone maintenance. *Am J Drug Alcohol Abuse*, 1994; 20(2): p. 173–97.

14. Amass, L, et al, Preferences for clinic privileges, retail items and social activities in an outpatient buprenorphine treatment program. *J Subst Abuse Treat*, 1996; 13(1): p. 43–9.
15. Pani, PP, et al, Prohibition of take-home dosages: negative consequences on methadone maintenance treatment. *Drug Alcohol Depend*, 1996; 41(1): p. 81–4.
16. Gelkopf, M., et al, Patient outcomes after initiation of Sabbath closure of a methadone maintenance clinic in Israel. *Psychiatr Serv*, 1998; 49(11): p. 1483–5.
17. Fountain, J, et al, Diversion of prescribed drugs by drug users in treatment: analysis of the UK market and new data from London. *Addiction*, 2000; 95(3): p. 393–406.
18. Cairns, J, Methadone-related deaths in Ontario. 2000, Ontario Coroner's Office: Toronto.
19. Vormfelde, SV, and Poser, W, Death attributed to methadone. *Pharmacopsychiatry*, 2001; 34(6): p. 217–22.
20. Sanchez-Carbonell, X, and Seus, L, Ten-year survival analysis of a cohort of heroin addicts in Catalonia: the EMETYST project. *Addiction*, 2000; 95(6): p. 941–8.
21. Frischer, M, et al, Mortality and survival among a cohort of drug injectors in Glasgow, 1982–1994. *Addiction*, 1997; 92(4): p. 419–27.
22. Scherbaum, N, et al, [Does maintenance treatment reduce the mortality rate of opioid addicts?]. *Fortschr Neurol Psychiatr*, 2002; 70(9): p. 455–61.
23. Caplehorn, JR, et al, Methadone maintenance and addicts' risk of fatal heroin overdose. *Subst Use Misuse*, 1996; 31(2): p. 177–96.
24. Bell, J, and Zador, D, A risk-benefit analysis of methadone maintenance treatment. *Drug Saf*, 2000; 22(3): p. 179–90.
25. Zanis, DA, and Woody, GE, One-year mortality rates following methadone treatment discharge. *Drug Alcohol Depend*, 1998; 52(3): p. 257–60.
26. Buster, MC, van Brussel, GH, and van den Brink, W, An increase in overdose mortality during the first 2 weeks after entering or re-entering methadone treatment in Amsterdam. *Addiction*, 2002; 97(8): p. 993–1001.

ABOUT THE COLLEGE

The College of Physicians and Surgeons of Ontario is the self-regulating body for the province's 23,000 doctors. It issues certificates of registration to doctors to allow them to practise medicine, monitors and maintains standards of practice through peer assessment and remediation, investigates complaints against doctors on behalf of the public, and disciplines doctors who have committed an act of professional misconduct or are incompetent.

The privilege to self-regulate is given to the medical profession by society on the understanding that the profession will exercise its authority in the public interest. In actuality, the College is a professionally-led organization working in partnership with the public.

Just more than half of the governing Council of the College are physicians, 16 elected by the profession and three appointed by universities. The other 13–15 Councillors are public members, appointed by the government. They bring a variety of experience and come from regions across Ontario.

The role and authority of the College is set out in the Regulated Health Professions Act, the Health Professions Procedural Code, the Medicine Act, and the regulations made under these Acts. Council, directly and through its committees, sets policy and supervises College activities.

The College's Strategic Plan

The strategic plan focuses on the College's core function—regulating the practice of medicine in Ontario in the public interest—and commits us to a high standard of accountability and transparency.

College Vision

The best quality care for the people of Ontario by the doctors of Ontario.

Goals

The College's vision will be implemented by:

Advocating for quality health care in partnership with other stakeholders;

Integrating the roles of clinical education, evidence-based clinical practice, and regulatory responsibilities to improve patient care at the individual and system level;

Evaluating and improving the effectiveness and efficiency of the current investigative and disciplinary processes, and identifying potential alternatives;

Accelerating efforts to find creative ways to address physician resource needs without compromising registration standards;

Providing publicly accessible regulatory information about physicians;

Engaging stakeholders in a public debate about the limits of medicine and focusing on what patients can expect from their physicians;

Establishing a comprehensive and effective communication plan to improve recognition of the College by its stakeholders;

Establishing an effective and transparent governance model for the College.

