# METHADONE DOSAGE AND OPIOID OVERDOSE:

# A SECONDARY ANALYSIS OF SUPERVISED CONSUMPTION SITE DATA

**TALIESIN MAGBOO CAHILL**

Thesis submitted to the University of Ottawa in partial fulfillment of the requirements for the degree of Master of Science in Nursing

School of Nursing

Faculty of Health Sciences

University of Ottawa

## Abstract

### Background

Opioid overdoses have killed almost 20,000 Canadians since 2016. To address this, Canada has established supervised consumption sites where people can use drugs in the presence of trained staff and get access to pharmacological treatments such as methadone. However, there is very little research on whether supervised consumption clients use methadone, or whether their use of methadone prevents opioid overdose.

### Methods

A secondary data analysis of information collected from one supervised consumption site was undertaken in order to explore relationships between client self-reported methadone dosage and subsequent observed same-day opioid overdose.

### Results

Statistical analysis showed no correlation between methadone usage and reduced chance of opioid overdose. However, the most common dosage of methadone reported (30mg/day) was far below the minimum therapeutic dose of methadone.

### Conclusion

Clients of supervised consumption sites often report being prescribed methadone, but not at a dose high enough to reduce opioid overdose.

**Acknowledgements**

**Dr. J. Craig Phillips:** Thank you not only for agreeing to be my thesis supervisor, but also for your mentorship and patience during the last couple years. I have learned so much from you and will be forever grateful.

**Dr. Michelle Lalonde & Dr. Jane McCall:** Thank you for agreeing to be on my advisory committee, and for generously sharing your knowledge and wisdom with me.

**Chris:** Thanks for putting up with me during this years-long project, and for all the excellent writing advice.

**Nikki Ho & Joanna Binch:** Thanks to my fellow students, not only for your suggestions and advice, but mostly for providing much-needed emotional support throughout this entire process and beyond.

**Rob Boyd, Oasis Program Director, SHCHC:** Thank you for supporting my graduate studies and for graciously allowing me to use our SCS data for this study.

**The clients of the SHCHC SCS:** Thank you for being the best teachers I have ever had.

## Dedication

to Morning Jeff

## Preface

1. Dr. J. Craig Phillips, RN, PhD

   Full Professor, School of Nursing, Faculty of Health Sciences, University of Ottawa

2. Dr. Michelle Lalonde, RN, PhD

   Associate Professor, School of Nursing, Faculty of Health Sciences, University of Ottawa

3. Dr. Jane McCall, RN, PhD

   Nurse Educator, St. Paul's Hospital

4. Taliesin Magboo Cahill, RN

   MSN Student, University of Ottawa

Dr. Phillips (CP) is the thesis supervisor, and Dr. Lalonde (ML) and Dr. McCall (JM) were members of the thesis advisory committee.

Taliesin Magboo Cahill conceived of the research idea and study design, performed all data analysis, and wrote the thesis.

CP, ML, and JM approved the research concept and study design.

CP and ML reviewed the data analysis.

CP, ML, and JM reviewed the thesis in full and provided feedback on concepts and content.

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## Abbreviations

| | |
|---|---|
| BC | British Columbia |
| BCCSU | British Columbia Centre on Substance Use |
| CAMH | Centre for Addiction and Mental Health |
| CDSA | Controlled Drugs and Substances Act |
| CI | confidence interval |
| GOC | Government of Canada |
| MOHLTC | Ministry of Health and Long-term Care (Ontario) |
| NP | nurse practitioner |
| OAT | opiate agonist therapy |
| OUD | opiate use disorder |
| SCS | supervised consumption site |
| SHCHC | Sandy Hill Community Health Centre |
| US | United States |

## A Note on Terminology

There are many different names for rooms where people use illicit drugs under the supervision of trained staff. For clarity, these are all referred to as supervised consumption sites in this document, except in Chapter Three where the difference between supervised consumption sites and overdose prevention sites in Canada is explained.

# Chapter One: Introduction

## The Overdose Crisis

From January 2016 to September 2020, 19,355 Canadians died of opioid overdose (Government of Canada [GOC], 2021). These deaths represent a steep rise in fatalities from previous years (GOC, 2021). This increase in fatal opioid overdoses is attributed to the introduction of fentanyl and fentanyl analogues into the illicit drug supply, replacing heroin and prescription opioids (GOC, 2021). Fentanyl is synthetic opioid which is so concentrated that it is very difficult to dose accurately, resulting in an increase in the risk of overdose when people are unintentionally exposed to it, or use more fentanyl than they intended to (GOC, 2021).

## Four Pillars Approach

To address this public health crisis, the Canadian government has invested in a four-pillar approach: prevention, treatment, enforcement, and harm reduction (GOC, 2020). The harm reduction approach encompasses policies and programs which serve to address the sequelae of substance use, without requiring abstinence from use (GOC, 2020). In Canada, this approach has recently included the establishment of several supervised consumption sites (SCS) across the country (GOC, 2020). Supervised consumption sites are places where people are legally permitted to use illicit substances in the presence of professionals who are trained in opioid overdose response (GOC, 2020). These SCSs are also meant to serve as places where people with opioid use disorder (OUD) can be connected to medical services and addiction treatment (GOC, 2020). Before 2017, SCS were limited to two sites in Vancouver, BC, but now there are several in many provinces (Kerr et al., 2017; GOC, 2020).

**Opiate Agonist Therapy**

The gold standard treatment for OUD is opiate agonist therapy (OAT): medications which occupy the same receptors in the brain as illicit opioids but stay in the body longer and have a reduced euphoric effect (Taha, 2018). These medications are not only intended to prevent opioid withdrawal and reduce people's cravings for more dangerous opioids like fentanyl, but also to reduce the risk of fatal opioid overdose (British Columbia Centre on Substance Use [BCCSU], 2017). The mechanism of overdose prevention occurs in two ways; 1) clients on OAT may reduce their exposure to illicit opioids because of reduced cravings; and 2) the effect of any illicit opioids used is diminished because neuro-receptors are already occupied by another opiate agonist (BCCSU, 2017). In Canada, the first and second-line medications prescribed for OUD are methadone and buprenorphine-naloxone (Taha, 2018).

Buprenorphine-naloxone is a newer treatment for OUD and was introduced in Canada in 2007 (Health Canada, 2002). It combines the opioid buprenorphine with the opioid antagonist naloxone in one medication (Chen et al., 2014). The naloxone in buprenorphine-naloxone is included only as an abuse deterrent, since it will cause immediate withdrawal when injected but is inactive when taken orally (Chen et al., 2014). Buprenorphine is a partial agonist of the opioid receptors in the brain, and this partial agonism both reduces the ability of the medication to have a euphoric effect and decreases the likelihood of significant respiratory depression that may result in overdose (Bruneau et al., 2018). The increased safety profile of buprenorphine-naloxone makes it easier to prescribe and patients are allowed to take home several days' worth of medications at one time (Bruneau et al., 2018). Buprenorphine-naloxone can, however, cause uncomfortable precipitated withdrawal symptoms during treatment initiation due to buprenorphine's affinity for opioid neuro-receptors; these withdrawal symptoms may be more

severe and prolonged for patients who use fentanyl (Silverstein et al., 2019). For these reasons (the risk of precipitated withdrawal and client preference for a full opioid agonist) clinicians may prefer to prescribe methadone rather than buprenorphine to clients who inject drugs (Srivastava et al., 2017).

Methadone has been used for over 50 years as a treatment for OUD in Canada (Srivastava et al., 2017). It is a long-acting opioid that is a full agonist of opioid receptors in the brain (Bruneau et al., 2018). Originally brought to Canada as an experimental treatment to manage short-term opioid withdrawal in one clinic, there are now hundreds of methadone maintenance program clinics across Canada (Eibl et al., 2017; Fischer, 2000). Although methadone is an effective treatment for OUD, it can also cause opioid overdose itself (Bruneau et al., 2018). A unique feature of methadone's pharmaceutical properties is that it has a very long half-life, but the true length of its effectiveness and sedative properties varies widely from person to person (BCCSU, 2017). This trait makes methadone particularly difficult to prescribe safely, and as a result it is one of the most heavily regulated prescribed medications in Canada. People on methadone are started on a very low dose, and that dose is slowly titrated up to avoid over-sedation (College of Physicians and Surgeons of Ontario [CPSO], 2011). At the beginning of treatment, people must present to the pharmacy every day to receive their methadone dose. Those who miss their daily dose of methadone more than a couple times might have their dosage halved or may have to start from their initial dose again (CPSO, 2011). These rules mean that the length of consistent, uninterrupted treatment on methadone has a significant impact on the dosage prescribed. People on methadone must usually undergo regular observed urine drug screens to ensure they are taking the medication (CPSO, 2011). The restrictive nature of these

guidelines has led to the colorful nickname people often use to describe methadone: “liquid handcuffs” (Frank et al., 2021, p. 3).

OAT is the only evidence-based treatment that improves health outcomes for people with OUD (Bruneau et al., 2018). The effectiveness of OAT in reducing all-cause mortality as well as overdose-related mortality is well-studied and indisputable (Sordo et al., 2017; Wakeman et al., 2020). Despite the importance of OAT, there is little recent published research specifically measuring OAT uptake for people diagnosed with OUD in Canada. A 2016 study suggests that there were 77 OAT recipients for every 100 people who inject drugs in Ontario (Jacka et al., 2020). In 2019, there were over 55,000 OAT prescriptions written each month in Ontario, and around 3000 written each month for the Ottawa area, but this data is not linked to number of OUD diagnoses (Ontario Drug Policy Research Network, 2020). A 2020 retrospective study from BC gives the clearest picture of OAT coverage for people with OUD. It suggests 71% of the 55,470 people diagnosed with OUD from 1996 to 2017 had received OAT, but that only 33% were currently engaged in treatment (Piske et al., 2020).

A systematic review ($n$ = 37 studies) of the barriers to OAT uptake from a client perspective suggests many reasons that people with OUD might not be successfully retained in OAT treatment (Hall et al., 2021). Several studies in this review referenced personal and social factors such as client understanding of and attitude towards OAT, including stigma and fear of side effects (Hall et al., 2021). There were also logistical and regulatory barriers reported; these varied from lack of childcare for appointment or transportation to the pharmacy, to difficulty with the inflexibility with clinic requirements, especially for those with a “chaotic lifestyle” (Hall et al., 2021, p. 9).

**Research Purpose and Questions**

Clients of supervised consumption sites who use opioids are the target population for OAT because they may consume illicit opioids several times each day, risking overdose each time. However, there is very little published research on clients of SCS and their uptake of OAT in general or methadone specifically. Given that one of the purposes of SCS is to connect people to treatment, it is important to know not only whether clients of SCS are being prescribed methadone, but also to determine whether methadone may have the desired effect, reduction of opioid overdose, in this population.

Every SCS in Canada collects administrative data which it reports to both the federal and provincial governments (GOC, 2020b; Ministry of Health and Long-term Care [MOHLTC], 2018). This study is a secondary data analysis of the administrative data collected from an SCS in Ottawa to analyze associations between the OAT and subsequent same-day opioid overdose. The following research will be addressed:

1. Are the clients of supervised consumption sites on OAT?
2. If so, what kind of OAT (methadone or buprenorphine-naloxone) are they on, and what dosage do they report being prescribed?
3. Is there a relationship between the dosage of methadone clients report being prescribed and the likelihood they will experience an opioid overdose in a supervised consumption site during a visit?

Additionally, this study is an initial inquiry into what we can learn from supervised consumption site data when we look at it from a public health research perspective.

Answering these questions and examining this data will add to the evidence-base for providing care and treatment for people on OAT and people at risk of opioid overdose. This

quantitative research might also serve as a basis for future qualitative research examining OAT uptake amongst SCS clients from a client perspective.

## Theoretical Framework

The theoretical framework underpinning this study is Krieger's ecosocial theory. This theory was developed by Krieger in 1994 in order to expand upon the multicausal "web" theory of disease which epidemiologists had begun to favour in the 1960s (Krieger, 1994). The "web" model directs attention to immediate risk factors and proximal causes of the disease in question (the centre of the web) and does not make allowances for the fact that the cause of disease in populations might be quite different from the cause of an individual case (Krieger, 1994, p. 891-892). In contrast to the "web" model, ecosocial theory suggests that so-called "distal" causes of disease — such as societal structures, socioeconomic class, and culture — may be just as directly causal as the biomedical lifestyle factors our system finds easiest to address (Krieger, 1994). Ecosocial theory goes on to suggest that solving these issues which may be the primary cause of health problems in society requires a focus on these societal structures rather than the traditional biomedical focus on individual risk factors and behaviour. For example, a recent essay by Krieger on race and health proposes that data on "racialized health inequities" (2021, p. 1) is as vital to collect as data about race, when we want to understand the latter's relationship to disease trajectory and health outcomes.

### *Relevance to the Research Questions*

With regards to this research study, ecosocial theory prompts us to consider opioid overdose not merely as a consequence of an individual using too much opioids, but as a complex relationship between treatment modality (e.g. methadone), the structures surrounding that modality, the intentions of the client, and the body's physical response. This is consistent with

Krieger's central thesis "Explanations of disease distribution cannot be reduced solely to explanations of disease mechanisms, because the latter do not account for why rates and patterns change, in complex ways, over time and place" (Krieger 2012, p. 937). Berben et al. (2012) use an ecosocial framework to describe all the factors that go into a patient's adherence to medication treatment: health system, social/economic, condition-related, therapy-related, and patient-related (p. 637). They propose a model for interventions to improve medication adherence which goes beyond patient-level "risk factors" to address micro-level concerns like trust in a specific clinician, meso-level factors like clinic accessibility, and macro-level factors like drug coverage (Berben et al., p. 641).

Ecosocial theory is the basis of Rhodes' risk environment model of substance use (Rhodes, 2009). The risk environment model posits that the multi-faceted context of use affects the level of harm experienced by people who use drugs (Rhodes, 2009). Again, this shifts the "focus for change from individuals alone to the social situations and structures in which they find themselves" (Rhodes, 2009, p. 194). McNeil et al. (2014) use this model as a framework to understand how hospitals can be dangerous for people who use drugs, due to policies which force them to use in hiding or keep their pain withdrawal from being treated. In this way the patient is not necessarily the focus of the interventions designed to keep them in the hospital until they are safe to discharge; the hospital and its structures (the "environment") need to become less risky (McNeil et al., 2014). The corollary to the risk environment model is the establishment of an environment which would enable healing and reduce drug harms (McNeil et al., 2016).

Ecosocial theory and its related frameworks are particularly appropriate for studying methadone, which is not just a substance with pharmaceutical properties, but itself an "assemblage of relations" between the patient, drug, clinic, clinic and pharmacy staff, and the

outside world (Rhodes, 2018). Treatment with methadone is not just taking a medication: "treatment begins when the patient accepts the limited schedule for receiving methadone, the daily inquiries of his life, the humiliation of urinating in front of a nurse" (Gomart, 2002, p. 117). Interventions to improve OAT uptake and retention, or indeed solve the overdose crisis, must address the entirety of the OAT experience, or risk environment, in order to be effective (Krebs et al., 2021). This study aims to present a picture of what OAT looks like for SCS clients that goes beyond the binary states of being on or off OAT towards an understanding of how OAT is being used and what the observable effects of OAT are.

**Structure of the Thesis**

This thesis is presented as a monograph with five chapters, including this introduction (Chapter One). Chapter Two is a review of the literature on supervised consumption sites, opioid overdose, opiate agonist therapy and methadone dosage. In Chapter Three, I present a description of the operations of the SCS where this data was collected, including staffing, other relevant on-site service provision, and documentation. Chapter Four presents the research methods and the results of statistical data analysis. Chapter Five is a discussion of this study's findings, the strengths and limitations of this study, implications for health policy and nursing practice, and suggestions for further research.

**Positionality Statement**

"Positionality requires the researcher to acknowledge and locate their views, values, and beliefs in relation to the research process" (Manohar et al., 2017, p. 3). Although positionality statements have become standard in qualitative research, they are much less prevalent in quantitative studies like this secondary data analysis (Jafar, 2018). However, the nature of my relationship to the SCS where this study's data is pulled from requires that I explicitly state

where I stand in relation to this research, in order to identify possible sources of bias in either the presentation or interpretation of the data.

Positionality is often expressed via a duality; researchers identifying themselves as either inside or outside the topic and setting being studied (Holmes, 2020). For the purposes of this research, however, my point-of-view encompasses both insider and outsider perspectives. I place myself firmly inside the professional structure I am researching; I have worked at the SHCHC SCS since its inception and am currently its clinical team lead. This position has given me access to the data which has not been made available to external researchers. As one of the nurses who staffed the SCS during the study time-period, I also produced some of the data I am analysing in this study. This insider perspective represents a double-edged sword; although both the study design and the research questions I ask require intimate knowledge of the data collected, my familiarity with the place and people being studied represent potential opportunities for bias.

There is a growing call in North America for people who have lived or living experiences of substance use to be incorporated in drug research (Walker, 2021). Indeed, one of the central tenets of harm reduction as a practice is: “Nothing about us without us” (Denis-Lalonde et al., 2019). Although I identify as an insider in terms of my relationship to the SHCHC SCS as an organization, I do not have experience with the illicit substances commonly used by clients of SCSs, nor do I have personal experience of being on OAT. Thus, my perspective on the data and findings in this study are from an outsider point-of-view; that of a clinician, rather than a client of the SCS or someone who uses drugs. It is my hope that any additional research prompted by my findings incorporate the words and thoughts of people who use drugs, both as subjects of qualitative research, and as investigators themselves.

## Chapter Two: Literature Review

A literature review of concepts related to the independent variables (OAT status, methadone dosage, substances used) and dependent variable (opioid overdose) in this study was conducted between May 2020 and June 2021. There were two main foci for this review: methadone dosing and supervised consumption sites (SCS). I performed searches using the PubMed and PsycINFO databases. Two search strings were used: 1) methadone AND ((dose or dosage) OR (overdose)) 2) "supervised consumption site" OR "supervised injection site" OR "safe injection site" OR "supervised injection facility" OR "drug consumption room" OR "overdose prevention site" OR " safe consumption site". Inclusion criteria included: articles available in English or French, articles published in the last thirty years, and articles which concerned research performed in the US, Canada, Europe, New Zealand, or Australia. This time period was chosen in order to include as many articles as possible which may speak to the variability of methadone prescribing over time; no articles on SCS were published before this time period. These geographic locations were chosen because these countries share similar substance use trends and have fairly broad access to treatment (United Nations Office on Drugs and Crime, 2010). In addition to peer-reviewed journal articles, this literature review includes grey literature in the form of publicly available statistics on SCS in Canada, and Canadian provincial guidelines for methadone prescribing.

### Methadone

In order to determine the relationship between methadone, SCS clients, and opioid overdose, it is first necessary to understand what the literature says about what the optimal methadone dosage is for people with OUD. What follows is an exploration of methadone dosage across several measurable health outcomes and a comparison of these dosages against the

prescribing guidelines in place in Canada during the study period (March 11th to September 30th, 2019). This exploration begins with a discussion on the complexity of methadone research.

Methadone is a medication that has been used to treat OUD in Canada for several decades (Srivastava et al., 2017). Although approved as a treatment for anyone using opioids, large-scale expansion of methadone maintenance treatment in Canada expanded as illicit heroin use became more popular in the 1970s and 1980s (Fischer, 2000). Therefore, much published research involves studies conducted before the large-scale introduction of fentanyl into the North American drug supply in the mid-2010s (Pardo et al., 2019). For this reason, historical research on methadone must be interpreted with caution, since it was often conducted with people using heroin, while the most common illicit opioid used today is fentanyl (GOC, 2021).

It is also important to note that access to methadone and the regulations around prescribing it vary widely from country to country; most research on methadone has been conducted in the United States where pathways to treatment on methadone are relatively limited when compared to Canada (Priest et al., 2019). For example, in the US methadone can only be dispensed at special clinics, not at neighborhood pharmacies (Priest et al., 2019). Studies performed in countries where both substance use trends and health care are quite different from Canada may not be generalizable to a Canadian context.

Further complicating matters, researchers often combine results for both standard OUD treatment modalities (methadone and buprenorphine-naloxone) making it difficult to tease out the effectiveness of each drug alone. Although methadone and buprenorphine-naloxone can both treat opioid cravings and withdrawal, they are different pharmacologically, and are prescribed and dispensed differently (See Chapter One for a complete discussion on the two medications).

This makes it problematic to rely on studies of OAT in general to inform a study on methadone specifically.

Published literature on methadone may also consider one or several different outcomes, making the results from one study difficult to compare to another. A 2020 literature review examining how various studies measured the success of OAT for people with OUD found several different metrics: abstinence from opioid use, study retention, retention in care, all-cause mortality, number of overdoses, and level of opioid withdrawal (Biondi et al., 2020, p. 260). Even amongst these different measures, there was variation on how the outcomes were measured or terms were defined. For example, some studies used self-report to determine if clients were abstinent from illicit substance use; others used urine drug tests (Biondi et al., 2020). Subjective data may not correlate with objective observation. This variance in definitions makes it difficult to compare the outcomes of certain dosages across studies.

Of special concern is the fact that the presence or absence of continued opioid use is a primary outcome in several studies on OAT (Biondi et al., 2020). Given that people who use opioids may not necessarily intend on abstaining from illicit drug use, using this outcome as the definitive measure of optimal methadone dosage may not acknowledge different client goals.

***Methadone Dosage***

Most methadone prescribing guidelines cite a 2003 Cochrane systematic review which suggests that daily doses of 60 to 100mg/day of methadone were more effective than lower doses in reducing illicit opioid use and retaining clients in care (Faggiano et al., 2003). Doses below 30mg may be sufficient to prevent opioid withdrawal but may not be sufficient to prevent continued opioid use (Bell & Strang, 2020). A 2009 retrospective chart review from the United States asserts that people who continue to use illicit opioids while on methadone may need doses

greater than 100mg per day (Fareed et al., 2009). There is no maximum safe dose of methadone indicated in the literature (Canadian Agency for Drugs and Technologies in Health, 2013). A 1999 study mentions a mean dose of 211mg/day for "high-dose" patients, with a dosing range that topped out at 780mg/day (Maxwell & Shinderman, 1999). A systematic review of OAT reports that the average daily dosage range of methadone for studies included in the review was 47 to 116mg (Sordo et al., 2017).

While there is a general consensus on a 60mg dose minimum for effective methadone prescribing, the literature suggests that many people on OAT are being prescribed less than that amount. One study of methadone treatment programs in the United States points out that 23% of clients were receiving doses below 60mg/day (D'Aunno et al., 2019). A recent Canadian study of people who inject drugs revealed that many who were prescribed methadone were prescribed less than the most recent clinical guidelines recommend and amounts that study participants found inadequate (Artenie et al., 2019). Therefore, although we know what the minimum therapeutic dosage of methadone is, there is a significant number of people with OUD who are not being prescribed that amount, and thus are not benefiting from methadone's positive effects on various outcomes.

***Methadone Dosage and Retention in Care***

Retention in care does not have a universal definition in the substance use literature but is generally meant to suggest regular engagement with clinicians over a period of time after the initial start of treatment (Martin et al., 2019). Clients retained in care for OUD for over a year have reduced all-cause mortality compared to those on treatment for under a year (Ma et al., 2019). However, the chaotic nature of some people's substance use can make it difficult for them to engage with the health care system on a consistent basis (Martin et al., 2019). Clinic policies

which recommend discharging clients for behaviour that may be expected from those with OUD (continued substance use) also have a deleterious effect on retention in care (Martin et al., 2019). Because methadone is a medication which requires continued engagement in order to maintain an active prescription, it is important to examine the relationship between methadone dosage and retention in care.

A meta-analysis ($n$ = 18 studies) on retention in methadone treatment programs points out that doses over 60mg/day were better at retaining clients in care than doses less than 60mg/day (Bao et al., 2009). Similarly, a study of methadone treatment in Ireland with 2035 participants found that the 12-month dropout rate was associated with lower doses of methadone (Durand et al., 2021). The correlation between methadone doses higher than 60mg/day and retention in care was also reported in studies from Ukraine, Chicago, and Baltimore (Farnum et al., 2021; Kelly et al., 2011; Maxwell, 2002).

There are comparatively few studies on retention in care for those being prescribed more than 100mg/day of methadone. A BC study reports that the median dose of those who had been retained in methadone maintenance treatment for 36 months or more was 118.3mg/day (Nosyk et al., 2010). A more recent Vancouver study also suggests that people prescribed higher doses (>100mg/day) of methadone were less likely to discontinue treatment (Lo et al., 2018).

***Methadone Dosage and Illicit Opioid Use***

Several studies indicate that higher methadone doses may be required if the desired outcome from treatment is abstention from illicit opioid use (Kimber et al., 2016; Kelly et al., 2011; Termorshuizen et al., 2005; Maxwell & Sarz, 2002). Research in Amsterdam found that 60mg/day doses of methadone were more highly associated with continued heroin use than doses higher than 100mg/day (Termorshuizen et al., 2005). Similar associations were reported in

Chicago by Maxwell and Sarz (2002). Two Chicago studies specifically tested methadone's ability to block the "subjective effects of heroin" at different doses (Donny et al., 2002, 2005). People on low (50mg/day), medium (100mg/day), or high (150 mg/day) doses of methadone were given medicinal heroin to inject and asked to report on what they could or could not feel; those on doses of 100mg/day or above were much less likely to "feel" the heroin they were using (Donny et al., 2005). A meta-analysis of studies of US veterans suggests a fair amount of nuance to this association. They found that 38% of US veterans were able to maintain abstinence from illicit opioid use did so on less than 60mg/day, whereas 16% required over 100mg/day (Kimber et al., 2016). These findings suggest that while clients may not need a high dose of methadone to achieve abstinence, prescribers should be open to prescribing these higher doses, and clients should not be discouraged from increasing their methadone dosage higher than 100mg/day.

***Methadone Dosage and Opioid Overdose***

Although higher doses may be more effective at retaining clients in care or eliminating illicit opioid use, the literature regarding methadone dose and opioid overdose is more complicated. The relationship may have less to do with specific dosage and may instead be related to whether a client has just initiated treatment or is in the maintenance phase of methadone treatment.

The first few weeks on methadone are when people are at the highest risk of experiencing a fatal overdose (Bahji et al., 2019). There are two possible, and distinct, reasons for this: an initiation that is either too fast, or too slow. An overly assertive induction might cause an iatrogenic (i.e., caused by the prescriber) opioid overdose, due to methadone's long half-life (Baxter et al., 2013). On the other hand, an induction period that proceeds too slowly may not provide enough stability and reinforcement to curb illicit opioid use, leading to a high risk of

overdose from illicit use without the protection of a therapeutic methadone dose (Saxon & McCance-Katz, 2016). The decision to pursue treatment is also a factor; deciding to start treatment may occur during a time of chaotic use when it is difficult to adhere to methadone's stringent treatment protocols (Buster et al., 2002). The first few weeks of treatment may not only have a high mortality rate, but a high drop-out rate as well (Srivastava & Kahan, 2006). An Irish study on methadone treatment retention found that 49.7% ($n$ = 1353) of all "dropout events" from methadone occurred in the first 90 days after treatment initiation (Durand et al., 2021, p. 3).

There does not seem to be a consensus on when the maintenance phase of methadone treatment starts. The CPSO methadone guidelines (2011) define the maintenance phase as any time after the first six weeks of treatment, when clients are likely to be at the "optimal methadone dose" (p. 41). A systematic review of mortality and OAT defines it as any time after the first two weeks of treatment (Ma et al., 2019). This systematic review goes on to suggest that the mortality rate for those on all forms of OAT was lowest during this maintenance period (Ma et al., 2019). They also found no significant difference between the mortality rate of those on low (< 60mg/day) or high-dose (> 60mg/day) methadone (Ma et al., 2019). This seems to suggest that mortality risk is associated with a certain stability of treatment irrespective of methadone dosage.

***Methadone in the Age of Fentanyl***

There are comparatively few studies on the use of methadone for OUD at a time when the illicit opioids people are using contain fentanyl. Fentanyl is a more potent opioid than heroin but has a shorter half-life, thus requiring more frequent injections to stave off opioid withdrawal (Ciccarone et al., 2017) Qualitative research amongst people who have used both heroin and fentanyl describe the subjective experience of the two drugs as significantly different: "The rush

[from fentanyl] is incredible . . . you really feel like you're King Kong or Godzilla. The rush is 10 times stronger" (Ciccarone et al., 2017, p. 149).

Stone et al.'s (2018) retrospective study on the effectiveness of methadone compared results between people using fentanyl and people using other opioids. This study suggests that people using fentanyl were less likely to achieve abstinence from it, but that methadone was still protective against mortality in this population; there were no deaths among study participants who remained in methadone maintenance treatment during the ten-month study period (2018).

As for dosage, Stone et al. (2018) found that the methadone doses associated with abstinence from illicit substance use were slightly higher in the group who had been using fentanyl, with a median dose of 100mg/day. This suggests that fentanyl may increase the need for higher doses of methadone for treatment to be effective. Chandra et al. (2021) found that there was still intentional fentanyl use in a group of clients in Connecticut who were being prescribed over 80mg/day of methadone. Bisaga (2019) asserts that those using non-prescribed fentanyl may need methadone doses over 120mg/day in order to reduce their cravings.

### *Methadone Prescribing in Canada*

Until 2018, methadone prescribing in Canada was provincially regulated (Eibl et al., 2017). The government gave an exemption to the Controlled Drugs and Substances Act to allow trained physicians to prescribe methadone, and the provincial physician regulatory bodies released guidelines on how methadone could be prescribed (Eibl et al., 2017). These guidelines included directions on what to do if clients missed doses, how often physicians should perform a urine drug screen, and general guidance on dosing (Bruneau et al., 2018). After 2018, the government removed the methadone prescribing exemption, allowing both physicians and nurse practitioners to prescribe methadone as needed (GOC, 2018). At that point, the provincial

physician regulatory bodies stopped regulating the prescription of methadone and many regulatory bodies (including the CPSO) stopped issuing or updating guidance for prescribers.

A document intended to synthesize provincial guidelines for the treatment of OUD to provide a national standard was recently published in May 2021 (Centre for Addiction and Mental Health (CAMH), 2021). These new guidelines were created in response to the increase in opioid overdoses related to the introduction of fentanyl into the illicit drug supply (CAMH, 2021). However, in the absence of standardized guidance, many physicians may have relied on the previous provincial guidelines under which they were trained for suggestions on the safe and appropriate ways to prescribe methadone. In Ontario, those guidelines were last published in 2011 (CPSO, 2011), when the drug supply was quite different, and opioid overdose deaths were comparatively low.

A look at previous guidelines suggests that while for the most part there was consensus on methadone dosage, there were some practice suggestions which may have affected the way that methadone was prescribed during the time period of this study (March 11$^{th}$ to September 30$^{th}$, 2019). In Ontario, for example, there was a requirement for clients to get an electrocardiogram before methadone dosages could be increased past 150mg/day (Bruneau et al., 2018). This requirement was merely a suggestion under the BC guidelines. Similarly, the maintenance phase of methadone treatment in BC allowed for a 10mg dose increase every 5-7 days; the Ontario guidelines are similar but suggested a 5-10mg increase over the same period of time (Bruneau et al., 2018). These differences allowed prescribers in BC a little more freedom in increasing methadone dosages as quickly as possible.

While it is too soon to determine if prescribers are using the new 2021 CAMH guidelines, they are intended to encourage prescribers to prioritize retention in care wherever possible. For

instance, although they encourage ECGs for clients in methadone maintenance, they acknowledge that "the probability of mortality from non-retention on OAT in a patient who does not wish to change treatment options may exceed the mortality risk presented by an elevated QTc interval" (CAMH, 2021, p. 16). Similarly, they acknowledge the harms that can be done by an over-reliance on urine drug screens, which can increase client impressions of stigma or being punished (CAMH, 2021). The section on methadone dosage in these guidelines encourages a titration schedule customized to the client based on opioid tolerance, other substances used and comorbidities (CAMH, 2021). This includes suggested dose increases of 5-15mg every three to five days for those using "high-potency opioids" like fentanyl (CAMH, 2021, p. 26). This dosage titration schedule would allow some people starting methadone to get to a dose of 60mg in a week, rather than a minimum of two weeks as per the older Ontario guidelines (CAMH, 2021).

***Summary***

This literature review suggests a clear minimum effective dose of 60mg/day of methadone across several measurable outcomes, including abstention from illicit opioid use and retention in care. More research needs to be done to determine if higher doses of methadone (>100mg/day) should be promoted for people who use fentanyl. In terms of mortality risk, the evidence is less clear, because the initiation period of methadone can be deadly if doses are either too high or too low. While previous prescribing guidelines may have been sufficient to address opioid overdose risk in the pre-fentanyl era, prescribing guidelines which allow for some flexibility in methadone dosing are needed to address the escalation of opioid overdose risk, while maintaining safety in the initiation period.

Clients using SCS represent a sub-population of people who use drugs. This group may or may not use opioids and may or may not be on methadone. Because this study concerns

methadone dosage specifically for clients using SCS, what follows is a literature review of SCS that focuses on opioid overdoses and OAT.

**Supervised Consumption Sites**

The first legally sanctioned SCS was established in 1986 in Berne, Switzerland (Woods, 2014). This health intervention spread across Western Europe and dozens of SCS were established there by the mid-2010s (Woods, 2014). It is unclear how much data was collected at these SCSs, but most of the published research on SCSs concerns sites outside of Europe (Potier et al., 2014). In fact, 68% of studies cited in a 2014 systematic review of SCS took place in Vancouver, and most of those studies were undertaken with clients of one SCS, Insite (Potier et al., 2014).

When Insite was established, it was the site of several original research studies (Potier et al., 2014). This is because Insite was initially conceived as a research pilot, and the research was conducted to demonstrate that its existence would be beneficial to both people using the site and the neighborhood surrounding it (Wood et al., 2004). Research was used as a tool to legitimize SCS for a government who was not particularly favorable towards harm reduction services (Lupick, 2017). However, Vancouver is quite different from the rest of Canada as it has a longstanding history of having the highest rates of homelessness and substance use in the country (Neufeld et al., 2019). As such, Vancouver has seen the establishment of services targeting this population, including a coordinated healthcare and housing system (PHS Community Services Society), an active drug user organization (Vancouver Area Network of Drug Users), and provincial organizations dedicated to substance use research and disease prevention (British Columbia Centre for Substance Use; British Columbia Center for Disease Control). There is a difference in the nature of substance use, as well as the level of support for harm reduction and

treatment between Vancouver and the rest of Canada. Therefore, given that most of the SCS research literature comes from the same site in Vancouver, it may be difficult to extrapolate these results to the rest of Canada

### *SCS Overdose Rate*

Although overdose rate (number of overdoses divided by number of visits over the same period of time) is a standard metric for SCS, the various definitions of overdose as well as the nature of substance use (and substances used) in SCSs makes it difficult to make a good comparison of that rate from one site to another (Andresen & Boyd, 2010). Shortly after Insite opened, a chart review found a 0.13% overdose rate in the first year of operations (Kerr et al., 2006). During roughly the same time period, the overdose rates at SCS in Germany and Sydney, Australia were found to be much higher: 0.64% and 0.70%, respectively (Kimber et al., 2003, p. 229). A study of overdoses at Insite found that clients were 4.8 times more likely to overdose there in 2017 than in 2010 given the changing drug supply and the introduction of fentanyl (Notta et al., 2019).

The most recent available data from Insite reports an overdose rate of 0.77% in 2019 (Vancouver Coastal Health, 2020). During the same year, an unsanctioned SCS located in the US reported an overdose rate of 0.51% (Kral et al., 2020). There are no publicly available statistics on SCS in Canada as a whole, but the government reported 15,000 overdoses and medical emergencies during 2017 to 2019, a period which saw over 2,000,000 visits to an SCS in Canada (GOC, 2020b).

### *SCS Clients and OAT*

There are few studies on OAT utilization by SCS clients, and the few that exist do not necessarily define the nature of the treatment their clients' access. These studies do suggest,

however, that there is at least moderate uptake of OAT by those who are using SCS. A 2019 study from Australia indicates that over half of the clients at one SCS were on drug treatment at the time of registration (Power et al., 2019). A clear majority of SCS clients in Denmark were or had been on an opiate substitution drug: methadone, buprenorphine, or heroin (Toth et al., 2016). A study of SCS in Catalonia (Spain) found that almost half of SCS clients were taking a treatment medication (Folch et al., 2018). Research on SCSs in Toronto discovered that those clients who used SCS frequently were more likely to be on OAT than occasional users (Scheim et al., 2021). A proposed cohort study in France suggests an intriguing way to measure the relationship between SCS and treatment by comparing OAT usage rates by people who inject drugs in cities with SCS and cities without SCS (Auriacombe et al., 2019).

Although Insite has been the subject of more research than any other SCS, there are no studies which specifically describe the relationship between Insite's clients and OAT, except for one study which speaks to an increased number of Insite clients on methadone after having attended detoxification services (Wood et al., 2007). Kennedy et al.'s (2019) Vancouver study found a correlation between being on methadone and cessation of SCS use despite active injection drug use; reasons for this relationship were not assessed.

***Summary***

Given the variable nature of SCS service provision, opioid overdose definition, and local differences in substance use, it is difficult to draw conclusions from the literature on opioid overdose rate in SCSs. As to OAT usage by SCS clients, several studies suggest that there are substantial numbers of SCS client who are on OAT at any given time. There are no published studies which address OAT dosage for SCS clients, or which have addressed the association between OAT and overdose risk in this specific population.

# Chapter Three: The SHCHC SCS

## SCS and the Overdose Crisis

The first sanctioned SCS in Canada, Insite, was established in 2003 (Kerr et al., 2017). After its inception the federal government of the time actively worked to close it (Kerr et al., 2017). A Supreme Court challenge followed when that effort failed. The Conservative government then created complicated guidelines for the express purpose of making it more difficult to establish further SCS across Canada (Kerr et al., 2017). It was only when the opioid overdose rate began to rise in 2016 and a Liberal government came to power that there was movement to expand SCS to provinces other than BC (Kerr et al., 2017). By early 2017, there were tentative plans in several provinces to open SCS, but no firm dates for when these sites would open (Kerr et al., 2017). In the meantime, the number of opioid overdose fatalities continued to rise (GOC, 2020a).

## Overdose Prevention Sites in Ontario

To respond to the increase in opioid overdoses caused by the introduction of illicit fentanyl into Canada's drug supply, the BC Ministry of Health allowed the creation of overdose prevention sites (OPS), locations where people could use drugs under supervision, without having to go through the long process of getting a federally sanctioned site approved (Kerr et al., 2017). These "pop-up" sites were often run or staffed by people who use drugs and did not necessarily have the wrap-around services expected at formally sanctioned SCS (e.g., nursing care and referrals to treatment; Wallace et al., 2019). However, they did have the overdose antidote drug naloxone and staff who were trained to respond to overdoses and mitigate adverse outcomes that can result from an overdose (Wallace et al., 2019).

Inspired by these grass roots efforts and frustrated by the slow pace of sanctioned SCS in Ontario, drug user activists started an OPS in an urban park in Toronto, Ontario (Pagliaro, 2018). Led by long-time harm reduction worker Zoe Dodd, the Moss Park OPS consisted of a tent staffed by volunteers whose main purpose was to monitor for, and respond to overdoses (Pagliaro, 2018). Although technically illegal, there was no real effort to shut Moss Park OPS down, and after several months, the site got approval to operate as a federally sanctioned OPS (Pagliaro, 2018).

**SCS in Ottawa**

Soon after the Moss Park OPS opened in Toronto, a group of activists and harm reduction-oriented nurses opened their own unsanctioned OPS in a small park in Ottawa, a couple of blocks from a large homeless shelter (Kupfer, 2017). Similar to Toronto, this site was opened during a time when there were existing plans to open sanctioned SCS in the city, but no firm dates as to when these sites would open were set (Kupfer, 2017). Both the Mayor of Ottawa and neighborhood groups openly expressed disapproval of the OPS's activities and location (Foth, 2021). Perhaps as a result of the impact of having an informal, unsanctioned OPS operating in the nation's capital, the federal government gave fast approval for an interim SCS to open nearby (CBC News, 2017). This interim sanctioned SCS was operated under the exemption granted to SHCHC for their SCS but was located in a different location and operated by Ottawa Public Health (CBC News, 2017).

By 2018, the interim SCS operated by Ottawa Public Health became a permanent SCS, and three additional SCS were opened by other health care centres in the city: Ottawa Inner City Health, Somerset West CHC, and Sandy Hill CHC (Payne, 2019). As of the writing of this

thesis, the four SCS in Ottawa are still open and run by the same organizations (Ottawa Public Health, n.d.).

**About the SHCHC SCS**

SHCHC is a community health centre (CHC) located just east of Ottawa's traditional tourist district, the Byward Market, and within walking distance of several downtown homeless shelters. Because of its downtown location, there are several pharmacies which dispense methadone within walking distance of SHCHC, including one on the same block. Like most CHCs, SHCHC serves a population primarily defined by a geographical catchment area, with a focus on those clients experiencing barriers to health care access (Booth et al., 2020). Besides primary care services, SHCHC provides interdisciplinary care via some on-site specialists (e.g., chiropody, lung health, counselling, psychotherapy) (SHCHC, n.d.). SHCHC also provides social services and case management.

The SCS at SHCHC is part of Oasis, a harm reduction-based program located in the same building as the rest of the CHC, and which provides medical and social services specifically for people at-risk of HIV and HCV due to substance use or sex work. It consists of a sterile needle and syringe program, medical clinic, drop-in, and case management program. Although Oasis has existed for over 20 years, the SCS is a relatively new addition; it was opened in April 2018 and has operated continuously since that time. The services provided in Oasis are operated independently from the SCS but share some of the same staff.

Clinical services available at Oasis include an on-site addiction medicine program where people can access OAT during most weekdays. OAT is prescribed by fee-for-service physicians who are not salaried members of SHCHC's staff but are contractors who use the space and are provided administrative support while billing the province for their services. During this study's

time period, the SHCHC SCS was the only SCS in Ottawa where OAT prescribing was available on-site rather than through a referral to external providers.

***Physical Environment***

The physical entrance to the Oasis Program and SHCHC's SCS is via the same entryway used by the rest of the clients of the CHC. After proceeding through this main entrance, clients present at a room where sterile harm reduction supplies are provided, and they can express their intention to consume substances. It is in this room that clients register for the SCS (Appendix A) and where they are asked initial questions about the substances they are using and whether they are on methadone or buprenorphine-naloxone. After these questions are answered, clients proceed into the consumption room.

The consumption room is approximately 4 x 5 metres in size (see Figure 1). It consists of 5 booths separated by short walls, and a desk where SCS staff can observe and document drug consumption. The clients in each booth face a large mirror which shows the upper half of a client's body. This mirror has two purposes: to assist clients in visualizing injection locations (e.g., in the jugular vein), and to assist SCS staff in assessing clients' level of consciousness, skin colour, and respiratory rate. After clients consume their substances, they can stay in the room for a maximum time limit of 30 minutes, or until consumption room staff feel comfortable discharging them. All overdose documentation takes place in the consumption room.

Clients who leave the consumption room generally proceed to leave the centre, although there is a small room (the "chill room") in which a client who does not require medical monitoring can stay if they need to rest or collect themselves.

**Figure 1**

*Picture of the Supervised Consumption Room at SHCHC*


*Note:* © Sandy Hill Community Health Centre. Reprinted with permission.

### *Staffing*

The SHCHC SCS is staffed primarily by harm reduction workers, who have various academic backgrounds including Bachelor of Social Work or Social Service Worker diplomas. Many have experience working in homeless shelters or other social service organizations. The harm reduction workers provide much of the administrative and behavioural support for all SCS

operations. The consumption room is staffed at all times by two people: a nurse (Registered Nurse or Registered Practical Nurse) and a harm reduction worker. The nurse and harm reduction worker work together in the consumption room to assist clients, respond to overdoses, and complete documentation.

***Documentation***

Both the federal exemption to operate an SCS, and the provincial agreement to fund an SCS require the collection and reporting of data on various metrics associated with SCS services (MOHLTC, 2018). The registration and visit forms for the SHCHC SCS were designed with federal and provincial reporting requirements in mind, with some additional questions added by SHCHC's SCS management.

From the beginning of SHCHC SCS operations until January 2020, all documentation with regards to both initial registration and individual visits was done via paper forms. Harm reduction workers would fill out all registration forms, and the initial sections of the visit forms. In the consumption room, both the nurses and harm reduction workers were responsible for any remaining visit documentation including assessments of the clients before and after substance consumption, and overdose intervention or response. After both visit and registration forms were completed, the information on the forms was entered into electronic spreadsheets by SCS staff. Both the electronic spreadsheets and the paper visit and registration forms are stored for an indefinite period on-site at SHCHC.

These spreadsheets were used to provide data for reports requested by the federal and provincial governments. The federal government requires regular reporting data on SCS as a condition of the exemption from the CDSA which allows them to exist. These reports include information on the number of visits, the substances used, overdoses, and basic demographic data

for clients (GOC, 2020b). The Ontario provincial government is the primary funder of most SCS in the province and requires detailed monthly reports on SCS visits and other services provided to SCS clients (MOHLTC, 2018). The data they request is similar to what the federal government asks for, with the addition of detailed information on wraparound services provided, including referrals to addiction medicine treatment, primary care, mental healthcare, and social services (MOHLTC, 2018).

# Chapter Four: Research Methodology and Results

## Study Design

This study is a secondary data analysis of administrative data collected when clients registered for or visited the SCS at the SHCHC from March 11th to September 30th, 2019. This data was originally collected to fulfill the requirements for the centre's federal exemption from the *Controlled Drugs and Substances Act [CDSA]* (S.C. 1996, c. 19), as well as to fulfill the provincial government's guidelines for funded SCS (MOHLTC, 2018). To date, there have been no published studies using this data set. See Appendix A for permission from SHCHC to use this data.

The time period for this study (March 11th to September 30th, 2019) was chosen because the practice of documenting reported methadone and buprenorphine-naloxone dosages at SHCHC SCS visits started on March 11th. I limited the visits used in the study to the six-month time period after March 11th in order to examine a discrete time period well before the global COVID19 pandemic and its effect on drug supply and harm reduction programming in Canada (GOC, 2021).

The research questions addressed in this study were prompted by the unique nature of data collected by SCSs, making secondary analysis of this administrative data an obvious choice for study design. There has been much published research on the association between OAT and opioid overdose (Keen et al., 2021; Santo et al., 2021). The data collected by SHCHC, however, differs significantly from the data sources from which most of this existent research is drawn. Much of the research on opioid overdoses concerns fatal overdose, or overdose resulting in a hospital visit (Leece et al., 2020; Pearce et al., 2020). Other research on overdoses uses client-self-reported data (Dunn et al., 2016). SHCHC SCS visit data, in contrast, presents a chance to

examine non-fatal overdose (whether it results in a hospital visit or not) in an objective, measurable way. Additionally, the existing research on OAT and overdoses rarely specifies the dosage of OAT a client may be prescribed – length of time in treatment is often used as a proxy measure instead. Although SHCHC SCS data is self-reported, it represents a rare chance to analyze associations between dosage of OAT and subsequent, same-day opioid overdose.

**Data Source**

All information collected for the period of time covered in the data set used in this research was collected on paper by the staff at SHCHC. The registration forms were filled out when a client first visited the SCS and consisted of information provided entirely by the client (See Appendix C). Demographic information was not verified by staff to ensure client anonymity, a preference expressed by people who use drugs when consulted about how they wanted SCS to operate in Ottawa (Bayoumi, 2012). Due to the stigma around illicit drug use, requiring verified demographic information is generally thought to be a deterrent to SCS utilization. A report on service needs for potential SCS users in Edmonton, Alberta suggested that only 36% of them would use an SCS if required to show government identification (Hyshka et al., 2016, p. 43).

SCS visit forms were filled out by staff each time a client visited the site, and included information provided by the client as well as information provided by staff (See Appendix D). Clients were asked if they had a recent overdose, whether they were on methadone or buprenorphine-naloxone, and what substances they intended to use in the site. Clients on methadone or buprenorphine-naloxone would regularly volunteer to identify the dosage they were prescribed, and this information was entered by staff when provided. During each visit, staff of the site entered their assessments of the client before and after their substance use, the

time of use, what medical interventions were initiated, what other services the client received in the site, and what referrals were provided. The information on each paper registration and visit form was then entered by staff of SHCHC into electronic spreadsheets. All possible client identifiers (e.g., names, initials) were removed from electronic spreadsheets before being provided to the principal investigator for use in this study.

**Ethics Approval**

Approval for using this data was given by the Sandy Hill Community Health Centre (See Appendix A). The University of Ottawa Research Ethics Board gave approval for this secondary data analysis (See Appendix B). The data sets used in this study are stored on a password-protected USB and will be physically destroyed via pulverization after 5 years.

**Participant Characteristics**

The study participants were the 273 clients of the SCS at SHCHC who registered to use the SCS for the purposes of consuming substances by oral, intranasal, and/or injection before the end of the study time period (September 30, 2019). The most common method of consumption was via injection (99.6% of visits), with intranasal or oral consumption comprising very few visits. Besides demographic information on gender and ethnicity, there was no information collected on clients' income level, education, employment status, and living situation. A 2017-2019 study on people who inject drugs in Canada which included Ottawa as a study site suggests that most (48%) had not finished high school and had a recent history of unstable housing (62.6%) and financial strain (86%) (Tarasuk et al., 2020).

**Sample**

It is important to note that the population for this study is measured in visits to the SCS instead of unique clients. Although each visit to the site is associated with a client code, these

codes were not verified with the registration data by staff each time a client visited the site, and clients were not discouraged from changing their codes at will. Clients may have decided to change their codes purposefully in order to ensure the anonymity of their data. They may also have confused their codes with those given to them at other SCS in Ottawa and provided the wrong codes in error. For this reason, the researcher in consultation with the thesis advisory committee for this study decided that it would be impossible to rely on these codes as accurate representations of unique client data, and instead treated each visit to the SCS as a separate entity. Therefore, for the purposes of this study the sample consists of 12,099 independent events (the visits to the SCS during the study time period of March 11th, 2019, to September 30th, 2019). Although it is clear from a comparison of the number of unique individuals registered to the SCS ($n$ = 273) and the number of visits to the site ($n$ = 12,099) that the visits to the site represent multiple visits by certain clients, there is no way to reliably associate visits to specific clients. This means that this study treats data points that may be related to each other as independent data.

**Study Objectives**

The purpose of this secondary data analysis was to explore the data collected at visits to one SCS to determine whether there were any relationships between information provided by the client and any subsequent opioid overdose event in the SCS. Specifically, this study intended to identify:

- the relationship between substances used and opioid overdose
- the relationship between clients' report of being on OAT and their odds of experiencing an opioid overdose in the SCS

- whether the dosage of methadone a client reported they were on correlated to odds they experienced an opioid overdose in the SCS

## Dependent Variable

### *Opioid Overdose*

The dependent variable used in this study was the occurrence of an opioid overdose in the SCS. There is no universal definition of what constitutes an 'opioid overdose' in the medical literature (Binswanger et al., 2019). The SCS at SHCHC uses a definition suggested by the Ontario MOHLTC for the purposes of reporting – the administration of medications in the form of oxygen and/or naloxone (MOHLTC, 2018). This definition concurs with the limited published research on the subject, which suggests a case definition that includes altered level of consciousness, the need for respiratory support, and the administration of the opioid antagonist naloxone (Binswanger et al., 2019). Therefore, for the purposes of this study, only those visits which resulted in the use of oxygen or naloxone were considered opioid overdose events. Visits which resulted in overdose were coded as one; visits which did not result in an overdose were coded as zero.

## Independent Variables

### *Substance Used*

Clients entering the SCS were asked what substance or substances they intended to use in the site and each of these substances represent a discrete independent variable. Use of the substance was coded as one; if a substance was not used during the visit, it was coded as zero. For the purposes of data analysis, substances were examined individually and also grouped together with others based on whether or not they were opioids or stimulants. It is important to note that there was no mandatory drug checking service active in the SCS during the time of this

study that could independently identify the chemical composition of substance used by clients. As a result, this variable is based solely on client self-report and not on independent identification of the substance the client reported they would use in the site.

### *Opiate Agonist Therapy*

Clients entering the SCS were asked if they were on methadone or buprenorphine-naloxone, and their self-report of being on each of these medications represents a separate independent variable. Visits where clients reported being on a medication where coded as one, visits where they did not report being on a medication were coded as zero.

### *Opiate Agonist Therapy Dosage*

When asked if they were on methadone or buprenorphine-naloxone clients very often volunteered the dosage of medication they were on. Because buprenorphine-naloxone usage was reported much less frequently, especially for clients using opioids, this study concentrated on the dosage of methadone clients reported being prescribed. Methadone dosage was coded as a separate independent continuous variable in the initial statistical analysis. For the purposes of this study, where dosage values were not normally distributed and skewed towards the right, median was used as the measure of central tendency. In order to tease out any relationships that may have existed for a certain dosage range rather than a discrete dosage, an additional categorical variable was created for ten milligram dosage ranges. Any statistical tests performed on the continuous dosage variable were also performed on the categorical variable.

## Analysis

All data analysis was performed using the Statistical Package for the Social Sciences program, version 27.

### *Demographic Information*

Information on the participants in this study was collected on forms filled out when clients registered for the SCS (See Appendix C). Descriptive analyses were performed on this data to describe the participants in this data set as a whole in terms of gender, ethnicity, history of overdose, and history of substance use. Because specific participants could not be reliably attached to SCS visit data, data analysis of participant characteristics was done separately from analysis of SCS visits.

### *Data Analysis of SCS Visits*

Data analysis of visits was carried out using the following steps:

1. For each variable (both dependent and independent), descriptive analyses were performed. Some dependent variables (e.g., substances with similar pharmacologic effect) were grouped for further analysis and comparison. For the continuous variable of methadone dosage, histograms were created in order to visualize and assess distributional shape for normality, kurtosis, and skewness.
2. Bivariate analysis was performed between variables to identify associations between independent variables, and between independent variables and the dependent variable. Chi-square analysis was used for the categorical variables, and Mann-Whitney U tests were used for the continuous variable of methadone dosage.
3. Correlation analysis was conducted to determine the strength and direction of any relationships between variables.
4. Binary logistic regression was performed in order to verify the lack of correlation between methadone dosage and opioid overdoses. The continuous variable of methadone

dosage was recoded as a categorical variable by 10mg dosage ranges for further logistic regression analyses.

5. Both bivariate analysis and logistic regression were carried out with stratified subgroups of the sample. Overdose rates were analyzed for the entire sample, for specific substances used, for the subgroup using opioids, and for the subgroup on OAT. Similarly, analysis of OAT was performed for subgroups using opioids or stimulants.

### *Extreme Outliers*

In order to assess the accuracy of the data, descriptive analysis was performed on the data set to identify outliers. Five visits (0.04%) out of the total number of visits ($n$ = 12,099) where the methadone dosage was beyond the normal accepted dosage range for methadone were removed from the data set before analysis was performed, as these were most likely to be data entry errors.

### *Missing data*

The most common independent variable missing from this data set was dosage of methadone or buprenorphine-naloxone; 4.8% ($n$ = 284) of the visits where clients reported being on OAT were missing this data. Visits missing this data were excluded from any analysis of dosage amounts but were included in general analyses of opiate agonist therapy.

## Results

### *Participant Characteristics*

See Table 1 for a list of the participant characteristics gathered at registration for the 273 clients registered by the end of the study period. Most clients ($n$ = 204; 75%) were male, and most were between the ages of 25 and 44. A significant proportion of clients did not give an answer for ethnicity, but the most common response for those who answered was white (60%).

Most clients (*n* = 142; 63%) reported a history of overdose, and the most common substances clients reported having used recently were fentanyl (*n* = 186), crack (*n* = 176), and heroin (*n* = 175).

**Table 1**

*Demographic and Substance Use Characteristics of Participants at Registration*

| | *n* | % |
|---|---|---|
| Gender | | |
| Female | 65 | 24 |
| Male | 204 | 75 |
| Other[a] | 4 | 1 |
| Age | | |
| 24 and under | 18 | 7 |
| 25 to 34 | 107 | 39 |
| 35 to 44 | 76 | 28 |
| 45 to 54 | 51 | 19 |
| 55 to 64 | 16 | 6 |
| 65 and over | 5 | 2 |
| Ethnicity[b] | | |
| Indigenous | 29 | 11 |
| Black | 9 | 3 |
| Latino | 2 | 1 |
| Middle-Eastern | | |
| White | 165 | 60 |
| Overdose status | | |
| Overdose in last 30 days | 14 | 16 |
| Overdose in last 6 months | 57 | 21 |
| Ever overdosed | 71 | 26 |
| No | 93 | 34 |
| Crack | | |
| Ever used | 32 | 12 |
| Used in last 30 days | 156 | 57 |
| Used in last 6 months | 20 | 7 |
| No | 56 | 21 |
| Benzodiazepines | | |
| Ever used | 36 | 13 |
| Used in last 30 days | 91 | 33 |
| Used in last 6 months | 18 | 7 |
| No | 115 | 42 |
| Crystal Meth | | |
| Ever used | 33 | 12 |
| Used in last 30 days | 123 | 45 |
| Used in last 6 months | 20 | 7 |
| No | 83 | 30 |

| | | |
|---|---|---|
| Cocaine | | |
| Ever used | 25 | 9 |
| Used in last 30 days | 182 | 67 |
| Used in last 6 months | 23 | 8 |
| No | 34 | 12 |
| Morphine | | |
| Ever used | 45 | 16 |
| Used in last 30 days | 129 | 47 |
| Used in last 6 months | 35 | 13 |
| No | 51 | 19 |
| Fentanyl | | |
| Ever used | 21 | 8 |
| Used in last 30 days | 169 | 62 |
| Used in last 6 months | 22 | 8 |
| No | 52 | 19 |
| Heroin | | |
| Ever used | 38 | 14 |
| Used in last 30 days | 148 | 54 |
| Used in last 6 months | 27 | 10 |
| No | 51 | 19 |

*Note.* $n = 273$. Not all participants answered all questions. Substances are listed in the order questions were asked on the registration form.

[a] Answers included *Transfemale*. *Nonbinary*, and *X*

[b] Only one ethnicity recorded for each client

### *Descriptive Analysis of SCS visits*

**Substances Used.** See Table 2 for a full list of the frequencies and percentages of substances clients reported using during visits to the SCS. The most common substance clients reported using was fentanyl at 55% ($n = 6751$) of visits, and clients used opioids at 70% ($n = 8473$) of visits. Stimulant drugs were used at 31.7% of visits (crystal meth 11.5% [$n = 1397$], prescription stimulants 8% [$n = 963$], speed 6.6% [$n = 794$], cocaine 4.3% [$n = 516$], crack 1.4% [$n = 166$]). At 4.3% of visits [$n = 520$], clients reported using both an opioid and a stimulant during the same visit.

**Table 2**

*Self-Report of Substances Used at Visit*

| | *n* | % |
|---|---|---|
| Benzodiazepines | 7 | 0.1 |
| Crack | 166 | 1.4 |
| Crystal Meth | 1397 | 11.5 |
| Cocaine | 516 | 4.3 |
| Dilaudid | 1030 | 8.5 |
| Fentanyl | 6751 | 55.8 |
| Heroin | 223 | 1.8 |
| Methadone | 12 | 0.1 |
| Morphine | 457 | 3.8 |
| Ritalin/Biphentin[a] | 963 | 8.0 |
| Speed | 794 | 6.6 |
| Steroids | 4 | 0.0 |
| Other | 305 | 2.5 |

*Note.* $n$ = 12099. Clients could report using more than one substance per visit.
[a] Both are prescription stimulants.

**Route of Administration.** There were 52 visits for intranasal administration of substances, and 2 visits for oral administration of substances. The rest of the visits (*n* = 12,945) were for injection of substances.

**Opioid Overdose Rate.** 2.2% (*n* = 264) of all visits resulted in an opioid overdose event.

**OAT Usage.** At 48.9% (*n* = 5919) of the visits clients reported being on OAT – 45.3% (*n* = 5486) on methadone and 3.6% (*n* = 435) on buprenorphine-naloxone. During most visits (99.97% [*n* = 5916]) clients reported being on one medication or another, with only 3 visits where clients reported being on both medications at once.

**Table 3**

*Self-Report of Opiate Agonist Therapy Prescribed to Person*

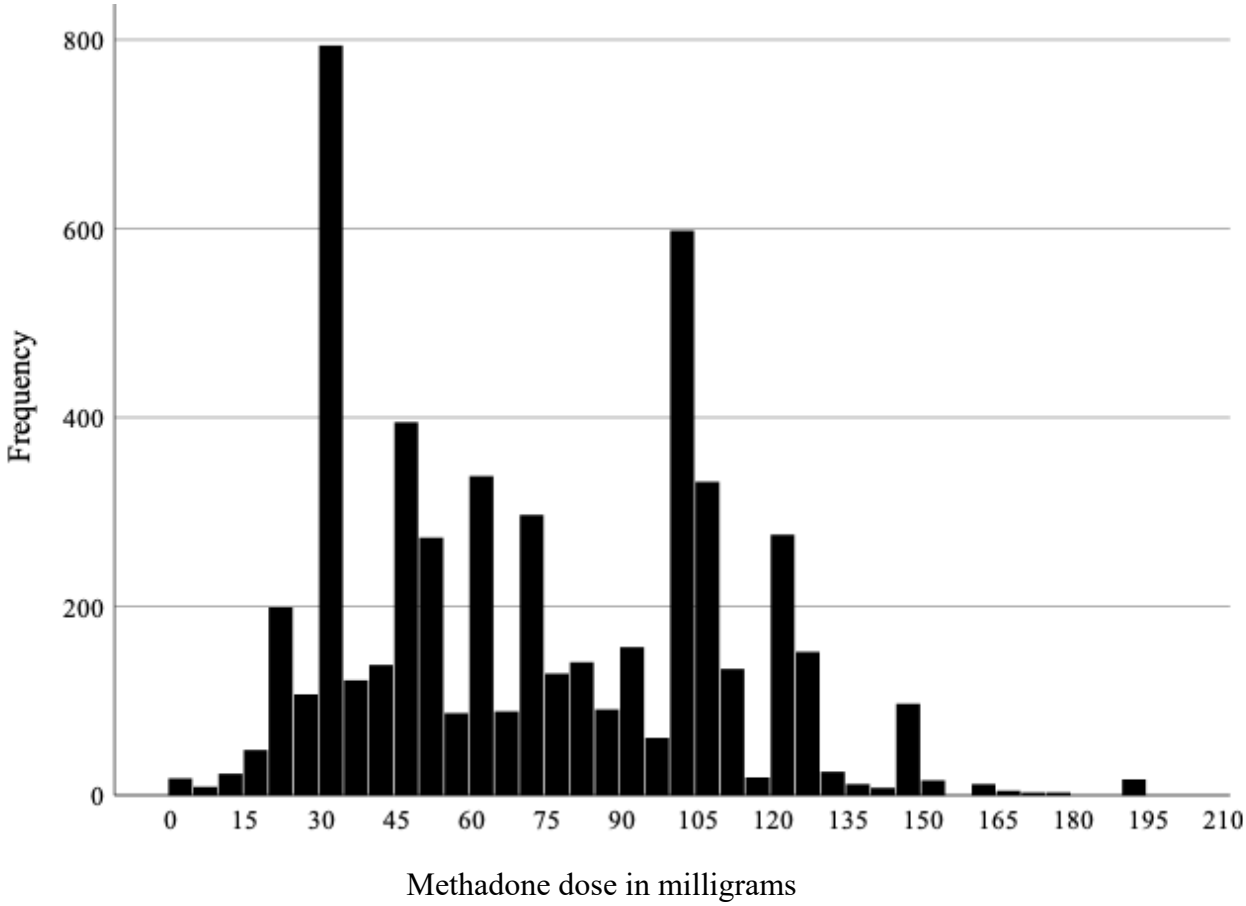
| | *n* | % |
|---|---|---|
| Opiate Agonist Therapy | 5919 | 48.9 |
| Methadone | 5486 | 45.3 |
| Buprenorphine-naloxone | 435 | 3.6 |

*Note.* *n* = 12099. Clients could report being on no medication, either medication or both.

**Methadone Dosage**. See Figure 2 for histogram of methadone dosage for the sample. The most common methadone dosage clients reported being prescribed was 30mg; 14.3% (*n* = 786) of all visits, and 17.1% (*n* = 608) for those visits where clients reported using opioids. The median methadone dosage for the sample as a whole (*Mdn* = 65) was higher than the median for those visits where clients reported using opioids (*Mdn* = 55).

**Figure 2**

*Methadone Dosage Frequency*



***Bivariate Analysis***

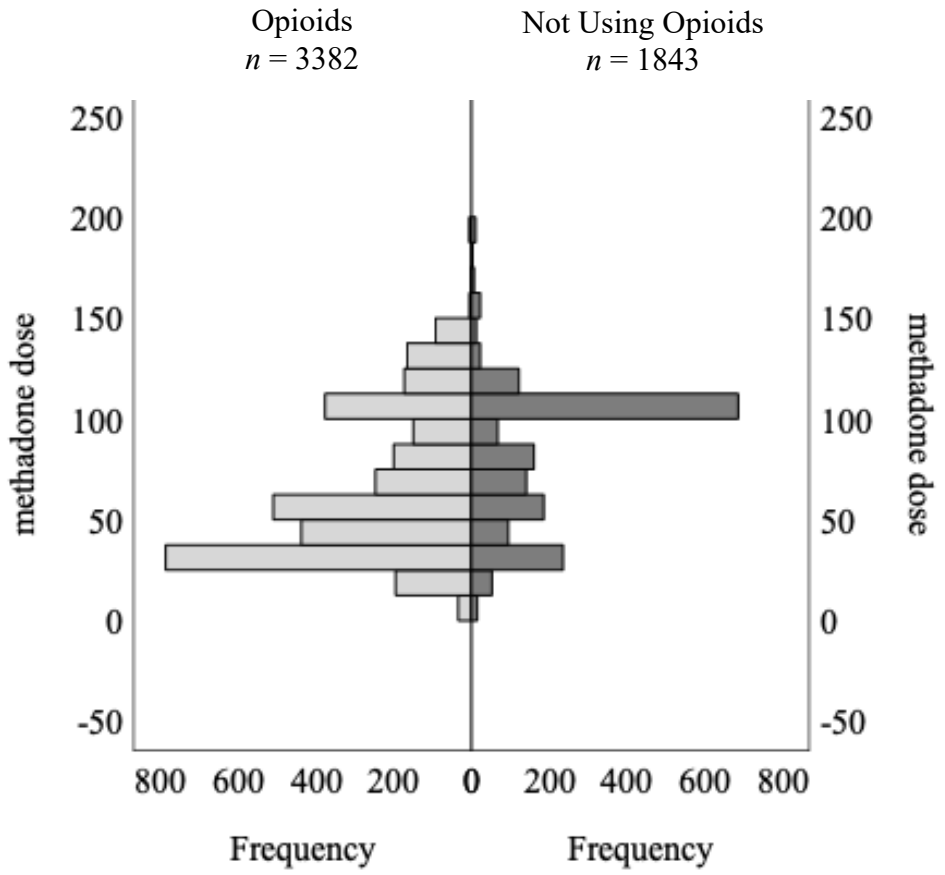
**Substance Used and Opioid Overdose**. There was a statistically significant correlation between the kind of substances clients reported using during visits and risk of opioid overdose; visits where clients reported using opioids were more likely to result in opioid overdose, $\chi^2$ (1, $n$ = 12099) = 91.392, $p$ = <.001.

**Opiate Agonist Therapy.** There was no statistically significant difference in the likelihood of opioid overdose for visits depending on whether a client was on OAT or not, $\chi^2$ (1, $n$ = 12099) = 1.597, $p$ = .206. This lack of significance held when this analysis was repeated only for the subgroup of visits where clients used opioids, $\chi^2$ (1, $n$ = 8396) = .107, $p$ = .744.

**Methadone Dosage by Substance Used**. Because the methadone dosage in this population was not distributed normally, a Mann-Whitney U test was performed in order to determine whether the median methadone dosage clients reported differed based on the substances they reported using during visits to the SCS. The methadone dosages reported during visits where clients used opioids (*Mdn* = 55) were statistically significantly lower than those where they did not (*Mdn* = 90), U = 3926559.50, $p$ = .000. Figure 3 is a histogram showing these results.

**Figure 3**

*Methadone Dosage Frequency by Type of Substance Consumed at Visit*




*Note.* Substances represented by *Not Using Opioids* above include benzodiazepines, cocaine, crack, crystal meth, prescription stimulants, speed, steroids, and other.

### *Logistic Regression*

**Methadone Dosage and Opioid Overdose.** Binomial logistic regression analyses were performed in order to further explore any association between methadone dosage and opioid overdose for visits where clients reported using opioids. Visits where clients reported being on 30 mg or less of methadone were compared to visits where clients did not report being on OAT at all; neither was a statistically significant predictor of opioid overdose (see Table 4). Similarly, recoding methadone dosage into a categorical variable from a continuous variable did not reveal any significant associations.

**Table 4**

*Regression Analysis Summary for Methadone Dosage and Opioid Overdose During Visits When Opioids Were Used*

| | *B* | *SE* | *Wald* | *df* | *p* | Odds Ratio | 95% CI for Odds Ratio | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | Lower | Upper |
| On 30mg of methadone or less | .069 | .208 | .110 | 1 | .741 | 1.071 | .712 | 1.612 |
| Not on OAT | -.073 | .192 | .144 | 1 | .705 | .930 | .638 | 1.355 |
| Constant | -3.482 | .118 | 870.694 | 1 | <.001 | .031 | | |

*Note.* $n$ = 8473. Abbreviations: OAT, methadone or buprenorphine-naloxone.

# Chapter Five: Discussion

What follows is a summary of key findings from my secondary data analysis, and a synthesized discussion of the main themes revealed by these findings. I review nursing implications and make recommendations for practice, education, administration, and research. Finally, I lay out this study's strengths and limitations.

## Key Findings

### *Participant Characteristics*

**Age and Gender.** Table 1 presents the demographic information on SCS clients as collected in their initial registration form for the SCS. The gender and age breakdown of SHCHC SCS clients is similar to client demographics found in a global systematic review of SCS, and to the available statistics on Canada's SCSs in the aggregate from 2017 to 2019 (GOC, 2020b; Potier et al., 2014). Men aged 25 to 45 years old make up the majority of SCS clients. This finding is also consistent with the most recent demographic information for people who inject drugs in Canada. (Tarasuk et al., 2020). Although SCSs allow alternate forms of consumption (oral, intranasal), injection was by far the most common route for drug consumption in SHCHC's SCS ($n$ = 12,945; 99.6%).

**Race and Ethnicity.** Data on client race or ethnicity was so incomplete as to make it difficult to draw conclusions on the racial/ethnic makeup of SHCHC SCS clients. When data was present, clients were only encouraged to include one answer, rather than include all racial or ethnic information they felt applied to them. Missing ethnicity data is common in demographic data collection (Aspinall & Jacobson, 2007; Derose et al., 2013). The categories used for race and ethnicity are often unclear or overlapping, and people of mixed heritage may have preferred not to answer rather than choose a single identity with which to identify (Kiran et al., 2019). It

could also be possible that clients of the SCS wished to provide as little information about themselves as possible in order to preserve their anonymity or protect themselves against racism or other forms of oppression (Taylor, 2017). This lack of reliable race or ethnicity demographic data is problematic because it makes it difficult to tailor interventions to different groups. For example, Indigenous Canadians have a much higher rate of fatal opioid overdose than white Canadians (Lavalley et al., 2018). Prisons also have a disproportionate number of Indigenous Canadians who are incarcerated for drug-related crime (Lavalley et al., 2018). If SCSs do not collect meaningful and comprehensive race and ethnicity data, it is impossible to tell if Indigenous Canadians or Canadians from other races or ethnicities are benefitting from the harm reduction intervention.

**History of Opioid Use and Overdose.** Most clients ($n$ = 142; 63%) registering for the SHCHC SCS had experienced opioid overdose in the past (Table 1). This contrasts with the general experience of people who inject drugs in Canada, only a quarter of whom reported ever experiencing an overdose in a 2017-2019 study (Tarasuk et al., 2020). It is, however, consistent with research that suggests that people who use SCSs were more likely to have experienced a non-fatal opioid overdose than people who inject drugs but do not use supervised injection sites (Kennedy et al., 2019). Non-fatal opioid overdose is a significant predictor of subsequent fatal opioid overdose among people who inject drugs (Caudarella et al., 2016). Given that the most frequent substances that clients reported using when they registered for the SHCHC SCS were opioids (Table 1), the prevalence of previous opioid overdose experience is an expected finding which also implies that the SHCHC SCS is serving a population which is at high risk of opioid overdose-related fatality.

**Summary.** Overall, the participant characteristics of the clients of the SHCHC SCS are similar to those reported at other SCS in Canada and around the world, suggesting that the SHCHC SCS is not an outlier in terms of age and gender representation. The dearth of additional demographic data (e.g., race, ethnicity) represents a missed opportunity to determine if the SCS is serving specific populations who may be at higher risk of negative outcomes from substance use.

### *SCS Visits*

As discussed in Chapter Three, client codes were not verified at the time of client visits, making them ill-suited for longitudinal study. Thus, the rest of the findings discussed apply to statistical analysis of SCS visits, rather than analysis data from unique clients.

**Opioid Overdose Rate.** In the literature (both published and grey) on overdoses and SCS, the amount of opioid overdoses experienced at the site is most often expressed as the ratio of overdoses to visits to an SCS, regardless of substance used (Vancouver Coastal Health, 2020; Andresen & Boyd, 2010; Kimber et al., 2003). For the time period covered in this study, the overdose rate at the SHCHC SCS was 2.2% - an average of 2.2 opioid overdoses per 100 visits to the SCS. This rate is higher than the overdose rate reported by Insite in Vancouver for 2019 (0.77%; Vancouver Coastal Health, 2020) and that reported by all SCSs in Ottawa for April to September, 2019 (1.3%; Ottawa Public Health, n.d.).

As discussed previously in Chapter Two, comparing the overdose rate from one site to another is complicated by the fact that there is no single agreed-upon definition of opioid overdose event that is used by all SCSs, and because the drug supply and substance use may be quite different from site to site. Recent qualitative research highlights the difference in policies, client profile, and substance use between the four SCS in Ottawa, including SHCHC's SCS:

"Everyone is a little bit different, so every site is going to have a different flair and different clientele. It's not a one size fits all." (Haines & O'Byrne, 2020, p. 196). Given these differences, it would be difficult to draw any conclusions by comparing the overdose rate at SHCHC SCS with other sites; the overdose rate could instead be used to compare different time periods at one specific site, as done by Notta et al. in an article showing the increasing opioid overdose incidence at Insite when drug supply changed (2019).

**OAT Usage Reported at Visit.** At roughly half the visits to the SCS, clients reported being on OAT. It is impossible to determine how many unique clients included in this study were prescribed OAT during the study time period, but the frequency with which clients reported that they were on OAT shows that OAT uptake is not uncommon in this population. This is consistent with the available research on OAT and SCS clients, which shows that many of them are on OAT either at the time of registration, or if surveyed during their stay (Power et al., 2019).

**Methadone Dosage and Substance Used.** During visits where clients reported being on OAT, they were much more likely to report being on methadone than on buprenorphine-naloxone (Table 3). As previously discussed in Chapter 2, this finding is unsurprising given that methadone is a full opioid agonist and often considered the preferred treatment for people who use fentanyl (Bruneau et al., 2018). For visits where clients reported being on methadone, there was a statistically significant difference between the methadone dosage reported by those clients using opioids during a visit and those using other substances. Visits where clients reported using opioids were associated with lower dosages of methadone than visits where clients used stimulants and other substances (Figure 3).

The correlation between visits for stimulant use and higher doses of methadone is interesting given that stimulant use is often associated with reduced likelihood of retention in

methadone programs (Lo et al., 2018). Although being retained in care does not itself mean that clients were prescribed higher dosages of methadone, it would be difficult for clients who were not retained in care to obtain those higher dosages, given the requirements for consistent clinic and pharmacy attendance for dosage increases (Bruneau et al., 2018). This unexpected finding raises the question of whether stimulant use may have been initiated after clients reached higher doses of methadone. Recent qualitative research on the relationship between stimulant use and methadone suggests that people on methadone may use stimulants to counteract the sedative effects of methadone and to be able to function in their daily lives (McNeil et al., 2020). Others use stimulants as a replacement for opioids since methadone makes it difficult by design to experience euphoria from simple opioid intake (McNeil et al., 2020). More research is needed to explore the nature of this relationship between methadone and stimulant use.

**Opiate Agonist Therapy and Opioid Overdose.** The evidence of OAT's effectiveness in reducing fatal opioid overdose mortality is clear (Pearce et al., 2020). However, this secondary data analysis of SCS visits found no statistically significant correlation between OAT usage and reduced likelihood of same day opioid overdose. This unexpected finding may be partially explained by the number of visits where clients reported being on 30mg of methadone. A dose of 30mg was the most frequent methadone dosage reported during visits to the SCS, especially for those visits where clients reported using opioids (see Figures 2 and 3). However, 60mg of methadone is widely understood to be the minimum therapeutic dosage for preventing fatal overdoses (Faggiano et al., 2003). Clients who reported being on lower dosages of methadone may not have been taking enough methadone to protect them from experiencing an opioid overdose. Additionally, the overwhelming prevalence of 30mg as a reported dosage makes

drawing conclusions between opioid overdose and other doses of methadone difficult, if not impossible.

Because this study looks at OAT usage reported at visits, rather than by unique clients, there is more than one possible explanation for 30mg being the most common methadone dosage reported by clients. Clients on a sub-therapeutic dosage of methadone may have visited the SCS more frequently, because lower dosages of methadone are less likely to prevent opioid withdrawal or treat opioid cravings (Bell & Strang, 2020). This would result in more visits where clients reported lower methadone doses; clients on higher doses may need to visit the SCS less frequently. Another possible explanation is that clients who visit SCSs may be less likely to be on higher doses of methadone. Methadone is titrated up slowly, requiring daily pharmacy visits and regular appointments with a prescriber in order to access higher doses. It may be that clients who are regularly using illicit substances are not able to attend either the pharmacy or a methadone clinic consistently, given both the need to raise money to buy these substances, and the effort it may take to acquire them (Ivsins et al., 2020). It is quite possible that both these explanations are true, and together serve to reinforce the prevalence of lower methadone dosages in the SCS.

**Summary.** This study demonstrates that opioid overdoses were no less likely to have occurred during SCS visits where clients using opioids reported sub-therapeutic doses of methadone compared to visits where clients using opioids did not report being on OAT. This finding demonstrates that although there is room for improvement in the number of SCS clients accessing OAT, an equal concern is whether clients have been retained in methadone maintenance long enough to access a methadone dosage which may protect them from opioid overdose.

## Themes

The main discussion points raised by the findings of this study can be grouped into two distinct themes: methadone prescribing and SCS data collection. Below I discuss these themes in light of the results of this secondary data analysis and informed by the ecosocial theory framework.

### *Methadone Prescribing Practices and Retention in Care*

Studies on OAT often focus on retention in care, which is not a clearly defined concept, but is often expressed by whether someone who was prescribed OAT is still on OAT at certain pre-determined intervals, usually 3 months to one year (Timko et al., 2016). There is evidence to support that being on OAT reduces all-cause mortality, and that the longer people are on OAT, the more protective it is (Bao et al., 2019, Martin et al., 2019). However, because studies on retention measure OAT at certain intervals, they may not be capturing what happens to clients between those time periods, and how they are progressing on OAT. This is especially problematic when we look at methadone treatment. Because methadone titration requires consistent clinic attendance and pharmacy pickup, clients may be "retained in care" during follow-up but may not have increased their dose to a therapeutic amount. They may instead miss enough doses that they have to "start again" as described in an interview with a methadone client in Ottawa: "[My] girlfriend missed her drink for 3 days and [the clinic] have a policy that you are cutoff if you miss your drink for 3 days. You have to go back to your doctor and do a urine test and start at 30 [mg dose]. If you are at 60 or 80 so be it" (Jeske & O'Byrne, 2019). Given the prevalence of 30mg doses among SCS client visits, it may be that clients are not able to reach higher doses of methadone but are instead restarting treatment repeatedly.

Looking at methadone treatment from an ecosocial perspective demands that we see these low methadone dosages not merely in terms of a "risk factor" for overdose, but that we examine the broader context to search for "causal pathways" which may be affecting SCS clients as a whole (Krieger et al., 2013, p. 110). This entails looking at the barriers clients may be facing as a system problem rather than an area of personal responsibility.

Qualitative research reveals that clients find many aspects of acquiring methadone unpleasant. This includes the observed urine drug screens, stigma from clinic staff and confusing clinic rules (Jeske & O'Byrne, 2019). Because the subjective and protective effects of methadone are not felt until several weeks into treatment, clients must endure the negative aspects of methadone acquisition without any positive reinforcing effects such as reduction in withdrawal symptoms or the need to supplement with unregulated substances (Marshall et al., 2021). The result of these two opposing forces (low methadone dose and high-barrier access to methadone) is that clients may be stuck in a vicious circle of continual methadone replacement restarts or drop out of treatment altogether. The fact that the starting doses of methadone (<30mg) are not protective of same-day opioid overdose in the SCS suggests that these continual restarts provide no therapeutic benefit to people who are on methadone and continuing to use opioids.

The problem of sub-therapeutic methadone dosing has not gone unnoticed by prescribers. A group of addiction medicine physicians in Ontario recently released a guideline to methadone prescribing which attempts to address the issues in the early weeks of methadone treatment, when the risk of iatrogenic overdose is high, but the risk of drop-out is higher. The META:PHI guidelines propose supplementing the lower starting doses of methadone with slow-release oral morphine, which has a more predictable half-life than methadone (Bromley et al., 2021). The idea is to prevent opioid withdrawal in those beginning days, but with an opioid that has a shorter

and more predictable half-life than methadone (Bromley et al., 2021). In addition to this supplementation, they propose various strategies to reduce barriers to methadone treatment, including reducing the frequency of urine drug screens, leaving standing orders for 30mg restarts for clients who have dropped out of treatment, and requiring fewer clinic visits (Bromley et al., 2021). See Appendix E for a summary comparison of the META:PHI guidelines and the CPSO 2011 guidelines. This guidance, while comprehensive, comes in the form of suggestions from a specific community of practice, rather than a regulatory body; it remains to be seen whether they will be implemented by the broader community of prescribers.

During the COVID-19 pandemic, several countries relaxed their rules on OAT prescribing and dispensing to reduce the risk of disease transmission that may have been associated with frequent trips to clinics or pharmacies (Joudrey et al., 2021). These efforts, although primarily intended to protect clients from infectious disease, may have had a secondary effect of reducing some of the systemic barriers people who use drugs face in getting OAT (Walters et al., 2020).

Although the outcomes of relaxed OAT guidelines have yet to be measured, these new COVID-19 OAT protocols show that the substance use care system is capable of rapid change in response to threats to the health of its clients. This adaptation let us envision the system becoming an “enabling environment” which works on many levels to prevent opioid overdose deaths (Walters et al., 2020). In the context of the SHCHC SCS, this “enabling environment” may require the wide-spread adoption of prescribing practices which encourage the fewest interruptions to methadone maintenance treatment, rather than just simply encouraging clients to start OAT.

### *SCS Data*

The reason that this secondary data analysis was undertaken was not only to determine associations between OAT and opioid overdose for SCS clients, but also to demonstrate how the data collected by SCSs can be used to identify points for intervention to improve the care of the people who use them. Although there is a large body of qualitative research conducted with people who use drugs in communities across Canada, the quantitative data collected during every visit to an SCS that remains largely unanalyzed by researchers.

The registration and visit data featured in this secondary data analysis is collected by SCSs for submission to both the government of Canada (which grants permission to operate SCSs) and the province of Ontario (which funds most SCSs in the province). These data sets are not widely or consistently available. What limited information that is published is often broad or several months old by the time it appears. In contrast, the data collected at other health care settings like hospitals or primary care settings is often made available to researchers in reports intended to inform not only health care providers and their practices, but the public as well. Organizations like ICES (an Ontario health care research organization) and the Canadian Institute for Health Information use administrative data from a variety of health care settings to identify trends that directly influence health care spending and policy. During the COVID-19 pandemic, the public relied on timely access to health data to determine what personal protective equipment to wear or whether to be vaccinated; public health officials used this data to make decisions on whether to close schools or stage reopening plans (Erica et al., 2021). This is not the case with SCS data.

There has been an overdose crisis for several years now in Canada (GOC, 2021). Had it been made public in a manner similar to data related to COVID19, data collected by SCSs could

have been used to serve as an early warning system to alert the public when particularly toxic drugs entered the country, or to warn policymakers of the increasing risk of overdose amongst people who use multiple substances. One might question the ethics of data collection if that data is not used to benefit the communities it is collected from, especially if it is collected without their input.

Chapter Three reviews the issues with data collection at SCS that have affected how this secondary data analysis was conducted. Because the same client may have used different codes, data was analyzed by visit rather than by unique client. It is true that if the data had been collected on computer, in a more methodical way, we may have been able to examine methadone dosage by unique client. This may have given additional insight into methadone dosage for SCS clients on a longitudinal basis. However, clients may have purposefully attempted to avoid this level of surveillance by using different codes.

Marginalized people have often been skeptical of how epidemiological data may be used against them (Taylor, 2017). The use of unregulated drugs is illegal in Canada with the exception of the SCS environment; SCS attendance implies a level of criminal activity that may affect several aspects of clients lives, such as employment, immigration status, and even ability to retain custody of their children. This is why the GOC allows SCS records to be anonymous, unlike other healthcare settings, but it is also why the clients of SCS may further hinder any efforts to identify them by mixing up the codes. Thus, there are two competing interests at play when looking at using SCS data for research – client desire for privacy, and the need for data to improve client health outcomes.

There is a practical solution to data collection with marginalized groups such as clients of the SHCHC SCS – involving the clients themselves in deciding what data should be collected

and how that data can be used. In this way, the clients are not: “bodies to be treated as troves of data, and as risks to be calculated. We are people to be consulted” (Bernard et al., 2020). There is a precedence of involving people who use drugs in the research on their community (Souleymanov et al., 2016). This involvement should move past research studies and be incorporated into the data collected by governmental organizations as well:

> Effective use of public health surveillance data is crucial but must be implemented with extensive community engagement. People must be given context for disease surveillance, to understand how data is collected and used. They must understand what risks could pose to individuals, and how those risks are mitigated. (Seiler et al., 2020, p. 38)

Chapter Two discusses the overrepresentation of Vancouver-based research in the body of peer-reviewed literature on SCS. Since 2017 dozens of SCS have been established across Canada (GOC, 2020a). They do not yet exist in every province, but they have expanded to communities quite different from urban Vancouver. There are SCS in smaller cities, in Francophone cities, and in the more politically conservative Prairie provinces (GOC, 2020a). The SCS experience in these other communities has yet to be fully examined by researchers. This means that smaller cities and towns attempting to implement SCS must often rely on research and grey literature developed in a context quite different from their own (Bardwell & Lappalainen, 2021). Similarly, the application requirements for SCSs in smaller communities have been developed with larger cities in mind based on existing research and data; imposing the same requirements on smaller communities hampers the establishment of SCSs there (Russell et al., 2020).

Addressing the unique nature of substance use in different communities requires that we diversify SCS research (Bardwell & Lappalainen, 2021). Using the existing data which has already been collected by SCSs in Canada to fulfill legal requirements is a low-barrier way to get an idea of SCS clientele and their needs with regards to both service provision and treatment.

## Recommendations

Given that the opioid overdose crisis continues unabated despite efforts to promote both treatment and harm reduction, there is great need for targeted and evidence-informed strategies. What follows are a list of recommendations derived from the results of this study in order to inform clinical practice, administration, and research. These recommendations are intended for a broad audience of people who provide services for people who use drugs. I then provide a list of nursing-specific recommendations in the areas of education, harm reduction service provision, and OAT prescribing.

### *Clinical Practice*

Individual prescribers should employ strategies to get patients to therapeutic dosages of methadone as quickly as possible including following the META:PHI methadone guidelines for people using fentanyl (Bromley et al., 2021) or the new CAMH OAT prescribing guidelines (CAMH, 2021). These strategies should be evaluated for effectiveness once broadly adopted. Clinicians who do not prescribe medications but who work in settings for people with OUD should be aware of the limitations of methadone maintenance treatment at lower doses, and advocate for policies which encourage retaining clients in continuous care.

### *Administration*

People designing and providing services for people who use opioids should not only prioritize OAT access but should also focus on strategies to promote access to therapeutic doses

of all OAT medications. This may include funding inpatient beds to allow for safe, rapid methadone titration (Hemmons et al., 2019) or low-barrier OAT clinics which allow for flexibility in clinic attendance (Strike et al., 2013).

People in charge of SCS administration include those who manage individual SCSs and those who oversee broader SCS programming in Canada (in both federal and the provincial governments). All administrators should ensure that data is collected for the primary purpose of improving health outcomes for clients (or prospective clients) of the SCS and includes complete demographic data wherever possible. Data on race and ethnicity of SCS clientele is particularly important to collect to make sure SCSs are designed in a way to best serve their local population. People with lived experience of SCS use should be consulted when plans for data collection are being formed to ensure that data is collected fairly and for just purposes in ethical ways that respect the dignity and humanity of SCS clients. People who use SCSs should also be consulted as to how data can be collected in a way that reflects unique users.

***Research***

This study suggests a possible correlation between a low methadone dose and frequency of SCS visits, and a lack of correlation between OAT status and observed non-fatal overdose in the SCS. There are many avenues for further research which may explore the nature of these associations both for SCS clients and the broader population of people on OAT. Longitudinal studies which study methadone dosage for unique clients over time may suggest methadone treatment trajectories beyond mere retention in care: frequent stops and starts related to variable clinic attendance, or involuntary treatment interruptions due to hospitalization or incarceration. Qualitative research with clients being prescribed different doses of methadone may uncover

reasons why clients may have difficulty advancing their methadone dose beyond 30mg, or whether there is a preferred methadone dose for individuals using different substances.

### *Nursing-specific Recommendations*

**Nursing Education.** Substance use affects people at every age, and in every care setting, but discussions on substance use and treatment are not consistently incorporated into nursing education. A survey of substance use in Canadian undergraduate nursing programs found that 56% of students had not received education about methadone or buprenorphine-naloxone (Gagnon et al., 2020). Graduate nursing students in the US also frequently reported that they received no substance use education at all (Compton & Blacher, 2020). Although harm reduction is listed as an entry-to-practice competency for registered nurses in Ontario, the term and nature of the education to be provided to meet this competency are left undiscussed in the provincial regulatory body's guidelines (College of Nurses of Ontario, 2018). The urgency of the opioid overdose crisis demands not only that OAT be specifically incorporated into undergraduate education, but that it be incorporated with enough nuance and depth to discuss methadone's particular pharmacological properties, prescribing guidelines, and dosage.

**Nursing and SCS.** There is currently no requirement for nurses to staff SCS in Canada, and provincial requirements for SCS in Ontario suggest only that a health care professional be present onsite during operation (MOHLTC, 2018). However, there is a long history of nurses in Canada being involved in harm reduction programming in general, and in staffing SCSs in particular (Danda, 2021; Pauly & Goldstone, 2008).

Recently, an international working group of nurses who work in SCS created a consensus document on SCS nursing (Gagnon et al., 2019). It suggests that knowledge of OAT is a foundational competency for nurses working in SCSs (Gagnon et al., 2019). A systematic review

on the role of nurses in methadone maintenance, however, suggests that even those who dispense methadone have knowledge gaps about the risks and benefits of the medication and proper dosage (Go et al., 2011). Given that SCS clients are often on OAT, specific guidance on appropriate methadone dosing for SCS clients should be incorporated into training for SCS nurses.

**Nurse Practitioners and Methadone.** So far, all guidance on methadone prescribing in Ontario has come from physician regulatory bodies or physicians themselves. Since the government removed the requirement for an exemption to prescribe methadone in 2018, nurse practitioners (NPs) in Canada have been permitted to prescribe methadone (College of Nurses of Ontario, 2018). However, it is unclear to what extent Canadian NPs have incorporated methadone prescribing into their practice. The College of Nurses of Ontario does not specifically regulate methadone prescribing by Ontario NPs or provide NP-specific education or guidance (College of Nurses of Ontario, 2018). A recent qualitative study of NPs in Nova Scotia suggests that knowledge gaps regarding OUD in general and methadone in particular might be significant barriers to NPs' provision of methadone maintenance treatment (Bates & Martin-Misener, 2021). Given the novelty of methadone prescribing by NPs in Canada, efforts to expand access to OAT and methadone should include education strategies tailored to NPs.

## Strengths

This study is the first to use SCS administrative data to link OAT usage with same-day non-fatal opioid overdose. The dataset consists of a large number of visits, accumulated over 6 months ($n$ = 12,099, March 11$^{th}$ to September 30$^{th}$, 2019), giving clear snapshot of OAT and opioid overdose at a certain period of time. Although the independent variables (e.g., substance used, methadone dosage) are based on self-report, the dependent variable (opioid overdose) is

based on the independent observation of trained individuals, using a consistent set of criteria (the administration of medicine in the form of oxygen and/or naloxone). The study is a clear demonstration of what can be learned from SCS data, interpreted within the local context of OAT availability.

**Limitations**

In addition to any effect that data collection may have had on interpretation of this study, (previously discussed in Chapters Three and Four), there are two additional significant limitations. It is a single-site study which analyzes data collected for a brief period of time (March 11th to September 30th, 2019). Although the client demographics of the SHCHC are similar to those of other supervised consumption sites, access to OAT is not. Therefore, results pertaining to OAT usage and dosage may not be generalizable to SCSs where OAT is not available onsite, or SCSs located in areas where methadone is not readily available at pharmacies nearby. Additionally, recent research from Toronto has shown that clients who use SCS frequently may be more likely to be on OAT than people with opiate use disorder who do not use SCS or use them infrequently (Scheim et al., 2021); for this reason, this study's results may not be applicable to other populations who use opioids.

The time period for this study was specifically chosen because it occurred before the global COVID19 pandemic and its myriad effects on both the illicit drug supply and number of overdoses in Canada. COVID19 caused interruptions to both the drug supply and harm reduction programming which together may have contributed to the large increase in opioid overdoses across Canada after March 2020 (GOC, 2021). Both the increased opioid overdoses and a desire to decrease any COVID19 transmission that may have occurred during illicit drug acquisition (both buying and selling) led to initiatives in certain parts of the country (including Ottawa)

where “safer supply” hydromorphone was prescribed to people with OUD as a replacement for illicit fentanyl (Bahji et al., 2021). Both the pandemic and efforts taken to mitigate its effects on people who use drugs had significant effects on the context of substance use in Canada. Thus, the results of a study using data from 2019 or earlier may not be applicable to the circumstances of substance use in subsequent years.

**Conclusion**

This secondary data analysis is an exploration of administrative data collected at supervised consumption visits from March 11th to September 30th 2019. There are two main findings from this study’s statistical analyses. First, a high number of SCS visits are associated with clients reporting being on 30mg or less of methadone. Second, there was no correlation between client report of OAT usage during a visit and reduced chance of opioid overdose during a visit. Although this study does not purport to show causation, the findings suggest not only that the ability of OAT to prevent opioid overdose is dependent on dosage, but also that sub-therapeutic methadone dosage is a significant problem for SCS clients who are already at a high risk of fatal opioid overdose. Recently published prescribing guidelines which serve to address barriers to therapeutic methadone dosage should be adopted by prescribers and encouraged by program administrators.

An additional finding of this study is that SCS data is underutilized as a tool to address the growing opioid overdose crisis in a timely manner. This data should be collected and disseminated publicly for the express purposes of saving lives, rather than just being held for administrative purposes alone.

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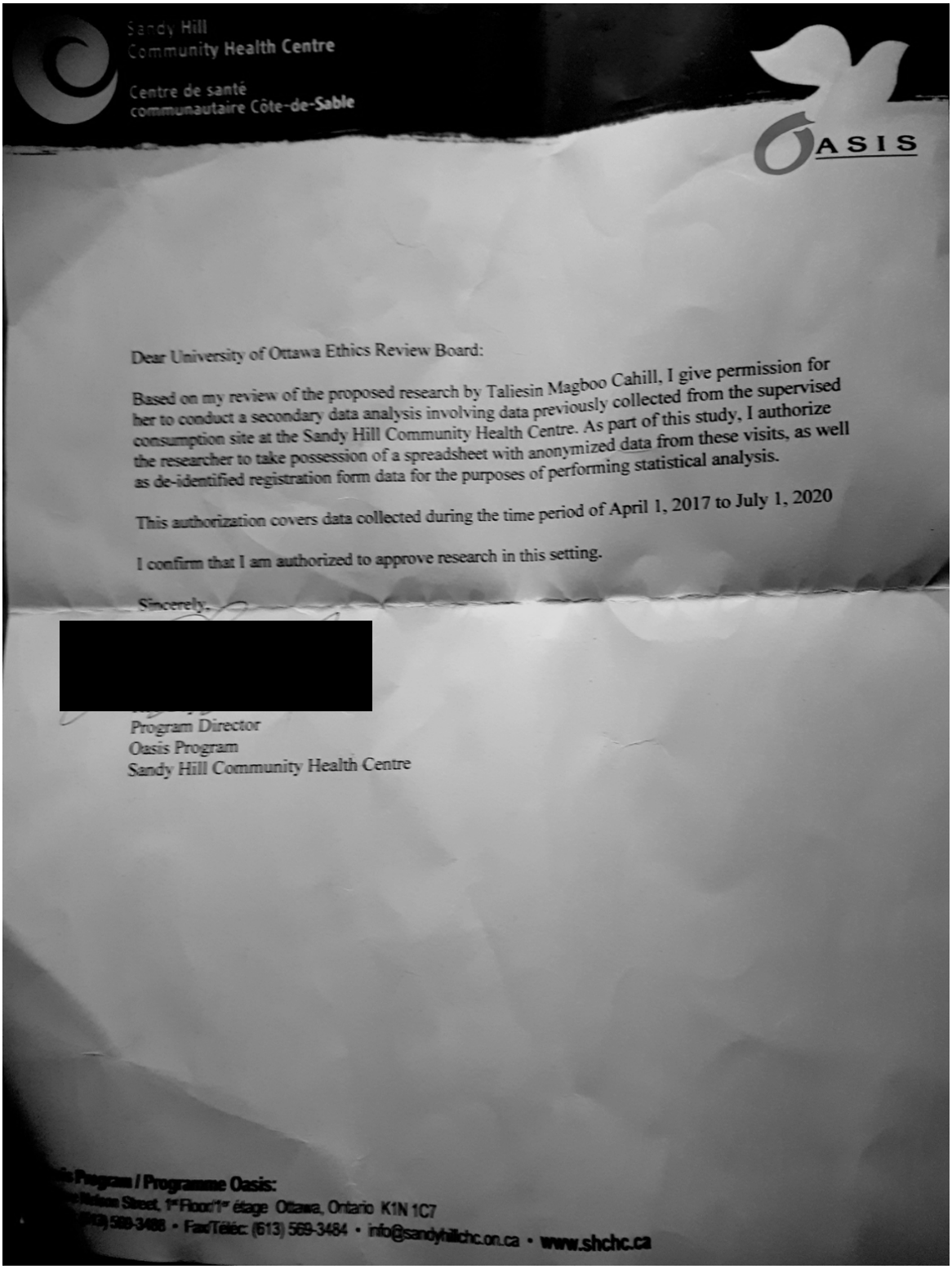
# Appendix A

## Permission to Use SHCHC SCS Data



Sandy Hill
Community Health Centre

Centre de santé
communautaire Côte-de-Sable

OASIS

Dear University of Ottawa Ethics Review Board:

Based on my review of the proposed research by Taliesin Magboo Cahill, I give permission for her to conduct a secondary data analysis involving data previously collected from the supervised consumption site at the Sandy Hill Community Health Centre. As part of this study, I authorize the researcher to take possession of a spreadsheet with anonymized data from these visits, as well as de-identified registration form data for the purposes of performing statistical analysis.

This authorization covers data collected during the time period of April 1, 2017 to July 1, 2020

I confirm that I am authorized to approve research in this setting.

Sincerely,

[redacted]

Program Director
Oasis Program
Sandy Hill Community Health Centre

...is Program / Programme Oasis:
...Rideau Street, 1st Floor/1er étage Ottawa, Ontario K1N 1C7
...(613) 569-3488 • Fax/Téléc: (613) 569-3484 • info@sandyhillchc.on.ca • www.shchc.ca

# Appendix B

## University of Ottawa Ethics Approval

Université d'Ottawa
Bureau d'éthique et d'intégrité de la recherche

University of Ottawa
Office of Research Ethics and Integrity

### CERTIFICAT D'APPROBATION ÉTHIQUE | CERTIFICATE OF ETHICS APPROVAL

| | |
|---|---|
| **Numéro du dossier / Ethics File Number** | H-11-20-6089 |
| **Titre du projet / Project Title** | The correlation between methadone dosage and the likelihood of opioid overdose: a secondary data analysis of supervised injection site visit data |
| **Type de projet / Project Type** | Thèse de maîtrise / Master's thesis |
| **Statut du projet / Project Status** | Approuvé / Approved |
| **Date d'approbation (jj/mm/aaaa) / Approval Date (dd/mm/yyyy)** | 06/11/2020 |
| **Date d'expiration (jj/mm/aaaa) / Expiry Date (dd/mm/yyyy)** | 05/11/2021 |

**Équipe de recherche / Research Team**

| Chercheur / Researcher | Affiliation | Role |
|---|---|---|
| Taliesin CAHILL | École des sciences infirmières / School of Nursing | Chercheur Principal / Principal Investigator |
| J. Craig PHILLIPS | École des sciences infirmières / School of Nursing | Superviseur / Supervisor |

**Conditions spéciales ou commentaires / Special conditions or comments**

550, rue Cumberland, pièce 154
Ottawa (Ontario) K1N 6N5 Canada

550 Cumberland Street, Room 154
Ottawa, Ontario K1N 6N5 Canada

613-562-5387 • 613-562-5338 • ethique@uOttawa.ca / ethics@uOttawa.ca
www.recherche.uottawa.ca/deontologie | www.recherche.uottawa.ca/ethics

# Appendix C

## SHCHC SCS Registration Form

Sandy Hill Community Health Centre
Centre de santé communautaire Côte-de-Sable

### *Supervised Injection Service Registration Form*

Date: _____/_____/_____
mm dd yyyy

Code: __ __ / __ / X/ __ __ __ __
(Code = FIRST TWO letters of mother's name / FIRST letter of client's name / X / year of birth /
Handle (optional): _____

**Registration Process**

□ SIS Rights & Responsibilities □ Injection Room Protocols Review
□ Emergency Contact Option Reviewed

Emergency Contact Name: _____ Relationship: _____

Contact Info (telephone, email and/or agency): _____

Ethnicity: _____ □ Prefer not to say

How did you hear about us? □ Existing client □ NEP Staff □ Peer □ Worker □ Detox
□ Health Care Provider □ Probation □ Police □ Website □ Other: _____

**Substance Use History**

| | | | | |
|---|---|---|---|---|
| Heroin | □ Last 30 days | □ Last 6 months | □Ever | □ No |
| Morphine/Hydromorphone | □ Last 30 days | □ Last 6 months | □Ever | □ No |
| Fentanyl | □ Last 30 days | □ Last 6 months | □Ever | □ No |
| Cocaine | □ Last 30 days | □ Last 6 months | □Ever | □ No |
| Crystal Meth | □ Last 30 days | □ Last 6 months | □Ever | □ No |
| Benzodiazepines | □ Last 30 days | □ Last 6 months | □Ever | □ No |
| Crack | □ Last 30 days | □ Last 6 months | □Ever | □ No |

Other: _____

Age of first IV use: _____
Have you injected in public in the last 6 months? □ Yes □ No
Have you shared injection equipment in the last year? □ Yes □ No

**Overdose**

Have you ever overdosed? □ Last 30 days □ Last 6 months □Ever □ No
Have you been trained on how to use naloxone? □ Yes □ No

Do you have a naloxone kit?
□ Yes □ I lost my kit □ I used my kit □ No, I would like one today. □ No, I'm not interested.

**What services have you accessed at the centre in the past?**

□ Drop-In □ Walk-in Clinic □ Primary Care Services (regular NP or physician here)
□ OAT □ Case Management □ Counseling Services
□ Smoking Cessation □ Social Services □ Other: _____

□ Profile created/updated Staff Initials: _____

# Appendix D

## SHCHC SCS Visit Form

**SHCHC Supervised Injection Service Visit Form**

New **Oasis SIS** Client? Yes ☐

Visit Date: _____/____/_____ (mm / dd / yyyy) Arrival Time:_____

Code:_____ Handle (optional):_____

Risk Factors (self-disclosed or observed): ☐ Youth ☐ Intoxicated ☐ Pregnant ☐ 1st Time Injector ☐ Methadone/Suboxone: _____ ☐ Recent OD: _____

Drugs to be injected:

☐ Crack ☐ Speed ☐ Cocaine ☐ Steroids ☐ Dilaudid/Hydro ☐ Fentanyl
☐ Heroin ☐ Benzos ☐ Crystal Meth ☐ Methadone ☐ Morphine ☐ Ritalin/Biphentin
☐ Other:_____

Route: ☐ Intravenous ☐ Intramuscular ☐ Nasal ☐ Oral

Do you intend to use the drug checking service? ☐ Yes ☐ No Staff Initials: _____

**Intake Worker Notes**

**Nursing Pre-Consumption Assessment**

Client Accessed Consumption Room ☐ Yes ☐ No Time: _____ EDT:_____ Booth #:_____

Level of Consciousness ☐ Normal ☐ Drowsy ☐ Intoxicated ☐ Nodding

**Post-Consumption Assessment**

Consumption Completed ☐ Yes ☐ No _____ _____ _____ _____

Level of Consciousness ☐ Normal ☐ Drowsy ☐ Nodding ☐ Overdose

Other Presentations ☐ Dyskinesia ☐ Rigidity ☐ Confusion ☐ Agitation

Overdose Intervention ☐ Oxygen ☐ Naloxone ☐ EMS Called

Client discharged to post-consumption area? ☐ Yes ☐ No Time:_____

→ ☐ Client declines post consumption monitoring

| Services Received | Referrals Received |
|---|---|
| ☐ Harm Reduction Education (safer injection, etc.)<br>☐ Supportive Listening/Counselling<br>☐ Drug Checking Service<br>☐ Naloxone (training or refills)<br>☐ Assistance with injection<br>☐ Wound Care<br>☐ Snack Pack<br>☐ Health Teaching: _____<br>☐ Clinical Services: _____<br>☐ Other: _____ | **Substance Use Services:** ☐ OAT ☐ SAR/OAARS<br>☐ Detox ☐ AMHS Counseling ☐ SCS/NEP<br>**Social Support:** ☐ Oasis Drop-In ☐ Food Programs<br>☐ Shelter ☐ Income Support (OW/ODSP)<br>☐ Centre 454 ☐ Social Services Walk-In (ID/OHIP)<br>☐ Housing Worker ☐ Clothing<br>**Clinical Services:** ☐ Oasis Clinic ☐ Case Management<br>☐ Oasis Counseling ☐ Mental Health Services<br>☐ TED Program ☐ Salvation Army Van<br>☐ Non-Emerg Transfer ☐ Rapid HIV Testing ☐ ER<br>☐ Other:_____ |

Staff Name:_____ Signature:_____

| Post-Consumption Nursing Notes |
|---|
| **Date/Time:** |
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# Appendix D

## META:PHI Guidelines Summary

### Summary

The recommendations given above are largely consistent (albeit different in emphasis) with the CPSO guidance document. However, we advise some novel practices, as summarized below:

| New recommendation | CPSO statement |
|---|---|
| (2e) After four consecutive missed doses, the dose of methadone should be reduced by 50% or to 30mg, whichever is higher.<br><br>For patients who miss five or more consecutive doses methadone should be restarted at a maximum of 30mg and titrated according to patient need. SROM at a maximum starting dose of 200mg can be added on the day of a restart, as long as the patient has not become completely opioid-abstinent. | (S6.14) If the patient misses two or more consecutive doses during the early stabilization phase, the MMT physician shall cancel all subsequent doses, assess the patient in person, and restart the patient maintaining this dose for at least three consecutive days.<br><br>(S6.15) The MMT physician shall reduce the dose to 30mg or less when a patient has missed four or more doses of methadone during the late stabilization and maintenance phases.<br><br>(S6.16) The MMT physician shall reduce the dose by 50% or to a dose of 30mg or less when a patient has missed 3 consecutive days during the late stabilization and maintenance phases. |
| (2g) Methadone dose increases should not be delayed due to the absence of an ECG. | (S6.18) The MMT physician shall order an ECG with a calculated QTc interval for patients on doses above 150mg. |
| (3a) Use prescription management practices that promote treatment retention, including phone assessments, extending prescriptions, or leaving longer duration methadone prescriptions for 30mg at the pharmacy so patients can restart treatment. | (S6.9) The MMT physician shall assess the patient in-person prior to each dose adjustment.<br><br>(G6.3) The MMT physician should ensure doses are only increased after the patient has been assessed in person, and it is determined that the patient is experiencing cravings or ongoing opioid use, and/or a constellation of withdrawal symptoms. |
| (3b) Prescribe take-home doses with due caution, beginning after at least one month of observed daily dosing. | (G8.2) The MMT physician should ensure the first weekly take-home dose is prescribed only after the patient has been in the program for two months, and prior to take-home dose acquisition the patient has had at least one week without problematic substance use, as determined by history and UDS. |

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