

Correlates of tapering initiation and success at an opioid agonist
treatment program in Northern Ontario

by

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Abstract

Currently, there is limited research on the correlates of tapering initiation and success in opioid agonist treatment (OAT). This research is part of a community-based participatory research study conducted in collaboration with a First Nation to describe and identify the benefits and areas of improvement for a community-based OAT program in Wiikwemkoong Unceded Territory. The study utilized retrospective chart review data for all active clients seeking treatment at the community-operated opioid replacement clinic, Naandwe Miikan, between May 2014 and December 2019. The correlates in this study were education level, age, gender, start drug, start dose in morphine equivalent dose (MED), and clients' number of children. Standard binary logistic regression was used to model the binary variables taper initiation and taper success. Models demonstrated that taper initiation and success were influenced by start dose in MED and start drug, respectively. There were no significant findings related to the sociodemographic correlates. The results from this study have assisted in reducing the substantial gap in knowledge surrounding correlates of taper initiation and taper success in a remote Northern Ontario setting. Findings also identified electronic record limitations that impede robust evidence-based practice at the community level to track the added value of various strengths-based, cultural and community services on clients' well-being and recovery. Lessons learned identify the need for data sharing agreements across health and mental health services in future research using patient chart data to investigate potential correlates of tapering initiation and success in opioid agonist treatment programs.

Keywords: Opioid agonist treatment, Indigenous peoples, First Nations, community-based participatory research, opioid tapering, tapering initiation, tapering success, retrospective chart review, tapering correlates

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Situating Myself

Before I present this thesis, I would like to situate myself in my research to give readers more context on who I am and why I am interested in research on this topic. My name is Matthew Henry-Hubert Zizys LeBlanc. I was born in Toronto, Ontario, the youngest in a family of six. I am French-Canadian on my father's side and Lithuanian on my mother's side. During my childhood, my family and I moved between Vancouver, Kelowna, and Toronto. While the majority of my life has been spent within the heart of Toronto, my early experiences in Vancouver and Kelowna were highly influential. In particular, as a result of the beautiful surroundings, I developed an affinity for the outdoors. This affinity has stayed with me throughout my life, and I believe this is an underlying influence in my interest in rural healthcare. In middle to late childhood, I was enrolled into a French immersion school. I believe that being enrolled into this program was beneficial as I was able to learn about the culture and language of a nation that is part of my identity. Similarly, during these years, I spent time during the summers at a Lithuanian language and culture camp. Attending this camp allowed me to learn about a culture and language that was oppressed in the past. My Lithuanian grandparents often recounted the oppression Lithuanians faced during the Russian occupation, and why they were forced to come to Canada. Reflecting on my nationalities, I believe that both have motivated me to work with Indigenous communities, communities that have been and continue to be impacted by colonialism and its oppressive practices of abolishing language and culture.

In high school, I became very interested in the international organization Doctors Without Borders. As a result, I was, and still am, fascinated with the delivery of healthcare services to rural and remote areas. In 2011, I travelled to Kenya for three weeks with Free the Children to help build a local school and teach in the community. While there, our group also

delivered a large amount of healthcare supplies to the local clinic. Immediately following this trip, I began my undergraduate degree in Health Studies at the University of Waterloo in Waterloo, Ontario. Before graduating, my goal was to continue to pursue international aid; however, international travel became less safe than it once was. Around this time, I started to learn more about the neglect and hardships that Indigenous peoples of Canada were being subjected to as a result of colonialism's legacy. I have always had a profound respect for all people and cultures and an interest in providing equitable care to those in need. Thus, I decided to refocus my research interests to healthcare in Canada and Indigenous communities. My original research interest was to collaborate with Indigenous communities, through community-based participatory action research (CBPAR) and photovoice, to evaluate and transform Western healthcare services to be more culturally appropriate for Indigenous communities. However, this research interest had shifted when I was encouraged to work on a study that was ongoing and thus, more suitable for a Master's degree timeline. As a result, my interest and study began to revolve around the ongoing opioid crisis.

The opioid crisis has had a personally devastating impact on my life from an early age. When I was 10 years old, my father passed away from an accidental opioid overdose. Initially, the truth of his passing was shielded from me, and I had attributed his death to a seizure that I assumed was related to the pseudo-parkinsonian symptoms he had developed as a side effect to his prescribed opioid use. However, in the early stages of this study I began questioning the circumstances of his death and it was revealed to me that it was in fact related to an accidental overdose precipitated by a relapse following unsuccessful treatment for opioid use disorder. This revelation challenged me throughout my years in this program, and there were many times where I considered that my closeness to the topic would prevent me from moving forward. Eventually,

I sought to overcome this challenge to uncover answers as to why my father and many others had become dependent on opioids, in the hopes that this research may help prevent unnecessary and accidental deaths to opioids. Throughout the research process, I chose to focus on the effects that sociodemographic and dosing characteristics may have on tapering initiation and success. My father's unsuccessful tapering during methadone maintenance treatment and eventual relapse were the catalyst for this decision. This brings me here today, where I write this thesis in defence of my Master's degree in Interdisciplinary Health at Laurentian University.

Table of Contents

Abstract	iii
Acknowledgements	iv
Situating Myself.....	vi
List of Figures	xi
List of Tables	xii
List of Appendices	xiii
Glossary	xv
1.0 Introduction.....	1
1.1 Background and Literature Review	2
1.1.1 Impact of the Opioid Crisis in Indigenous Communities.....	6
1.1.1.1 Land Dispossession	7
1.1.1.2 Acculturation	8
1.1.1.3 Social Marginalization.....	9
1.1.1.4 Political Oppression and Devastating Population Decline	10
1.1.1.5 Impact of the COVID-19 Pandemic on the Opioid Crisis in Indigenous Communities	11
1.1.1.6 Situating the Impact of the Opioid Crisis in Indigenous Communities.....	12
1.1.2 Opioid Agonist Treatment Options	13
1.1.3 Tapering in Opioid Agonist Treatment	16
1.1.4 Influence of Drug History and Toxicology Results on Tapering.....	20
1.1.5 Influence of Sociodemographic Characteristics on Tapering	22
1.1.6 Influence of Emotional Health Inquiry on Tapering	24
1.1.7 Influence of Patients’ Motivations for Treatment on Tapering.....	25
1.1.8 Conclusion.....	26
1.2 Approach and Context	27
1.3 Purpose of Study	30
1.4 Research Question	30
2.0 Methodology	32
2.1 Study Design	32
2.2 Study Population	34
2.3 Inclusion and Exclusion Criteria.....	34
2.4 Data Collection Method	36

2.5 Data Elements	39
2.6 Data Management	42
2.7 Ethics	42
3.0 Results	44
3.1 Effect of Drug and Sociodemographic Characteristics on Taper Initiation During OAT ..	44
3.2 Effect of Drug and Sociodemographic Characteristics on Taper Success	48
4.0 Discussion	52
4.1 Study Limitations	56
4.2 Study Strengths	58
5.0 Conclusions and Recommendations	60
5.1 Recommendations	60
Postscript	62
References	64

List of Figures

Figure 1. Flow chart depicting the inclusion and exclusion criteria used for research question...35

List of Tables

Table 1. Descriptive statistics (frequency/%) for clients' drug and socio-demographic variables and taper initiation during OAT (based on N=102).....	45
Table 2. Odds of taper initiation in relation to education level, age, gender, start drug, start dose (MED), and clients' number of children as correlates (based on n=102).....	46
Table 3 Descriptive statistics (frequency/%) for clients' drug and socio-demographic variables and taper success during OAT (based on N=53).	49
Table 4. Odds of taper success in relation to education level, age, gender, start drug, start dose (MED), and clients' number of children as correlates (based on n=52).....	50

List of Appendices

Appendix A.....	74
Gender.....	74
Age.....	74
Intake Date.....	74
Drug(s) of Choice.....	74
Average Daily Use.....	75
Length of Use.....	75
Route.....	75
Emotional Health.....	76
Social History.....	76
Marital Status.....	77
Number of Children.....	77
Custody.....	77
Household.....	77
Household Substance Abuse.....	77
Awareness of Others.....	77
Currently Employed.....	78
Highest Level of Education.....	78
Clients' Motivations for Treatment.....	78
Treatment Doses.....	78
Toxicology Data.....	78
Opioids.....	79
Amphetamines.....	79
Benzodiazepines.....	80
Anti-depressants.....	80
Anti-psychotics.....	80
Cannabinoids.....	80
Other.....	81
Illicit Substances in November 2018.....	81
Illicit Substances in November 2019.....	81
Taper Data.....	82

Current Reduction in Treatment Doses	82
Current Tapering Length	83
Previously Enrollment in an OAT	83
Appendix B	84
Summary Demographic and Treatment Statistics for Naandwe Miikan:	84
Gender of Clients	84
Age of Clients	84
Intakes Per Year	85
Starting Treatment Drug by Year	86
Treatment Length	86
Taper Data	87
Toxicology Results in November 2018	87
Toxicology Results in November 2019	93
Positive Toxicology Results for 2018 and 2019 for Illicit Substances	98
Taper Initiation Results for Naandwe Miikan 2014-2019	100
Education Level	100
Age	101
Gender	102
Start Drug	103
Start Dose	103
Number of Children	104
Taper Success Results for Naandwe Miikan 2014-2019	105
Education Level	105
Age	106
Gender	106
Start Drug	107
Start Dose	108
Number of Children	109
Appendix C	110

Glossary

Hyperalgesia – An increased sensitivity to feeling pain and an extreme response to pain.

Methadone – Replacement opioid used in the treatment of opioid use disorder.

Opioid Agonist – Opioid agonists such as methadone and Suboxone are therapeutic drugs that activate opioid receptors in the brain to help treat opioid dependence and withdrawal symptoms.

Opioid Agonist Treatment (OAT) – OAT involves taking medications such as oral buprenorphine/naloxone, methadone, or injectable extended-release buprenorphine to treat opioid use disorder.

Opioid Analgesic – Medications that act on opioid receptors and are used for pain relief.

Opioidergic – Chemically functions to directly modulate opioid systems in the body or brain.

Partial Agonist – An agonist which is unable to induce maximal activation of a receptor, regardless of the amount of drug applied.

Suboxone – A partial opioid agonist composed of buprenorphine-naloxone to treat opioid use disorder.

Tapering – The process of gradually lessening or reducing dosage.

Tapering Initiation – First dose data point that led to a clear pattern of reduction over at least a period of 3-months.

Tapering Success – Consistent adherence to the opioid agonist treatment program.

1.0 Introduction

When faced with the potential impacts of long-term (>3 months) opioid agonist therapy (OAT), exploring alternative treatment options that seek to transition opioid dependent individuals (ODIs) toward lower dose agonist therapy can be beneficial for both clients and their communities. Firstly, long-term OAT increases an ODI's risk for immune system depression, hormonal disturbances, hyperalgesia, fractures, and mortality (1-3). Importantly, these risks are linked to dose, where risks are more prevalent at higher doses (4). Thus, transitioning to lower doses through tapering programs can reduce the inherent risks of high dose maintenance therapy. Secondly, appropriately tapering high dose ODIs can reduce the burden on healthcare utilization by reducing emergency department visits and hospitalizations associated with high dose treatment risks (5,6). With these potential benefits of tapering in mind, it is important to emphasize that tapering is not without its risks. Failure to properly taper an ODI may result in relapse and adverse effects consistent with ODIs on long-term high dose treatment.

While there are no generally accepted guidelines on how to effectively taper an ODI, there is some evidence from the literature that can provide potential solutions to help minimize the associated risks of tapering (6-9). Of the limited studies conducted involving the evaluation of taper programs, results suggest that slow tapers and individualized approaches often produce more promising patient outcomes, compared with fast and generalized approaches (1,4,7,10). One such example promoting the need for individualized approaches to tapering, Kuntz et al. (2021), emphasize the importance of considering patients' clinical factors and personal circumstances when tapering. However, it is difficult to find conclusive evidence as to which clinical factors and personal circumstances stand as the most critical for ensuring successful

tapers. Based on a collaboration with a First Nations community and community leaders' interest in monitoring how the community-based OAT program supported tapering, the current study sought to investigate multiple factors examined in prior evaluations, to determine the potential correlates of tapering initiation and success for clients accessing the clinic. In order to shed light on this community-identified research question, this quantitative study used a retrospective chart review of all active clients at the community-operated opioid replacement clinic, Naandwe Miikan, in Wiikwemkoong Unceded Territory. The retrospective chart data was collected from all active clients' electronic medical records in order to determine the relative influence of correlates for taper initiation and/or taper success.

1.1 Background and Literature Review

Over the past two decades, Canada has been challenged with increasing trends in prescription opioid misuse and related harms (11-21). The most infamous pharmaceutical drug, largely held responsible for these increasing trends is oxycodone, sold under the brand name OxyContin (14,19,22-27). In 2000, Health Canada approved OxyContin and added the pharmaceutical drug to the Ontario provincial drug formulary (12-15, 22). This decision, in conjunction with OxyContin's aggressive marketing campaign, led to significant increases in opioid prescribing trends and prescription opioid misuse and related harms, one that two decades later is now widely viewed as the start of Ontario's opioid crisis (12-15,22). According to Dhalla et al. (2009), prescribing of OxyContin increased by 850% between January 1991 and May 2007 (22). In 2006, OxyContin accounted for roughly a third of all opioid prescriptions dispensed in Ontario that year (22). Moreover, the increased prescribing trends of OxyContin increased the

number of deaths attributable to opioids by 41%, and the number of deaths specifically attributable to OxyContin itself by 416% in a five year period from 1999 to 2004 (22).

Evidence suggests that the increased trends in opioid misuse and related harms occurring during and after OxyContin's introduction are a direct result of Purdue Pharma's (the pharmaceutical company manufacturing OxyContin), aggressive marketing tactics (12,22,25,26). Since its introduction as an opioid analgesic, OxyContin has been heavily marketed towards physicians as a miracle drug for pain (22,25-27). Throughout its marketing campaign, any concerns of abuse liability were downplayed and fraudulently reported as being almost non-existent (19,24-28). The original label stated, "Delayed absorption as provided by OxyContin tablets, is believed to reduce the abuse liability of a drug" (24,29,30). OxyContin, as prescribed, is a long-acting opioid analgesic with a delayed and extended absorption over 24-36 hours (22,26,30). Additionally, the FDA labelling provided warnings of the abuse liability if the drug was not administered orally, specifically citing "crushing" and "intravenous injection" of the drug (30). OxyContin had been steadily securing its place at the top of the pharmaceutical market for opioids for five years before negative media attention surrounding the drug's abuse, addiction, diversion, and overdose rates reached a boiling point (19,25,27).

In light of rising concerns of OxyContin's true risk for abuse and addiction, the FDA subsequently (in 2002), ordered Purdue Pharma to revise its claims on the original labelling to include information on the drug's potential for abuse and dependence. Purdue Pharma was also ordered to amend the original claim to state that data was not available on the reduced liability due to a delayed absorption (29,30). Eventual depositions of Purdue Pharma's Executives revealed that clinical trials had not been conducted to support the claims originally made on OxyContin's potential for abuse and addiction (26,29). Still, the eventual uncovering of Purdue

Pharma's strategies occurred too late. Pharmaceutical representatives had promoted the drug's safety and addiction risk during the initial years following its introduction into the pharmaceutical market (26,29). Combined with multiple financial incentives to prescribe the drug, the majority of physicians overlooked the fact that chronic prescription opioid addictions could develop in less than two weeks of use, with risks for addiction significantly increasing the longer the patient used the prescribed drug (26,28,31).

The promotion of OxyContin and incentives to prescribe occurred at a time when pain assessment and treatment were being treated as the fifth vital sign, meaning pain was being given equal importance alongside the other four vital signs: blood pressure, heart rate, respiratory rate, and temperature (19,26). The subjectivity and ambiguity of pain between individuals led to drastic increases in inappropriate OxyContin prescriptions for a wide array of acute and chronic pain (26,27). Physicians that recognized the true addictive nature of the drug and continued to express concerns were challenged by a growing community of Purdue Pharma representatives and pro-OxyContin physicians (26). The heavy emphasis on assessment and treatment of pain at this time, alongside success with the use of OxyContin at treating cancer related and non-cancer related chronic pain when taken as prescribed, led to a call to all physicians and dentists across the United States by Purdue Pharma that: "Prescribing OxyContin for pain was the moral, responsible, and compassionate thing to do..." (26). This call further suppressed criticism of anti-OxyContin physicians and bolstered pro-OxyContin physicians to new heights. What followed was an unprecedented shift in the overprescribing and lenient prescribing for the opioid analgesic that heralded a widespread crisis still affecting numerous communities two decades later. This shift in prescribing trends led to a dramatic increase in ODIs. Additionally, OxyContin at this time was so readily available, and the demand among ODIs was so high, that what

emerged was the practice, known as drug diversion, of using and/or selling prescriptions for non-medical purposes (12,15,19,22,25-27).

Across the United States and Canada, opioid overdoses as a result of drug diversion have plagued communities to the point of requiring mandated implementations of prescription monitoring programs (PMPs) for OxyContin (15-16,19,26-28). To offset the limited supply that patients could now receive due to the PMPs, the illegal manufacturing and selling of opioids has continued to this day (25,26). In 2007, Purdue Pharma pleaded guilty to charges of deceptive marketing in the United States and were fined in excess of 600 million USD (22,26,29). Six years later, in 2012, OxyContin and its substitutes were no longer manufactured or supported by Canada's federal and provincial drug programs (12-16,22). In the years since these new regulations, there has been an expected decline in OxyContin prescriptions and OxyContin-related overdoses; however, of particular concern, opioid prescriptions in general have continued to steadily increase (32). Research suggests that the restrictions placed on OxyContin increased the prescribing of opioids of comparable strength to meet the demands of pain treatment, defined as a 'substitution effect' (14-17). Additionally, opioid related deaths have continued to rise (12,15-17,23,32,33).

In Ontario, there was an increase from 867 opioid related deaths in 2016 to 1474 opioid related deaths in 2018 (33). More recently, it is necessary to analyze opioid related deaths in the context of the COVID-19 pandemic. In 2020, the number of opioid related deaths in Ontario increased to 2,426 (34). According to Gomes et al. (2021), "the absolute number of opioid-related deaths increased considerably across geographic regions of all population densities, with numbers nearly doubling in rural areas" (34 p20). Lockdown measures introduced during the COVID-19 pandemic led to reductions in OAT accessibility (35,36). As a result, criminal

markets began to flourish due to their virtually unrestricted access to illicit drug supplies, leading to an increased risk of overdose (34,37). Of note, the increased risk of overdose is largely attributed to the continued rise of fentanyl in illicit markets (34). In fact, fentanyl accounted for 87% of deaths in Ontario during the pandemic, an increase of 12% from the pre-pandemic prevalence of 75% (34). While the COVID-19 pandemic occurred after the data period we were investigating and as such did not factor into the analysis for this study, it is important that future studies consider the impact that the pandemic has had on the ongoing opioid crisis.

1.1.1 Impact of the Opioid Crisis in Indigenous Communities

To better understand the current state of the opioid crisis facing Indigenous communities in Canada, it is necessary to examine the historical, social, and political underpinnings that have heavily influenced present circumstances. Indigenous peoples represent a population in Canada that are particularly affected by opioid-dependence (18,21,36,38-44). For example, a study analyzing the impact of the opioid crisis on First Nations in British Columbia found that 12.8% of all overdose deaths in 2018 were among First Nations people, representing a 4.2 times greater rate of overdose deaths compared to other residents (43,44). The elevated levels of opioid dependence among Indigenous peoples have been attributed to the intergenerational trauma and abuse caused by colonialism and the Indian Residential Schools (IRS) (18, 21, 38-43). After the arrival of settlers in Canada, Indigenous communities were subjected to “land dispossession, acculturation, social marginalization, political oppression, and devastating population decline with increased morbidity and decreased life expectancy” (41 p2). Unfortunately, the traumatic effects of colonialism are not merely relics of the past; instead, the lasting, devastating effects of this historical period are still present today. While contemporary manifestations of the lasting effects of colonialism exist in many social and political forms, the effects are often particularly observed

within healthcare settings (38,45). Rural and remote opioid replacement services represent one area within the realm of healthcare where these effects are overwhelmingly present (11,21).

1.1.1.1 Land Dispossession

Land dispossession displaced Indigenous peoples to remote communities and reservations, which hindered and continue to hinder their ability to access high quality opioid replacement services (46). When compared to urban communities, rural and remote communities are known to suffer from a lack of primary care physicians, pharmacists, and nurses (11,47). This is especially troublesome when the two most common opioid replacement services, methadone and Suboxone, require a primary care physician, pharmacist, or nurse to dispense and monitor treatment doses (11,18,48). To further complicate matters, a methadone license is required to dispense and monitor methadone treatment (48,49). Only a limited number of rural and remote communities possess easy access to the health-care professionals listed above, let alone those with a methadone license (11,18). As such, readily increasing rural and remote access to methadone treatment has been regarded as being infeasible (49). In an effort to address the infeasibility of methadone treatment in rural and remote communities, all but two Canadian provinces have allowed Suboxone to be provided by health-care professionals without a specific license (48). While this alternative treatment option addresses concerns over a lack of licensed opioid service providers, it does not address the continued lack of health-care professionals in these regions. As a result, rural and remote community members requiring opioid replacement services often need to travel to more centralized institutions that have access to health-care professionals (11,50,51). Because treatment for opioid-dependency can last months to years, rural and remote community members are often required to not only travel to centralized locations that provide opioid replacement services, but to establish residency there as well (39).

Understandably, this is typically not economically feasible. Thus, land dispossession drastically impacts the current opioid crisis facing Indigenous peoples and communities by limiting access to high quality opioid replacement services and increasing the presence of economic barriers.

1.1.1.2 Acculturation

The processes of acculturation and assimilation that were introduced after the arrival of the settlers produced xenophobic tendencies that have had lasting effects (38,41,42).

Contemporary manifestations of the xenophobic tendencies accredited to colonialism's emphasis on acculturation and assimilation exist today in the perpetuation of racial discrimination targeting Indigenous peoples (38,45). In healthcare settings, this has led to poorer health outcomes, reduced access to necessary resources, and delayed or inadequate medical interventions, compared to non-Indigenous peoples (38,41). Furthermore, the increased risks that Indigenous peoples have for cardiovascular disease, metabolic disorders, mental illness, and alcohol and drug use, are still viewed by some health-care professionals as cultural characteristics (45).

Framing this increased risk as a cultural characteristic, rather than the result of trauma and the devastating effects of colonialism and IRS, perpetuates culturally insensitive and racist views (38,41,45). In the case of opioid replacement services, health-care professionals that cultivate culturally insensitive and racist views can discourage Indigenous peoples dependent on opioids from continuing treatment. What results is the promotion of a negative self-concept, at a time when health-care professionals should be supporting the patient in their journey to recovery. Of note, it is well regarded that a negative self-concept is correlated to increased substance use (38,52). Thus, the individual and systemic racism targeting Indigenous peoples, brought upon and perpetuated by colonial structures, negatively affects the self-concepts of opioid-dependent Indigenous peoples and promotes increased substance use.

1.1.1.3 Social Marginalization

Social marginalization due to political and economic disenfranchisement negatively influences health and accessibility of healthcare services (38,41). This is emphasized in the socially and economically deprived areas to which many Indigenous peoples have been marginalized (41). Indigenous peoples from these areas list economic barriers to healthcare services, as well as psychological stress and educational barriers (41). Consequently, these barriers influence each other and can perpetuate the inaccessibility to healthcare services. Lower education levels can result in lower socio-economic status, which can cause and exacerbate psychological stress, with the consequence that individuals are less likely to access healthcare services when needed (41). In addition, the effects of social marginalization are frequently associated with an increased risk for substance use (21,53,54). Concerningly, substance use, with an emphasis on opioid use, can further increase the social marginalization imposed on substance-dependent individuals by their respective communities (55). In a similar fashion to the effects of acculturation, the negative perceptions of substance-dependent individuals as “‘always high”, thieves, and untrustworthy’ (55 p433) by members of their communities impacts their self-concept in a way that can create a cycle of dependency (55). Importantly, while community differences exist, exclusion from spiritual practices is another form of marginalization uniquely facing opioid-dependent Indigenous peoples (55). Exclusion from spiritual practices, such as sweat lodges, affects an individual’s spiritual aspect of being, which can create a state of disharmony and unbalance (56,57). This disharmony affects the relationships between the three other integral aspects of being for Indigenous peoples: physical, mental, and emotional (58). Thus, the detrimental effects of colonialism’s legacy of social marginalization increases an

individual's risk of substance use, which can further increase perceived and actual marginalization, negatively affecting their holistic self.

1.1.1.4 Political Oppression and Devastating Population Decline

During the colonization of Canada, Indigenous peoples were subjected to political oppression, evidenced by the Indian Act and IRS, which resulted in devastating population decline (38). At that time, policies were designed to exploit, assimilate, and eradicate Indigenous peoples (38,42). Central to these colonial policies were the government-funded and church-led IRS, which represented “the most striking contemporary example of a systematic assault on Indigenous peoples and Indigenous ways of life” (59 p117). Indigenous children were forcibly removed from their families and their communities, as the federal government and the churches did not agree with Indigenous ways of life, believing that “Aboriginal parenting, language, and culture were harmful to Aboriginal children” (38 p4). Today, the effects of political oppression and devastating population decline “persists through collective and intergenerational trauma and loss of culture, language, and tradition” (59 p117). The intergenerational trauma and abuse inflicted by colonial policies have been directly linked to negative physical and mental health outcomes, increased suicide rates, and increased substance use rates among Indigenous peoples (21,38,42,58). In regards to increased opioid use among Indigenous peoples, many opioid-dependent individuals attribute their dependencies to prescriptions liberally provided by “fly-in” physicians working on short-term contracts for Health Canada, the federal department that administers Aboriginal health care” (39 p1447). The cultural genocide during the colonization of Canada resulted in culturally inappropriate healthcare services that do not consider factors important to Indigenous peoples (51). In the absence of a concentrated effort by physicians and researchers to collaborate with Indigenous communities to create opioid-replacement services

that incorporate Indigenous health beliefs and practices, the injustices imposed on Indigenous peoples and communities may persist. Thus, the devastating population decline and assault of Indigenous ways of life by way of political oppression have significantly contributed to the increased trends in opioid use observable today.

1.1.1.5 Impact of the COVID-19 Pandemic on the Opioid Crisis in Indigenous Communities

While increased trends in opioid use were observable prior to the COVID-19 pandemic, the pandemic exacerbated the opioid crisis disproportionately in Indigenous communities. A report prepared in 2021 by The Chiefs of Ontario and The Ontario Drug Policy Research Network found that, “the number of deaths related to opioid poisonings more than doubled during the pandemic (from 50 to 116 deaths; 132% relative increase among First Nations people), compared to a 68% increase among non-First Nations people” (40 p15). As previously stated, the rise in opioid related deaths has been largely attributed to the continued rise of fentanyl in illicit markets – markets which saw a boom due to lockdown measures and subsequent reductions in OAT accessibility (34-36). The current state of the opioid crisis, especially in Indigenous communities, has reinforced the urgency for effective OAT treatment programs. It is important to emphasize that this is not a novel crisis brought on by the COVID-19 pandemic, but one that has been ongoing for decades. As such, there are existing strategies that have been designed and implemented by Indigenous communities to treat opioid dependencies in their communities. This aligns with Article 23 of the United Nations Declaration on the Rights of Indigenous Peoples, which states “Indigenous peoples have the right to determine and develop priorities and strategies for exercising their right to development. In particular, indigenous [sic] peoples have the right to be actively involved in developing and determining health, housing and

other economic and social programs affecting them and, as far as possible, to administer such programmes through their own institutions” (60 p18). An example of this self-determination being exerted in developing and determining health programs – and the focus of this study - is the community-operated OAT clinic Naandwe Miikan in Wiikwemkoong Unceded Territory on Manitoulin Island, Ontario, Canada (51). Naandwe Miikan was established in May 2014 to address community concern over inaccessibility of appropriate opioid treatment services, and the increases in criminal behaviour related to obtaining opioids to self-medicate (36). Services offered at Naandwe Miikan are focused on providing culturally safe care to address the rising rates of opioid dependencies in the community (36). Instead of solely treating the physical aspects of opioid dependencies – as is generally the case with mainstream models of OAT - Naandwe Miikan incorporates “a holistic approach to recovery, integrating cultural approaches, educating the community on harm reduction, and maintaining a long-term recovery goal of eliminating drug therapy when this can be done safely” (36 p7). As part of the self-determination in health, the community leadership is greatly interested in monitoring the effectiveness of the clinic model, which led to this study.

1.1.1.6 Situating the Impact of the Opioid Crisis in Indigenous Communities

Before introducing the available OAT options, it is necessary to situate the impact of the opioid crisis in Indigenous communities. It is crucial to consider the aforementioned structural determinants of health linked to colonialism when seeking to address inequalities in proximal and intermediate determinants of Indigenous health (58). When examining some of the determinants of health evidenced to contribute to opioid use, namely, adverse childhood experiences, historical abuse and trauma, poor living conditions, and reduced access to adequate educational and employment opportunities, it is clear that colonialism and IRS may have direct

and indirect effects on these domains of Indigenous health (38,41,58,59). As researchers and health-care professionals, we cannot hope to provide meaningful program evaluations and/or recommendations with Indigenous communities if we ignore the most influential structural determinants (58). For this study, limitations in the data and restrictions imposed due to the COVID-19 pandemic made it infeasible and impossible to fully analyze and evaluate our clinic of interest within an Indigenous social determinants of health intersection. Measures assessing more proximal social determinants were limited to education level, age, gender, and clients' number of children. However, this study sought to address this limitation by collaborating with Wiikwemkoong Unceded Territory to ensure that meaningful evaluations and recommendations could still be generated based on available information. This study is focused primarily on the biological aspects of opioid use and treatment seen in mainstream models of OAT, that can be studied with the limited information present in the patient charts. Due to these data limitations, this thesis is less focused on the holistic and cultural programmatic approaches that exist at Naandwe Miikan, however, these important areas that reflect more of the Indigenous understanding of health and well-being are explored in other portions of the larger research study through provider and client interviews (36).

1.1.2 Opioid Agonist Treatment Options

There has been a surge in pharmacological treatment options available in Canada for opioid dependency – which began with methadone maintenance treatment (MMT), followed by an increase in the availability of buprenorphine-naloxone (Suboxone) programs as a MMT alternative (13,48,61). In recent years, there has been growing interest in alternative OAT treatment options, which include buprenorphine extended-release injection (Sublocade), slow-release oral morphine, and diacetylmorphine and hydromorphone injections (62,63). It is

important for future researchers to be aware of these newer alternatives; however, for the remainder of this thesis, the focus will be solely on explaining and evaluating the two OAT treatment options available at Naandwe Miikan at the time of this study, MMT and Suboxone. MMT and Suboxone programs aim to replace the dependency on opioids with therapeutic doses of methadone or Suboxone, respectively, to sufficiently reduce the negative effects of withdrawal symptoms and cravings (1,9,64). While the primary goal is to improve patient quality of life through symptom control – facilitating a return to employment, school, family, and social life, there are also beneficial secondary goals for communities with OAT programs (65). Examples of secondary benefits include a reduction in the societal and economic burden of opioid dependency, demonstrated by marked declines in opioid-related criminal activities and decreased healthcare costs associated with frequent and/or repeated reliance on primary detoxification interventions (64,66,67). After sufficiently reducing the impact of withdrawal and cravings, it is possible for an ODI to have an easier time transitioning to long-term opioid therapy (LTOT) – defined as replacement treatment lasting 3-months or more – or to an abstinence approach, generally precipitated by an individualized taper schedule (1,64).

As of 2018, Canadian national guidelines recommend Suboxone, as the first line of treatment for individuals presenting with opioid-dependencies (48,61). Suboxone is a partial opioid agonist that is administered sublingually to treat and manage opioid dependencies (18,48,49,61). Suboxone has been demonstrated to be effective at achieving detoxification by managing withdrawal symptoms, and preventing relapse through stabilization based on prolonged use of substitution medication in treatment programs (18,48,61). Additionally, compared to full opioid agonists, such as methadone, evidence suggests that Suboxone has a reduced risk of overdose, abuse liability, and side effects (48,61,68,69). To understand this

increased safety profile, it is necessary to view Suboxone's components, buprenorphine and naloxone, in isolation. Buprenorphine, the partial opioid agonist component, has a higher affinity to the brain's opioid receptor, allowing it to displace methadone, morphine, and heroin to provide extended opioidergic effects over a period of 24 hours or more with an inherent maximal effect on the opioid receptor that is lower than competing agonists (61). The lower maximal effect on the opioid receptor allows for a decreased risk of complications associated with unintended overdoses, primarily respiratory depression (61). Naloxone, the opioid antagonist component, is not activated when Suboxone is administered sublingually. However, if an ODI attempts to crush or dissolve Suboxone so that the drug can be administered in an alternate fashion, e.g., snorting or intravenous injection, naloxone's opioid antagonistic effect activates to block the brain's opioid receptor, preventing the euphoric effects of buprenorphine (61). While the available literature supports Suboxone's increased safety profile over full opioid agonists, recommended treatment and length must be tailored to the severity of an individual's opioid dependency and their desired treatment outcome (48,61).

In the event that an ODI does not respond well to treatment with Suboxone, or if the patient suffers from more severe opioid dependency, then treatment guidelines recommend using methadone (48,61). MMT involves the supervised administration of methadone, a full opioid agonist, by a licensed health-care provider (11,48,61). Since methadone does not have a limit to its effect on the opioid receptor, as Suboxone does, methadone doses can be adjusted to suit the specific needs of an ODI. In essence, this means that methadone can continue to manage withdrawal symptoms in ODIs with more severe dependencies, whereas Suboxone is unable to effectively manage comparable symptoms once the opioid receptor has been activated by buprenorphine. This is potentially a more effective treatment option if the ODI presents with a

severe dependency, characterized by a long history of opioid use, injection heroin use, high tolerance, and frequent use (61). ODIs presenting with these characteristics have shown greater treatment retention when treated with methadone instead of Suboxone (70,71). However, comparing the use or effects of methadone and Suboxone is not practical, as it is not uncommon for ODIs to transfer between the two treatment options over time, as required (72). In situations where Suboxone is not eliciting an appropriate therapeutic response to pain and withdrawal symptoms for an individual, a transfer to methadone treatment is often initiated. Similarly, when the risks of methadone maintenance outweigh the benefits of switching to Suboxone, a methadone taper is often initiated, which allows for an ODI to transfer to Suboxone more effectively (65,73). A methadone taper prior to the transfer to Suboxone is important, as performing this transfer for an ODI receiving an average MMT dose between 60-100 mg has been shown to increase relapse and worsen treatment outcomes (73). Instead, tapering the methadone dose to 30-40 mg or less prior to treatment transfer is recommended in order to reduce the risk of relapse for the ODI. Before, during, and after a decision to initiate a transfer either from Suboxone to methadone, or vice versa, it is imperative that three criteria are closely monitored and evaluated: 1) prevention and effective management of withdrawal symptoms; 2) reduction in opioid cravings; and, 3) improvement in physiological functions that were affected by the prolonged unsanctioned use of opioids (74).

1.1.3 Tapering in Opioid Agonist Treatment

In regards to pharmacological treatment dosing plans, a patient can follow three routes of treatment administration: abstinence-based, long-term maintenance, or tapering. Firstly, it is important to note that an ODI can follow an abstinence-based plan, but this is not recommended, as there are documented low retention and high relapse rates that can lead to overdose (48,61). It

is the relapse to previously tolerated doses of illicit opioids that can occur following treatment dropout – typically an instance where the ODI has been maintained on a lower dose – that is a crucial risk for overdose. Of course, this risk exists for all treatment plans, however, the documented lower retention rates specifically for abstinence-based models is a primary concern. Still, abstinence is often documented in the literature as a treatment goal and used as a measure of treatment success (72,75,76). However, there is an important distinction in the abstinence that is sought in these instances. Here, abstinence is often used to describe abstinence of illicit opioids during treatment, not the treatment opioids themselves. While abstinence from illicit opioids is arguably a universal goal of all OAT programs, abstinence-based treatment plans that seek to prevent the use of opioids – both illicit and prescribed – are substantially riskier and less effective than OAT in the primary care management of ODIs (7,71,72,80). With this in mind, the majority of OAT plans recommend either long-term maintenance or tapering. Long-term maintenance involves the prolonged administration of therapeutic doses of either methadone or Suboxone to treat chronic non-cancer pain (CNCP).

Tapering involves the gradual reduction in an ODI's methadone or Suboxone dose generally for one of three reasons: 1) facilitate a transfer from methadone to Suboxone; 2) facilitate a transfer from OAT to abstinence from opioid agonist therapy; or, 3) arrive at an overall safer therapeutic dose. Critically, long-term maintenance and tapering are not mutually exclusive. For example, over a five-year treatment period, an ODI may undergo multiple instances of periodic tapering, followed by long-term maintenance until the ODI's body is ready to tolerate this cycle again. Interestingly, while both long-term maintenance and tapering treatment plans are routinely recommended depending on the ODI's unique situation, published studies and patients favour tapered approaches to treatment (77). In fact, while conducting a

comprehensive review of tapered approaches to opioid treatment, Davis et al. (2020) found that 75% of ODIs with CNCP chose to taper their opioids when the option was offered by their physician (77). Tapering is beneficial for both ODIs who fit the criteria to initiate tapering, as well as local communities by reducing the availability of potent opioids that can be diverted (78). Moreover, a preference for tapering benefits office-based physicians by allowing them to treat more patients and reduce the need for long-term maintenance – which could reduce the overall financial impact of OAT on healthcare spending. (75,77).

At a glance, community and clinical preference for a tapering approach appear overwhelmingly beneficial; however, it is immensely important that the judgment of when to taper by both physicians and ODIs not be clouded by a desire to taper before the ODI is ready to do so. A shift in treatment recommendations in this regard could prove fatal for ODIs that are not physically or emotionally fit for taper initiation. Studies have provided evidence that forced or inappropriate tapers can significantly increase psychological (suicidal ideation, depressive and anxious symptoms) and physical (withdrawal symptoms, increased pain sensitivity) distress that can eventually lead to treatment dropout, relapse, and/or death (1,4,6,7,10,73,81). Supposing, then, that tapering is suitable and appropriate for an ODI, the question becomes: what is the recommended taper length? This is a difficult question to answer, as there is not a definitive answer outlined in the literature. Recent studies have examined and evaluated tapering mechanics, but few have compared treatment lengths. More often than not, an ODI's treatment length is so specific to their unique situation – such as, drug history, route of administration, severity of opioid dependence, individual response to methadone vs. Suboxone, and history of treatment dropout and/or relapse - that comparison between ODIs is not feasible (1,6,8,77). Therefore, recommendations for treatment lengths places more emphasis on a physician's

subjective experience with past treatment of ODI's specific situations, instead of the limited evidence available.

While the specifics of length are arguably at the physician's discretion, consensus has been reached on the rate or speed at which tapering is performed. In general, recommendations favour a slow approach to tapering, slowing further when the original dose has significantly been reduced (6,7,65,72,74,79). When there is mismatch between rate of tapering and specific patient needs, as can be the case in moderately paced tapering plans, there is a risk of destabilization, characterized by increased psychological and/or physical distress (6,7,9). In 2016, the AFN Special Chiefs Assembly expressed concern over tapering opioid-dependent individuals off Suboxone too quickly, stating that "withdrawal symptoms – insomnia, anxiety, cravings – can last for months after the last dose of opioids" (82). Importantly, continued use of illicit opioids during and after treatment, a common problem among ODIs, often occurs due to the patients' strong desire to avoid withdrawal symptoms associated with destabilization (10,77,83).

Two critical methods to guard an ODI from potential destabilization include ensuring the ODI can pause the taper when needed and achieving a sufficiently slow pace to a taper for the specific individual – which will involve experimenting with dose responses to the management of pain and withdrawal symptoms, effectively prolonging treatment regimens (84). Highlighting the need to prolong treatment regimens, Katt et al. (2012) found evidence to support that a 1-month treatment program was more effective at achieving treatment retention and completion, compared to a tapering program of 5 days (68). Furthermore, some studies have recommended treatment programs of 6-months to a year, suggesting that early tapering, even as early as 1-month, was detrimental to ODIs, as this increases the risk of relapse and withdrawing from the treatment program (21,49). National guidelines provide evidence that short (7-28 days) and long

(28-56 days) taper programs are not recommended if treatment has not been successful and/or sustained in the past (61). Additionally, if treatment has been successful and/or sustained and the patient decides they wish to taper, a slow, extended, taper approach over months to years is recommended (61).

Management of withdrawal symptoms alone has shown to negatively affect retention rates, thus increasing relapse rates, suggesting that it is necessary to incorporate concurrent counselling and rehabilitation services to address the factors that led to opioid dependency in the individual (13,18,20,23,25). However, the implementation and/or evaluation of available counselling and rehabilitation services is outside the scope of this study. Instead, there is a need to examine individual factors outside of the mechanics of the treatment itself, and their potential influence on tapering success as a necessary first step in understanding the mechanisms of treatment and other rehabilitation services. For example, in recent years, there has been a growing interest in examining OAT programs from the perspective of ODI-specific factors that would influence an individual's tapering success, potentially leading to reductions in treatment dropout, relapse, and/or death. The following outlines ODI-specific factors found to influence tapering, including drug history and toxicology, sociodemographic characteristics, clients' emotional health, and their motivation for treatment.

1.1.4 Influence of Drug History and Toxicology Results on Tapering

Two such ODI-specific factors that may have an effect on an individual's tapering success are the ODI's drug history and their toxicology results. Firstly, an ODI's drug history may potentially predict concurrent illicit opioid use, and negatively influence taper success. For example, heroin is an illicit opioid particularly emphasized in the literature for its role in influencing tapering outcomes among ODIs (85-87). To understand heroin's role here, it is

essential to view the opioid from its preferred route of administration. Heroin is typically administered intravenously, which places individuals at risk for a much stronger opioid dependency (85-87). Treatment for a strong opioid dependency would likely involve MMT, initially at a larger dose to meet the requirements of a stronger dependency. Over time, there would be a gradual attempt at tapering this large methadone dose down to a sufficiently low dose that could then be used to transition the ODI to Suboxone's greater safety profile. It is at this gradual taper attempt that a history of heroin use can prove problematic. Since heroin use would necessitate a higher dose than the average treatment dose used to maintain positive treatment outcomes, a gradual taper attempt could elicit withdrawal symptoms and increased sensitivity to pain, both of which may promote taper discontinuation and/or relapse (73,85). Additionally, an individual's reason for initial opioid use is important in predicting likelihood for relapse. For instance, successful outcomes may be compromised if an individual initially began using opioids for the purposes of getting high as opposed to treating symptoms of pain, as is common with the use of heroin (85). Still, there are cases where an ODI's resolve in seeking successful treatment could offset the risks of a history of heroin use. For example, a study by Woodcock et al. (2016) found that participants with a higher number of lifetime heroin quit attempts maintained longer periods of abstinence from concurrent illicit opioids during a Suboxone dose taper (79).

Aside from a history of illicit heroin use, three other drug histories have been considered to negatively influence tapering outcomes. Firstly, concurrent benzodiazepine use – both illicit and prescribed - during OAT has long been considered a risk factor for relapse and overdose. When considering risks to tapering outcomes, Sturgeon et al. (2020) found that concurrent benzodiazepine use increased the risk of dropout from both long-term opioid tapering and buprenorphine transition treatment plans (78). Similarly, a systematic review on predictors of

successful OAT by Orlikova (2017) also found that benzodiazepine use, often obtained illicitly, had a negative effect on maintenance and retention (88). Secondly, recent studies have suggested concurrent amphetamine use to pose a similar risk for treatment maintenance and retention. It is not evident why amphetamines pose such a risk, however, it is plausible to suggest that the drug-seeking behaviour typically present in individuals seeking diverted supplies of illicit drugs could reinstate a habit of purchasing opioids from these illicit markets. Lastly, cocaine has been considered to affect treatment maintenance and retention in a similar fashion as benzodiazepines and amphetamines. Unique to cocaine, however, is a relatively recent increase of nearly 60% from 2010 to 2015 in cocaine-related overdoses (74). Importantly, these cocaine-induced overdoses have occurred in the presence of synthetic opioids, of which methadone and Suboxone are included (74). Moreover, synthetic opioids are popular in illicit drug markets as cutting agents for other drugs or sold on their own.

To confirm the presence of concurrent illicit substance use during treatment, toxicology tests are performed. The toxicology results tend to verify the substances that are having a particularly potent impact on a community. Historical use of illicit substance markets could predict a tendency for an ODI to self-medicate when they believe that tapering and/or treatment are insufficiently managing their withdrawal symptoms. Thus, it is the interplay between an ODI's knowledge and familiarity of illicit opioid markets within their communities that poses a significant risk to long-term treatment maintenance and retention.

1.1.5 Influence of Sociodemographic Characteristics on Tapering

Sociodemographic characteristics provide vital information that has been shown to impact tapering outcomes (20,71,88-91). Namely, age, number of children, living arrangements, employment status, and level of education have been previously investigated for their effects on

treatment maintenance and retention (20,71,88-91). For example, past studies analyzing predictors of successful OAT have found that younger ODIs, particularly those between the ages of 18 and 25 years, have an increased risk of dropping out of treatment due to relapse and concurrent illicit substance use, compared to older ODIs (20,72,88). This discrepancy in treatment outcomes depending on age could be explained by older adults having greater opportunities to seek treatment in the past, which has led to greater resolve to see treatment through to the end and/or has led to the development of a more refined treatment plan with the physician based on past experimentation. Next, Orlikova (2017) found that the presence of children influenced ODI's drug history and use, which in turn influenced tapering outcomes (88). In particular, it was concluded that heroin, marijuana, and benzodiazepines were the illicit substances preferred by ODIs without children; while ODIs with children tended to substitute heroin use with increased use of illicit opioids with less risk and social stigma, such as illicit methadone, and increased use of legal substances, such as tobacco and alcohol (88). Moreover, an ODI's living arrangements may influence tapering outcomes. Undoubtedly, ODIs living in the same household as other ODIs can pose a significant risk for relapse and discontinuation of treatment. Conversely, living in a supportive household with individuals not using other substances may positively influence treatment outcomes (92). Lastly, employment status and level of education represent potential income security that could influence an ODI's treatment outcomes. Studies have shown that individuals who are currently employed and have higher levels of education have an increased likelihood to continue treatment and abstain from concurrent illicit substance use (91). On the other hand, unemployment among ODIs may negatively impact the individual and their communities, by necessitating criminal behaviour in order to afford illicit substances, which can include increasing the availability of illicit

prescription substances in a community through the process of diversion of the medications prescribed to their friends, families, or themselves. Of note, Davis et al. (2020) recommended employing unemployed ODIs who had shown success in tapering, as this may provide support and stability that would further encourage successful treatment outcomes (77). It is clear that one's level of social support and stability is critical to treatment progress and outcomes.

1.1.6 Influence of Emotional Health Inquiry on Tapering

At intake, an emotional health inquiry is typically conducted which can elucidate an ODI's presenting emotional status (93). Responses may uncover additional correlates of tapering outcomes. The presence of depression, anxiety, and/or post-traumatic stress disorder (PTSD) are emphasized as potential correlates found within the emotional health inquiry (7,77,85,88,94).

In recent years, it has been debated whether depression positively or negatively influences treatment outcomes for ODIs. For example, Berna et al. (2015) suggest that depression, among other factors, is a key predictor in tapering discontinuation and relapse (94). Additionally, others have suggested that a history of depression predisposes an ODI to increased sensitivity to pain and withdrawal symptoms that may present themselves during tapering, increasing the risk of tapering discontinuation and relapse. Conversely, a study conducted by Weiss and Rao (2017) found that ODIs with major depressive disorder "had nearly twice the odds of achieving a successful outcome" (85 p6). Similarly, Orlikova (2017) also found that ODIs with major depressive disorder showed increased treatment retention rates and, in fact, a decreased risk of concurrent illicit substance use (88). It is not entirely clear what the explanations are for these findings, however, it has been hypothesized that for the ODIs being treated with Suboxone, the antidepressant effects of buprenorphine may be one explanation (88).

Another possible explanation that has been considered is that depressed ODIs may be more motivated to continue treatment in order to achieve more stability in their lives (88).

In terms of anxiety, the influence of a history of anxiety seems to be most important during the decision to taper. Anxiety over fear of increased pain and withdrawal symptoms can cause an ODI to be unwilling to initiate or continue tapering (7). However, contrary to popular belief, particularly among ODIs, Davis et al. (2020) concluded “most patients tapered off opioids do not experience increased pain, and in fact, may experience a reduction in pain intensity over time” (77 p590). Thus, it is logical that given the appropriate education and resources during the tapering decision making process, an ODI should feel confident that their fears of increased pain and withdrawal symptoms with tapering may be unfounded. Lastly, PTSD has also been emphasized for its potential influence on tapering outcomes (77). Notably, the presence of PTSD has been highlighted as requiring specific attention when considering tapering, as tapering has demonstrated increases in suicidal ideation for this population (77). Thus, it is critical to consider factors of emotional health when deciding to taper, as inappropriate tapers can lead to outcomes that significantly differ for specific populations of ODIs, ranging from relapse to death due to overdose.

1.1.7 Influence of Patients’ Motivations for Treatment on Tapering

Lastly, ODIs’ motivations for treatment can influence tapering initiation (77,90). It is well established that ODIs who are motivated to treat their opioid dependencies are more likely to request taper initiation, compared to ODIs lacking motivation (77,90). Furthermore, it has been suggested that this motivation for treatment could also improve treatment retention (77,90). Specific motivations that have been documented include: family/custody/children; personal health concerns; employment; maintain abstinence from illicit opioids; legal concerns; financial

concerns; and, education concerns (77,90,95-99). One motivation that requires increased consideration is patients' concern over the well-being of their children and their desire to regain custody in situations when child protection services are involved (95-99). For example, studies have suggested that this motivation can act as both a barrier and facilitator to seeking treatment, due to fear of children being removed from their care and child reunification, respectively (95-97). Concernedly, by acting as a barrier to seeking treatment, parents may inadvertently be exposing their children to adverse experiences (99). As a result, this fear of loss of custody, may in fact, increase reporting of opioid dependent parents to child protection services, perhaps preventing the possibility of regaining custody in the future (95-97). Additionally, parents with a greater number of children have been found to be more likely to experience child protection service involvement (97,98). This reinforces the need to implement treatment programs that advocate for and assist with client motivations, and increasing their support systems (36,97). More evidence for the relative influence of specific reasons or incentives for tapering and treatment are needed to improve program development and patient supports.

1.1.8 Conclusion

Based on a review of the literature, the issue of tapering is very complex, and outcomes can significantly differ between ODIs depending on the multiple factors that have been shown to influence the therapeutic success of tapering. It is vitally important that physicians not initiate tapering as a generalized treatment – instead, they must closely consider the above factors when specifically tailoring the taper initiation and maintenance plan to the ODI. An inappropriate tapering plan can severely affect not only the patient, but the surrounding community as well, further increasing the burden of the ongoing opioid crisis.

1.2 Approach and Context

In 2017 Wiikwemkoong Unceded Territory Chief and Council resolved to work with Drs. Maar and Manitowabi at the Northern Ontario School of Medicine University and their team on community-based research to address opioid misuse. The impetus for the development of this study was the concern over the serious individual, family, and community consequences of opioid addictions identified by health and mental health care providers, as well as leadership, tribal police services and the justice sector. The consequences identified included: opioid-related morbidity and mortality; property thefts; stealing of opioids directly from pharmacies, health centers, or elders; trafficking of women and children to pay for drugs; and, new supplies of additional opioids through the infiltration of organized crime from southern communities (36).

A strengths-based approach was used to develop an understanding of what success entails regarding OAT in this community. In evaluating OAT success in mainstream clinics, Hooker et al. (2022) identified seven themes of success reported by physicians and patients, including: “staying sober; tapering off buprenorphine; taking steps to improve physical and mental health; improved psychological well-being; improved relationships; improved role functioning; and, decreased stigma and shame” (100 p3). Comparatively, these themes of success resonate at the community-operated OAT clinic, Naandwe Miikan. Given that the data for this study was collected through a retrospective chart review of clients’ intake and dosing characteristics, it was not possible to evaluate success that would require client feedback – such as improvements in physical and mental health, and relationships and role functioning, and decreases in stigma and shame. However, the ultimate goal of Naandwe Miikan is “safely reducing reliance on medication when possible” (36 p9). As such, this study was focused on evaluating OAT success in respect to tapering characteristics. Additionally, this study incorporated a strengths-based

approach in order to advance self-determination and self-governance in this community. In collaboration with this community, the primary goal of this research was to provide resources and data surrounding the evaluation of Naandwe Miikan to empower future program developments and monitoring. Specifically, identifying correlates of tapering initiation and success based on clients' intake and dosing data addresses a gap of highlighted importance in the community's evaluation of past OAT success.

To promote the propagation of respectful, honest, and collaborative dialogues between Indigenous and Western knowledge and worldviews, a community-based participatory action research (CBPAR) approach used in the overall project was also used in this chart review study. CBPAR is presented as an alternative research approach designed to “replace the exploitative elements of the dominant research paradigm” (101 p21). Integral to CBPAR is the inclusion of the community throughout the research process (102). The control over the research must, first and foremost, be within the community.

Michael Anthony Hart (2002) states, “In an Aboriginal approach [to helping], it is especially essential to nurture the relationship between the person being helped and the helper and to enhance its development and growth as part of helping” (103 p54). Collaborating with Indigenous communities experiencing elevated rates of opioid-dependency to evaluate community-driven opioid-replacement programs, requires a commitment to build and foster honest, respectful relationships between Indigenous community members and academic researchers. Importantly, community-driven opioid replacement programs can provide increased supportive environments and treatment guidelines that focus on the cultures and values that meaningfully represent “the person being helped”. This approach can nurture the relationship

between the opioid-dependent individual and the service provider, facilitating positive development and growth that is necessary to overcome opioid-dependency (38,52).

In recognition of the importance of and the need for collaboration with the community of Wiikwemkoong Unceded Territory, four collaboration sessions with interagency staff were held in July 2019 to support this work with a community dialogue. The purpose of the sessions was to facilitate the integration of opioid addictions services using a whole community approach. The approach builds on the Community Wellness Development Team planning and existing Wiikwemkoong Unceded Territory community services. Sessions were planned with interagency managers and each agency was invited to send two or more representatives. The report “Wiikwemkoong Community Response to Support Recovery from Opioids” was submitted for presentation to the Interagency Meeting in March of 2020, however the meeting was postponed until March 2021 due to the COVID-19 pandemic (104).

This research study aims to collaborate with the large northern First Nation of Wiikwemkoong Unceded Territory to learn about the needs of First Nations people with opioid dependencies in order to return to a state of good health known as *mino-bimaadiziwin*. Community consent for this research has been received via a band council resolution to conduct this research from the Wiikwemkoong Unceded Indian Reserve Chief and Council.

Currently, promoting honest and respectful collaborations between Indigenous and Western worldviews is crucial, in order to explore the gap in the knowledge surrounding culturally appropriate opioid-replacement services (18,21,23,57). Communication between both worldviews can produce novel initiatives that emphasize the strengths each worldview possesses in opioid treatment and healing. Moreover, community-driven initiatives can improve current treatment services by promoting the establishment of treatment programs that are community-

specific. Tailoring treatment programs to specific communities can ensure that appropriate languages, cultures, and values are co-created with the appropriate community.

1.3 Purpose of Study

The purpose of this study was to identify correlates of tapering initiation and success, using patient electronic medical record data, that are specific to Naandwe Miikan, an opioid agonist treatment program in Wiikwemkoong Unceded Territory.

In May 2014, the community-operated OAT clinic Naandwe Miikan opened in Wiikwemkoong Unceded Territory on Manitoulin Island, Ontario, Canada. Naandwe Miikan was established to address community concern over inaccessibility of appropriate opioid treatment services, and the increases in criminal behaviour related to obtaining opioids to self-medicate (36). Services offered at Naandwe Miikan are focused on providing culturally safe care to address the rising rates of opioid dependencies in the community (36). Instead of solely treating the physical aspects of opioid dependencies – as is generally the case with mainstream models of OAT - Naandwe Miikan incorporates “a holistic approach to recovery, integrating cultural approaches, educating the community on harm reduction, and maintaining a long-term recovery goal of eliminating drug therapy when this can be done safely” (36 p7).

1.4 Research Question

This study sought to answer the following research question:

“What is the effect of education level, age, gender, start drug, start dose in morphine equivalent dose (MED), and clients’ number of children, on taper initiation and success during opioid agonist treatment (OAT) among First Nations Clients at Naandwe Miikan

in Wiikwemkoong Unceded Territory retained in the program from May 2014 to December 2019?”

2.0 Methodology

This study used a retrospective chart review of all the clients categorized as “currently active” as of December 2019 at the community-operated opioid replacement clinic, Naandwe Miikan, in Wiikwemkoong Unceded Territory. Dose data and demographic statistics were collected monthly from the first intake date to the last recorded dose date for all clients active as of December 2019. Additionally, toxicology data was collected for all active clients for November 2018 and November 2019.

2.1 Study Design

Retrospective studies, which have been recognized to account for a significant amount of published clinical health research, have been defined by Panacek (2007) as, “[studies] in which the events of interest have already occurred before the research project is begun” (105 p1). The retrospective nature of these studies has popularized their use as cost and time efficient research designs, as the relevant observations and measurements are often gathered within a particular location or database, facilitating data extraction (105-109). Moreover, retrospective chart reviews, defined by Worster and Haines (2004) as “any study that uses pre-recorded, patient-focused data as the primary source of information to answer a research question” (109 p187) are understood in the literature as being the most common form of retrospective research (105,108,109). In the absence of descriptive baseline and demographic statistics for the patient-focused data in question, retrospective chart reviews are valuable to address this gap in knowledge. Quantitative patient-focused research that incorporate retrospective chart reviews has the potential to address this gap in knowledge, as well as, recommend and implement future studies to answer additional questions that may arise from the initial investigation of the data.

While retrospective chart reviews are crucial in analyzing and reporting baseline statistics and promoting future research studies, their implementation and frequent lack of methodological standards have been criticized (105,106,108-110). To address this area of concern, the current study has incorporated guidelines that have been developed and recommended by previous research studies to reduce and/or eliminate common errors surrounding retrospective chart review implementation and reporting.

Moreover, using secondary internal data originally collected for patient charts, this study operated within a data-driven approach to developing a research question and analysing the research. While the use of secondary data increased the availability of convenient and cost-effective data, there were two key limitations that presented themselves. Firstly, as is true for all chart review studies, this data was initially documented for clinical purposes. The data were not collected with the intention to answer or address specific research questions, and as a result, not all the variables were consistently documented in a manner that is desirable for research (111).

However, in the process of data cleaning, generating frequency tables and analyzing variable responses to determine data quality, I became familiarized with the strengths of the available data, improving our understanding of the advantages of our dataset. Lastly, a frequent criticism towards secondary data is that researchers using this data are not privy to all of the details or entry modifications that may have occurred during data collection (111). To address this, I documented a list of variables and client responses that required further clarification and achieved clarification by discussing this list with a community co-researcher who had served as the case manager at the clinic, and was familiar with the data's original collection methods.

2.2 Study Population

This study entailed a secondary analysis of data derived from the Naandwe Miikan opioid therapy clinic. The target population included all active clients and those with closed case disposition for a period of five years (n=223). Ultimately, I utilized a census of all active clients to identify our study population. The data was made available for research by the community. The data set included in the study was all active clients with intake dates from May 2014 to December 2019 (n=143). Since the available data is only for current clients (as of December 2019) and the data is only for one opioid therapy clinic, it is important to note that the generalizability of the study population is a primary limitation. The selected records had to adhere to the following inclusion and exclusion criteria.

2.3 Inclusion and Exclusion Criteria

Of the total client intake records, the data for 80 clients were excluded due to inaccessibility of the data for this study if the client's file had been closed by the treatment program physician - either due to treatment success, transfer to another clinic, current relapse, or death, categorizing them as not current clients as of December 2019. Of note, if a client had left the treatment program at any point between May 2014 and November 2019, but had returned for a completed or scheduled December 2019 treatment, their data was included in this study (i.e., were active clients). Thus, client data was included in this study so long as they were recognized as an active client at Naandwe Miikan as of December 2019, defined as already having received or having a scheduled December 2019 treatment. The inclusion and exclusion criteria are represented in Fig. 1 below. Of the 143 active clients, the data for one client was excluded due to the fact that the client was seeking treatment for cannabis use and not opioid use disorder.

Additionally, of the 142 active clients seeking treatment for opioid use disorder, the data for 40 clients was excluded due to missing data for gender, age, and education level.

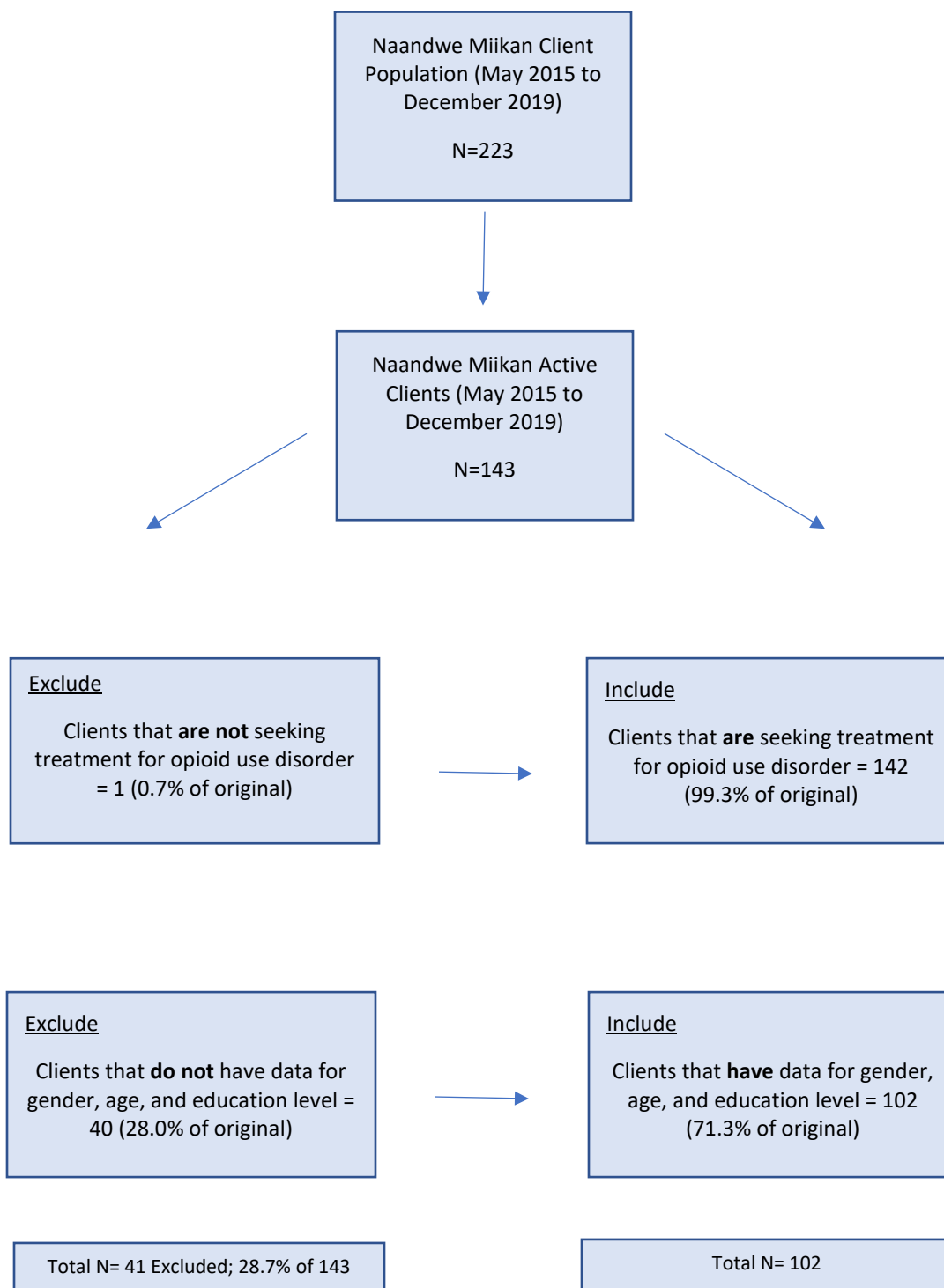


Fig 1. Flow chart depicting the inclusion and exclusion criteria used for research question.

2.4 Data Collection Method

Record extraction for the 143 active clients at Naandwe Miikan began in December 2019 and ended in February 2020. The client data was collected using NOVX Systems' PatientVu electronic medical record (EMR). There were two distinct data collection strategies employed, involving two researchers. First, Suboxone and methadone dose data were collected for all of the active clients at Naandwe Miikan. This data was unable to be collected from NOVX Systems' PatientVu EMR using queries; instead, two researchers collected the data by manual chart review. Computer-facilitated searching of EMRs are often the norm for this research, mainly due to their reduced time and cost in the research process (112-115). To protect patients at Naandwe Miikan during this stage of the collection period, a researcher approved by the community to access raw treatment dose data from the electronic medical records recited the dose values in milligrams to a second researcher, who then recorded this data in an Excel document. This occurred in a private room to maintain high standards of confidentiality. Monthly treatment doses for Suboxone and methadone were extracted for the period May 2014 to December 2019 using the client's treatment intake date as a respective monthly reference point, with an acceptable period of received or scheduled treatment either one week ahead or behind the intake reference date. For example, if a client's intake date was November 14th, 2016, each monthly dose data would be determined as the closest to the 14th of every month thereafter, within an acceptable range between the 7th to the 21st. Treatment dose data that fell outside of a client's respective acceptable range was labelled as "No Script in Range (NSIR)" and colour coded as blue in the Excel spreadsheet. Additionally, if at any point a client switched to the alternate drug, either Suboxone or methadone, this was recorded as "switched to [alternate drug]" and colour coded as orange in the Excel spreadsheet. At this point, if treatment switched once more, this

was recorded as a new treatment intake date for the respective drug. In alignment with Panacek's (2007) "10 Commandments for Performing Chart Review Research", the quality of the data at this stage was assured by randomly selecting clients and confirming treatment doses using duplicate entry techniques (105).

Secondly, intake data from standardized electronic intake forms was collected for the 143 current clients at Naandwe Miikan. To protect patients at Naandwe Miikan during this stage of the collection period, a researcher approved by the community to access raw client data from the electronic medical records printed each client's electronic intake form once they had been edited by removing any identifying information. Subsequently, the data was extracted from the printed copies and recorded by another researcher into a separate Excel document. All data included in the standardized intake forms were recorded as unique variables. Once entered, the paper copies were destroyed.

Tapering data was established through our collection of the monthly program treatment doses, which were collected for all active clients, as of December 2019, from May 2014 to December 2019. Through an analysis of the monthly treatment doses, combined with an understanding of the mechanics of tapering within opioid agonist treatments, definitions were formed for what constituted "current tapering" and "historical tapering". Once a therapeutic dose had been achieved, it was observed that any reductions in treatment doses that followed consistently occurred in 1 to 3-month intervals. With this in mind, a client was considered to have had a history of tapering if there was an observed pattern of 1 to 3-month reductions in their treatment doses. Importantly, if the reduction was severe – usually a dose reduced drastically to a recognizable treatment starting value consistent with early methadone and Suboxone doses – this was indicative of treatment restarts, which were not considered as current or historical tapers. In

order to distinguish between signs of very early stages of tapering, signs of dose reductions that may occur when finding and arriving at a therapeutic dose, and signs of current tapering, active clients had to have dose data that depicted a clear pattern of reduction over at least a period of 3-months – leading up to and including December 2019 – to be considered “current tapers”. The first dose data point that led to a clear pattern of reduction over at least a period of 3-months was defined as “taper initiation”. “Taper success” was defined as consistent adherence to the opioid agonist treatment program – instances of program dropout and relapse (defined as a drastic fluctuation in treatment dose, indicative of relapse and/or steps to achieve a new therapeutic dose), were considered as “unsuccessful tapers”.

Throughout the data collection period, multiple versions of the two Excel documents were saved to protect against errors in the collection process. Moreover, as Panacek (2007) recommends, frequent meetings were held to monitor the data collection and study progress and there were frequent conversations with community-assigned current and former clinic staff to help answer questions about the data (105). Consistent data recording was ensured from the beginning, and any major changes in a key study variable prompted a re-collection of the data for the respective variable for each client. Once both the dose and intake data were extracted, they were cleaned and converted to SPSS for analysis. Importantly, after the files had been merged and converted to SPSS, quality assurance checks of the data were performed by randomly selecting clients and comparing every variable’s data point between the SPSS and Excel documents.

2.5 Data Elements

Data for this study was collected using clients' electronic intake forms, as well as clients' electronic medical records (EMRs).

Clients' electronic intake forms provided the following data elements:

- Gender
- Age
- Intake Date
- Drug(s) of Choice (DoC) (18 substances were assessed: morphine; fentanyl; carfentanyl; codeine; hydromorphone; heroin; methadone; Suboxone; oxycodone; other opioids; cocaine; barbituates; amphetamines; alcohol; cannabis; cigarettes; benzodiazepines; and, crystal meth)
- Average Daily Use of DoC
- Length of Use of DoC
- Route of administration of DoC
- Medication History
- Past Medical History
- Family History
- Emotional Health (based on an 'Emotional Health' questionnaire asked at intake – responses were 'yes' or 'no' for 11 conditions or events related to emotional health)
- Social History (14 variables were included: marital status; number of children; whose custody the children are in; who lives in their household; if those living

with them abuse alcohol/drugs; if those close to them are aware of their drug problem; if they are currently employed; current occupation; usual occupation; last job held; employed from-to; highest level of education; if they are receiving financial support; and, if they drive.

- Previous Enrollment in an OAT program
- Clients' Motivations for Treatment (responses provided during an intake interview)
- Clients' Starting Treatment Drug (methadone or Suboxone)
- Clients' Starting Treatment Dose

Clients' electronic medical records (EMRs) provided the following data elements:

- Monthly Treatment Doses
- Toxicology Data (7 categories, which included 58 substances, were screened: opioids; amphetamines; benzodiazepines; anti-depressants; anti-psychotics; cannabinoids; and, other)

From the data collected from clients' EMRs, namely monthly treatment doses, it was possible to identify dosing patterns that would be consistent with our definition of tapering – observed dose reductions across a period of at least 3-months. Through an analysis of the interpretive tapering data, further data elements were collected that include: current reduction in treatment dose; current tapering length; and, previous taper history within this OAT.

For the purposes of this study, only the following were included and analyzed in the results:

- Highest Level of Education (from the ‘Social History’ portion of the electronic intake forms)
- Age
- Gender
- Starting Treatment Drug
- Starting Treatment Dose
- Clients’ number of children (from the ‘Social History’ portion of the electronic intake forms)
- Taper data (generated using ‘Monthly Treatment Doses’ of clients’ EMRs)

These data elements were included into the subsequent analysis and results due to their relationship(s) to correlates of tapering success previously investigated in similar studies (20,71,88-91,97,98). Moreover, clients’ number of children was included as a potential measure of Indigenous determinants of health – that may assess or act as a proxy for early childhood experiences and family supports (97,98). As well, clients’ number of children was included because concerns over family and regaining custody of children was the second most reported motivation for seeking treatment for clients at Naandwe Miikan. However, although we set out to use this measure for the stated reasons, data on client motivations was excluded due to low client response rates. Additionally, certain data elements – namely, DoC and associated variables (average daily use, length of use, route of administration), past medical history, emotional health, and toxicology data – were initially intended to be included in further investigations. However, it simply was not possible to include these variables as a result of incomplete intake forms and low client response rate.

2.6 Data Management

To protect clients at Naandwe Miikan both during and after the research study, client data was anonymized with the use of unique identifiers to ensure client confidentiality. Moreover, identifying information was removed before the data was received for collection. Only one academic researcher affiliated with this study had access to the data for collection, processing, and analysis. No client names were kept in the collected data. No community researchers had access to the raw data, to ensure that the community researchers could not infer the identity of the 143 clients. Additionally, safeguards were in place to protect the confidentiality and security of the data. Data obtained was stored in locked filing cabinets, on password protected computers, and on password protected external hard-drives for backups in research offices at the Center for Rural and Northern Health Research (CRANHR) and an approved Laurentian University residence, both in Sudbury, Ontario. The Laurentian University residence had to be approved and added to the ethics application due to the restrictions on office access brought on by COVID-19. Data will be kept for as long as it can be safely and securely stored. In the event of future community-driven studies investigating areas that are similar to this study, future use of the data may be warranted. Furthermore, if in the future the data obtained during this study can no longer be safely and securely stored, the data will be shredded and all electronic versions destroyed.

2.7 Ethics

This study was approved by the Laurentian University Research Ethics Board, as well as the Manitoulin Anishinabek Ethics Review Committee (Appendix C). As well, Chapter 9 of the TCPS2 specifies that community consent for this research is required. Community consent for this research was received via a Band Council resolution from the Wiikwemkoong Unceded

Territory Chief and Council. Lastly, the clients included in this study have not provided individual consent as individual consent is not recommended in chart review research for the following reasons. For this study population, it is impractical to seek consent, as this would identify the clients as dependent on opioids within the community, potentially putting these individuals at risk for social and psychological harms. Additionally, chart data is currently used for reporting to the Ministry of Health. Similarly to the Ministry approach to handling individual health information, this study complies with the Personal Health Information Act, 2004, Paragraph 44, “Disclosure for Research” (116). In accordance with Paragraph 44, we have submitted a copy of the decision of a research ethics board that approves the research plan to a health information custodian, and we are in agreement with the custodian’s conditions and restrictions regarding the use, security, disclosure, return or disposal of the information (108). As this study complies with this paragraph, individual consent was not required and can even be considered harmful for this study population.

3.0 Results

From the original sample of all active clients at Naandwe Miikan as of December 2019 (n=143), 41 clients were excluded due to incomplete and missing data on the extracted intake and dose measures. The remaining clients (n=102) had complete data for education level, age, gender, start drug, start dose in milligrams of morphine equivalent dose (MED), and clients' number of children. Additionally, based on logical interpretations of the dosing data for the 102 clients, it was possible to determine the probable opioid taper history, including taper initiations and discontinued tapers, for each client. Of the 102 clients with data on taper history, it was determined that 53 clients (52.0%) had tapers initiated during treatment. Subsequently, by investigating the client taper history – namely, discontinued tapers due to poor adherence - it was possible to determine if the 53 clients were successful or not with their taper programs. This study sought to examine factors that may influence both clients' taper initiations and clients' taper outcomes.

3.1 Effect of Drug and Sociodemographic Characteristics on Taper Initiation During OAT

Frequency descriptive statistics for clients' education level, age, gender, start drug, start dose and number of children, and taper initiation during OAT are presented in Table 1. Results showed that taper initiation did not vary significantly between clients that did not finish high-school and clients that had finished high-school/GED or university/college. Table 1 also shows that about 68% of clients (n=69 of 102) were 18-34 years of age. As well, more clients between the ages of 18-34 years demonstrated taper initiation, however not significantly more than older clients. More females had initiated tapers compared to males (statistically non-significant). Although roughly 63% of clients (n=64 of 102) began treatment on Suboxone, the number who

had tapered versus not was no different than for clients who started treatment on methadone. However, when comparing taper initiation between clients entering treatment with a starting dose of 50-149mg MED and clients entering treatment with a starting dose of 150-300 or more mg MED, more clients presenting with a lower starting dose had tapers initiated, which was statistically significant at the 0.05 level. Last, there was no significant difference in taper initiation found between clients with 0-2 children and clients with 3 or more children. Graphs for the data presented in Table 1 can be found in Appendix B (Figs. 24-29).

Table 1. Descriptive statistics (frequency/%) for clients' drug and socio-demographic variables and taper initiation during OAT (based on N=102).

Education Level	Total N	No Taper Initiated [avg%]	Taper Initiated [avg%]
Did not finish high-school	53 [52.0%]	25 [47.2%]	28 [52.8%]
High-school/GED or University/College	49 [48.0%]	24 [49.0%]	25 [51.0%]
Total	102	49 [48.0%]	53 [52.0%]
Age			
18-34 years old	69 [67.6%]	31 [44.9%]	38 [55.1%]
35 or more years old	33 [32.4%]	18 [54.5%]	15 [45.5%]
Total	102	49 [48.0%]	53 [52.0%]
Gender			
Male	57 [55.9%]	30 [52.6%]	27 [47.4%]
Female	45 [44.1%]	19 [42.2%]	26 [57.8%]
Total	102	49 [48.0%]	53 [52.0%]
Start Drug			
Suboxone	64 [62.7%]	29 [45.3%]	35 [54.7%]
Methadone	38 [37.3%]	20 [52.6%]	18 [47.4%]
Total	102	49 [48.0%]	53 [52.0%]
Start Dose			
50-149 mg MED	38 [37.3%]	14 [36.8%]	24 [63.2%]
150-300+ mg MED	64 [62.7%]	35 [54.7%]	29 [45.3%]
Total	102	49 [48.0%]	53 [52.0%]

Number of Children			
0-2 Children	70 [68.6%]	33 [47.1%]	37 [52.9%]
3 or more Children	32 [31.4%]	16 [50.0%]	16 [50.0%]
Total	102	49 [48.0%]	53 [52.0%]

A standard binary logistic regression was used to model the binary variable of taper initiation during OAT at Naandwe Miikan (using no taper initiation during OAT as the reference category). The correlates were education level, age, gender, start drug, start dose in MED, and clients' number of children. Table 2 presents the odds ratio [$\text{Exp}(B)$] and the 95% confidence intervals (CI) for odds ratios for each correlate. Four models were used: Model 1 includes the control variables education level, age, and gender; Model 2 includes the addition of the correlate start drug; Model 3 includes the addition of the correlate start dose (in mg MED); and, Model 4 includes the addition of the clients' number of children. Starting dose (in mg MED) in Model 3 was a statistically significant correlate of taper initiation; clients with a starting dose greater than 150 mg MED were 56% (CI = 0.19, 1.04) less likely than clients with starting doses under 150 mg MED to initiate taper during OAT (Block X^2 (1, N=102) = 3.709, $p = 0.054$). While statistically significant, the Nagelkerke pseudo R^2 indicated that the model (Model 3) accounted for about 7% of the total variance ($R^2 = 0.074$).

Table 2. Odds of taper initiation in relation to education level, age, gender, start drug, start dose (MED), and clients' number of children as correlates (based on n=102).

<u>Variables Entered</u>	<u>Model 1</u>	<u>Model 2</u>	<u>Model 3</u>	<u>Model 4</u>
	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
<u>Education Level</u>				
Did not finish high-school	ref.	ref.	ref.	ref.
High-school/GED or University/College	1.03 (0.46, 2.30)	0.99 (0.44, 2.23)	0.95 (0.42, 2.19)	0.97 (0.42, 2.24)
<u>Age</u>				
18-34 years	ref.	ref.	ref.	ref.

35 or more years	0.73 (0.31, 1.73)	0.75 (0.31, 1.80)	0.80 (0.33, 1.96)	0.75 (0.29, 1.96)
<u>Gender</u>				
Male	ref.	ref.	ref.	ref.
Female	1.44 (0.65, 3.22)	1.45 (0.65, 3.25)	1.41 (0.62, 3.20)	1.43 (0.63, 3.28)
<u>Start Drug</u>				
Suboxone	--	ref.	ref.	ref.
Methadone	--	0.75 (0.33, 1.72)	0.71 (0.31, 1.64)	0.70 (0.30, 1.63)
<u>Start Dose (mg MED)</u>				
50-149 mg MED	--	--	ref.	ref.
150-300+ mg MED	--	--	0.44 (0.19, 1.03) *	0.45 (0.19, 1.04)
<u>Clients' Number of Children</u>				
0-2 Children	--	--	--	ref.
3 or more Children	--	--	--	1.19 (0.46, 3.11)
Constant	1.046	1.014	1.144	1.168
-2 Log Likelihood	139.620	139.166	135.458	135.330
Model Chi-Square [df]	1.625 [3]	2.079 [4]	5.788 [5]	5.915 [6]
Block Chi-Square [df]	--	0.454 [1]	3.709 [1] *	0.127 [1]
Nagelkerke R ²	0.021	0.027	0.074	0.075

* $p \leq .05$, ** $p \leq .01$, *** $p < 0.001$

Based on a classification threshold predicted probability of target group membership of 0.5, there was negligible additional variance explained upon addition of clients' number of children in the final model (Model 4) ($R^2 = 0.075$). Number of children was statistically non-significant and did not appreciably influence taper initiation (Block $X^2(1, N= 102) = 0.127$). Classification success for the cases based on a classification cut-off value of .500 for predicting membership in the taper initiation group demonstrated an overall prediction success rate of

60.8% and correct prediction rates of 58.5% for clients with taper initiation during OAT and 63.3% for clients without taper initiation during OAT.

3.2 Effect of Drug and Sociodemographic Characteristics on Taper Success

Frequency descriptive statistics for clients' education level, age, gender, start drug, start dose and number of children, and taper success during OAT are presented in Table 3. First, results showed that taper success varied between clients that did not finish high-school and clients that had finished high-school/GED or university/college. Fewer clients that had finished high-school/GED or university/college succeeded with tapers (measured by adherence to taper plan – i.e., no relapse or increases in daily dose in mg) as compared to those who did not finish high school. However, this finding was not statistically significant. Second, there were more clients aged 35 years + with taper success than clients ages 18-34 years (60% versus 39.5%, respectively), however, this was not statistically significant. Third, there was a gender difference in taper success. Of the 53 total clients with tapers initiated during treatment, the number of clients were divided evenly between male and female groups, yet fewer females succeeded with their tapers. While only 34% of taper clients (n=18 of 53) began treatment on methadone, more (approximately 25% more) had taper success than clients beginning treatment on Suboxone. This finding was statistically significant at the 0.05 level. There was no difference in taper success frequency between clients entering treatment with a starting dose of 50-149mg MED and clients entering treatment with a starting dose of 150-300 or more mg MED. Last, Table 3 demonstrates that fewer clients with 0-2 children succeeded in their tapers, compared to clients with 3 or more children; however, this was not a statistically significant finding. Graphs for the data presented in Table 3 can be found in Appendix B (Figs. 30-35).

Table 3. Descriptive statistics (frequency/%) for clients' drug and socio-demographic variables and taper success during OAT (based on N=53).

Education Level	Total N	Taper Unsuccessful [avg%]	Taper Successful [avg%]
Did not finish high-school	28 [52.8%]	13 [46.4%]	15 [53.6%]
High-school/GED or University/College	25 [47.2%]	16 [64.0%]	9 [36.0%]
Total	53	29 [54.7%]	24 [45.3%]
Age			
18-34 years old	38 [71.7%]	23 [60.5%]	15 [39.5%]
35 or more years old	15 [28.3%]	6 [40.0%]	9 [60.0%]
Total	53	29 [54.7%]	24 [45.3%]
Gender			
Male	27 [50.9%]	12 [44.4%]	15 [55.6%]
Female	26 [49.1%]	17 [65.4%]	9 [34.6%]
Total	53	29 [54.7%]	24 [45.3%]
Start Drug			
Suboxone	35 [66.0%]	22 [62.9%]	13 [37.1%]
Methadone	18 [34.0%]	7 [38.9%]	11 [61.1%]
Total	53	29 [54.7%]	24 [45.3%]
Start Dose			
50-149 mg MED	24 [45.3%]	14 [58.3%]	10 [41.7%]
150-300+ mg MED	29 [54.7%]	15 [51.7%]	14 [48.3%]
Total	53	29 [54.7%]	24 [45.3%]
Number of Children			
0-2 Children	37 [69.8%]	22 [59.5%]	15 [40.5%]
3 or more Children	16 [30.2%]	7 [43.8%]	9 [56.2%]
Total	53	29 [54.7%]	24 [45.3%]

A standard binary logistic regression was used to model the binary variable of taper success during OAT at Naandwe Miikan (using unsuccessful tapers – defined as discontinued tapered doses or relapses to previous increased doses during ongoing tapering). Correlates were the education level, age, gender, start drug, start dose in mg MED, and clients' number of

children. Table 4 presents the odds ratio [$\text{Exp}(B)$] and the 95% confidence intervals (CI) for odds ratios for each correlate. As with the tapering initiation modelling, four models were used: Model 1 included the control variables education level, age, and gender; Model 2 reflected the addition of start drug; Model 3 included the addition of the correlate start dose (in mg MED); and, Model 4 included the addition of clients' number of children. The influence of starting drug (Suboxone or methadone) in Model 2 was a statistically significant correlate of taper success; clients on methadone were 3.5 times (CI = 0.97, 12.77) more likely than clients on Suboxone to succeed with tapering during OAT. Model 2 accounted for about 22% of the total variance in taper success (Nagelkerke pseudo $R^2 = 0.216$), which was a 9% increase from the variance previously explained with only the control variables present.

Table 4. Odds of taper success in relation to education level, age, gender, start drug, start dose (MED), and clients' number of children as correlates (based on n=52).

<u>Variables Entered</u>	<u>Model 1</u>	<u>Model 2</u>	<u>Model 3</u>	<u>Model 4</u>
	OR (95% CI)	OR (95% CI)	OR (95% CI)	OR (95% CI)
<u>Education Level</u>				
Did not finish high-school	ref.	ref.	ref.	ref.
High-school/GED or University/College	0.42 (0.13, 1.38)	0.34 (0.10, 1.21)	0.35 (0.10, 1.22)	0.33 (0.09, 1.20)
<u>Age</u>				
18-34 years	ref.	ref.	ref.	ref.
35 or more years	2.34 (0.61, 9.01)	2.55 (0.62, 10.44)	2.60 (0.63, 10.76)	2.88 (0.63, 13.10)
<u>Gender</u>				
Male	ref.	ref.	ref.	ref.
Female	0.52 (0.16, 1.70)	0.51 (0.15, 1.73)	0.53 (0.15, 1.89)	0.49 (0.13, 1.86)
<u>Start Drug</u>				
Suboxone	--	ref.	ref.	ref.
Methadone	--	3.51 (0.97, 12.77) *	3.56 (0.97, 13.06) *	3.83 (0.99, 14.85) *
<u>Start Dose (mg MED)</u>				

50-149 mg MED	--	--	ref.	ref.
150-300+ mg MED	--	--	1.15 (0.33, 4.03)	1.12 (0.32, 3.95)
<u>Clients' Number of Children</u>				
0-2 Children	--	--	--	ref.
3 or more Children	--	--	--	0.74 (0.16, 3.37)
Constant	0.948	1.165	1.163	1.130
-2 Log Likelihood	67.562	63.677	63.629	63.477
Model Chi-Square [df]	5.440 [3]	9.324 [4]*	9.372 [5]	9.525 [6]
Block Chi-Square [df]	--	3.885 [1]*	0.048 [1]	0.152 [1]
Nagelkerke R ²	0.130	0.216	0.217	0.220

* $p \leq .05$, ** $p \leq .01$, *** $p < 0.001$

Based on a classification threshold predicted probability of target group membership of 0.5, the results of the final logistic analysis suggested that the 4-correlate model – the model which included the addition of start drug – indicated a statistically significant correlate of taper success, Block $\chi^2(4, N= 53) = 9.324, p= <0.05$. Odds ratio coefficients did not differ negligibly across models to the final Model 4. As well, the Nagelkerke pseudo R^2 did not significantly improve outside of the addition of start drug in Model 2. Classification success for the cases based on a classification cut-off value of .500 for predicting membership in the taper success group was moderately high, with an overall prediction success rate of 73.6% and correct prediction rates of 58.3% for clients with successful tapers during OAT and 86.2% for clients with unsuccessful tapers during OAT.

4.0 Discussion

The aim of this study was to evaluate correlates of taper initiation and success at a rural First Nations community-based OAT program in Northern Ontario. The results of this study have assisted in reducing the gap in knowledge surrounding sociodemographic and dosing factors that may influence taper initiation and taper success in a First Nations OAT program in Northern Ontario. Improvements in this area of research are critical, as there is scant evidence available to aid physicians in initiating and completing opioid tapers among their patients (89). Additionally, in collaboration with the community of Wiikwemkoong Unceded Territory, this study sought to empower future OAT program developments and monitoring and advance self-determination in this community. To our knowledge, this is the only study conducted examining the effect of education level, age, gender, start drug, start dose (in mg MED), and clients' number of children on methadone and buprenorphine tapering initiation and success in OAT programs in Canada. Our primary findings suggest that clients' starting dose is a correlate of taper initiation, and clients' starting drug is a correlate of taper success.

Studies examining clients' starting dose and tapering provide explanations as to why an increased taper initiation at 150 mg MED or less was observed. Of note, Bentzley et al. (2015) have found evidence to support that achieving a pre-taper maintenance dose that was tolerated and appropriate for the client improved taper outcomes (72). In this instance, clients with starting doses of 150 mg MED or greater were less likely to initiate tapers. As such, it can be argued that 150 mg MED or more represents a pre-taper maintenance stage, where the client is dependent on a higher dose and must be safely maintained before a taper could be considered. Inappropriate tapers occurring before a client has achieved a stable maintenance period have been shown to precipitate the onset of withdrawal symptoms and can result in relapse and/or treatment

discontinuation (1,4,6,7,10,73,81). This emphasizes the need for an individualized approach to tapering to ensure that treatment programs can be adapted to suit clients' specific needs and circumstances. Our observed significant finding of tapering initiation being more likely in clients with 150 mg MED or less demonstrates that, at this specific OAT, this was a treatment dose that was low enough to indicate that a tapering program could be initiated.

Additionally, there is evidence to support our finding that clients receiving methadone were more successful with their tapering programs. Firstly, when a client is tapered off methadone, there is commonly a transition to Suboxone, as long as the client can tolerate the opioid-agonist. From there, clients can continue long-term opioid maintenance with Suboxone until a suitable pre-taper maintenance phase has been tolerated long enough, where they then may wish to initiate a new taper, either to a lower maintenance dose, or abstinence. It must be noted that a Suboxone taper with the goal of abstinence is not advised. Studies demonstrate that many patients that are tapered off Suboxone to abstinence tend to relapse to illicit opioid use following treatment (72). In relation to our findings, this could explain why Suboxone tapers were less likely to succeed, compared to methadone tapers.

Secondly, clients on methadone typically require an increased dose to address moderate to severe dependencies. In reference to our observed taper initiation dose of 150 mg MED or less, clients on methadone achieving this dose will have sufficiently maintained a gradual dose reduction over months to be considered for taper initiation. As a result, it can be said that they have lessened their dependency severity and resulting withdrawal risks enough to facilitate a transition to Suboxone. If tolerated, it can be understood that this transition would be more successful than a Suboxone taper with abstinence as the ultimate goal. Lastly, given guideline recommendations towards Suboxone as a safer alternative to methadone, and the fact that

Suboxone is more feasible for remote treatment programs, it is understandable that there would be an increased desire to taper methadone clients toward a Suboxone transition. While our data quality for patient motivations and treatment preferences was incomplete and not included in the analyses, it could be possible that clients were motivated to transition to Suboxone, and this motivation – a factor previously identified in similar studies as a correlate for taper success – could explain our observed increased taper success for clients on methadone (10). Further studies specific to our context could seek to evaluate this potential correlate in the future.

Clients' number of children was included in the study to see if our findings concur with studies examining parenting and opioid use disorders (OUDs). Luo et al. (2019), in their study investigating MMT outcomes of parents and non-parents, found that parental concerns over the well-being of their children was an intrinsic motivator influencing their decisions to seek treatment for OUD (90). Similarly, a series of OAT service provider interviews conducted by Kennedy et al. (2018) which confirmed that clients who expressed family as a motivator for seeking treatment, were more likely to be willing to initiate opioid tapering (89). Interestingly, our results demonstrate that clients with children did not differ significantly from clients without children when examining tapering success. It is true that previous studies on substance abuse and parental status did not identify differences in treatment outcomes, however, these studies did not specifically examine methadone and buprenorphine (90,117,118). While our findings were not statistically significant regarding this potential correlate, there is a need for future tapering programs, and OAT programs in general, to be individualized and to treat the whole client. In this instance, providing resources for parent and child supports can potentially reduce associated stressors that may interfere with taper adherence and outcomes. Additional resources and support in multiple client-specific sectors can serve an important role in reducing the impact of opioids

on communities by decreasing the stigma associated with OUD and increasing community resiliency.

Education level has previously been documented as a potential correlate for tapering outcomes. In 2019, a study examined how education level affected taper speed and found that individuals with high-school education or less were significantly associated with a higher maximum dose reduction rate (64). It is unclear why those with less than college or university education tend to prefer riskier, rapid tapers. We did not find a significant association between education level and tapering outcomes in our study, however, future studies could benefit from including this as a potential correlate in their investigations.

Studies investigating the effect of age on tapering outcomes are limited and inconsistent. In 2021, Kuntz et al. found that clients between 21-49 years of age were more likely to undergo taper programs that reduced their opioid use by 50% (10). It is unclear why this was the case; however, it may be explained by the perception that younger clients may be more willing and motivated to seek treatment. Interestingly, other studies have found that older clients may be more receptive to taper programs and have a higher likely to succeed. A possible explanation for this lies in the belief that older clients have had the potential for more addiction medicine encounters in the past which may positively influence their current and future treatment programs (20). Our study did not find a significant association between age and tapering outcomes, although there is still a basis for its inclusion in future studies.

Fenton et al. (2019) found evidence to suggest that physicians were less likely to recommend tapers based on sex, as they perceived men to respond to such recommendations with anger or violence, compared to women (64). Similarly, our findings suggest more women initiated tapers, however this was not statistically significant more than the frequency of men

initiating. Still, it is plausible that a bias towards recommending taper initiation could manifest itself. Thus, this highlights the need for more research in this area in order to appropriately guide providers in the tapering process.

An area of particular interest, for which we were unable to include variables for analyses, was the effect of emotional health on tapering outcomes. A study conducted by Braden et al. (2009) found that clients with depression and anxiety, in addition to chronic non-cancer pain, were more likely to request opioids, or be prescribed opioids in response to reported or observed distress (119). In regards to tapering outcomes, Kuntz et al. (2021) found that clients experiencing depressive and anxious symptoms were more likely to discontinue tapering programs, and clients undergoing concurrent mental health treatment were more likely to succeed (10). This led to an interesting hypothesis by the researchers that suggested a possibility that anti-depressants may increase tapering success. One of the data elements collected for this study included toxicology data, which depicted anti-depressant use. Unfortunately, the poor data quality for this particular element led to its exclusion from the final analyses. As depressed and anxious clients represent a potentially significant population of clients seeking OAT, future studies are encouraged to investigate the impact of emotional health and concurrent mental health treatment on tapering outcomes.

4.1 Study Limitations

This study has some important limitations. First, the files for the clients who had discontinued treatment at this program were closed or marked as inactive. Discontinuation of treatment could be due to a variety of reasons, including clients moving to a new clinic, client successfully completing treatment, client discontinuing treatment, or client being deceased. I

only had access to active treatment clients (as of December 2019). This represents a significant loss of a crucial area of interest for program evaluation. Access to inactive and closed files could have provided very valuable data on clients that have left treatment – both for treatment completion and treatment dropout related to relapse or death. Moreover, this data could have been instrumental in generating results that were more reflective of the effectiveness of the community-operated OAT clinic, and thus, more directly beneficial to the community and Naandwe Miikan. As we could not capture the sociodemographic and dosing characteristics of clients who had left treatment, our findings are not reflective of the general population accessing this OAT program.

Second, the data quality showed some inconsistencies between clients. This was to some degree expected, because the study used secondary data that was originally collected for clinical purposes, rather than answering specific research questions. Variables of interest from client intake forms and electronic medical records had to be excluded from the analyses due to frequently missing information.

Third, the taper data was generated through my own interpretation of the doses and patterns I observed in reviewing the active clients' charts. Tapering characteristics were not reported in the charts and it was not possible to confirm if the client tapers reported in the results truly occurred as intentional taper initiation. However, based on a review of taper guidelines and patterns that I observed during my literature review, I determined that the taper results in this thesis properly reflect dose decreases that would fall under the definition of a taper. Additionally, large dose decreases were confirmed in conversations with community-assigned current and former clinic staff to be indicative of treatment restarts, and thus, were not considered tapers by

staff and in this thesis. Still, without confirmation of clients' true tapering characteristics, the findings must be interpreted with caution.

Fourth, this study primarily evaluated Naandwe Miikan with a focus on the clinical aspects of opioid use and treatment based on the available client health record data. As such, the holistic and cultural approaches offered at Naandwe Miikan that address areas of healing and treatment that are unique to Indigenous communities were not able to be evaluated in this thesis, but are addressed in other parts of the larger research study (36).

Fifth, this study only evaluated the treatment options that include treatment with Suboxone and methadone, as these were the only treatments available at the time of the chart review. Recently, there has been increasing interest in the use of buprenorphine extended-release injections (Sublocade), as well as non-buprenorphine alternatives in the form of slow-release oral morphine and diacetylmorphine and hydromorphone injections. Future studies could benefit by evaluating the impact of these newer treatment options on OAT outcomes.

Lastly, our findings are specific to an OAT program in Northern Ontario and not likely to be generalizable to OAT programs in other regions.

4.2 Study Strengths

Despite these identified limitations, this study has some valuable strengths. First, this study collaborated with the community of Wiikwemkoong Unceded Territory and the community-operated OAT clinic Naandwe Miikan to generate valuable baseline sociodemographic and dosing data that was previously unknown. The assessment of the state of the data from when the clinic opened in May 2014 to December 2019, provided the community

with baseline data that could allow the clinic to evaluate the effectiveness of their OAT program, and to inform current and future program practices.

Second, while the inconsistencies in data reporting for intake, dosing, and tapering data were key limitations, they are also important strengths of this study in general, as they highlighted critical areas with missing information that can inform future health record collection practices. This was pivotal to the development of community specific recommendations that address these gaps in knowledge. Additionally, discovering the areas of inconsistent reporting improved my ability to recognize the strengths of our dataset.

Third, our reasonably large population for research on OAT in northern, rural Indigenous communities was a study strength. As this study used a retrospective chart review of all active clients between May 2014 and December 2019, our findings more accurately reflect the characteristics of this clinic's client population.

Lastly, our findings are community specific and thus, provide the most benefit to the community of Wiikwemkoong Unceded Territory. In the absence of agreed upon guidelines for tapering, it can be argued that it is impractical to evaluate a clinic's tapering effectiveness through comparison with other rural and urban clinics, where the client populations could be vastly different. Thus, providing meaningful findings that appropriately reflect Naandwe Miikan's active client population is an important strength of this study.

5.0 Conclusions and Recommendations

In conclusion, while this study identified starting dose and starting treatment drug as clinic-specific correlates for taper initiation and taper success, respectively, there is a need for future studies to address the significant gaps present in the literature surrounding tapering outcomes. Additionally, in the absence of specific evidence-based clinical guidelines for tapering, providers are encouraged to individualize taper programs and adopt pre-taper maintenance phases with prolonged and gradual dose reductions, to ensure the safety of the client and appropriately address clients' needs surrounding pain and withdrawal symptoms.

This study provided meaningful baseline sociodemographic and dosing data that will be beneficial to Naandwe Miikan. The data and findings collected from this study have been used in the development of a community report in collaboration with Wiikwemkoong Unceded Territory to support recovery from opioids. Future studies at this clinic can incorporate the collected data and our primary findings to continue to address specific community concerns and successfully reduce existing gaps in knowledge surrounding OAT programs in Northern Ontario.

Based on my research, I provide an initial set of recommendations to improve data quality at the community level for OAT reporting, evaluation and decision making at the local level.

5.1 Recommendations

Recommendations from this study focus on two main areas – data reporting and usability, and future studies. For data reporting and usability, I recommend the following to improve data quality for community-based reporting, evaluation and decision making:

1. Ensure that intake and dosing data are consistently collected.
 - a. Specifically, emotional and mental health at intake were inconsistently reported. This data could have important implications on concurrent treatment guidelines by identifying underlying issues that may be contributing to opioid use.
2. Report instances of tapering initiation and track tapering lengths and trends.
3. Improve access to inactive/closed files for research and evaluation purposes.
4. Implement functionality for clinic data to be collected using queries for research and evaluation purposes.
5. Record community-specific holistic and cultural approaches offered to compliment OAT programs.
6. Consistently report concurrent cultural, rehabilitation, and treatment program names and histories for each client in client charts.

For future studies, I recommend the following:

1. Evaluate the effect of client emotional and mental health on tapering initiation and success.
2. Evaluate the effect of sociodemographic and dosing characteristics on tapering initiation and success for active and inactive clients.
3. Evaluate the effect of newer treatment options - such as, Sublocade, slow-release oral morphine, and, diacetylmorphine and hydromorphone injections on OAT outcomes.
4. Evaluate the effect of holistic and cultural approaches on OAT outcomes.

Postscript

To close my thesis, I would like to look back on what I hoped to achieve with my research. Recalling the personally devastating impact that the opioid crisis has on me with the passing of my father, I sought to uncover answers as to why my father and many others had become dependent on opioids, and if possible, help prevent unnecessary and accidental deaths to opioids in the future. While there are many pathways that can lead to opioid dependencies, in my father's case, I discovered that it was due to an unfortunate practice of liberal and inappropriate prescriptions that took place in the 1990s. Treatment guidelines were not well defined back then, and I believe health-care providers were discontinuing treatment too early and inappropriately planning taper speeds – both of which contributed to increases in relapse and accidental overdose. I had seen experiences similar to my father's documented throughout my review of the published literature, and within various books, documentaries, and newspaper articles. What I had not seen adequately represented prior to beginning my thesis was the impact of the opioid crisis specifically in Indigenous communities. Throughout my literature review, I became more aware of the direct role that colonialism and IRS have had on the health and well-being of Indigenous peoples and continue to have on the increased health disparities experienced by Indigenous communities. This opened my eyes to other pathways of dependency that demonstrate why Indigenous communities are particularly vulnerable to opioid use disorders.

When looking at preventing unnecessary and accidental deaths to opioids in the future, I believe there are some answers that I have learned throughout this thesis. Above all, it is crucial that health-care providers and patients work together to discuss treatment expectations and plans. It would not be right for me to suggest, for example, “tapering for all patients”, as I believe this is inappropriate when examining each patients' unique history of dependency and respective

stage in treatment. However, if a patient is seeking to eliminate drug therapy and they are fit to do so (demonstrated by previous adherence to pre-taper maintenance doses and/or adherence to treatment programs in the past), I do think this can be achieved. What I haven't addressed yet in this section, but would like to stress here, is that I do not think treatment doses alone can lead to sustained abstinence. Instead, it is necessary to consider and either directly treat or provide resources that address the underlying reasons that led to each patient's unique pathway of opioid dependency. This is where I believe mainstream models of OAT can learn from Naandwe Miikan's incorporation of holistic and cultural approaches to recovery, that do not solely treat the physical and biological aspects of health and well-being. If there are not concurrent healing and treatment programs available that can support a patient's recovery both during and after treatment, then I do not believe it is possible to appropriately and adequately reduce unnecessary and accidental deaths to opioids related to treatment dropout and/or relapse.

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Appendix A

Data elements collected and how responses were coded:

Gender

Gender was collected as recorded in clients' electronic intake forms. Gender included only male and female categories, the electronic intake forms and EMR did not include any gender fluid categories. Genders were recorded as '1' for males, or '2' for females.

Age

Clients' dates of birth were collected from their electronic intake forms that were accessible through NOVX Systems' PatientVu EMR. The dates of birth were recorded in the format MM/DD/YYYY. Subsequently, the dates of birth were compared with the intake dates on the electronic intake forms in order to generate an age in years.

Intake Date

Clients' dates of intake were collected from their electronic intake forms that were accessible through NOVX Systems' PatientVu EMR. The intake dates were recorded in the format MM/DD/YYYY. In the event that clients left the program and returned after an unspecified period of time, a new intake date was not recorded. Instead, a return to the program was recorded as a new treatment start date under the 'Treatment Doses' section.

Drug(s) of Choice

Clients' drugs of choice were collected from their electronic intake forms that were accessible through NOVX Systems' PatientVu EMR. The decision for a drug to be listed as a drug of choice was made by the physician or physician-assistant following a client interview at intake and subsequently recorded in their electronic intake form. In total, 18 drugs were assessed, these include: morphine; fentanyl; carfentanyl; codeine; hydromorphone; heroin; methadone;

Suboxone; oxycodone; other opioids; cocaine; barbituates; amphetamines; alcohol; cannabis; cigarettes; benzodiazepines; and crystal meth. However, due to the infrequent response and quality of data for 7 of the 18 drugs, only 11 – morphine; fentanyl; codeine; hydromorphone; heroin; methadone; Suboxone; oxycodone; other opioids; cocaine; and, amphetamines – were included for further assessment. If a drug had been determined to be a drug of choice, it was recorded with a “1”. If a drug had been determined to not be a drug of choice, it was recorded with a “0”. The overall decision of a ‘drug of choice’ was determined through 6 additional variables present on the electronic intake forms: average daily use; average weekly use; length of use; route; age at first use; and, last use. However, due to the infrequent response and quality of data for 3 of the 6 variables, only 3 – average daily use; length of use; and, route – were included for further assessment.

Average Daily Use

Average daily use for presenting drugs was provided by the client during an intake interview. Responses recorded ranged from specific measurements such as milligrams, grams, etc. to more vague measurements such as daily, occasionally, once in a while, etc. The responses were then grouped respectively for each drug, in order to facilitate their analyses.

Length of Use

The length of clients’ current usage (based on their average daily use) was provided by the client during an intake interview. Lengths of use were recorded in months or years.

Route

The route of administration for each presenting drug was provided by the client during an intake interview. The routes of administration recorded for each of the 11 drugs assessed, include: nasal; oral; intravenous (IV); smoke; and, sublingual. Depending on the drug being assessed,

combinations of two alternating routes of administration were frequently reported, these were recorded as new values in SPSS, these included: nasal/oral; nasal/IV; nasal/smoke; smoke/oral; IV/smoke; and, IV/oral.

Emotional Health

The responses to the 'Emotional Health' questionnaires were provided by the clients during an intake interview. The questionnaire investigated the history and/or current presence of 11 conditions or events related to emotional health, these include: anxiety; depression; previous admittance to a psychiatric facility; previous treatment for any emotional problems; history of abuse (mental, sexual, or physical); previous suicide attempts; current depression; current suicidal ideation; current homicidal ideation; attention deficit hyperactivity disorder (ADHD); and, post-traumatic stress disorder (PTSD). Responses to each question were recorded as '1' for 'yes' and '0' for 'no'.

Social History

Clients' social histories were collected from their electronic intake forms that were accessible through NOVX Systems' PatientVu EMR. At intake, clients were asked to provide information on 14 variables, these include: marital status; number of children; whose custody the children are in; who lives in their household; if those living with them abuse alcohol/drugs; if those close to them are aware of their drug problem; if they are currently employed; current occupation; usual occupation; last job held; employed from-to; highest level of education; if they are receiving financial support; and, if they drive. However, due to the infrequent response and quality of data for 6 of the 14 variables, only 8 – marital status; number of children; whose custody the children are in; who lives in their household; if those living with them abuse alcohol/drugs; if those close

to them are aware of their drug problem; if they are currently employed; and, highest level of education – were included for further assessment.

Marital Status

Marital status was provided by the clients during an intake interview. Responses were recorded into 3 groups – single; in relationship; and, widowed.

Number of Children

Number of children was provided by the clients during an intake interview. Responses were recorded into 4 groups – no children; 1-2 children; 3-4 children; and, 5 or more children.

Custody

Whose custody the children are in was provided by the clients during an intake interview. Responses were recorded into 6 groups – parent/partner; self/full-custody; shared/joint-custody; grown/adults; grandparents; and, other (CAS involved; child on the way; and, aunt).

Household

With whom clients are living was provided by clients during an intake interview. Responses were recorded into 5 groups – family without children; family with children; friends; alone; and, other (Rainbow Lodge; roommate).

Household Substance Abuse

Whether or not those living in the same household as clients are abusing substances was provided by clients during an intake interview. Responses to this question were recorded as '1' for 'yes' and '0' for 'no'.

Awareness of Others

Whether or not those close to the clients are aware of the drug dependency was provided by clients during an intake interview. Responses to this question were recorded as '1' for 'yes' and '0' for 'no'.

Currently Employed

Whether or not clients were currently employed (as of intake date) was provided by clients during an intake interview. Responses to this question were recorded as '1' for 'yes' and '0' for 'no'.

Highest Level of Education

Clients' highest level of education achieved was provided by clients during an intake interview. Responses were recorded into 5 groups – did not finish high-school; high-school/GED; college/university; elementary/grade school; and, none.

Clients' Motivations for Treatment

Clients were asked for their motivations for seeking treatment during an intake interview. Responses were recorded into 5 groups – family/custody/children; personal/withdrawal/health; employment/financial/educational; maintain abstinence/continue treatment; and, legal concerns.

Treatment Doses

Program treatment doses were collected for all active clients, as of December 2019, on a monthly basis from May 2014 to December 2019. Treatment doses were recorded based on the treatment drug used, either Suboxone or methadone. Additionally, all Suboxone and methadone treatment start and end dates were collected from the EMR. All doses for both treatment drugs were recorded in milligrams (mg).

Toxicology Data

Toxicology data was collected for all active clients, as of December 2019, only for November 2018 and November 2019. In each case, the service date was recorded. The substances that were screened for each toxicology screen fell within seven categories: opioids; amphetamines; benzodiazepines; anti-depressants; anti-psychotics; cannabinoids; and, other. In total, 58 substances were screened for each client.

Opioids

For ‘opioids’, 17 unique substance screenings were recorded. The presence of each substance was recorded with either a ‘1’ to state that ‘yes’ the substance was present, or a ‘0’ to state that ‘no’ the substance was not present. Whether or not the substances were prescribed was also recorded with either a ‘1’ to state that ‘yes’ the substance was prescribed, or a ‘0’ to state that ‘no’ the substance was not prescribed. The 17 unique substances screened include:

hydromorphone; morphine; oxycodone; acetylmorphine; methadone; EDDP; buprenorphine; norbuprenorphine; naloxone; dextromethorphan; dextropropoxyphene; hydrocodone; codeine; tramadol; fentanyl; norfentanyl; and oxycodone.

Amphetamines

For ‘amphetamines’, 5 unique substance screenings were recorded. The presence of each substance was recorded with either a ‘1’ to state that ‘yes’ the substance was present, or a ‘0’ to state that ‘no’ the substance was not present. Whether or not the substances were prescribed was also recorded with either a ‘1’ to state that ‘yes’ the substance was prescribed, or a ‘0’ to state that ‘no’ the substance was not prescribed. The 5 unique substances screened include: ritalinic acid; methamphetamine; amphetamine; methylphenidate; and, methcathinone.

Benzodiazepines

For 'benzodiazepines', 5 unique substance screenings were recorded. The presence of each substance was recorded with either a '1' to state that 'yes' the substance was present, or a '0' to state that 'no' the substance was not present. Whether or not the substances were prescribed was also recorded with either a '1' to state that 'yes' the substance was prescribed, or a '0' to state that 'no' the substance was not prescribed. The 5 unique substances screened include: temazepam; oxazepam; nordiazepam; lorazepam; and, HO-Alprazolam.

Anti-depressants

For 'anti-depressants', 12 unique substance screenings were recorded. The presence of each substance was recorded with either a '1' to state that 'yes' the substance was present, or a '0' to state that 'no' the substance was not present. The 12 unique substances screened include: mirtazapine; sertraline; bupropion; HO-Bupropion; citalopram; trazadone; nortriptyline; venlafaxine; norfluoxetine; fluoxetine; duloxetine; and, mCPP.

Anti-psychotics

For 'anti-psychotics', 5 unique substance screenings were recorded. The presence of each substance was recorded with either a '1' to state that 'yes' the substance was present, or a '0' to state that 'no' the substance was not present. Whether or not the substances were prescribed was also recorded with either a '1' to state that 'yes' the substance was prescribed, or a '0' to state that 'no' the substance was not prescribed. The 5 unique substances screened include: quetiapine; norquetiapine; olanzapine; HO-Risperidone; and, haloperidol.

Cannabinoids

For 'cannabinoids', 1 unique substance screening was recorded. The presence of each substance was recorded with either a '1' to state that 'yes' the substance was present, or a '0' to state that

'no' the substance was not present. Whether or not the substances were prescribed was also recorded with either a '1' to state that 'yes' the substance was prescribed, or a '0' to state that 'no' the substance was not prescribed. The 1 unique substance screened include: THC-A.

Other

For 'other', 13 unique substance screenings were recorded. The presence of each substance was recorded with either a '1' to state that 'yes' the substance was present, or a '0' to state that 'no' the substance was not present. Whether or not the substances were prescribed was also recorded with either a '1' to state that 'yes' the substance was prescribed, or a '0' to state that 'no' the substance was not prescribed. The 13 unique substances screened include: cotinine; levamisole; gabapentin; pregabalin; benzoylecgonine; cocaethylene; diphenhydramine; ephedrine; pseudoephedrine; desmethylzopiclone; chlorpheniramine; cyclobenzaprine; and, N-desmethylocyclobenzaprine.

Illicit Substances in November 2018

Through the examination of the toxicology screen data provided for November 2018, the presence of illicit substances was recorded. Any substances that would be considered illicit without a prescription were evaluated and recorded with a '1' to state that 'yes' illicit substances were detected in November 2018, or a '0' to state that 'no' illicit substances were detected in November 2018.

Illicit Substances in November 2019

Through the examination of the toxicology screen data provided for November 2019, the presence of illicit substances was recorded. Any substances that would be considered illicit without a prescription were evaluated and recorded with a '1' to state that 'yes' illicit substances

were detected in November 2019, or a '0' to state that 'no' illicit substances were detected in November 2019.

Taper Data

Tapering data was established through our interpretation of the monthly program treatment doses, which were collected for all active clients, as of December 2019, from May 2014 to December 2019. Through an analysis of the monthly treatment doses, combined with an understanding of the mechanics of tapering within opioid agonist treatments, definitions were formed for what constituted 'current tapering' and 'tapering' in general. Once a therapeutic dose had been achieved, it was observed that any reductions in treatment doses that followed consistently occurred in 1 to 3-month intervals. With this in mind, a client was considered to have had a history of tapering if there was an observed pattern of 1 to 3-month reductions in their treatment doses. Importantly, if the reduction was severe – usually a dose reduced drastically to a recognizable treatment starting value consistent with early methadone and Suboxone doses – this was indicative of treatment restarts, which were not considered as current or historical tapers. In order to distinguish between signs of very early stages of tapering, signs of dose reductions that may occur when finding and arriving at a therapeutic dose, and signs of current tapering, active clients had to have dose data that depicted a clear pattern of reduction over at least a period of 3-months – leading up to and including December 2019 – to be considered 'current tapers'.

Current Reduction in Treatment Doses

Using the definition of 'current taper', it was possible to then calculate reductions in doses for all active clients identified as 'current tapers', as of December 2019. Reductions were calculated by comparing the treatment dose at taper initiation to the December 2019 treatment dose. Results were displayed in a percentage of dose reduction.

Current Tapering Length

Using the definition of ‘current taper’, it was possible to then calculate the length for all active treatments identified as ‘current tapers’, as of December 2019. Tapering lengths were calculated by comparing the month and year at tapering initiation to the month and year at tapering cessation. Results were displayed in months and years.

Previously Enrollment in an OAT

History of OAT enrollment was provided by clients during an intake interview. Responses were recorded as ‘1’ to state that ‘yes’ the client had previously been enrolled in an OAT, or ‘0’ to state that ‘no’ the client had not previously been enrolled in an OAT.

Appendix B

Summary Demographic and Treatment Statistics for Naandwe Miikan:

Gender of Clients

Gender was collected using the data from clients' electronic intake forms. Gender included only male and female categories, the intake forms did not include any gender fluid categories. Of the 142 active clients at Naandwe Miikan, 124 clients had their genders available for collection.

Based on the data available, 58 (47%) are females and 66 (53%) are males (See Fig. 1).

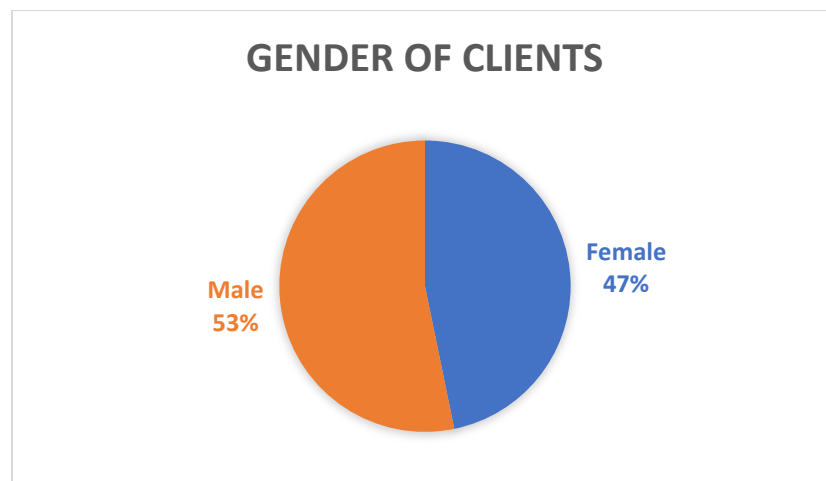


Fig. 1 – Gender of clients at Naandwe Miikan.

Age of Clients

Clients' dates of birth were collected from their intake forms and used to generate an age in years.

From this, age groups were created to better display the client ages at Naandwe Miikan (See Fig.

2). The average age of clients is 32.5 years of age.

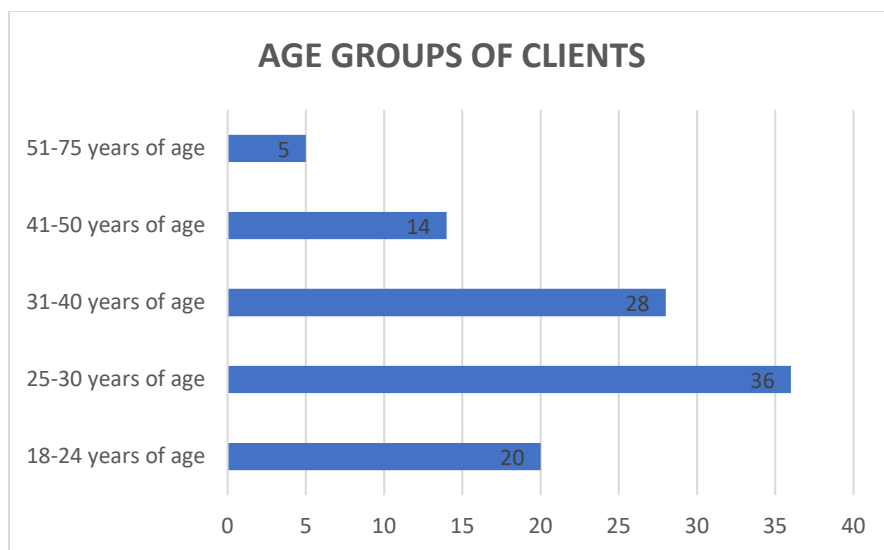


Fig. 2 – Age groups of clients at Naandwe Miikan.

Intakes Per Year

The intake dates for all 142 active clients at Naandwe Miikan were collected to determine the number of intakes per year between 2014-2019 (See Fig. 3).

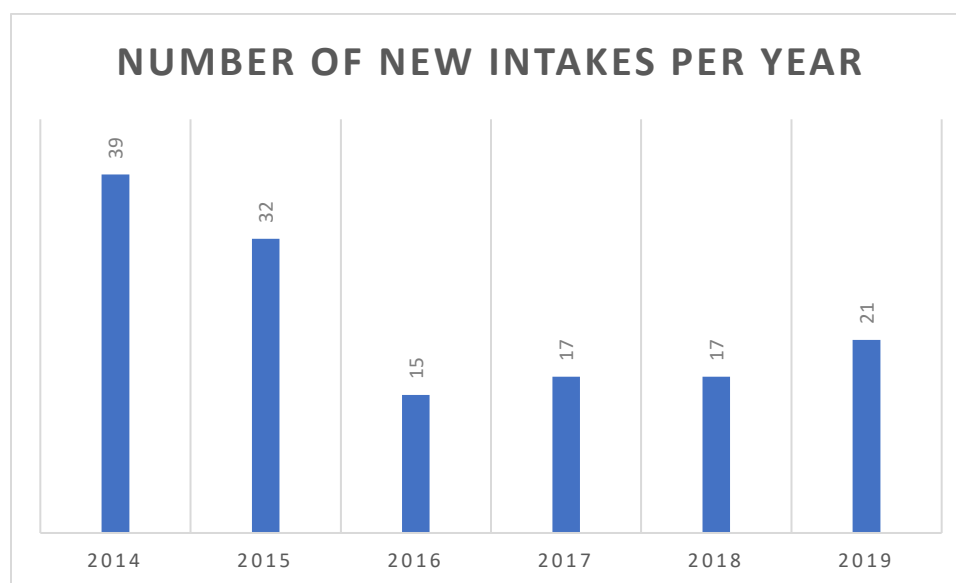


Fig. 3 – Number of new intakes per year at Naandwe Miikan.

Starting Treatment Drug by Year

The starting treatment drugs (either Suboxone or methadone) were collected for all 142 active clients to determine the number of clients receiving each drug as a starting treatment each year between 2014-2019 (See Fig. 4).

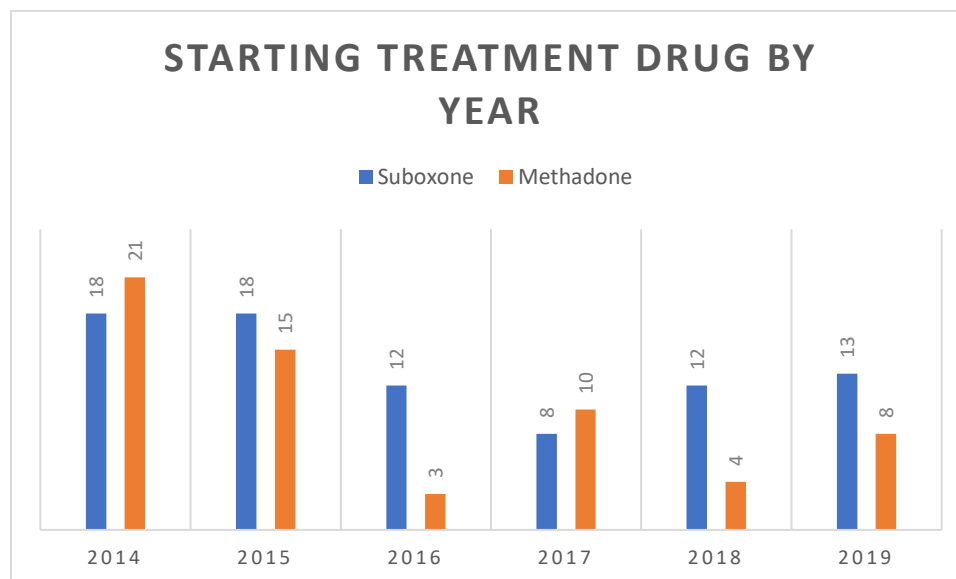


Fig. 4 – Starting treatment drug by year for clients at Naandwe Miikan.

Treatment Length

The treatment length was collected for each of the 142 active clients at Naandwe Miikan between 2014-2019 (See Fig. 5). The average treatment length was 38.5 months.

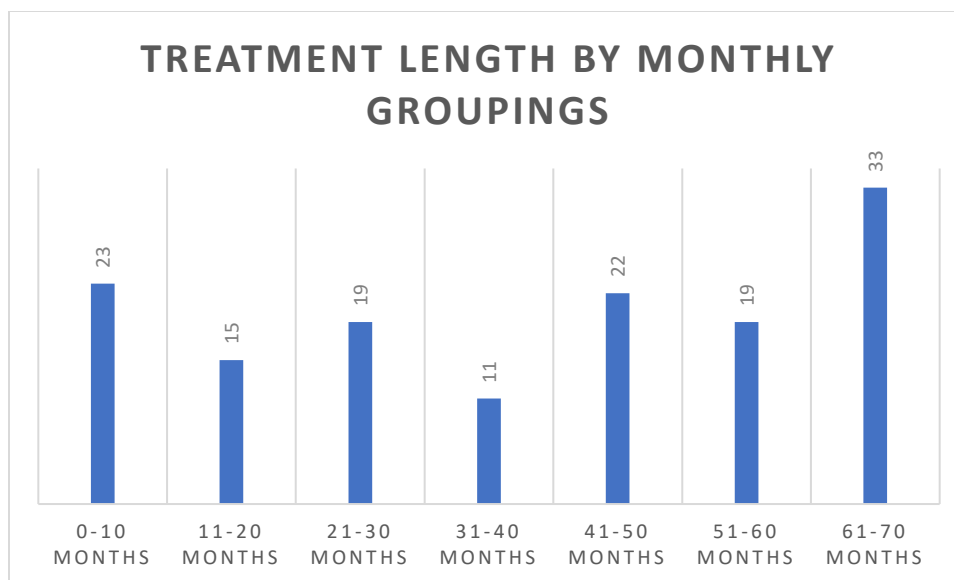


Fig. 5 – Treatment lengths (separated by monthly groupings) for clients at Naandwe Miikan.

Taper Data

The summary data surrounding number of clients currently tapering (as of December 2019), average reduction in treatment dose, and length of tapers were collected for each of the 142 active clients at Naandwe Miikan between 2014-2019 (See Table 1). Of the 142 active clients at Naandwe Miikan, 25% of all active clients are currently tapering (as of December 2019). Of the current tapers, clients experience on average a 49% reduction in treatment dose from taper initiation to the date of data collection (December 2019). Lastly, the majority of tapers (67%) were extended tapers over 1 to 4 years in length.

Table 1. Summary taper results for clients at Naandwe Miikan between May 2014 to December 2019.

SUMMARY TAPER RESULTS FOR METHADONE AND SUBOXONE DOSES	
Currently Tapering:	25% of all active clients
Mean Tapered Percent:	49% reduction in treatment dose
Length of Tapers	<1 year (33%); 1 to 4 years (67%)

Toxicology Results in November 2018

Toxicology results were collected for each of the 142 active clients at Naandwe Miikan for November 2018. The frequencies of clients with a detected substance were collected for 7 groups: Opioids, Amphetamines, Benzodiazepines, Anti-Depressants, Anti-Psychotics, Cannabinoids, and Other (see Fig.6).

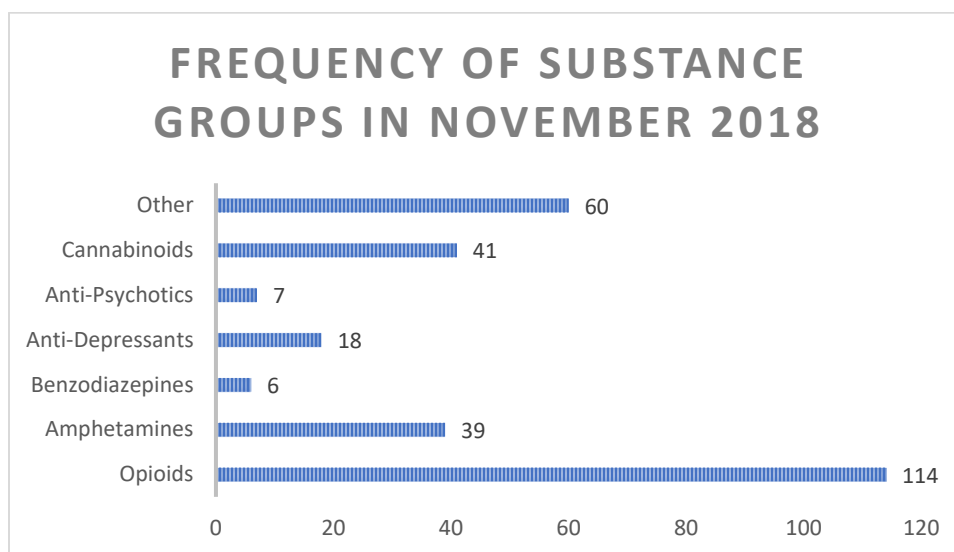


Fig. 6 – Frequencies of detected substance groups in November 2018 for clients at Naandwe Miikan.

For the group 'Opioids', 17 unique opioids were screened for based on the toxicology results. Frequencies of detected opioids were collected for each active client in November 2018 (see Fig.7).

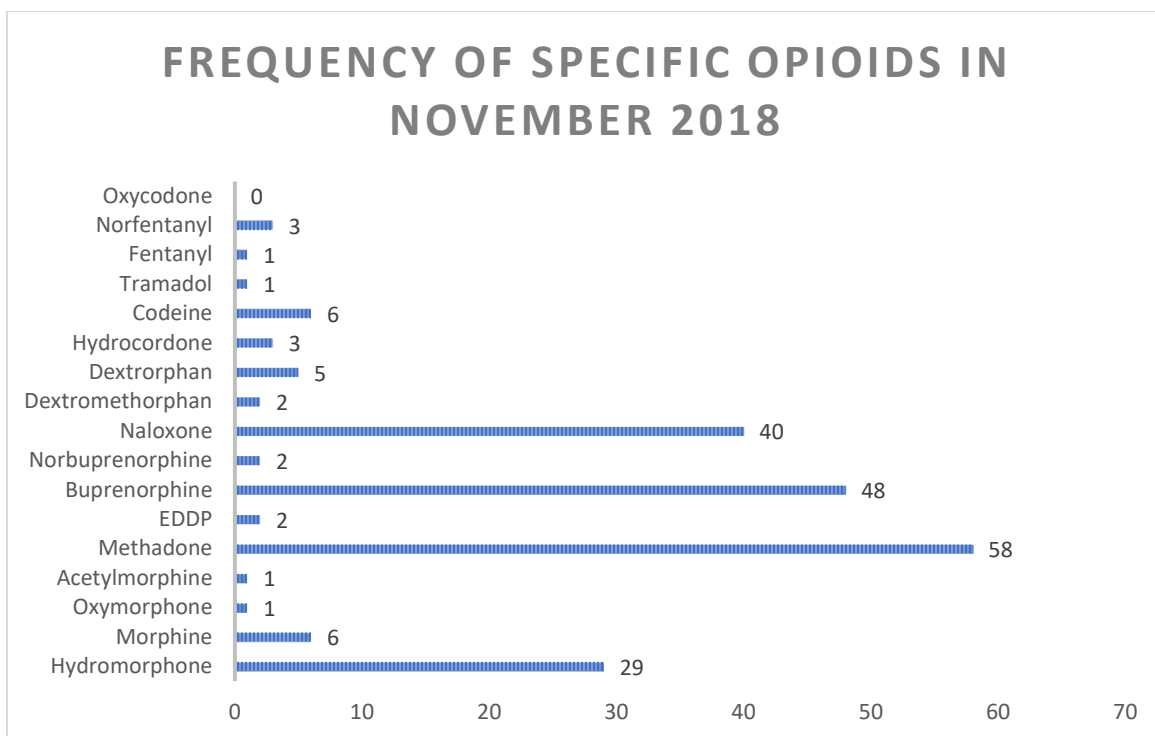


Fig. 7 – Frequencies of detected opioids in November 2018 for clients at Naandwe Miikan.

For the group ‘Amphetamines’, 5 unique amphetamines were screened for based on the toxicology results. Frequencies of detected amphetamines were collected for each active client in November 2018 (see Fig.8).

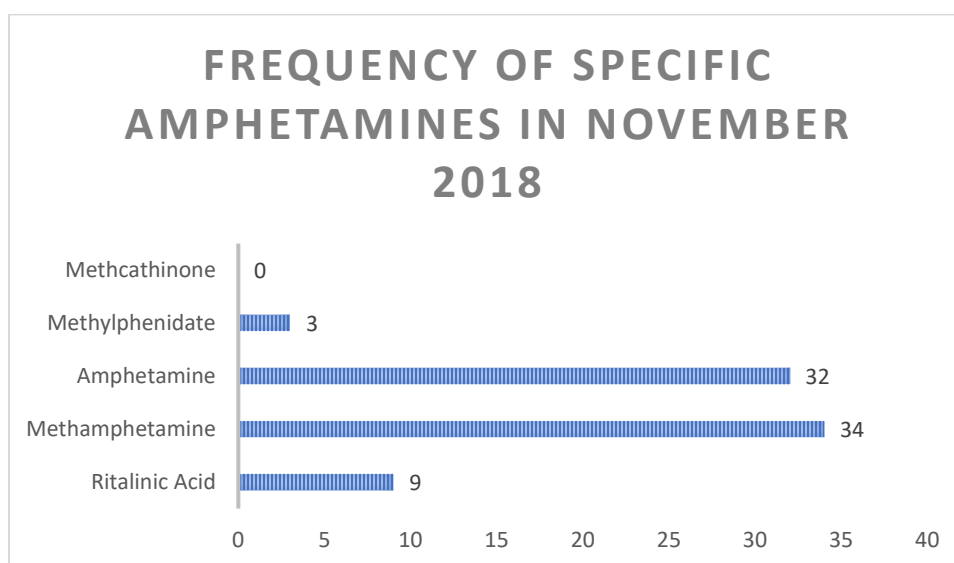


Fig. 8 – Frequencies of detected amphetamines in November 2018 for clients at Naandwe Miikan.

For the group ‘Benzodiazepines’, 5 unique benzodiazepines were screened for based on the toxicology results. Frequencies of detected benzodiazepines were collected for each active client in November 2018 (see Fig.9).

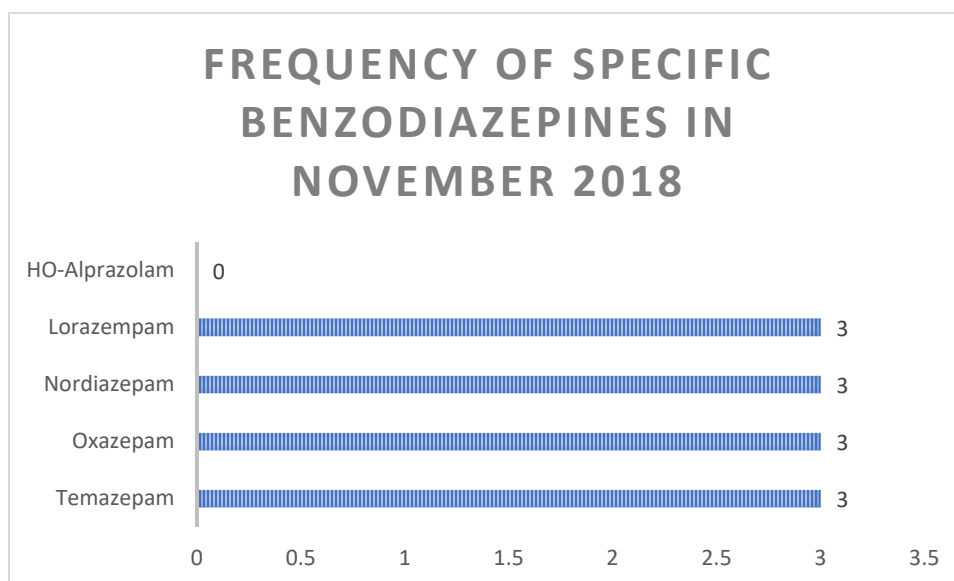


Fig. 9 – Frequencies of detected benzodiazepines in November 2018 for clients at Naandwe Miikan.

For the group ‘Anti-Depressants’, 12 unique anti-depressants were screened for based on the toxicology results. Frequencies of detected anti-depressants were collected for each active client in November 2018 (see Fig. 10).

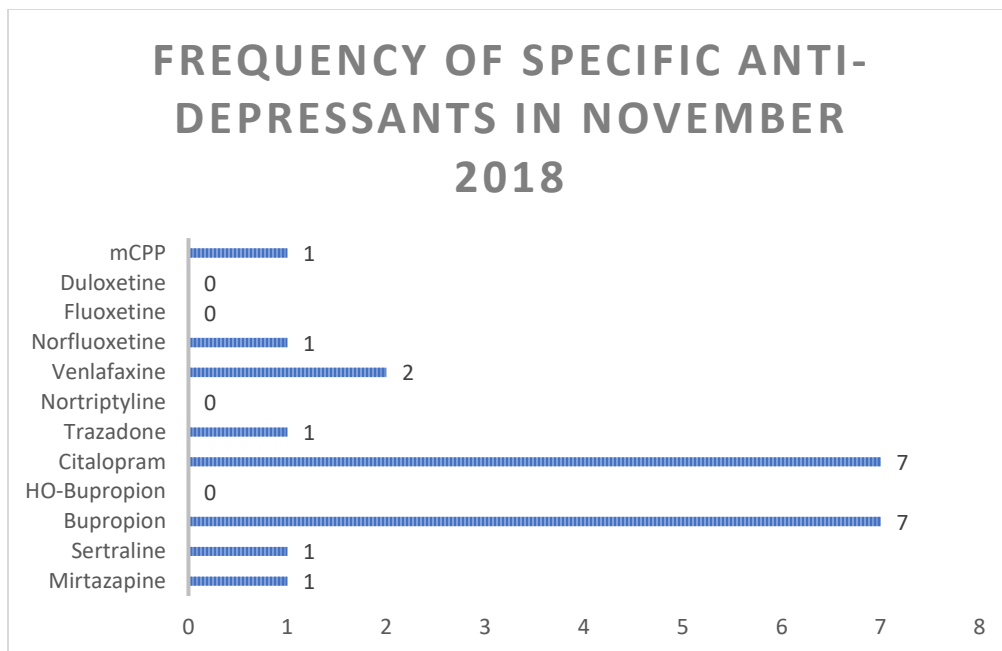


Fig. 10 – Frequencies of detected anti-depressants in November 2018 for clients at Naandwe Miikan.

For the group ‘Anti-Psychotics’, 5 unique anti-psychotics were screened for based on the toxicology results. Frequencies of detected anti-psychotics were collected for each active client in November 2018 (see Fig.11).

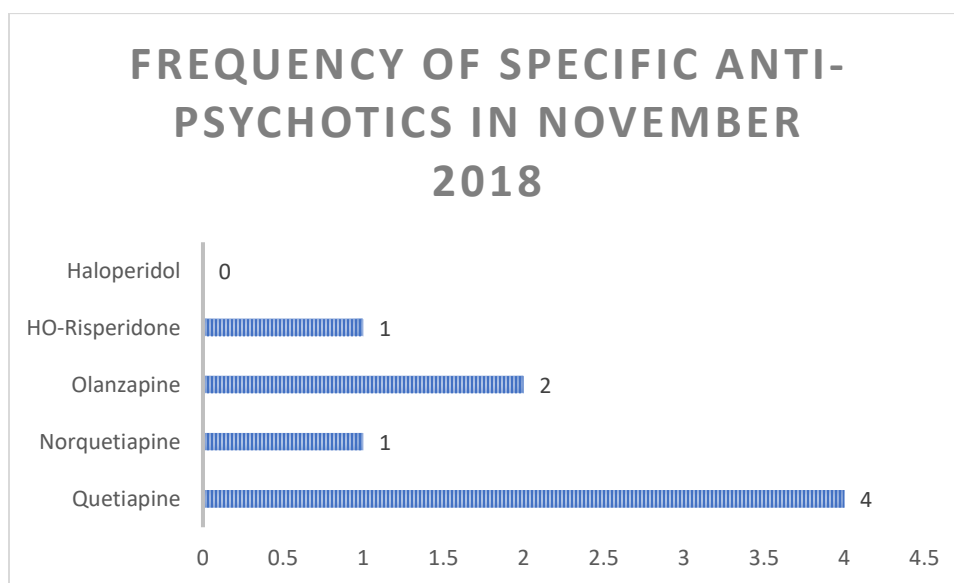


Fig. 11 – Frequencies of detected anti-psychotics in November 2018 for clients at Naandwe Miikan.

For the group ‘Cannabinoids’, 1 unique cannabinoid was screened for based on the toxicology results. The frequency of the detected cannabinoid was collected for each active client in November 2018 (see Fig.12).

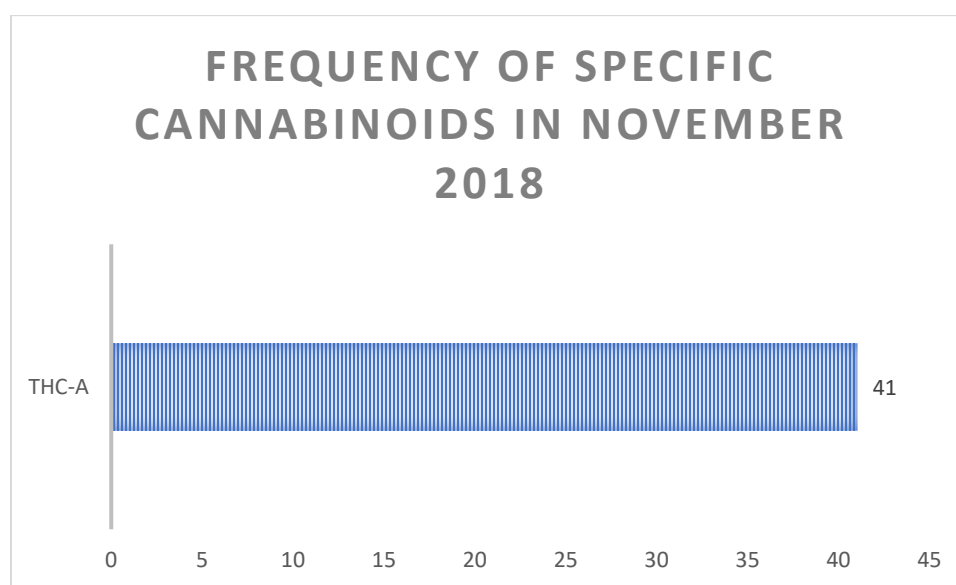


Fig. 12 – Frequency of detected cannabinoids in November 2018 for clients at Naandwe Miikan. For the group ‘Other’, 13 unique other substances were screened for based on the toxicology results. The frequency of detected other substances were collected for each active client in November 2018 (see Fig.13).

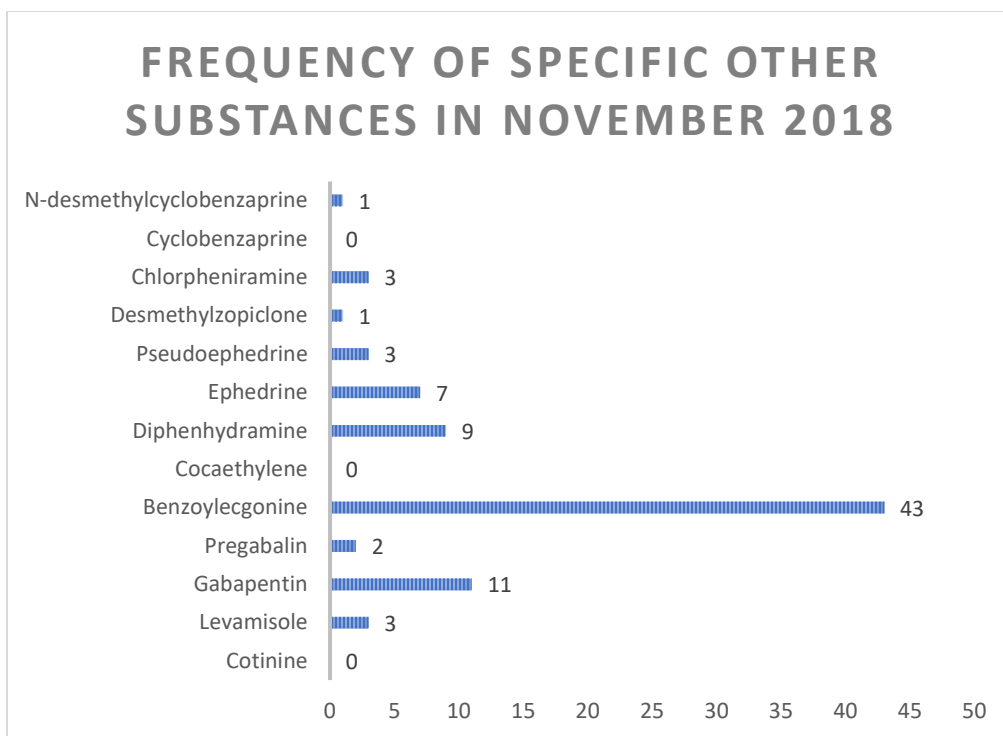


Fig. 13 – Frequency of detected other substances in November 2018 for clients at Naandwe Miikan.

Toxicology Results in November 2019

Toxicology results were collected for each of the 142 active clients at Naandwe Miikan for November 2019. The frequencies of clients with a detected substance were collected for 7 groups: Opioids, Amphetamines, Benzodiazepines, Anti-Depressants, Anti-Psychotics, Cannabinoids, and Other (see Fig.14).

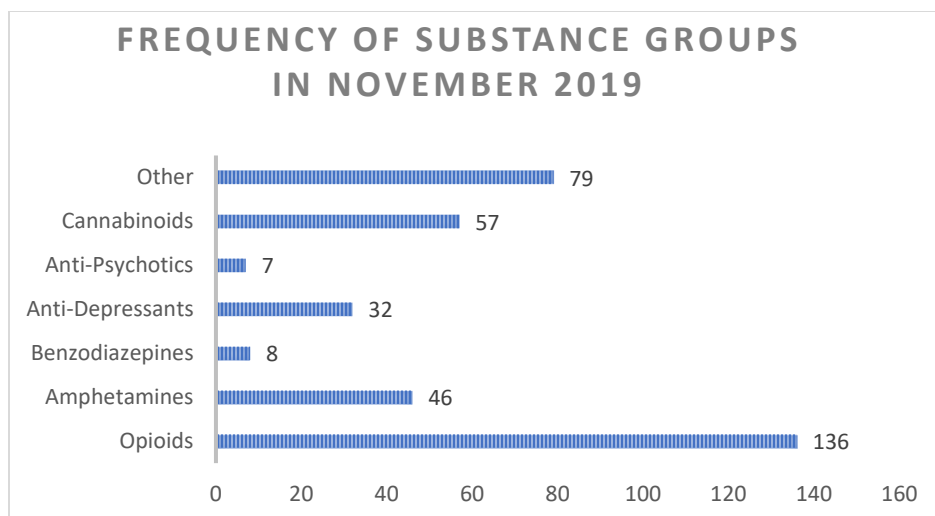


Fig. 14 – Frequencies of detected substance groups in November 2019 for clients at Naandwe Miikan.

For the group ‘Opioids’, 18 unique opioids were screened for based on the toxicology results. Frequencies of detected opioids were collected for each active client in November 2019 (see Fig.15).

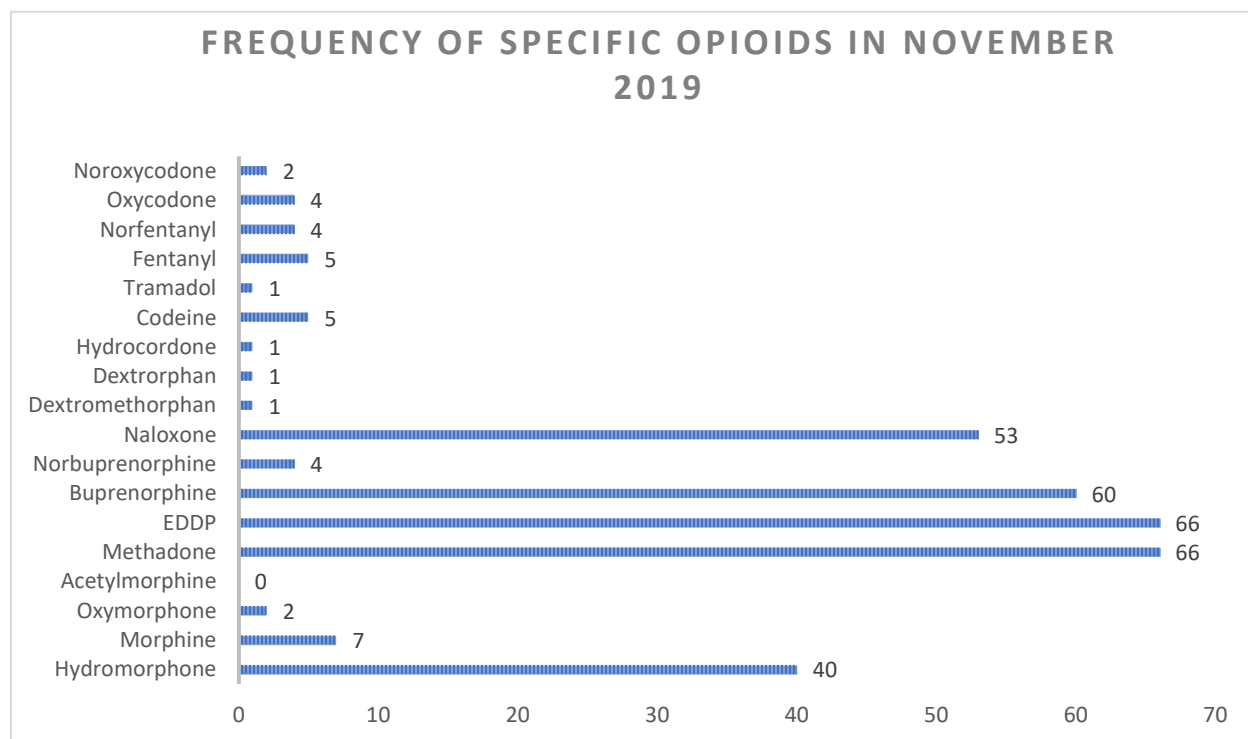


Fig. 15 – Frequencies of detected opioids in November 2019 for clients at Naandwe Miikan.

For the group ‘Amphetamines’, 5 unique amphetamines were screened for based on the toxicology results. Frequencies of detected amphetamines were collected for each active client in November 2019 (see Fig.16).

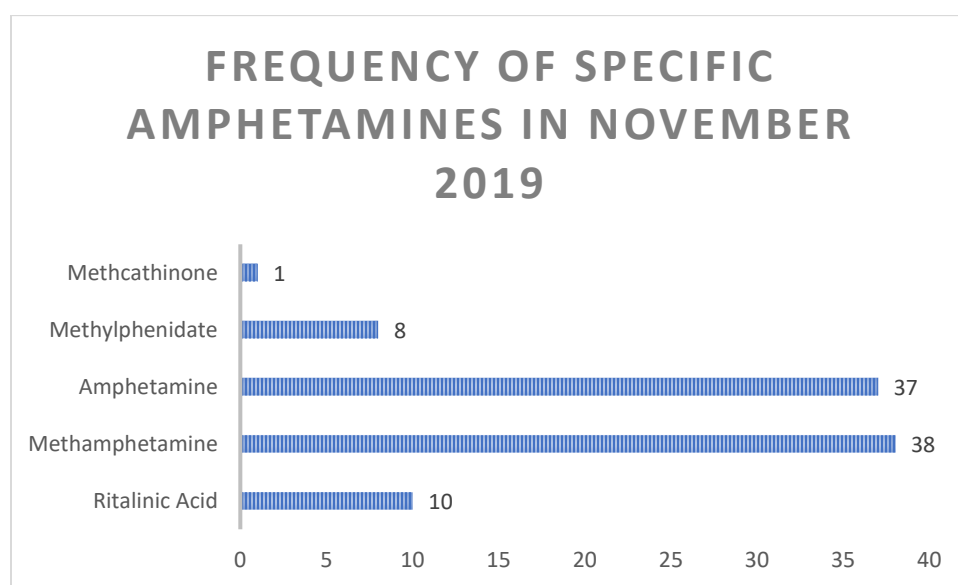


Fig. 16 – Frequencies of detected amphetamines in November 2019 for clients at Naandwe Miikan.

For the group ‘Benzodiazepines’, 5 unique benzodiazepines were screened for based on the toxicology results. Frequencies of detected benzodiazepines were collected for each active client in November 2019 (see Fig.17).

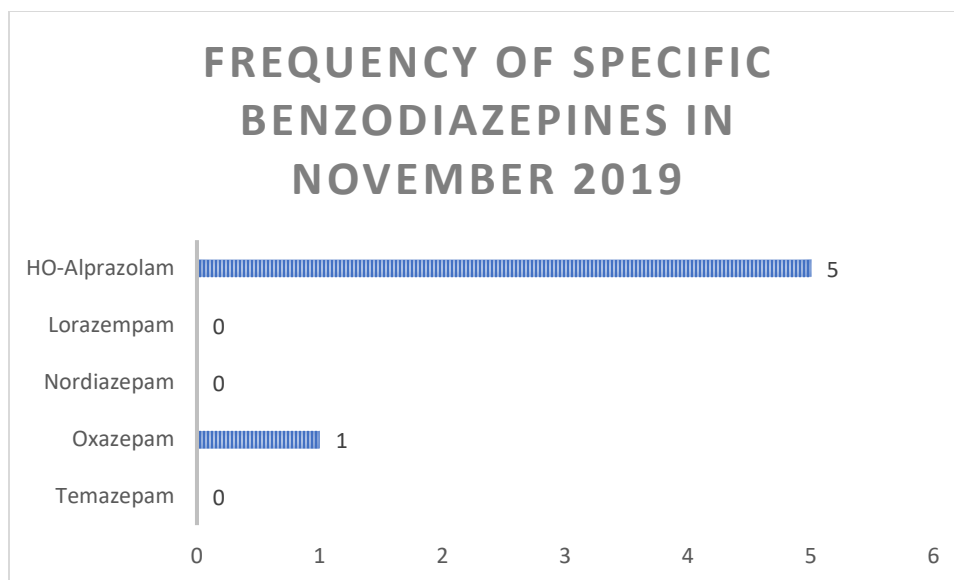


Fig. 17 – Frequencies of detected benzodiazepines in November 2019 for clients at Naandwe Miikan.

For the group ‘Anti-Depressants’, 12 unique anti-depressants were screened for based on the toxicology results. Frequencies of detected anti-depressants were collected for each active client in November 2019 (see Fig. 18).

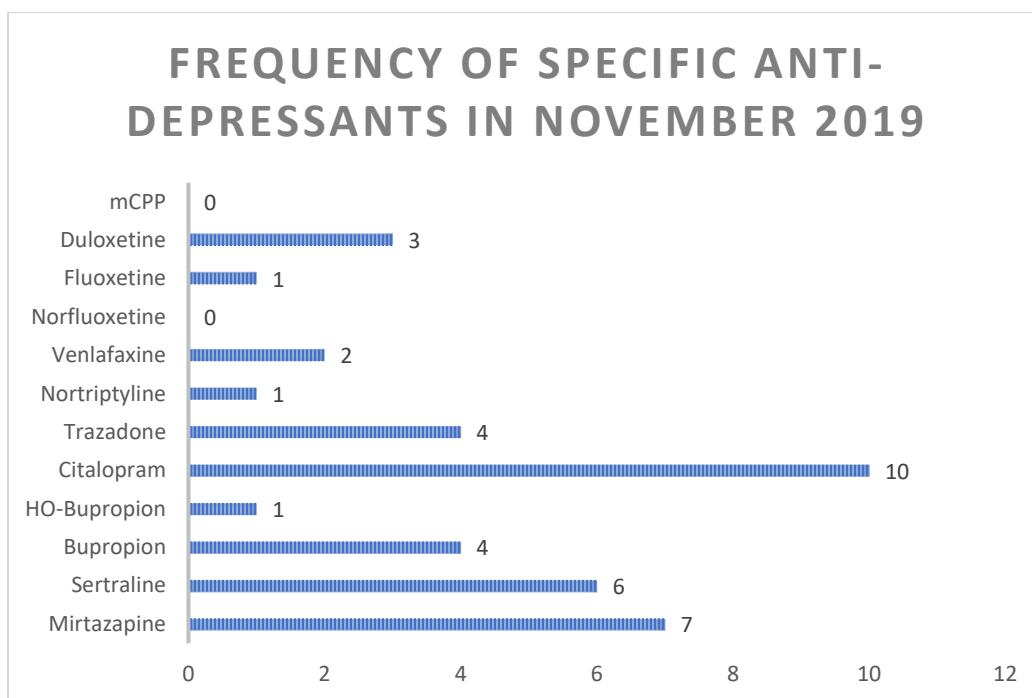


Fig. 18 – Frequencies of detected anti-depressants in November 2019 for clients at Naandwe Miikan.

For the group ‘Anti-Psychotics’, 5 unique anti-psychotics were screened for based on the toxicology results. Frequencies of detected anti-psychotics were collected for each active client in November 2019 (see Fig.19).

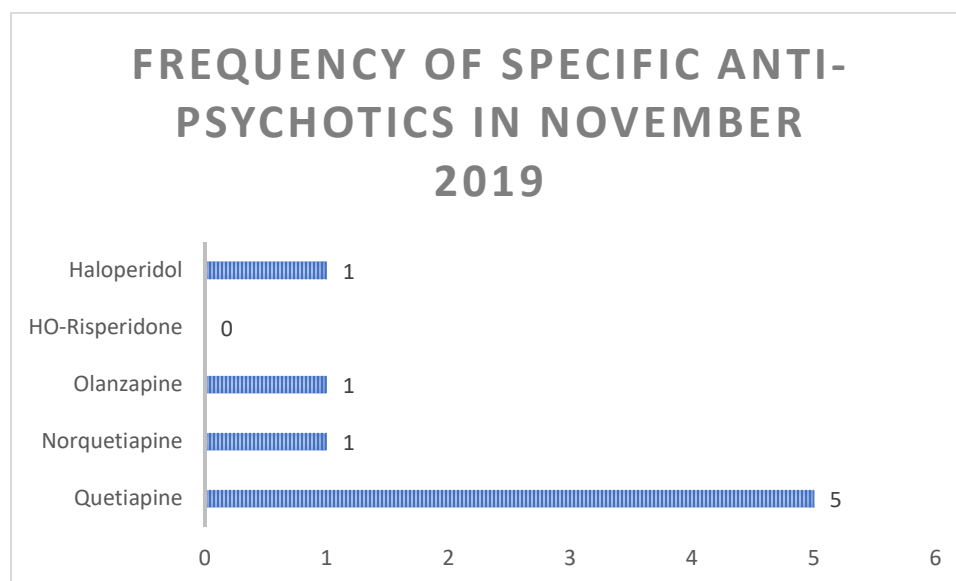


Fig. 19 – Frequencies of detected anti-psychotics in November 2019 for clients at Naandwe Miikan.

For the group ‘Cannabinoids’, 1 unique cannabinoid was screened for based on the toxicology results. The frequency of the detected cannabinoid was collected for each active client in November 2019 (see Fig.20).

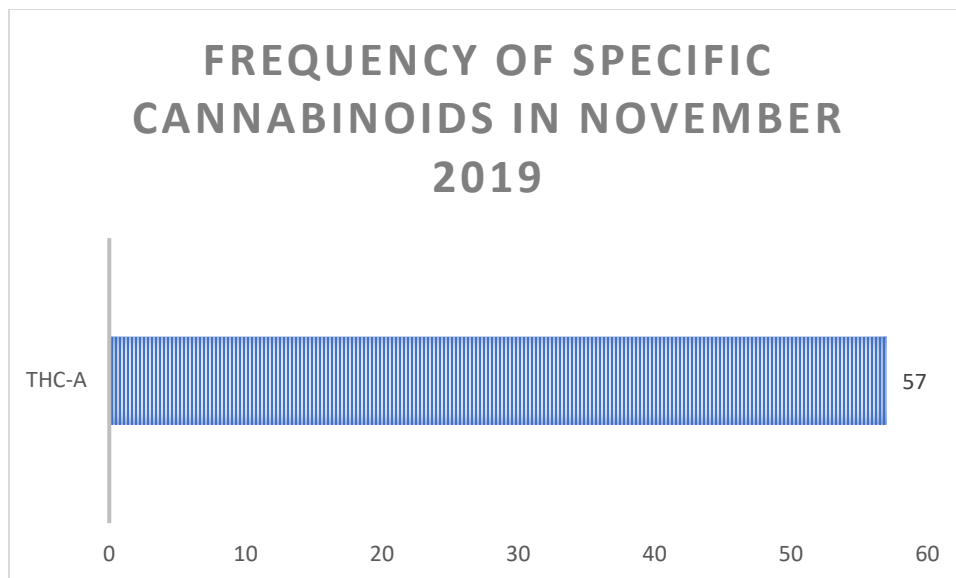


Fig. 20 – Frequency of detected cannabinoids in November 2019 for clients at Naandwe Miikan. For the group ‘Other’, 13 unique other substances were screened for based on the toxicology results. The frequency of detected other substances were collected for each active client in November 2019 (see Fig.21).

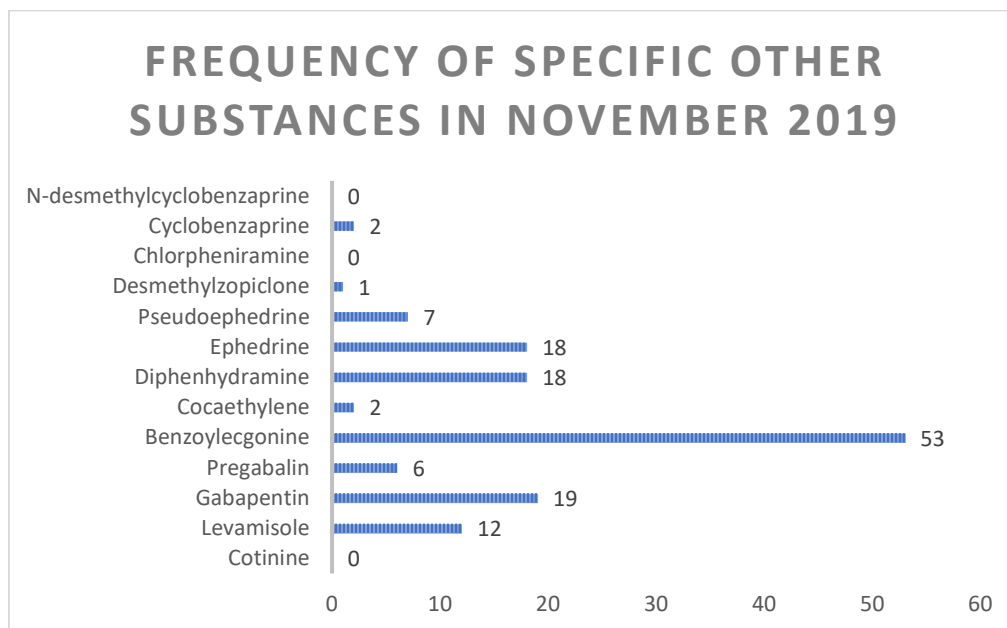


Fig. 21 – Frequency of detected other substances in November 2019 for clients at Naandwe Miikan.

Positive Toxicology Results for 2018 and 2019 for Illicit Substances

The toxicology results that were positive for illicit substances were collected from November 2018 and November 2019 toxicology screens for each of the 142 active clients at Naandwe Miikan. Illicit substances were defined as any substance from the 7 substance groups (See Figs. 6 & 14) that were detected in a client's toxicology results and not obtained via prescription.

In 2018, data for 115 toxicology results were collected. Of the 115 results, 70 (60.9%) clients were positive for illicit substances, and 45 (39.1%) were negative for illicit substances (See Fig.22).

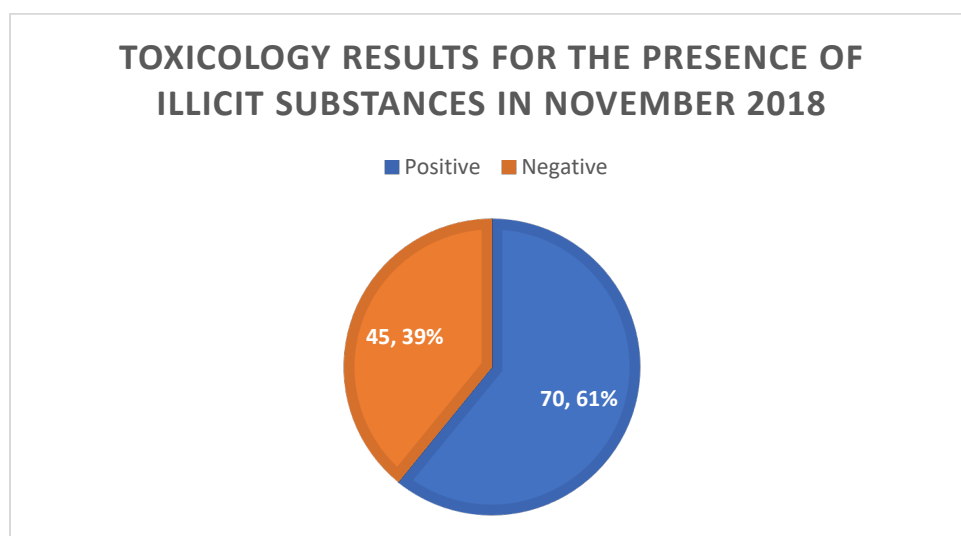


Fig. 22 – Toxicology results for the presence of illicit substances in November 2018 for 115 clients at Naandwe Miikan.

In 2019, data for 136 toxicology results were collected. Of the 136 results, 93 (68.4%) clients were positive for illicit substances, and 43 (31.6%) were negative for illicit substances (See Fig. 23).

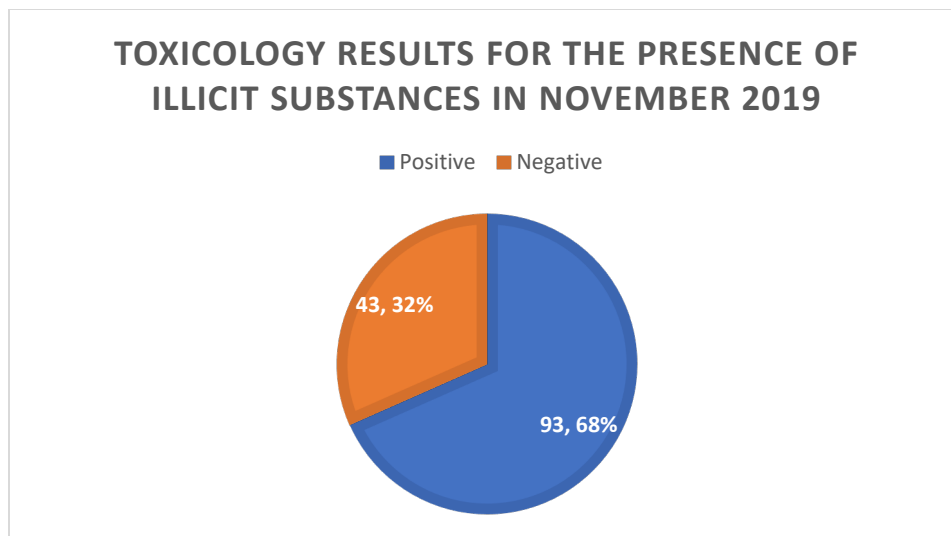


Fig. 23 – Toxicology results for the presence of illicit substances in November 2019 for 136 clients at Naandwe Miikan

Taper Initiation Results for Naandwe Miikan 2014-2019

A client was defined as having a taper initiated if there was an observed pattern of 1 to 3-month reductions in their treatment doses. Importantly, if the reduction was severe – usually a dose reduced drastically to a recognizable treatment starting value consistent with early methadone and Suboxone doses – this was indicative of treatment restarts and were not considered taper initiation events.

Of the 102 clients included in the analysis, 49 (48.0%) did not have tapers initiated, and 53 (52.0%) had tapers initiated.

The potential effects of education level, age, gender, start drug, start dose, and number of children, were considered when investigating tapering initiation.

Education Level

Of the 49 clients who did not have tapers initiated, 25 (51.0%) did not finish high-school, and 24 (49.0%) had finished high-school/GED or University/College. Of the 53 clients who had tapers initiated, 28 (52.8%) did not finish high-school, and 25 (47.2%) had finished high-school/GED or University/College. There were no significant findings (See Fig. 24).

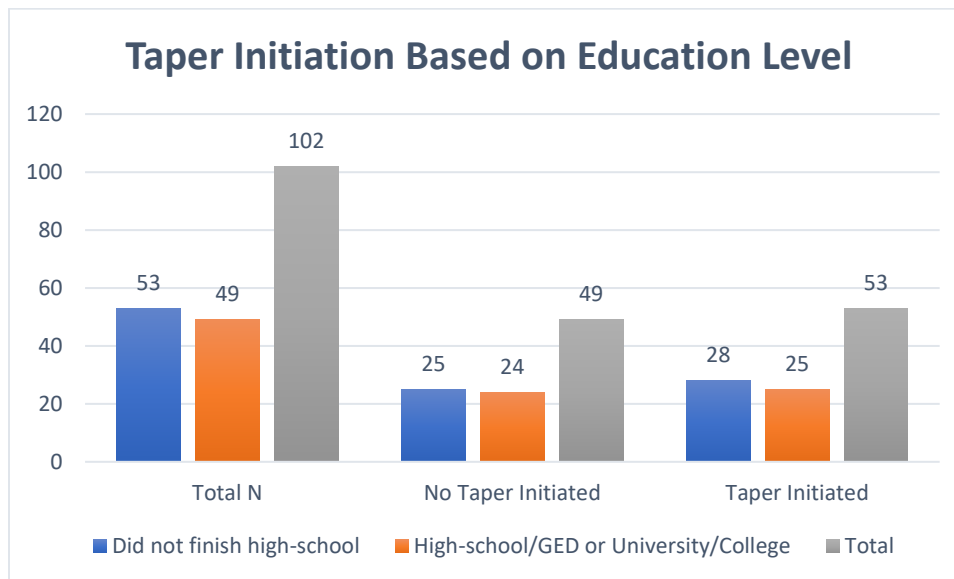


Fig. 24 – Results for taper initiation based on education level.

Age

Of the 49 clients who did not have tapers initiated, 31 (63.3%) were 18-34 years old, and 18 (36.7%) were 35 or more years old. Of the 53 clients who had tapers initiated, 38 (71.7%) were 18-34 years old, and 15 (28.3%) were 35 or more years old. There were no significant findings (See Fig. 25).

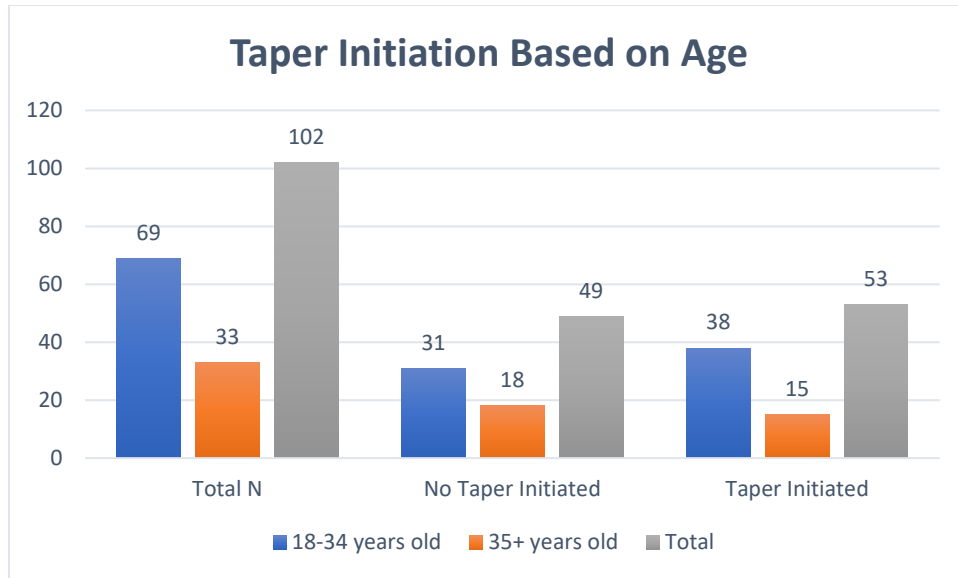


Fig. 25 – Results for taper initiation based on age.

Gender

Of the 49 clients who did not have tapers initiated, 30 (61.2%) were male, and 19 (38.8%) were female. Of the 53 clients who had tapers initiated, 27 (50.9%) were male, and 26 (49.1%) were female. There were no significant findings (See Fig. 26).

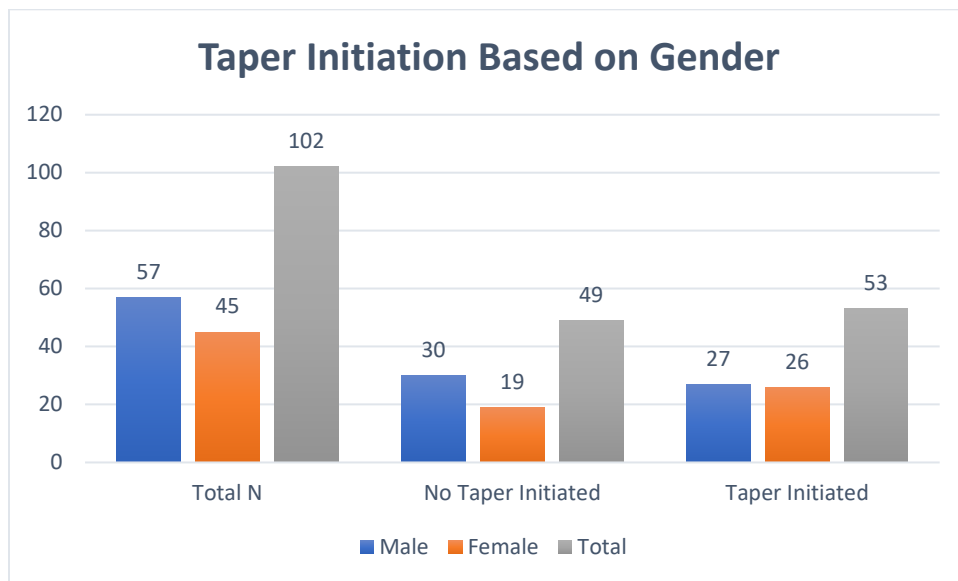


Fig. 26 – Results for taper initiation based on gender.

Start Drug

Of the 49 clients who did not have tapers initiated, 29 (59.2%) were started on Suboxone, and 20 (40.8%) were started on methadone. Of the 53 clients who had tapers initiated, 35 (66.0%) were started on Suboxone, and 18 (34.0%) were started on methadone. There were no significant findings (See Fig. 27).

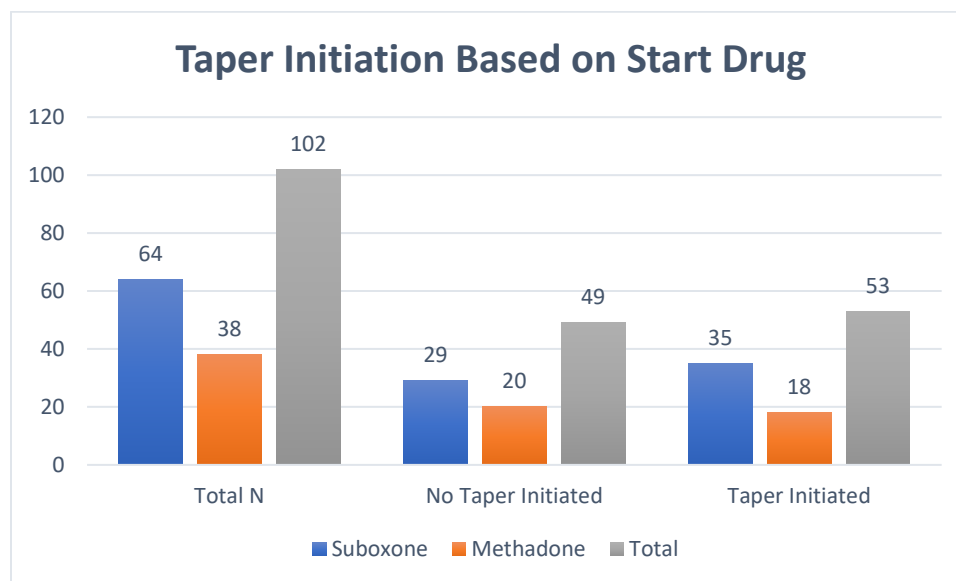


Fig. 27 – Results for taper initiation based on start drug.

Start Dose

Of the 49 clients who did not have tapers initiated, 14 (28.6%) had a starting dose of 50-149 mg MED, and 35 (71.4%) had a starting dose of 150-300+ mg MED. Of the 53 clients who had tapers initiated, 24 (45.3%) had a starting dose of 50-149 mg MED, and 29 (54.7%) had a starting dose of 150-300+ mg MED. Starting dose was a statistically significant correlate of taper initiation; clients with a starting dose greater than 150 mg MED were less likely than clients with starting doses under 150 mg MED to initiate taper during OAT (See Fig. 28).

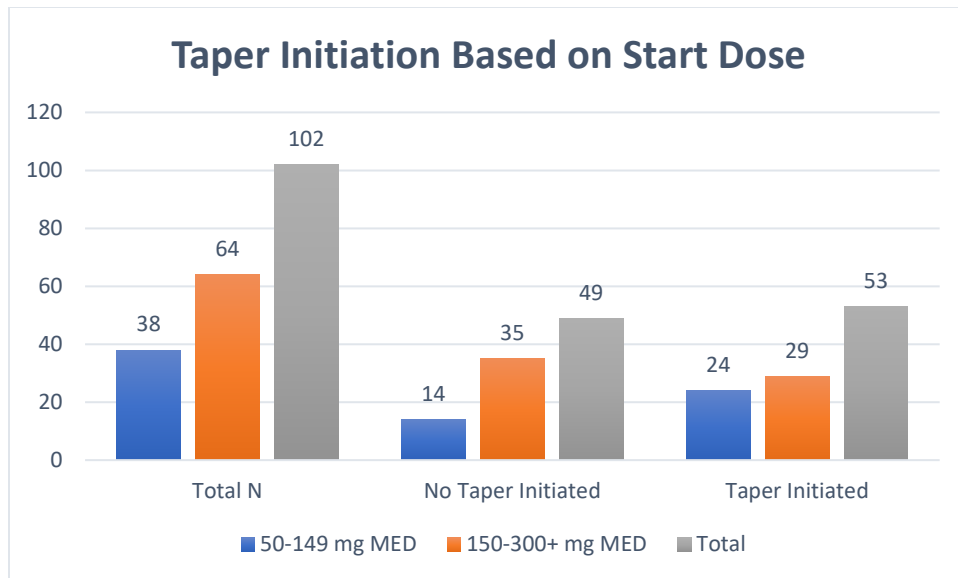


Fig. 28 – Results for taper initiation based on start dose.

Number of Children

Of the 49 clients who did not have tapers initiated, 33 (67.3%) had 0-2 children, and 16 (32.7%) had 3 or more children. Of the 53 clients who had tapers initiated, 37 (69.8%) had 0-2 children, and 16 (30.2%) had 3 or more children. There were no significant findings (See Fig. 29).

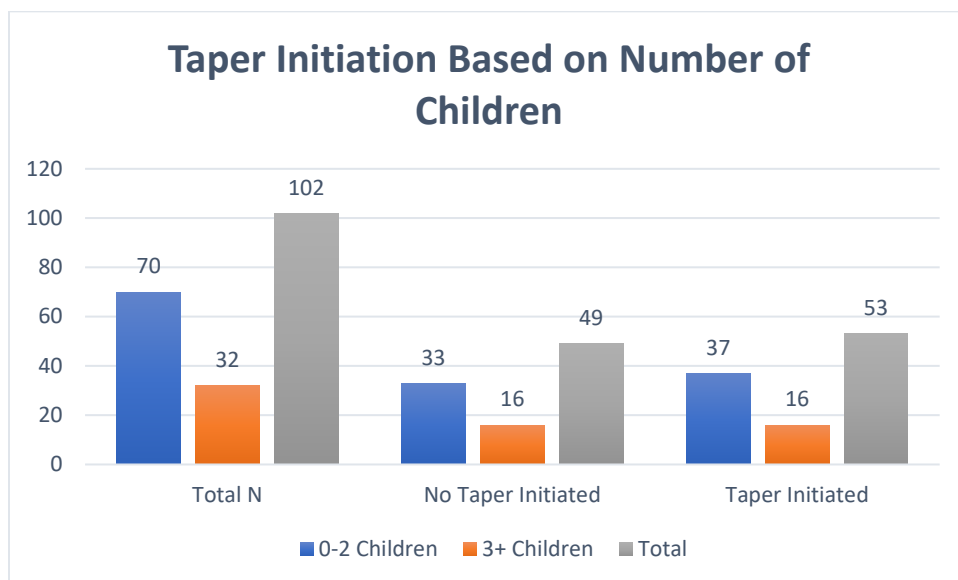


Fig. 29 – Results for taper initiation based on number of children.

Taper Success Results for Naandwe Miikan 2014-2019

Taper success was defined as consistent adherence to the opioid agonist treatment program – instances of program dropout and relapse (defined as a drastic fluctuation in treatment dose, indicative of relapse and/or steps to achieve a new therapeutic dose), were considered as “unsuccessful tapers”.

Of the 53 clients that had tapers initiated, 29 (54.7%) were unsuccessful, and 24 (45.3%) were successful.

The potential effects of clients’ drug and socio-demographic variables that were considered with taper initiation were used once again when investigating taper success.

Education Level

Of the 29 clients who had unsuccessful tapers, 13 (44.8%) did not finish high-school, and 16 (55.2%) had finished high-school/GED or University/College. Of the 24 clients who had successful tapers, 15 (62.5%) did not finish high-school, and 9 (37.5%) had finished high-school/GED or University/College. There were no significant findings (See Fig. 30).

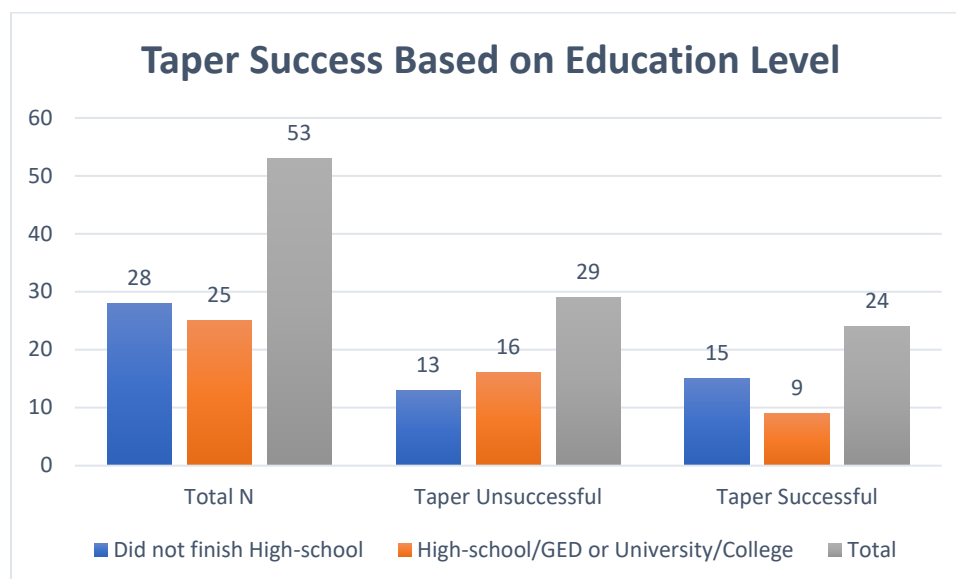


Fig. 30 – Results for taper success based on education level.

Age

Of the 29 clients who had unsuccessful tapers, 23 (79.3%) were 18-34 years old, and 6 (20.7%) were 35 or more years old. Of the 24 clients who had successful tapers, 15 (62.5%) were 18-34 years old, and 9 (37.5%) were 35 or more years old. There were no significant findings (See Fig. 31).

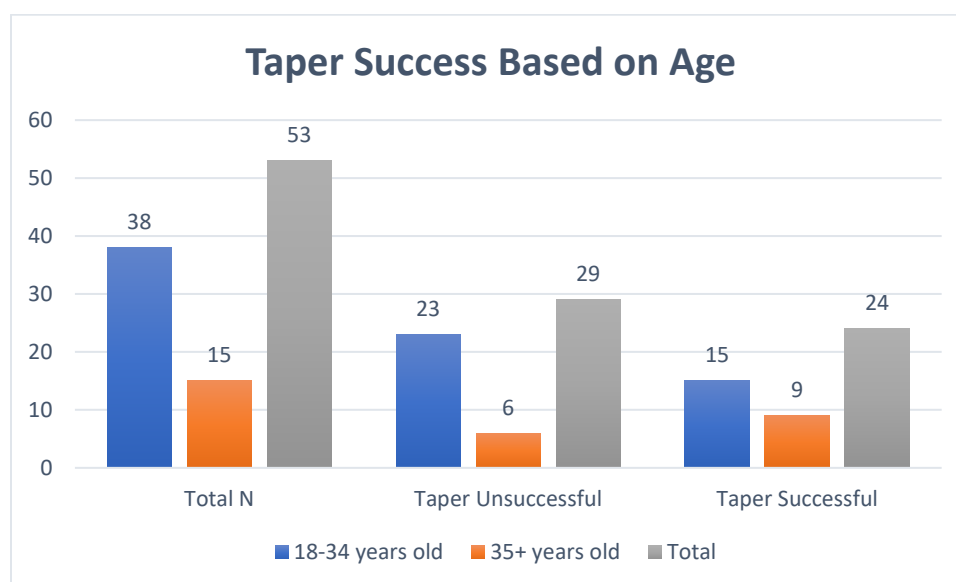


Fig. 31 – Results for taper success based on age.

Gender

Of the 29 clients who had unsuccessful tapers, 12 (41.4%) were male, and 17 (58.6%) were female. Of the 24 clients who had successful tapers, 15 (62.5%) were male, and 9 (37.5%) were female. There were no significant findings (See Fig. 32).

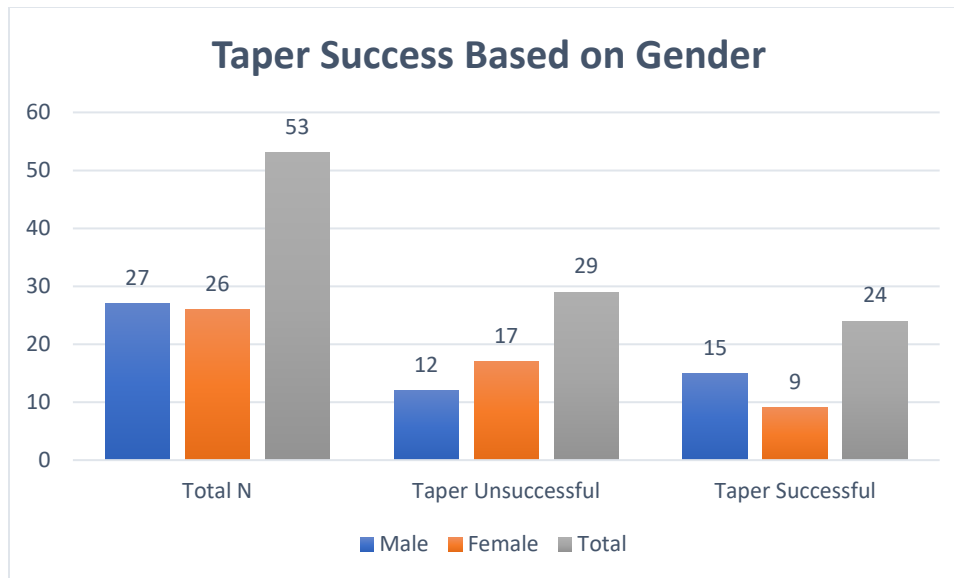


Fig. 32 – Results for taper success based on gender.

Start Drug

Of the 29 clients who had unsuccessful tapers, 22 (75.9%) were started on Suboxone, and 7 (24.1%) were started on methadone. Of the 24 clients who had successful tapers, 13 (54.2%) were started on Suboxone, and 11 (45.8%) were started on methadone. Starting dose was a statistically significant correlate of taper success; clients on methadone were 3.5 times more likely than clients on Suboxone to succeed with tapering during OAT (See Fig. 33).

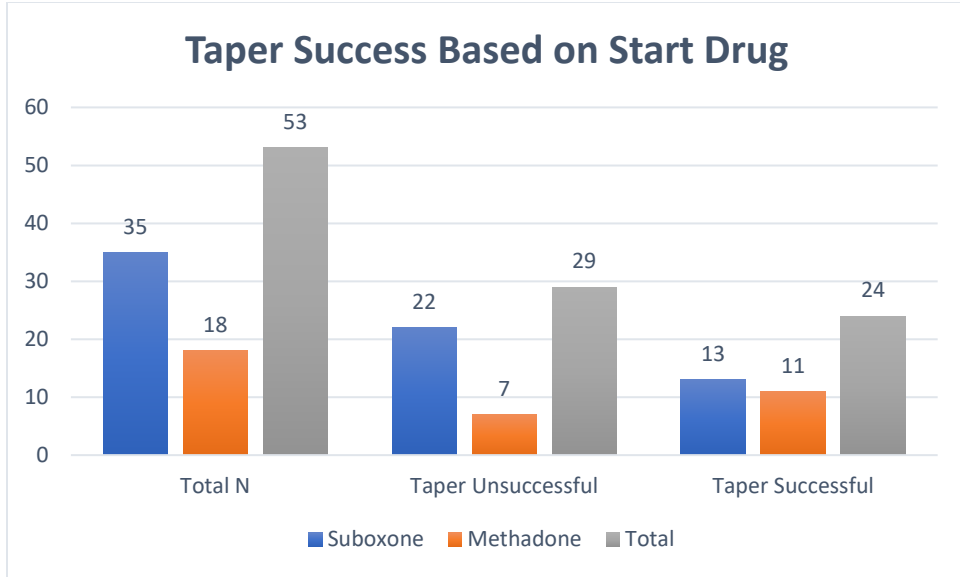


Fig. 33 – Results for taper success based on start drug.

Start Dose

Of the 29 clients who had unsuccessful tapers, 14 (48.3%) had a starting dose of 50-149 mg MED, and 15 (51.7%) had a starting dose of 150-300+ mg MED. Of the 24 clients who had successful tapers, 10 (41.7%) had a starting dose of 50-149 mg MED, and 14 (58.3%) had a starting dose of 150-300+ mg MED. There were no significant findings (See Fig. 34).

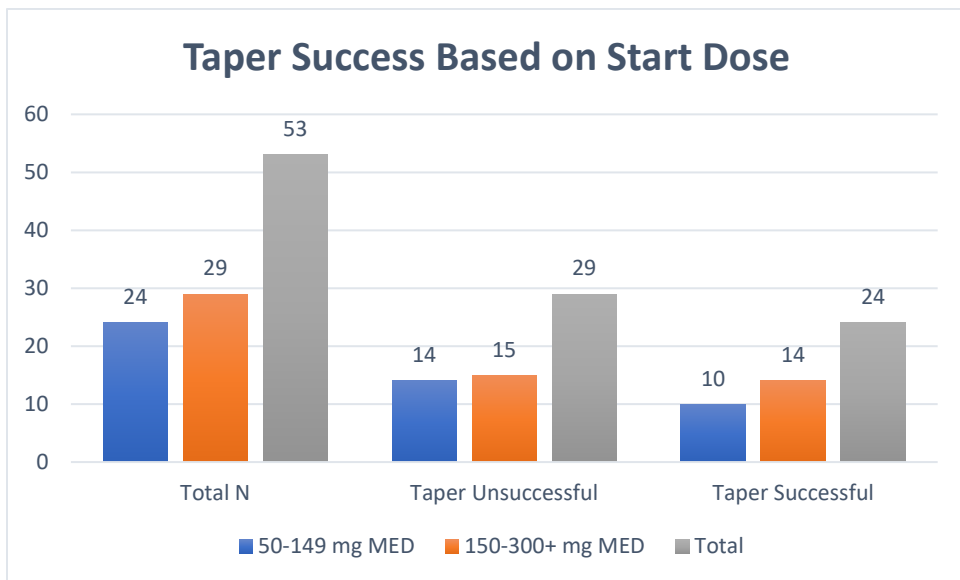


Fig. 34 – Results for taper success based on start dose.

Number of Children

Of the 29 clients who had unsuccessful tapers, 22 (75.9%) had 0-2 children, and 7 (24.1%) had 3 or more children. Of the 24 clients who had successful tapers, 15 (62.5%) had 0-2 children, and 9 (37.5%) had 3 or more children. There were no significant findings (See Fig. 35).

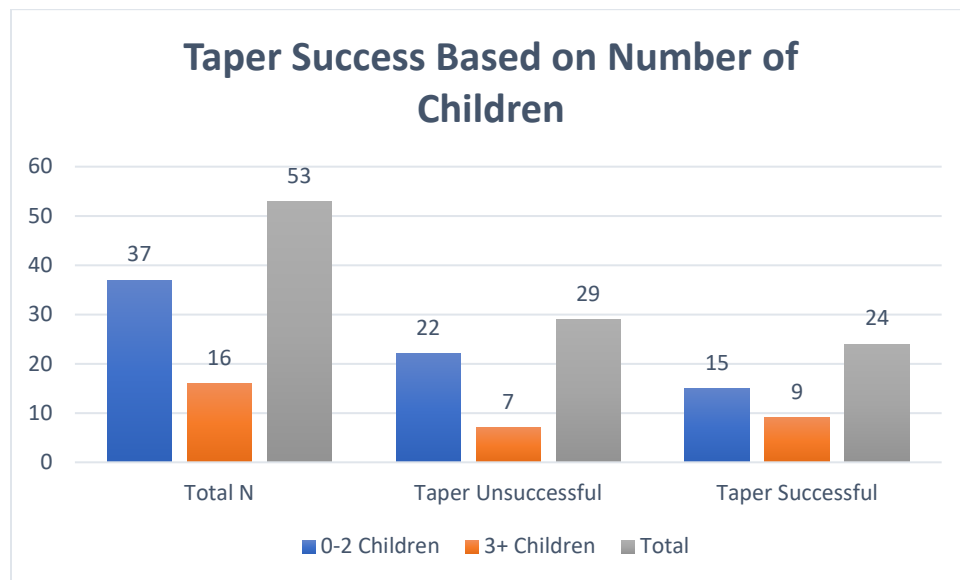


Fig. 35 – Results for taper success based on number of children.

Appendix C

**APPROVAL FOR CONDUCTING RESEARCH INVOLVING HUMAN SUBJECTS**

Research Ethics Board – Laurentian University

This letter confirms that the research project identified below has successfully passed the ethics review by the Laurentian University Research Ethics Board (REB). Your ethics approval date, other milestone dates, and any special conditions for your project are indicated below.

TYPE OF APPROVAL / New / Modifications to project X / Time extension	
Name of Principal Investigator and school/department	Marion Maar (PI) & Darrel Manitowabi (Co-PI) NOSM; Mariette Sutherland, Sheldon Tobe & Tim Ominika, Diana Urajnik, CRaNHR, (Co-Investigators); Lisa Boesch (Research Staff Technician); Kristin Rizkalla, Breton Burke, Matthew LeBlanc (Students)
Title of Project	Starting on a healing path rooted in First Nation cultural and clinical approaches to Opioid Replacement Therapy: Mino-bimaadiziwin after Addiction
REB file number	6013779
Date of original approval of project	June 11, 2018
Date of approval of project modifications or extension (if applicable)	December 4 th , 2018 May 23, 2019 Sept 11, 2019
Final/Interim report due on: <i>(You may request an extension)</i>	June 11, 2020
Conditions placed on project	

During the course of your research, no deviations from, or changes to, the protocol, recruitment or consent forms may be initiated without prior written approval from the REB. If you wish to modify your research project, please refer to the Research Ethics website to complete the appropriate REB form.

All projects must submit a report to REB at least once per year. If involvement with human participants continues for longer than one year (e.g. you have not completed the objectives of the study and have not yet terminated contact with the participants, except for feedback of final results to participants), you must request an extension using the appropriate LU REB form. In all cases, please ensure that your research complies with Tri-Council Policy Statement (TCPS). Also please quote your REB file number on all future correspondence with the REB office.

Congratulations and best wishes in conducting your research.

A handwritten signature in blue ink that reads "Rosanna Langer". The signature is written in a cursive, flowing style.

Rosanna Langer, PHD, Chair, *Laurentian University Research Ethics Board*