COVID-19 Opioid Agonist Treatment Guidance

August 2021 Update

The COVID-19 Opioid Agonist Treatment (OAT) Guidance was created to help guide OAT care for patients with opioid use disorder (OUD) and to support ongoing access to OAT care. At the time the document was created in March 2020, none of us could foresee the extent and duration of the challenges ahead, but we knew that ensuring continuity of access to OAT was of paramount importance. Given the overwhelming number of overdose deaths over the past year, this effort was a vital public health measure.

This update responds to questions from clinicians regarding the application of this guidance as of August 2021. In light of the current stage of reopening in Ontario, these are the current recommendations from the guidance group:

- Patients should be given advance notice that with resumption of more normal patterns of activity, this guidance will no longer apply directly. Patients can expect their physicians to resume more traditional approaches to carries and office visits. The intention of the COVID-19 Opioid Agonist Treatment Guidance was to support COVID-19 public health distancing measures by focusing on carry safety and de-emphasizing contingency management. Going forward, where it will benefit individual patients, clinicians may consider re-introducing elements of contingency management to their management of carries, with carry levels informed by urine sample results.
- The CPSO 2011 methadone guidelines referred to in the March 2020 COVID-19 Opioid Agonist Treatment Guidance have recently been rescinded, providing clinicians with greater scope to use clinical judgment. We encourage prescribers to consider their approach to carries (and other elements of care, including the frequency of office visits and urine drug screens) based on an assessment of clinical stability and the risks vs. benefits of carries. Studies (in press) on OAT care during the pandemic appear to demonstrate that increased carries have not been associated with increases in adverse events, and that carries have improved communication and relationships between patients and providers. For patients who have achieved or are maintaining stability on extended or "exceptional" carries, prescribers should consider maintaining this approach. It may also be appropriate to continue this practice for patients who have remained stable without regularly providing urine samples.

- · As all clinicians work toward finding a new balance in the model of care, consider the merits of virtual vs. in-person visits. While many patients appreciated the flexibility of virtual visits and felt this improved access to care, others experienced a decrease in the level of connection with their providers, and for some, access to technology posed a barrier to care. For some patients, virtual care will continue to be appropriate, while for other patients, it will now be important to resume in-person visits, regularly or intermittently. Ideally, clinicians and patients will discuss and agree on a format that supports access to high-quality care and that is compatible with work and family commitments.
- Encourage all patients to be vaccinated against COVID-19. To reduce barriers to vaccination, arrange for vaccines to be administered in the clinic setting when possible.

At this time, we do not foresee updating the guidance document. Should there be another lockdown, it would be appropriate for clinicians to implement the guidance promptly and in proportion to the scope of public health guidelines and restrictions. Further OAT resources are available on the META:PHI and CAMH websites. In particular, we refer all providers to the new CAMH document "Opioid Agonist Therapy: A Synthesis of Canadian Guidelines for Treating Opioid Use Disorder."

References:

Office of the Chief Coroner for Ontario. (2020). *Opioid mortality trends in Ontario in the context of* COVID-19 pandemic. Public Health Ontario. Accessed from: https://www.publichealthontario.ca/-/ media/event-presentations/2020/covid-19-substance-use-data-nov-10.pdf?la=en

COVID -19 Opioid Agonist Treatment Guidance

CAMH / META:PHI / OMA - This version: March 22, 2020

This document will be reviewed and updated as the COVID-19 pandemic evolves. Please check for the most recent version on the CAMH, CPSO and META:PHI websites.

Purpose and scope:

- This document provides a consensus interim guideline for management of opioid agonist therapy (OAT) with methadone and buprenorphine. It addresses office visits, remote visits, carry doses and frequency of urine drug testing during the COVID-19 pandemic in light of the need for physical distancing, self-isolation and quarantine while there is community transmission of COVID-19 in a prescriber's area of practice.
- This document supplements existing standards and guidelines and is a resource for practitioners who are clinically proficient in the prescription of OAT. It is not a general guide to prescribing OAT.
- Guidelines provide recommendations; they are not a standard, are not to supersede clinical experience/decision-making skills and are not intended to limit the scope of one's clinical practice.

Guideline within context of COVID-19 (see Appendix A):

- This document applies primarily to patients who are asymptomatic and practicing physical distancing as mandated by public health guidance.
- Patients who are asymptomatic and under isolation: Pharmacy delivery should be used if available. Virtual communication may be used to support witnessed dosing. If pharmacy delivery is not available, prescriber should closely coordinate patient attendance with pharmacy staff so that appropriate precautions can be taken.
- Patients who are symptomatic and/or quarantined, or presumed or confirmed COVID-19
 positive: Pharmacy delivery should be used if available. Virtual communication may be used
 to support witnessed dosing. All reasonable measures should be explored to support patients
 remaining in quarantine, including having a reliable, designated agent (e.g., family member or
 friend) to pick up or receive the carries. Practice may need to be modified outside the scope of
 this guideline on an individual basis, applying clinical judgment to weigh risks and benefits to
 patient and public in each case.

Terminology:

Carry/carries	Take-home doses of methadone and buprenorphine/naloxone for opioid use disorder treatment
UDS	Urine drug screens
Clear UDS	Urine drug screens that show the absence of illicit substances
Remote/remotely	Clinical care via telephone, OTN and other online platforms
MMTG	Methadone Maintenance Treatment Guideline (2011) published by the College of Physicians and Surgeons of Ontario
Bup/nal	Buprenorphine/naloxone

GUIDING PRINCIPLES

- Purpose of carries:
 - > Opioid agonist treatment (OAT) is the gold standard of care for opioid use disorder. It is essential that patients have safe and continued access to treatment during the COVID-19 pandemic.
 - > During this time of widespread COVID-19 community transmission, exceptional OAT carries can be considered as a way to provide ongoing care that balances the facilitation of physical distancing by reducing pharmacy and clinic visits with considerations of patient and community safety.
 - Some patients who might not have been considered eligible for methadone carries under MMTG may be given carries in light of the COVID-19 pandemic as per the criteria below.
 - > Given buprenorphine's safety profile, bup/nal carries are considered differently than methadone. With methadone, there are greater concerns with respiratory depression and overdose. Thus, the risks of community transmission of COVID-19 must be weighed against the known risks of overdose death due to diversion to the community or to overuse of methadone carries by the patient.
 - > During the COVID-19 pandemic, the role of UDS and carries in contingency management should be de-emphasized. In most instances, patients may be assessed remotely and may be managed without obtaining a UDS.
 - > UDS should be performed at the time of a clinical visit when the results can be discussed and are relevant to care, not on a fixed schedule or as a requirement for prescribing and dosing.

Clinical assessment of suitability for carries:

- > Assessment of suitability of carries is primarily a clinical assessment that relates to social stability and an individual's ability to manage carries safely rather than a clear UDS.
- > Patients who continue to use substances, including opioids, can receive carries unless they are at high risk/not suitable based on the criteria below.
- > Patients require safe storage for carries (i.e., a locked box) and safe housing.
- > Patients not suitable for carries if:
 - intoxicated or sedated when assessed.
 - unstable psychiatric comorbidity (acutely suicidal or psychotic)
 - recent overdose
 - currently using illicit substances in high-risk ways; particular caution to be exercised with methadone if patients are using alcohol or benzodiazepines in high-risk ways or injecting high-dose intravenous illicit opioids.

• Communications (see Appendix C):

- > Verify current contact information (e.g., phone numbers and email addresses) for all patients.
- > Provide increased support to patients via remote methods.
- Provide contact information to pharmacy colleagues to troubleshoot clinical scenarios as they arise. Collaborate with the pharmacy team to inform them of the patient's current health status as it relates to COVID-19 (e.g., asymptomatic, isolating, quarantined), assess for patient's clinical stability, make modifications to the current carry schedule and rationale, and ensure access to medication.
- Inform patients of your clinical decision based on this protocol. Explain the need to avoid inperson visits to the clinic or to pharmacies unless absolutely necessary.

• Safety and documentation:

- > Methadone carry safety should be assessed and documented, as per MMTG.
- > Clinicians should consider possible misuse or diversion and overdose risk.
- > Advise patients that exceptional carries are being given due to current public health emergency, and MMTG standards will reapply once it is over.
- Discuss and document issues related to safe storage and risks of carries, including overdose and death, as per MMTG.
- Document patients' statements that they have the ability to safely store increased number of carries.
- > Prescribers should continue their normal practice with respect to bup/nal storage safety.
- Patients should be directed to obtain naloxone overdose kits and educated in the use of naloxone.
- A carry agreement should be either signed or remotely agreed to and documented in the chart.
- Lost or diverted methadone carries should be managed as per MMTG. Lost or diverted bup/nal carries should be managed according to usual standard of care.

CLINICAL PRACTICE

Note: UDS should only be required in the context of a clinical assessment.

- Frequency of remote assessments:
 - > Whenever possible, remote assessments should be emphasized to support physical distancing and reduce overall risks.
 - > Assessments are important when clinical decisions are being made (e.g., when doses and carries are being adjusted).
 - > Assessments can be an important source of support to patients who no longer have access to meetings, groups or counselling. When a UDS is not required for carries, consider using technology to allow patients to connect with their provider without coming to the clinic.
 - Clinical judgment should apply when determining frequency of clinic visits.

• Bup/nal:

- > Perform clinical assessment of suitability for carries.
- > Clear UDS is not required for carries.
- > Doses of bup/nal do not need to be witnessed, unless to address some specific clinical issue. This will minimize time spent in pharmacy, reducing the risk to both patients and pharmacy staff.
- > Up to four weeks of bup/nal carry doses may be prescribed, regardless of how long patients have been on bup/nal; prescriber to use clinical judgment to determine whether to be progressive with carries (e.g., advancing from one to four weeks).
- > Very stable patients on bup/nal may be assessed less frequently (e.g., every six to 12 weeks).

· Methadone:

- > Perform clinical assessment of suitability for carries. If suitable, refer to table below.
- > The pre-COVID-19 "Carry Level" guides the transition to the "Carry Ladder," which will apply during COVID-19 community transmission (Table 1: Methadone Carries).
- > Once on the "Carry Ladder," patients may move up the steps on a weekly basis if they remain suitable for carries and if the prescriber judges this to be clinically appropriate considering risks and benefits. They may also move down the ladder as a result of safety considerations.
- > Non-consecutive carries are a way of reducing the frequency of pharmacy visits while reducing the risks of misuse/diversion of larger amounts of methadone. At their observed doses, patients are seen by a pharmacist and assessed for sedation/intoxication.
- > Starting with non-consecutive carries and progressing as per the table below can assist with developing patient and provider comfort around carry safety.

Table 1: Methadone Carries

Pre-COVID-19 "Carry Level"	"Carry Ladder" during COVID-19 community transmission	Nomenclature
0 and unsuitable for carries	No carries	COV-0
0 and suitable for carries	Only non-consecutive carries (up to 3 per week) *	COV-3
1	Up to 2 consecutive carries (up to 4 per week) *	COV-4
2	Up to 3 consecutive carries (up to 5 per week) *	COV-5
3	Up to 6 carries per week	COV-6
4	Up to 1 to 2 weeks	COV-13
5 or 6	Up to 2 to 4 weeks**	COV-27***

^{*} No clear UDS required.

- COV-0 to COV-5 (i.e., up to five carries per week; max. three consecutive doses):
 - > Do not require clear UDS.
 - > If assessed remotely, the patient does not need to provide a UDS.
 - Positive UDS should always be a discussion point regarding safety, stability and harm reduction. In most circumstances, level of take-home doses should not be reduced if the patient remains suitable for carries. Carries may still be increased as per the "Ladder" up to COV-5.
 - The prescriber may adjust the number of carries upwards or downwards on the "Carry Ladder" as per their clinical judgment around safety.

^{**}Monthly carry limits are a Ministry of Health recommendation regarding prevention of stockpiling of all medications during COVID-19.

^{***}Irrespective of diluent (i.e., Tang, apple juice, Crystal Light or Kool-Aid), microbial growth is likely to occur after two weeks of storage at room temperature. There should be refrigeration of carries if more than two weeks are provided.

• COV-6 to COV-27:

- > Patient should generally provide a UDS when each prescription ends; clear UDS is generally expected given the safety issues associated with six or more carries.
- > Positive UDS should prompt a discussion regarding safety, stability and harm reduction. Carries do not need to be reduced in light of a "slip" or isolated non-problematic use as long as the other parameters of stability remain intact. If the patient is less stable, carries can be reduced to COV-5 or less.
- > For some patients with long-term stability (including long-term clear UDS), it may be appropriate to prescribe up to six or more carries on an ongoing basis, with remote assessments without UDS.

Appendix A - Scope:

- Prescribers must ensure they have appropriate education, training and experience to competently assess and manage patients with opioid use disorder.
- Variables that may impact the application of these guidelines include individual patient variables, local COVID-19 issues, prescriber or patient ability to leave the home, distance and means of travel, access to sufficient supply of medications, clinic and pharmacy availability and other unforeseen issues.
- Individual clinical judgment is key. In individual scenarios, clinicians may need to assess risks and benefits and provide carries to selected patients more liberally or more restrictively than outlined here.
- For methadone, on matters not covered by this document, MMTG continues to apply.
- For bup/nal, on matters not covered by the document, previous standards of care apply.
- Although slow-release oral morphine (SROM) is not dealt with explicitly in this document, it may be considered in a future revision. It is understood that in all areas of medicine, including the prescription of SROM, clinicians will need to continue weighing risks and benefits for individual patients and may need to modify their existing practices to respond to the risks of current COVID-19 conditions.
- While this document provides guidance and assistance to prescribers who wish to modify their approach to patient care during this crisis, it does not necessitate any specific actions; prescribers may choose to make appropriate clinical decisions based on their prior treatment protocols.
- These guidelines will likely be revised as the COVID-19 pandemic evolves.

Appendix B - Special Considerations:

- New methadone starts: Methadone should be initiated in methadone-naive patients only after a comprehensive assessment (virtual or in-person), including a UDS. Prescribers should keep in mind that there is an increased risk of overdose in the first two weeks of taking methadone. This warrants more frequent clinical assessments, whether in-person or remotely. Consider waiting one month before initiating carries.
- Methadone restarts: Complete a virtual or in-person assessment and offer bup/nal as a preferred treatment option. If a patient wishes to restart methadone and a UDS cannot be performed, prescribers should consider using a lower starting dose of methadone.
- Patients who have missed doses (i.e., up to seven missed doses of methadone or 14 missed doses of bup/nal): Restart after an assessment (virtual), without a UDS.

Appendix C - Communications:

We are sources of credible information for patients who may not otherwise be receiving sound public health advice. This is an opportunity to inform, educate and model physical distancing.

Sample messages to be conveyed by providers:

- Communicate with all patients the unique seriousness of this situation.
- Communicate that their health care will be delivered partially by phone or other platforms so as to keep them safe and reduce their exposure to the general public.
- Discuss public health concerns, the need for personal protection, physical distancing and the community's responsibility to flatten the curve.
- Acknowledge that this is a stressful time and that stress can be challenging or triggering.
- Offer increased counselling services by phone or other platforms, with the intent of providing up-to-date medical information, reassurance and mindfulness de-stressing where appropriate.
- Offer online resources to patients.

Appendix D - Guidelines for Extended Remote Care:

- Consider using the telephone or online platforms to provide care.
- Review each patient's case individually, taking into account the fundamental concerns of stability, safety, storage, overdose risk, diversion risk, lapse or relapse, the new dangers associated with COVID-19 and current public health advice around physical distancing.
- Record the decision-making process, any deviations from these or standard guidelines, and clinical justifications in the patient's record.
- Use of this guideline assumes open, ongoing communication with patients. This means that
 patients are to stay in touch with the clinic (i.e., respond to calls from clinic, call the clinic for
 any changes, access clinic website for information [if such a medium is used]). If open, ongoing
 remote communication is not possible, it may be more appropriate to continue in-person care
 using standard carry parameters.

This document was prepared by physicians and pharmacists from varying practice settings, with consultation from colleagues across Canada.

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