



# **A NEW FRAMEWORK FOR METHADONE CARRIES**

**A person-centered evidence-informed approach to  
methadone take-home “carry” dosing**

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# TABLE OF CONTENTS

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- Summary of Recommendations** ..... 1
  - Framework..... 1
  - Carry ranges..... 1
  - Criteria for suitability of carries ..... 1
  
- Introduction** ..... 3
  
- Methodology** ..... 3
  
- Background** ..... 4
  - Historic approaches to take-home dosing: A focus on the risks of carries ..... 5
  - Risks of restricted access to carries ..... 6
  - Carries as contingency management ..... 7
  - The impact of COVID-19 ..... 8
  
- Principles For A New Carry Framework** ..... 9
  
- Criteria For Suitability For Carries** ..... 10
  - Ability to store carries securely ..... 10
  - Amount of time on methadone ..... 11
  - Stability ..... 11
  - Frequency of missed doses ..... 12
  - Recent substance use patterns ..... 12
  - Urine drug test results ..... 13
  
- Additional Considerations** ..... 15
  
- Process** ..... 15
  
- Pharmacy Considerations** ..... 17
  
- Appendix A: Summary of criteria** ..... 18
  
- Appendix B: Sample agreement for receiving take-home “carry” doses** ..... 19
  
- References** ..... 21

# A NEW FRAMEWORK FOR METHADONE CARRIES: A person-centered evidence-informed approach to methadone take-home “carry” dosing

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## SUMMARY OF RECOMMENDATIONS

### FRAMEWORK

Access to methadone take-home doses (“carries”) has potential benefits including treatment retention, decreased treatment disruption, and improvements in clinical and social stability. Decisions about carries should be based primarily on an assessment of the individual’s clinical and psychosocial stability and their ability to store and manage carries safely, in light of the risks and benefits associated with unsupervised dosing.

### CARRY RANGES

Carries can be considered as ranges, recognizing a relationship between the number of carries and the level of risk to both the individual and community.

- **Up to three non-consecutive carries per week** can assist with maintaining treatment and building stability, including for people who use substances in lower-risk ways and are able to store medication safely.
- **Four to six carries per week** are appropriate for people who are clinically and socially stable; this number is based on the increased risk associated with greater numbers of carries (particularly consecutive carries).
- **More than six carries** should be reserved for people with very consistent stability and experience with successfully managing take-home doses.

### CRITERIA FOR SUITABILITY OF CARRIES

**These criteria are intended to be a guide for decision-making, not implemented mechanically. Clinical decision-making should be individualized based on discussion between the care provider and the person taking methadone, in the context of a therapeutic alliance.** In individual scenarios, clinicians may assess risks and benefits and provide carries in ways that are either more liberal or more restrictive than outlined below.

Criteria for decision-making regarding carries include the following:

- **Ability to store carries safely:** A consistent and safe place to stay and a locking device are required to receive any carries.
- **Amount of time on methadone:**
  - A minimum of four weeks of treatment is typically required to begin receiving any carries, as the first month of treatment is often associated with frequent dose adjustments, ongoing substance use, and less overall stability. Regular assessment by a prescriber and pharmacist is an important safeguard during this time.
  - Consideration of four to six carries can take place after three months of treatment.

- Consideration of seven to thirteen carries can take place after twelve months of treatment and six months of successful management of weekly carries.
- Monthly carries may be considered after one year of successful management of thirteen carries.
- **Stability:** Stability is assessed by considering factors such as an individual's progress toward identified goals, their mental health, living situation, and management of daily activities and responsibilities including their medication. Access to carries can also enhance clinical and psychosocial stability if people are able to work and participate in family and social activities without missing medication doses. Note that stability is not equated with abstinence; some people can be socially stable while using substances.
  - People who are experiencing instability, including acute psychosis or suicidal states that could impair their judgment and ability to manage carries safely, are not suitable to receive carries.
  - Early/developing stability can be compatible with up to three non-consecutive carries if other criteria are also met.
  - Consistent, ongoing stability is expected for people to receive four or more carries.
- **Frequency of missed doses:** Missed doses can lead to loss of tolerance and possible overdose if doses are not adjusted appropriately.
  - Receiving a majority of weekly doses (i.e., five of seven) is a criterion for receiving any carries.
  - Observed doses should rarely be missed for people receiving more than three carries.
- **Recent substance use patterns:** Considerations should focus on whether the substance use (including use of unregulated substances, regulated substances such as alcohol and cannabis, and prescription medications such as benzodiazepines) combined with carries puts the individual or community at increased risk, or whether the substance use is lower risk and occurs in the context of overall stability:
  - High-risk substance use associated with regular blackouts, frequent overdose, unsafe situations, or impaired decision-making is not suitable for carries.
  - Lower-risk substance use that is not impacting an individual's immediate health or safety and is not associated with blackouts, memory loss, or overdoses in the past month can be compatible with up to three non-consecutive carries as long as other criteria are met.
  - To receive four to six carries, an individual should not be using substances in ways that impact safety, health, or overall stability, i.e., no overdoses or blackouts for at least three months.
  - To receive more than six carries, an individual is expected to be abstaining from unregulated substances, non-prescribed pharmaceutical medications, and high-risk use of regulated substances.
- **Urine drug test (UDT) results:** Test results should align with the person's prescribed medications and self-reported substance use:
  - A UDT that aligns with the person's prescribed medication and is consistent with self-reported substance use is compatible with up to three non-consecutive carries or four to six carries depending on other criteria.
  - Consistently negative urine samples for unregulated and non-prescribed substances are expected for people receiving more than six carries.

# INTRODUCTION

For most of the past three decades, methadone prescribing practices in Ontario have been governed by the Methadone Maintenance Treatment Program Standards and Clinical Guidelines created by the College of Physicians and Surgeons of Ontario (CPSO) (1, 2).<sup>1</sup> The CPSO guidelines provided a highly structured approach to methadone management with regard to dose initiation, titration, and the provision of take-home doses (also called *unsupervised doses* or *carries*). The guidelines emphasized the risks of carries (both to the individual and the community) and also structured carries as *contingency management*, i.e., incentives or rewards for abstinence from substance use. Program requirements such as frequent office visits, rigid urine drug testing schedules, and the requirement for prolonged daily attendance at a pharmacy for observed or supervised doses, along with a slow progression of carry provision, have been identified as barriers to the acceptability of methadone care and contributors to low treatment retention rates.

This document aims to provide a person-centered, evidence-informed framework for decisions about prescribing carry doses of methadone. Several intersecting events have prompted the creation of this document: the overdose epidemic, which has highlighted the critical importance of reducing barriers to effective and consistent opioid agonist therapy (OAT) as a strategy to reduce overdose death; COVID-19, which demonstrated that approaches to methadone carries could be modified to support continued access to care without increasing harms; and, in Ontario, the disengagement of the CPSO from oversight of the provincial methadone program and rescinding of the Methadone Maintenance Guidelines.<sup>2</sup> Recognition of the importance of including people with lived experience in the development of treatment guidelines and in particular in the care of people who use substances (“nothing about us without us”) has also played a role in bringing about a new approach to OAT guidelines. The framework proposed here is informed by the literature related to take-home dosing, including a review of issues around the benefits and risks of supervised and unsupervised doses, methadone toxicity, and methadone diversion, and by the combined clinical and experiential expertise of the authors.

# METHODOLOGY

Under the auspices of [META:PHI](#), a group comprised of three people with lived/living experience of methadone, two physicians with extensive experience in prescribing methadone, and a pharmacist with a focus on substance use disorders was formed to review the existing literature on methadone carries and formulate a new evidence-informed framework to replace the previous CPSO guidelines. The group’s terms of reference explicitly acknowledge the value of different types of experience and education and the partnership between all members of the group as co-creators of the new guidance document.

An electronic search was conducted on Medline and PsycInfo databases using subject heading search terms and keywords associated with the concepts of methadone, opioid agonist therapy, opioid substitution treatment, take-home dosing, contingency management, treatment retention, methadone diversion, and opioid-related deaths.

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<sup>1</sup> Prescribing was exclusively done by physicians with a Section 56 exemption until 2018, when NPs and non-exempted physicians were given methadone prescribing authority by Health Canada.

<sup>2</sup> <https://dialogue.cpso.on.ca/2021/03/methadone-maintenance-treatment-policy-rescinded/>

Keywords and headings were additionally derived by reviewing the titles and abstracts of identified articles and systematic reviews. Grey literature including provincial and national guidelines for opioid agonist therapy and medication safety were included. The bibliographies of included articles were scrutinized for additional references. Articles included were limited to studies and reports published since 1996 in English.

The resulting literature was reviewed and summarized around the themes of methadone and take-home dosing (benefits and risks, criteria, schedules, contingency management); treatment retention; urine drug testing; and opioid agonist therapy outcomes. The group reviewed the formal literature and considered the experiences and perspectives of the authors around each sub-theme with the support of a moderator. The moderator also conducted several sessions with the community advisors to offer an opportunity for discussion and clarification without clinicians present. Through an iterative process of discussion and refinement, the group generated the consensus-based set of principles and criteria presented below. The resulting document is not based on a GRADE framework for a number of reasons. The literature on contingent and non-contingent take-home dosing is limited in quantity and quality, often based on small cohorts and short-term follow-up; essentially, all of this literature would be graded as weak. Many studies have not considered the potential negative impacts of not having access to take-home dosing; thus, the outcomes measured do not reflect the experiences of people on OAT. In the absence of high-quality evidence, this document is informed by an updated review of evidence regarding the benefits and risks of take-home doses in the current context and by the expertise of people taking methadone as well those involved in prescribing and dispensing OAT.

This document has been reviewed by people with professional and/or personal experience of methadone. Unsurprisingly, the reviews differ considerably from one another, reflecting the reviewers' diverse perspectives and experiences: some reviewers thought the proposed framework did not represent a sufficient departure from previous guidelines, while others found the guidance too flexible, leaving too much to the provider's discretion. While we have not incorporated every suggestion made by every reviewer, we have carefully reconsidered and refined the approach proposed in this document based on the feedback we received.

## **BACKGROUND**

Patterns of opioid-related deaths have changed dramatically in the last ten years. In 2010, oxycodone was the most commonly found opioid at opioid-related deaths in Ontario; fentanyl was found in 110 deaths (19.3%) and methadone in ninety-three (16.3%). In 2020, fentanyl was present in 2,109 deaths (85.9%) (3). During the first year of the COVID-19 pandemic (March–December 2020), opioid-related deaths increasingly involved only non-pharmaceutical opioids from the unregulated drug supply, with fentanyl and its analogues accounting for over 99% of these deaths (4). As fentanyl and other synthetic opioids have become common in the unregulated drug supply, the protective effect of OAT on mortality for people with opioid use disorder has increased (5). However, engagement and retention in treatment continue to be challenging for a variety of reasons, including dissatisfaction with methadone dosing, the need for frequent visits, poor therapeutic relationships with some treatment providers, stigma, and restricted access to carries (6-12). Dissatisfaction with OAT is associated with treatment discontinuation and dangerous fentanyl exposure (13). Low treatment retention rates in spite of the strong evidence for the benefits

of OAT warrants examination of ways to improve treatment retention (5). Among other aspects of care that could be improved by being more person-centered, greater flexibility around carry dosing is valued by people taking methadone and is associated with improved quality of life and treatment retention (6).

## **HISTORIC APPROACHES TO TAKE-HOME DOSING: A FOCUS ON THE RISKS OF CARRIES**

Like all opioids, methadone is particularly dangerous for people with low opioid tolerance, but the risk of toxicity associated with methadone is greater than other prescription opioids due its long half-life and narrow therapeutic index (14, 15). Cross-tolerance to methadone is incomplete and variable (16), meaning that even people tolerant to other opioids are at risk of methadone toxicity. Among people prescribed methadone, the majority of deaths occur during the first four weeks of treatment (17), declining sharply by week four.

The contribution of prescribed and non-prescribed methadone to opioid-related deaths is real but difficult to clarify. For example, in an analysis of opioid-related deaths in Ontario between 2013 and 2016, Gomes et al. (18) found that of the 524 decedents for whom methadone was detected on toxicology, only sixty-nine (13%) had an active methadone prescription at the time of death. In a study of opioid-related overdose deaths in British Columbia between 2015 and 2017, methadone was associated with 130 of 1,789 cases of unregulated drug deaths for which toxicology was available; of the cases for which methadone was relevant, 38.5% had no methadone prescription in the sixty days prior to overdose (19). Determining whether methadone is the cause of overdose is also difficult due to concurrent polysubstance use, including unregulated opioids, alcohol, stimulants, and prescribed and non-prescribed benzodiazepines (19-21).

Methadone diversion thus poses a public health risk. Methadone becomes accessible within the community when carries are improperly stored, lost, stolen, shared, traded, or sold. Methadone's formulation – dispensed in a beverage that should be refrigerated – poses an additional risk to children, because it is more likely than capsules or tablets to be taken accidentally. Diversion is a recognized problem, with rates ranging from 5% to 34% of people taking methadone reporting ever having sold their carries (22-26). In Ontario, among people who did not receive additional unsupervised doses as part of COVID-19 measures but were receiving carries prior to the pandemic, 15% reported losing or misplacing their carries, 13% reported having carries stolen, 17% reported sharing carries with others, and 10% reported trading carries for food or other goods (27). This suggests that loss or diversion of carries exists despite stringent criteria intended to reduce its likelihood and despite reliance on urine drug test results as a marker of stability and abstinence from unregulated substances. Some authors have suggested that diversion of prescribed opioids will always exist (28); the most common reasons for diversion of methadone are to generate income or to help a friend or partner (22, 29-31).

The rationale for daily dispensing of methadone until stability is achieved addresses several concerns: people who are in the early stages of methadone treatment are at higher risk of death, so regular assessment of sedation and missed doses is safer; people who are actively using unregulated substances (or regulated substances such as alcohol or benzodiazepines in high-risk ways) are more likely to experience toxicity from the combination of substances,



hence the opportunity for assessment by a pharmacist is an important safeguard (32); and people who are actively using unregulated substances are more likely to misuse or divert their medication, putting themselves and others at risk. Despite this justification, evidence for the association between witnessed dosing and methadone safety is limited. A 2010 analysis found that methadone-related deaths in Scotland and England decreased substantially after the introduction of daily observed dosing (33). A 2017 Cochrane review of randomized controlled trials of supervised dosing for OAT found no difference in adverse events or mortality between people receiving daily witnessed dosing compared with take-home doses with either buprenorphine or methadone, but the authors graded the quality of evidence as low to very low due to the small number and low quality of the studies (34).

For these reasons, methadone treatment guidelines historically recommended daily attendance at a pharmacy or clinic for observed doses until the person had been on the program for eight to twelve weeks and had “stabilized”, typically meaning that they were receiving a consistent dose of methadone, were abstinent from opioids and other substances, were meeting the expectations of their program, and had stable housing and the ability to store methadone safely (1, 15, 35, 36). Carry doses were then increased gradually (e.g., at a rate of one additional weekly carry per month) and were typically contingent on regular urine drug tests demonstrating abstinence from substance use (1, 15, 35, 36). In this context, achieving carries was not only a marker of treatment success (i.e., defined as abstinence) but the means to accessing freedom of movement and flexibility for work, travel, and family life. In Ontario, the typical maximum number of carries was previously limited to six, requiring weekly attendance at a pharmacy for even highly stable patients; thirteen carries were allowed occasionally and generally only for very stable patients with work commitments that made weekly pharmacy attendance challenging (1).

## **RISKS OF RESTRICTED ACCESS TO CARRIES**

While there is evidence that supervision of methadone during the early months of treatment is associated with a reduction in methadone-related deaths (33), there is also extensive evidence that restricted access to carry doses can have a negative effect on people receiving methadone. Missed doses due to difficulty attending the pharmacy leads to withdrawal and potentially the use of other substances to treat the withdrawal symptoms. In a study of patients taking methadone in the UK, missed doses were identified as the most common reason for seeking non-prescribed methadone (21). Multiple missed doses requires dose adjustment, which typically necessitates an appointment for reassessment, leading to an increased likelihood of treatment interruption or discontinuation. In one qualitative study that explored the experiences and perspectives of people receiving methadone maintenance treatment (6), many participants likened daily pharmacy visits for observed methadone dosing to being in jail; not having access to carries increased people’s difficulty in managing their responsibilities, negatively impacted their quality of life by increasing their stress and anxiety, and was described as a deterrent to participating in treatment. Another qualitative study (37) focused on the stigma that some people receiving methadone experience as part of daily observed dispensing; participants in this study reported being overlooked or made to wait at the pharmacy in favour of “regular” customers; feeling singled out, othered, and embarrassed due to inadequate privacy for dosing; and being obliged to disclose their methadone prescriptions to others (such as employers) in order to accommodate daily pharmacy visits, leading to fear of discrimination. The experience of the authors who have been prescribed methadone echoes these perspectives from the literature. All of the authors who have been treated with methadone have had stigmatizing

experiences related to observed methadone dosing, describing parts of the process as demeaning, humiliating, and dehumanizing. Obligatory daily pharmacy visits create significant restrictions in one's working and personal life, preventing full engagement in other activities:

*“When I consider my own path of coming off of methadone, carries were not a part of my story. In fact, because of my inability to qualify for carries, I now recognize how these “observed” doses were barriers to me having a life, having a job, having a life that led me to want to live without drugs. In many ways, I came to accept that I was going to die while in active addiction. Observed doses meant that I could not accept work out of town, it meant that I could not spend time with family at Christmas without using. Without the responsibility of take-home doses I did not have stability, and with the guidelines that were necessary for me to qualify for carries I was unable to ever achieve that stability.”*

— Quote from author with experience of taking methadone

## CARRIES AS CONTINGENCY MANAGEMENT

The use of carries as contingency management is based on a type of behavioural therapy in which individuals are reinforced, or rewarded, for evidence of a desired behavioural change (38). Contingency management (CM) has been widely evaluated in the context of treatment for substance use disorders, primarily with reinforcers such as vouchers, gift cards, or the opportunity to win prizes for submission of drug-negative urine specimens (38). A meta-analysis of studies on contingency management and substance use treatment conducted between 1991–2004 found that voucher-based reinforcement therapy (i.e., rewards with a monetary value) were associated with higher rates of abstinence (39). Other studies have examined the impact of CM specifically in the context of patients taking OAT. A recent systematic review and meta-analysis of CM for patients receiving medication for opioid use disorder found that CM with financial incentives was associated with abstinence from use of other opioids (40). A UK trial involving people taking methadone found that CM for abstinence was not superior to treatment as usual (41).

The literature on using carry medication doses as CM to reward and reinforce abstinence is limited in quantity and quality, often based on small cohorts and short-term follow-up (42-45). Evidence for increased abstinence with carries given for negative urine drug screens was generally not significant (42, 44). Two larger studies found that CM with carries was associated with significantly better treatment retention, but comparable rates of opioid-negative urine tests (45, 46). In addition to treatment retention, other benefits to carries include improvements in the quality of the “helping alliance” of the relationship between the prescriber and the person taking methadone (47), new vocational and social activities (47), increased frequency of engaging in “alternative non-drug-related activities” (48), better life balance, less difficulty managing work and childcare, and less in-person contact with the methadone program (49). Carries are desirable to people on methadone; when offered a “menu” of possible reinforcers including payments for food, gasoline, or rent, weekly counseling, and controlling one’s own methadone dose, take-home doses (three per week) were the most highly ranked option among 111 patients enrolled in a methadone treatment program (50).

## THE IMPACT OF COVID-19

The COVID-19 pandemic prompted interim changes to methadone carry guidance worldwide in order to maintain access to methadone treatment while supporting physical distancing in light of public health recommendations (51-54). In the US, SAMHSA relaxed carry limits, allowing less stable patients up to thirteen carries and stable patients up to twenty-seven carries, an exemption that was extended for another year in November 2021 (55). In Ontario, the COVID-19 guidance document, which was initially written in March 2020 and updated in August 2021, suggested increasing the maximum number of carries allowed at one time up to a maximum of twenty-seven, and also allowing carries for people who were not previously eligible to receive them (56). The COVID-19 guidance document recommended that assessment of suitability for carries be based on social stability and an individual's ability to manage and store carries safely. Individuals who had not previously received carries could receive one to three non-consecutive carries per week. Those who had previously been receiving one or two carries per week (i.e., met previous carry criteria) could receive up to five carries per week. Urine drug tests and abstinence from substance use, including opioids, were not required to receive up to five carries. These changes were broadly implemented across the province, resulting in a significant immediate increase in the percentage of Ontarians dispensed seven, thirteen, and twenty-seven take-home doses of methadone (57). Among methadone recipients, the observed increases in take-home doses remained stable until the end of November 2020, when they began to trend towards pre-pandemic levels.

Several studies have now reported on outcomes related to relaxation of methadone take-home policies and found no negative treatment outcomes both among people previously stable on methadone and those previously not considered stable enough to be eligible for carries. Among clients attending an opioid treatment program in Washington state where mean take-home doses increased by almost 200% (from 11.4 carries per 30 days pre-COVID to 22.3 carries per 30 days), there were significant decreases in emergency department visits and no significant increase in overdoses or methadone-negative urine drug tests over the nine-month study period (58). In a study of clinically stable patients at two opioid treatment programs in Oregon, increased take-home doses (median eight vs. thirteen take-home doses per month pre- and post-COVID) were associated with less treatment discontinuation and fewer positive urine drug tests (59). In a retrospective propensity-weighted cohort study of people receiving OAT in Ontario, Gomes et al. (10) found that among 11,010 individuals previously receiving five or six carries, extending carries to thirteen or more was significantly associated with a lower risk of treatment discontinuation and interruption in therapy, and no significant increase in opioid-related overdose, all-cause mortality, and opioid-related death. Moreover, among 5,852 people who previously had daily observed doses of methadone, transitioning to carries was significantly associated with lower risks of opioid-related overdose, discontinuation of OAT, and treatment interruption. No association was found between initiation of take-home doses and risk of all-cause death or opioid-related death. Qualitative studies have found that both people receiving extended carries and those for whom carries were initiated under COVID-19 guidance reported experiencing benefits from more liberal carry policies, including saving time and money, increased time for employment and recreational activities, better life balance, pride and empowerment, increased openness between prescribers and prescription recipients, and reduced COVID risk (27, 49, 59, 60). Prescribers also reported appreciating having flexibility around implementation and improved relationships with patients (27, 60). Several groups have called for sustained changes in OAT guidelines including changes to management of carries (61-66).

Whether more flexible carry policies during the pandemic are associated with community harms is unclear. Three recent reports have identified increases in methadone-involved overdoses in the US since April 2020. A retrospective analysis of reports to the National Poison Data System found a 5.3% increase in the number of methadone exposures between March 2020 and March 2021 (67). Using CDC data, Kleinman et al. reported an increase in monthly methadone-involved deaths starting in April 2020 compared with expected values based on trends from 2007, with and without co-occurring synthetic opioid use (68). A second analysis of CDC data reported a significant increase in methadone overdoses in 2020 relative to 2019 (69). While these increases followed SAMHSA's relaxing of take-home policies, all the authors point out the challenges of attributing these deaths to methadone alone or to the expansion of take-home doses, including the expansion of opioid treatment programs generally and of telemedicine programs for OUD, lack of guidance from SAMHSA on how to implement changes, and misidentification or preferential identification of methadone as the cause of death. As carry practices evolve, it will be important to monitor public health impacts at a variety of levels.

## PRINCIPLES FOR A NEW CARRY FRAMEWORK

While the stringency of the CPSO guidelines for carry doses of methadone was intended to reduce the risk of harms from non-prescribed use and diversion, a more person-centered approach to carries balances these risks with the potential benefits of carries, including increased treatment retention, decreased treatment disruption and discontinuation, improvements in the therapeutic relationship, ability to manage work and family, increased social activities, and better life balance. These benefits can support the clinical and social stability of people taking methadone.

In light of early evidence that increased access to carries was not associated with increased adverse outcomes and a lack of high-quality data to inform the optimal approach to carries, this guidance framework recommends that decisions should be based primarily on an assessment of the individual's overall stability, their ability to store carries safely, and their ability to take them as prescribed. This approach treats the management of carries as a dynamic process, in which a person's substance use patterns, goals, and life circumstances may change over time. It recognizes a relationship between the number of carries and the level of risk to both the individual and the community.

The intent of this framework is to balance the need for a structured approach to decision-making with flexibility to adapt this guidance to individual circumstances. **This framework should guide decision-making that is individualized and based on discussion between the care provider and person taking methadone, in the context of a therapeutic relationship.** The authors with lived experience of methadone have shared that many aspects of their care are negatively impacted by systems that feel rigid and adversarial or arbitrary. It is important that expectations of the conditions under which carries will be added, maintained, or withheld are clearly understood by care providers and people receiving methadone.

In this framework, carries are considered as ranges with criteria that reflect the level of risk and the need for stability proportionate to the number of carries. We propose the following carry ranges:

- **Up to three non-consecutive carries per week** can be used to assist with maintaining treatment and building stability outside of a contingency management framework. People who use substances in ways that have little negative impact on their health or functioning and are able to store medication safely may be in this range.
- **Four to six carries per week** are appropriate people who are quite clinically and socially stable; this number is based on the increased risk associated with greater numbers of carries (particularly consecutive carries) and aligns with contingency management practices.
- **More than six carries at a time** should be reserved for people with long-standing and very consistent stability and experience with successfully managing take-home doses. Given the risks associated with larger numbers of take-home doses, these decisions should carefully weigh the risks and benefits of larger amounts of unsupervised methadone against those of attending a pharmacy more regularly.

## CRITERIA FOR SUITABILITY FOR CARRIES

We propose the following decision-making criteria, which are described below and summarized in Appendix A:

- Ability to store carries safely
- Amount of time on methadone
- Stability
- Frequency of missed doses
- Recent substance use patterns
- Urine drug test results

**The intent of these criteria is to support a structure and shared understanding for decision-making, while recognizing that individual circumstances may warrant a modified approach.** The rationale for decision-making should be documented.

## ABILITY TO STORE CARRIES SECURELY

The potency and long half-life of methadone create significant risks to those without tolerance. Carries should be stored in a manner that reduces the risk of inappropriate access or accidental ingestion by anyone other than the person to whom it is prescribed. Methadone poses additional risks to children because it is dispensed in a beverage. Most unintentional pediatric ingestions of medications occur at home and involve medications stored within reach of a toddler or child.

Expectations for secure storage of carries include a consistent and safe place to stay, as well as a locking device. A consistent and safe living environment could be a person's own home, or a safe environment with friends or family. Living on the street does not provide the necessary safeguards for safe storage, as medications can more easily be lost or stolen. If the person is staying in a temporary environment, such as a withdrawal management centre or a shelter, carries are only appropriate if they can be kept in a secure location and are not accessible to others.

All persons receiving carries must store them where others cannot access them. A locking device is required, either for the medication container or for the cabinet in which the medications are stored (70). When making decisions about carries, the care provider and the person taking methadone should discuss the risks of unintentional methadone diversion and ingestion, documenting assurance that medication can be safely stored.<sup>3</sup>

## AMOUNT OF TIME ON METHADONE

Generally, carries should not be given during the first four weeks of treatment. Although there is no literature regarding duration of treatment and carry outcomes, mortality rates are high during the first two to four weeks of treatment (17): missed doses are common, doses are adjusted frequently, substance use is frequently ongoing, and regular assessment by a prescriber and pharmacist is an important safeguard. Withdrawal symptoms due to sub-therapeutic doses may lead to early consumption of carries, placing the individual at increased risk of toxicity due to lack of full tolerance to methadone. Withdrawal can also be associated with higher-risk use of other substances, which could make it more difficult to apply judgment and to store medications safely. The first few weeks and months of treatment are an opportunity for the care provider and the person taking methadone to develop a trusting therapeutic relationship and discuss goals, challenges, and the person's social situation. During this period, it is also crucial to discuss the particular risks associated with methadone.

After four weeks of treatment, up to three non-consecutive carries can be considered when the person receiving methadone meets other criteria for carries and when the methadone dose is stabilizing and therapeutic. Consideration of four to six carries is typically appropriate for people who have been taking methadone for more than three months and when dose adjustments are infrequent. After one year of methadone treatment and six months of successful management of weekly carries, seven to thirteen carries can be considered; monthly carries may be considered after one year of successful management of thirteen carries.

## STABILITY

In the context of treatment for substance use and decisions regarding carries, the term *stability* includes both psychosocial and clinical stability. Classic indicators of (in)stability such as employment, income, steady relationships, and a history of incarceration (71-73) disadvantage people with substance use disorders.

When considering carry doses, a more nuanced assessment of stability can consider how the individual is establishing structures and routines that maintain connections within their community and protect against situational harms (74). An individual's stability may be reflected in their living situation and relationships, their progress toward identified goals, management of their daily activities (such as appointments, work, school, childcare, training, volunteering, etc.), and the strength of their community connections. Psychosocial and clinical stability also includes an individual's mental health status. For example, individuals with well-controlled bipolar or psychotic disorders may be stable and suitable for carries assuming other criteria are met, while active psychosis and acute suicidality are states that can impair a person's ability to understand instructions and exercise judgment in the moment, making carries unsafe.

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<sup>3</sup> See <https://ismpcanada.ca/resource/opioid-stewardship/> for handouts regarding opioid safety and storage.

Clinical stability includes additional elements related to treatment and well-being, such as an individual's mental health status, how consistently someone is taking their medication, and how the level of risk of their substance use is shifting. Substance use does not necessarily impair social stability; some people can be socially stable while using substances. The care provider's understanding of the level of stability develops over time and is strengthened by mutual respect, trust, and open communication in the context of the therapeutic relationship.

People who are experiencing instability or whose psychosocial and clinical stability is unknown are not suitable to receive carries. People who are developing stability may receive up to three non-consecutive carries if they meet criteria to do so. Four to six carries are appropriate for people who have consistent, ongoing stability, and more than six carries are appropriate for people who have maintained this level of stability over one to two years.

## **FREQUENCY OF MISSED DOSES**

Methadone is safest when it is consistently taken as prescribed, and this cannot be directly verified for carry doses. Frequent missed doses can be dangerous for people receiving methadone. Missing three or more consecutive doses leads to a loss of tolerance for which the dose of methadone should typically be reduced. Missed doses can also cause symptoms of opioid withdrawal; these symptoms could cause a person to consume their carries too quickly, increasing the risk of oversedation and/or overdose. For this reason, taking a majority of doses (i.e., five out of seven) is typically a criterion for receiving any carries, though there may be times when, weighing risks and benefits and the other carry criteria, a clinician determines that starting carries may help someone who is missing more than two doses per week to access their medication more consistently. People receiving more than three carries would be expected to rarely miss observed doses.

Frequent missed doses should prompt discussion and problem-solving around the reasons for missed doses. For example, pharmacies may have restricted hours on Sundays, making it difficult for individuals to receive their methadone. A single weekly carry may resolve this problem and prevent ongoing missed doses.

## **RECENT SUBSTANCE USE PATTERNS**

People receiving methadone may have a variety of goals and patterns of substance use, including abstinence from all substance use, abstinence from opioids but not other substances, or continued lower-risk use of opioids as well as other substances. When making decisions regarding carries, the provider should assess whether the substance use combined with carries puts the individual or community at increased risk, or whether the substance use is lower risk and occurs in the context of overall stability. Patterns of substance use that are in alignment with the individual's goals, that have little negative impact on overall health or functioning, and that do not impair carry management can be compatible with carry doses. The consensus of the group was that the impact of the substance use on a person's health, safety, stability, and ability to manage carries safely were more relevant to decisions regarding carries than the specific substance(s) being used or the method of use.

For example, individuals who experience memory loss or blackouts when using substances are at increased risk of overdose and may be unable to keep carries safe from others. This can occur with unregulated drugs as well as

prescribed opioids, benzodiazepines, alcohol, or combinations of the above. Intoxication or sedation at medical appointments or when attending the pharmacy is an indication that substance use is not occurring in the context of overall stability and that carries are therefore not safe. Recent overdose (i.e., within the past month) is a safety concern that also impacts decisions about carries; recent overdoses indicate high-risk substance use, which is not compatible with carries, regardless of the substances being used. Injection use of any substance is also associated with lower rates of psychosocial and clinical stability (72), increased risks of overdose, higher rates of risk-taking than other modes of use, and diversion of methadone carries (22). Although there are individuals who inject without apparent harms, injection use is difficult to disentangle from other factors associated with higher risk to both the individual and the public.

To summarize, individuals using substances in ways that impact their ability to manage medication safely are not safe to receive carries. People who use drugs in lower-risk ways, including injection not associated with blackouts or overdose in the past month, may be eligible for up to three non-consecutive carries if other criteria are met. People receiving four to six carries are expected to be using substances infrequently if at all, and in lower-risk ways, i.e., no blackouts, memory loss, or overdoses for at least three months. The decision to avoid more explicit conditions is intentional; when access to carries is associated with specific criteria such as the number of times per week someone uses, or whether they use cocaine but not opioids, people may be more likely to tell their providers what they need in order to gain that access. Basing decisions about carries on the impact of use may create the opportunity for more productive and honest discussions about substance use, goals, and harm reduction. People receiving more than six carries are expected to be abstinent from unregulated substances and not to use regulated substances such as alcohol and cannabis in high-risk ways.

## URINE DRUG TEST RESULTS

Urine drug testing (UDT) has been a standard element of methadone care for decades. Issues related to the types of urine drug testing, sensitivity, specificity, and nuances of interpretation are beyond the scope of this document and are reviewed in recent publications (75, 76). While there is little evidence that UDT has any effect on health outcomes for people taking methadone in itself (77, 78), test results can be a source of clinically relevant information. Urine drug screens are one part of assessing substance use and stability. Urine drug tests confirm non-prescribed opioid use during baseline assessment, confirm that prescribed medication is being taken, screen for other substance use during treatment, and detect the presence of other substances, including substances the person may be unaware they have been exposed to (75). Clinicians should be aware of their limitations and use UDT in ways that contribute meaningfully to clinical decision-making.

The purpose of testing as part of opioid agonist therapy is to provide a shared reference point for care providers and people receiving methadone; ideally, the urine test results confirm the person's self-report of the substances they are taking. For people receiving prescribed methadone, methadone should be present in the urine sample. When urine results indicate substance use, there should be a conversation about whether or how to alter treatment plans to help people receiving methadone to meet their goals. Unexpected urine drug test results should prompt a conversation to address issues with the treatment plan and/or identify any substances that were taken unknowingly, such as through the unregulated drug supply.



Urine drug testing should be a routine expectation of methadone care, with clear expectations around the frequency and purpose of testing. For results to be meaningful and person-centered, they should be done in conjunction with a clinical assessment and not on an arbitrary schedule. Urine samples should not be supervised, and urine samples may be left at a lab and not only at a clinic; this can reduce stigma and increase flexibility around sampling, especially for people receiving virtual care. A urine drug test is not appropriate when the result will not impact clinical care, and UDT should not be a requirement to receive a prescription renewal. Clinicians should explain that UDTs are intended to support safe and effective care, not to police people receiving methadone (75).

The BCCSU guide suggests a UDT frequency of monthly (or more or less frequently as clinically indicated) during titration and stabilization, and at least six to eight random tests per year for people with carries, with scheduled UDTs when clinically indicated. An adapted schedule for people working towards or receiving carries is suggested below. When people are building stability and establishing a therapeutic alliance with their care provider, more frequent samples are suggested; these would typically occur at the same time as a clinical visit. For people who have established long-term carries in the context of long-term stability, less frequent samples are indicated. Unannounced (i.e., random) urine tests may also be requested.

TREATMENT STAGE	UDT FREQUENCY
Titration, stabilization, and building carries	Usually up to four times per month, typically in conjunction with an appointment
Long-term carries, 6 or more	Usually every one to two months, typically in conjunction with a clinical assessment (more frequently if clinically indicated) At the request of the person receiving methadone, if they wish to know what is in their sample
Maintenance of methadone for people not receiving or working toward carries	Monthly OR more or less frequently as clinically indicated, in conjunction with a clinical assessment

Previous methadone guidelines emphasized UDT results as a principal indicator of stability (i.e., confirmation of abstinence) and a central criterion for accessing carries. This framework proposes that UDT results be weighed as one of several criteria for accessing carries. When urine results and self-reports align, this builds trust between care providers and people taking methadone. In this way, UDT can help to inform assessment of clinical stability and decisions about whether an individual should receive carries. For example, a urine sample that is negative for methadone metabolite indicates either that the urine was not produced by the person taking methadone, or that an individual is not taking their medication as prescribed; carries are not appropriate in these instances. If a person's UDT is positive for methadone metabolite and consistent with the substances the person reports taking, they may be eligible for carries, depending on other criteria. This approach is intended to facilitate honest communication within the therapeutic relationship. People receiving more than six carries would be expected to consistently have urine samples negative for unregulated substances and medications not prescribed to them.

## ADDITIONAL CONSIDERATIONS

As previously stated, this framework is intended to be implemented with consideration of individual circumstances. Providers should consider additional factors that may influence an individual's ability to attend a pharmacy frequently for observed dosing, such as proximity to the pharmacy, pharmacy hours, availability of transportation, work and/or school schedules, and family caregiving responsibilities. Unexpected situations, emergencies, or unique circumstances may warrant exceptions or individualized application of these guidelines, although the expectation of a plan for safe carry storage and management should be a firm baseline. Care providers should be open to problem-solving around these considerations; carries for exceptional circumstances may enable people receiving methadone to have fuller engagement in their lives without having to miss doses. This in turn can lead to a reduction in missed doses, more engagement in care, and improved stability.

When making a decision about travel carries, the benefits of the person being able to travel for work or vacation should be weighed against the risks of the person stopping methadone if they do not have carries for travel. If the person requests more carries than they usually receive, the care provider should assess their ability to store and manage carries safely in light of the number of carries being requested and other factors associated with the travel plan. Depending on the destination, guest dosing may be an option. One general approach to travel carries may be to increase in a manner that is proportional to their regular carries. For example, for people previously receiving zero to three carries, allow four to six carries for travel; for people previously receiving four to six carries, allow up to thirteen; and for people receiving thirteen carries, allow up to four weeks. A letter to accompany the person is good practice.

When people taking methadone transfer care, they should not routinely need to restart building carries with a new provider, providing there has not been a change in overall clinical stability. Follow-up may be closer for a period of time while the new care provider and person taking methadone get to know one another and factors that could detract from stability are monitored.

One situation of particular importance is recent release from incarceration; taking OAT pre-release is associated with reduced substance use, overdose, mortality, and reincarceration (79). Balancing the need for daily attendance at a pharmacy can be difficult in conjunction with the requirements to attend work and probation (80), yet the risk of drug-related death is elevated for the first four weeks post-release (81). In this context, care providers should explore strategies to support people taking methadone post-release with accessing their medication and consider starting up to three non-consecutive methadone carries earlier than they might otherwise.

## PROCESS

These criteria are intended to be a guide for decision-making, such that care providers and people taking methadone have a shared understanding of the framework under which carries will be initiated, increased, maintained, and withheld. **However, this suggested framework is not meant to be mechanically implemented. Clinical decision-making should be individualized and based on discussion between the care provider and the person taking methadone, in the context of a therapeutic alliance.** In individual scenarios, clinicians may assess

risks and benefits and provide carries in ways that are either more liberal or more restrictive than outlined here. In particular practice settings, care providers may develop approaches that respond to the needs of the community they serve and are shared between care providers in that setting. Decisions about carries, as with other aspects of OAT care, should be conducted in ways that support person-centered care, embodying respect, dignity, and shared discussion in decisions regarding care (82).

Up to three non-consecutive carries can be started when an individual has been on methadone for a minimum of four weeks, has a measure of clinical and psychosocial stability, is not using substances in ways that impact their immediate health or safety, and can store carries safely. Thereafter, carries can be increased by one carry per week at two- to four-week intervals up to six carries as the individual consistently meets criteria. Six months of stability with six carries is expected before an individual would receive seven or more carries (typically increased from six to thirteen). More than thirteen carries requires the highest level of stability and would be reserved for people who have been taking methadone for least two years and who have effectively managed thirteen carries for at least one year. Several studies (47, 83, 84) have reported high levels of patient satisfaction, good treatment retention, low or very low rates of drug use, and no evidence of diversion in patients receiving up to twenty-seven carries. In these studies, criteria for twenty-seven carries ranged from twelve months to five years of abstinence as well as successful experience with six carries.

If a person is not maintaining the expected level of stability and safety, carries may be reduced within the range (e.g., from five to four), or may move down a range (e.g., from six to three, or three to daily observed dosing). Reductions in carries should be considered and explained in light of the same criteria that are used for implementing and increasing carries, i.e., whether there are concerns about the person's clinical or psychosocial stability, judgment, and substance use that would impact safe carry storage and management. Situations that warrant returning immediately to all witnessed doses include lost or stolen carries, evidence of diversion, and evidence of urine tampering, as well as overdose and inability to store carries safely. Clinical judgment and knowledge of the circumstances of the person receiving methadone help to inform how quickly carries can be resumed when the individual again meets criteria for a given range.

Discussions about carries should occur when both the care provider and the person receiving methadone are not rushed and are able to fully engage in the discussion. If the person receiving methadone is experiencing withdrawal symptoms, intoxication, or sedation during an appointment, the conversation should be postponed. The conversation should review the risks of carries, the conditions under which they will be added or withheld, the dangers of taking methadone in ways other than as prescribed, the dangers of sharing methadone, and the importance of safe storage and carry management. The care provider should use plain language and ensure understanding by asking the person receiving methadone to explain the information back to them. Even if carries were discussed with an initial methadone agreement, a separate discussion is important at the time of carry initiation. Discussion of the agreement should be documented in the patient chart; some providers have a practice of reviewing and signing the agreement with the person taking methadone (see Appendix B for a sample agreement).

## PHARMACY CONSIDERATIONS

Clear expectations and communication between prescribers, pharmacists, and people taking OAT are important to support safe carry dispensing and management. Transitions between pharmacies and providers can create the potential for gaps in doses, overlapping doses, or doses being withheld unnecessarily.

Pharmacists may be required to assess someone who appears unwell and make a decision about whether it is suitable for them to receive an observed dose and/or a carry. In any situation where risks outweigh the benefits (e.g., significant intoxication, sedation, or behavioural issues that raise concerns about an individual's acute well-being), the dose should be held. If possible, the pharmacist should ask directly about recent substance use and provide counseling regarding self-monitoring and harm reduction. If the individual appears intoxicated, they can be asked to return later the same day; once their intoxication has resolved, they can receive their observed dose but not their carries later in the same day. While there is no requirement for the person who is prescribed methadone to be reassessed by a prescriber prior to receiving their dose, the prescriber can support the pharmacist by providing their contact information for case discussion, particularly after-hours, to minimize consequences associated with withheld doses. Prescribers should be notified of any missed or withheld doses, as this would impact decisions regarding carry safety.

As a standard practice at dispensing pharmacies, if a person misses an observed methadone dose on a day they were supposed to pick up carries, they should receive an observed dose on the day they attend. Carries should not be dispensed if the person has missed three consecutive doses.

## APPENDIX A: SUMMARY OF CRITERIA

CRITERIA	NO CARRIES	UP TO 3 NON-CONSECUTIVE CARRIES	4–6 CARRIES	7+ CARRIES
<b>Ability to store carries securely</b>	Living on the street or in unstable or unsafe housing  Unable to store carries in a manner and location that reduces the risk of inappropriate use	Consistent and safe living environment  Able to store carries in a manner and location that reduces the risk of inappropriate use  Locked box		
<b>Amount of time on methadone</b>	< 4 weeks	< 4 weeks	> 12 weeks	7–13 carries: 1 year, with at least 6 months of 6 carries  14–27 carries: 2 years, with at least 1 year of 13 carries
<b>Stability</b>	Not stable or stability unknown  Active psychosis, suicidality	Developing stability  Establishing routines around clinic/treatment expectations  Attending most appointments  No acute conditions that impair judgment or ability to manage carries safely	Consistent clinical and psychosocial stability  Stable routines around clinic expectations and medication management  Dose is stable  Stable living situations, employment, or participation in other regular activities  No acute mental health conditions that impair judgement or ability to manage carries safely	
<b>Frequency of missed doses</b>	Frequent	Missing 2 doses per week at most	Missed doses rare	
<b>Recent substance use patterns</b>	Higher-risk use that is impacting health, physical safety and overall well-being  Intoxicated or sedated at appointments  Regular overdoses or blackouts/memory loss	Lower-risk, not impacting immediate safety or health  In alignment with goals  Not intoxicated or sedated at appointments  No overdoses or blackouts/memory loss in the last month	Lower-risk, not impacting immediate safety or health, and overall stability  In alignment with goals  Not intoxicated or sedated at appointments  No overdoses or blackouts/memory loss in the last 3 months	No use of unregulated or unprescribed substances and no high-risk use of regulated or prescribed substances
<b>Urine drug screen results</b>	Negative for methadone or indications of tampering	Positive for methadone  Consistent with self-reported substance use	Positive for methadone  Consistent with self-reported substance use  Generally negative for unregulated and unprescribed substances	Positive for methadone  Consistently negative for unregulated and unprescribed substances

## APPENDIX B: SAMPLE AGREEMENT FOR RECEIVING TAKE-HOME “CARRY” DOSES

**In order to receive take-home doses of my medication (“carries”), I understand and acknowledge the following:**

1. There are expectations around my stability and my ability to store medications in a safe manner that must be met in order to receive take-home doses of methadone. This is because of the risks of methadone to people who do not have tolerance to it, and the risks to me if it is not taken properly. A single dose of methadone can be dangerous or fatal if consumed by someone who is not tolerant of that dose, especially if taken by a child. If I miss too many doses, I can also lose tolerance to the medication. If I take more than prescribed on a single day, this can also be dangerous or life-threatening.
2. When considering whether to prescribe carries, my care provider is concerned about my safety and the safety of my community. To assess my ability to manage carries safely, my care provider will consider:
  - a. My housing
  - b. How long I have been taking methadone
  - c. How often I miss doses
  - d. My stability (for example, how I am managing appointments, medication, work, school)
  - e. My substance use
  - f. My urine drug test results
  - g. Other factors that could affect my ability to manage carries safely, such as mental health changes
3. The number of take-home doses I receive will be based on my stability and ability to manage carries safely. As my stability increases and I have more experience managing carries safely, the number of carries will be gradually increased. If my stability decreases or I have difficulty managing carries safely, the number of carries will be decreased. These decisions are made in discussion with my prescriber, balancing the importance of the treatment working in my life, with the importance of my safety and the safety of the community.
4. In order to receive carries, I will need to manage my use of drugs and alcohol so that the impact to my health, safety, and stability is minimized, and such that it does not interfere with my ability to manage and store carries.
5. If I wish to receive a larger number of carries, I will need to minimize my substance use and be abstinent from medications not prescribed to me.
6. Urine drug testing is a routine part of methadone treatment. Urine drug tests provide information about what substances I have been taking or exposed to, which helps me and my prescriber develop the best treatment plan for me. I agree to provide a urine sample when requested. I understand that if my urine sample shows signs of tampering or indicates that I am not taking methadone as prescribed, I will lose my carries.
7. I will bring my carries to my clinic or my pharmacy within 24 hours of being asked to do so. If I do not without a valid reason, I may lose access to carries.
8. In order to receive carries I need to have a safe and consistent place to stay, not staying on the street.
9. I will store my methadone securely in a locking device (locked box, locked cabinet, or safe) that cannot be accessed by other people. I will keep my medication out of sight and out of reach.
10. I agree not to share, trade, sell, or loan my methadone under any circumstances. Any of these is a reason for my carries to be withdrawn indefinitely.
11. If carries are lost, they will typically be replaced with observed doses, and a review of the carry agreement will take place. If carries are lost, they will be reinstated gradually.

My signature below indicates that I agree to follow the obligations and responsibilities outlined in this agreement. I have had the opportunity to discuss and review this agreement with my care provider and my questions have been answered to my satisfaction.

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**Date**

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**Patient** (Signature)

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**Patient** (Printed Name)

**I confirm that:**

1. This form has been reviewed with the patient and they understand its content fully.
2. The patient was given time to ask questions about this agreement and seek clarification.
3. I will engage with my patient in discussing carry issues and use my clinical judgment along with current guidelines as a basis for treatment decisions. I will explain the reasons for decisions about initiating, increasing, or decreasing carries.

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**HCP** (Signature)

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**HCP** (Printed Name)

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