Exploring the Perceived Barriers and Facilitators to Equitable Access of Naloxone in Durham Region: A Pilot Study

by

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An oral defense of this thesis took place on December 16, 2021 in front of the following examining committee:

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The above committee determined that the thesis is acceptable in form and content and that a satisfactory knowledge of the field covered by the thesis was demonstrated by the candidate during an oral examination. A signed copy of the Certificate of Approval is available from the School of Graduate and Postdoctoral Studies.

Abstract

Through exploratory case study research, we examined naloxone distribution from community pharmacies and perspectives of service providers about barriers and facilitators to equitable access of naloxone through the Ontario Naloxone Program (for Pharmacies) in Durham Region, Ontario, Canada. The impact of the COVID-19 pandemic on access was also explored. Results from an environmental scan questionnaire (N=8) found that for community pharmacies, naloxone was available whenever requested and access was unchanged by pandemic conditions. Key informant interviews and demographic surveys (N=2) completed with service providers found perceived facilitators for equitable access included uninterrupted operations during the pandemic, and naloxone being available without cost and prescription. Integrating opioid prescribers into programs was recommended. Perceived barriers identified included stigma a lack of awareness of the programs. This study serves as a potential precursor to conducting a larger study to further explore equitable access to naloxone by program users across Ontario, Canada.

Keywords: health inequity; opioids; naloxone; case study.

Author's Declaration

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_____ Lucas Martignetti

Statement of Contributions

Dr. Winnie Sun contributed to the conception, design, and methodology of this study, and applied for ethics approval.

I completed the recruitment, data collection and analysis, and writing of this thesis.

I hereby certify that I am the sole author of this thesis and that no part of this thesis has been published or submitted for publication. I have used standard referencing practices to acknowledge ideas, research techniques, or other materials that belong to others. Furthermore, I hereby certify that I am the sole source of the creative works and/or inventive knowledge described in this thesis.

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List of Abbreviations

COVID-19 – Coronavirus disease 2019
CRISM – Canadian Research Initiative in Substance Misuse
MOHLTC – Ministry of Health and Long-Term Care
OEND – overdose education and naloxone distribution
ONP – Ontario Naloxone Program
ONPP – Ontario Naloxone Program for Pharmacies
THN – Take home naloxone

Chapter 1. Introduction

1.1 Background

Currently we are experiencing a global crisis in opioid-related harms, particularly prevalent across North America. In the province of Ontario, Canada, opioid-related deaths have increased each year since 2011 at an average rate of 45.9% per year, with over 10,600 deaths between 2011 and 2020, and over 2,300 deaths in 2020 alone, a single year increase of 51.7% (Office of the Chief Coroner for Ontario, 2021; Public Health Ontario, 2021). Opioids are a type of drug capable of providing pain relief by reducing pain signals released by neurotransmitters. Opioids include natural opiates such as heroin, morphine, and codeine, and synthetic drugs such as oxycodone, fentanyl, and carfentanil (Public Health Ontario, 2021). Over time, prescribed opioids and opioids diverted from their intended use likely contribute less to opioid-related deaths in Ontario than illicitly manufactured opioids such as fentanyl (Gomes et al., 2018), which is up to 100 times stronger than morphine (CAMH, 2021). In Ontario, a negative relationship has been found between the annual per capita volume of opioids dispensed and opioid-related overdoses, pointing to the possibility that reducing availability of prescription opioids may lead to increased consumption of potentially dangerous opioids such as fentanyl from unregulated drug markets (Ladha et al., 2021). As well, fentanyl is increasingly present in opioid-related deaths in Ontario, with the substance present in 76.3% of opioid-related deaths in 2019 (Public Health Ontario, 2021).

Naloxone, also commonly referred to by various brand names including Narcan, is used in the initial steps of treating opioid overdose. Naloxone can be made available to laypeople, often in the form of a naloxone kit that includes instructions on how to identify

an opioid overdose as well as how to administer naloxone to someone experiencing an opioid overdose (Canadian Pharmacists Association, 2017; Giglio, Li, & DiMaggio, 2015; Lewis et al., 2016; Mitchell et al., 2017). Naloxone access for laypeople is important, as the person overdosing may experience a number of harmful symptoms while waiting for administration by emergency first responders. One of the most dangerous opioid overdose symptoms when left untreated is respiratory depression (Richter et al., 1973). Adverse events resulting from a lack of oxygen including brain damage, paralysis, or death, become more likely the longer naloxone administration is delayed (Michiels, 2004; Richter et al., 1973; Santiago & Edelman, 1985; Zibbell, Howard, Clarke, Ferrell, & Karon, 2019).

Delivered by either needle injection or nasal spray when someone is experiencing an overdose, naloxone works to reverse this by acting as an opioid antagonist (Akil, Mayer, & Liebeskind, 1976; Devries, Rafie, & Polston, 2017; Wermeling, 2013). Further care focuses on supporting a patient's airway, breathing, and circulation, and additional naloxone may be administered as necessary (Boyer, 2012; Parthvi, Agrawal, Khanijo, Tsegaye, & Talwar, 2017).

The current naloxone distribution programs in Ontario are the Ontario Naloxone Program (ONP), the Ontario Naloxone Program for Pharmacies (ONPP), and the Provincial Correctional Facilities Take Home Naloxone Program. These programs provide naloxone kits to program users at no cost (Taha & Broker, 2018). The ONP, which began in October 2013, provides naloxone kits for clients of needle syringe and hepatitis C programs, as well as through participating community programs including outreach programs, community health centers, and withdrawal management programs.

The ONPP, which began in June 2016, distributes naloxone kits through participating pharmacies to past and current opioid users, as well as to friends and family of individuals at risk of an opioid overdose (Ontario Public Drug Programs Division, 2017). The Ministry of Community Safety and Correctional Services provides naloxone kits and training to at-risk inmates when they are released from custody (Ministry of Health and Long-Term Care (MOHLTC), 2019). As of December 2018, 290,000 naloxone kits have been distributed from 3,750 sites across all Ontario naloxone distribution programs, with at least 14,000 self-reported administrations (Canadian Research Initiative in Substance Misuse (CRISM), 2019).

While naloxone distribution programs have made recovery after an overdose significantly more likely, rates of accidental opioid-deaths remain high (Giglio et al., 2015). Past research on the experiences of individuals participating in naloxone programs often consists of quantitative studies with single groups of stakeholders such as physicians (Lacroix, Thurgur, Orkin, Perry, & Stiell, 2018). Qualitative studies have been done as well, again often with single groups of stakeholders (Dwyer, Fraser, & Dietze, 2016; Lewis et al., 2016). When studies have been done with multiple groups of stakeholders, these explore naloxone distribution programs in settings that are inaccessible to the public such as correctional facilities (Sondhi, Ryan, & Day, 2016). A knowledge gap exists where multiple stakeholder groups with experience participating in naloxone programs in Ontario, Canada have not been able to share their perspectives of barriers and facilitators to equitable access. Stakeholders of the ONP and ONPP include those who provide naloxone kits and training to clients as well as the clients themselves. Throughout this thesis, the term “service provider” will be used to refer to individuals

who distribute naloxone kits and education to clients through either the ONP or ONPP, while "program user" will be used to refer to these clients. Examples of service providers include pharmacists, nurses, community and public health workers, and volunteers. Program users include anyone who receives naloxone kits through community organizations or community pharmacies participating in the ONP or ONPP, respectively.

As well, the term "access" used throughout this thesis will refer to the ability for an individual to receive a naloxone kit through either the ONP or ONPP. The dimensions of access, established by Penchansky and Thomas (1981) and modified by Saurman (2016), can be broken down into the following: accessibility, availability, acceptability, affordability, accommodation, and awareness

Initially the plan for this study was to include four groups of participants. These groups consisted of service providers and program users of either the ONP or ONPP. The COVID-19 pandemic severely affected the ability to recruit all four groups of participants, particularly program users of either naloxone program. Public health measures including shutdowns, as well as changes to operating hours, locations, and capacities led to diminished or entirely absent traffic in the locations where people receive naloxone kits. For the safety of participants, study procedures were changed so that all interviews were to be done remotely. This made study participation more difficult particularly for potential participants who are experiencing poverty and/or homelessness or unstable housing, as many program users are. This means they are less able to participate as they don't have access to a reliable internet connection or telephone. Due to these restrictions, the scope of the study was reduced such that the number of interviews was decreased. Study participation from the program users was not feasible due to the

challenges of access to a virtual platform. This is an exploratory study that will serve as a precursor to future studies that will include a larger sample of participants, incorporating the perspectives of other individuals who use and work in both the ONP and the ONPP, and will expand the study sample recruitment to all regions of Ontario.

1.2 Study Purpose

This research study examines the factors that influence equitable access to Ontario's community-based naloxone distribution programs in Durham Region. The purpose of this research study is to utilize a qualitative descriptive approach to better understand the perceived facilitators and barriers that influence equitable naloxone access of the ONP and the ONPP. This study focuses on the examination of perspectives from key stakeholders including service providers. The Ministry of the Solicitor General - Take Home Naloxone Program will not be included in this research as this program only distributes naloxone to inmates from provincial correctional facilities upon being released from custody rather than to the general public (Ministry of Health, 2021)

As well, since the onset of the COVID-19 pandemic, there has been an increase in opioid deaths across all but one Public Health Unit in Ontario and a significant increase in fentanyl contributing to opioid-related deaths (Gomes et al., 2021). Along with this, pandemic protocols in Ontario have affected different sites of naloxone distribution including community pharmacies and community organizations. These changes include new protocols for use and/or entry of facilities, changing locations, and in some cases distribution sites have been shut down, either temporarily or for the duration of the COVID-19 pandemic thus far. To account for these changes, this study will also be examining the impact of the pandemic on accessibility of naloxone through the Ontario

Naloxone Program and Ontario Naloxone Program for Pharmacies. This research serves as an exploratory study, focusing on Ontario's naloxone programs as they exist in Durham Region, Ontario.

1.3 Research Questions

This study aims to explore the factors influencing equitable access to Ontario's community-based take home naloxone (THN) programs in Durham Region both before and during the COVID-19 pandemic. The overarching research questions for this study are:

"What do service providers of the Ontario Naloxone Program in Durham Region perceive to be facilitators and barriers to equitable access?"

and

"What do service providers of the Ontario Naloxone Program for Pharmacies in Durham Region perceive to be facilitators and barriers to equitable access?"

1.4 Significance of Study

By identifying the perceived facilitators and barriers to equitable access to community-based naloxone distribution programs, successful program planning and evaluation as well as strategies to address current service gaps can be identified. These findings can be useful to help inform policy decisions and future developments of Ontario's community-based naloxone distribution programs in order to promote the facilitators and reduce the barriers to naloxone access, as well as reducing the inequity of health outcomes among vulnerable populations.

While all socioeconomic groups are being affected by the opioid crisis, there is an overwhelming media and policy focus on white, middle-class people who have experienced overdose (Johnston, 2019). Despite this, a disproportionate amount of opiate-related harms are experienced by individuals with unstable housing, those living in lower-income areas, and those with incomes in the lowest two quintiles (Belzak & Halverson, 2018; Cairncross et al., 2018; Carriere, Garner, & Sanmartin, 2018). Between July 2017 and June 2018, 46.8% percent of opioid-related deaths occurred among people who were unemployed (Ontario Agency for Health Protection and Promotion (Public Health Ontario), Office of the Chief Coroner, & Ontario Forensic Pathology Service; Ontario Drug Policy Research Network, 2019). Compared to a non-First Nations individual, a First Nations person is five times more likely to experience an opioid-related overdose and three times more likely to die from an overdose (Belzak & Halverson, 2018). This may be related to a lack of cultural safety in health services and underlying disadvantages such as disproportionate poverty and lack of housing experienced by First Nations people (First Nations Health Authority, 2019). It is also important to look at the effects of the COVID-19 pandemic on access to naloxone as similar inequalities are found in regards to the disease's spread and morbidity (Snider, Patel, & McBean, 2021). By achieving a greater understanding of the potential facilitators and barriers to equitable access to naloxone, Ontario's naloxone programs can become more accessible and inclusive to all Ontarians who would benefit from these timely and life-saving programs.

1.5 Overview of Thesis

In Chapter 2, I present a review of literature, examining published perspectives of individuals involved with THN programs around the world regarding barriers and

facilitators to equitable access. I discuss the relevance of these findings to Ontario's naloxone programs in order to inform the inquiry's research questions and put this study in context of pre-existing research.

In Chapter 3, I present the methodology of this study. The components of the research design are discussed, including the theoretical frameworks used and study method and design. The setting, eligibility criteria for participants, and sampling method are presented here as well. The methodology of data collection (environmental scan and case study), management, and analysis are also presented along with the ethical considerations of conducting this research.

In Chapter 4, I present the results of the environmental scan and case studies.

In Chapter 5, I discuss and summarize the results, as well as the strengths and limitations of the study and future opportunities for research.

Chapter 2. Literature Review

The purpose of this chapter is to review the existing literature surrounding the perspectives of individuals participating in existing or prospective community take home naloxone programs in regards to facilitators and barriers to equitable access.

This literature review aims to:

(1) identify the sociocultural and program delivery factors influencing equitable access to take home naloxone programs as perceived by those who participate or would participate;

(2) explore knowledge gaps in the existing literature to identify additional research opportunities and lessons learned in relation to improving equitable access to take home naloxone programs in Ontario, Canada and beyond.

2.1 Inclusion and Exclusion Criteria

The search strategy for this literature review included journal articles, research papers and grey literature published until June 2021, when the literature search was completed. Preliminary searches found that little research had been done on the lived experiences of people involved in take home naloxone programs, and very little research had been done on either Ontario Naloxone Program. Articles searched were limited to those published in English. Keywords used included “substance use” or “substance abuse” or “opioid use” or “opioid addiction” or “overdose” to encompass literature that examined the use of opioids. The keywords “naloxone” or “Narcan” were included to focus the search to this opioid overdose reversal drug. Other keywords included “barriers” or “challenges” and “facilitators” or “enablers” as well as “perspectives” or “attitudes” or “views” or “perceptions” or “perceived”, to limit the search to literature

examining lived experiences related to facilitators and barriers to accessing naloxone programs. The criteria for article inclusion was that the literature must focus on naloxone access and use for opioid overdose reversal available to the public as this is the purpose of Ontario's naloxone programs. The exclusion criteria encompassed studies exploring the clinical or therapeutic use of opioids and opioid maintenance therapies, since these programs have broader goals and aims than Ontario's naloxone programs.

2.2 Search Strategy and Analysis

Searches were completed using the library databases of the Ontario Tech University including PubMed, Cochrane, and the Cumulative Index to Nursing and Allied Health Literature. The same key words and search strategy was maintained across all databases used. Eligible literature included full-text articles from peer-reviewed journals, editorials, letters, books, and protocols. All search results were retrieved for further review.

A total of 261 publications were retrieved. Abstracts were reviewed for relevancy, followed by a reading of the full article for all publications that remained or had no abstract. The reference lists of articles were examined for further relevant literature. A total of 49 articles were found to be relevant, including grey literature from CRISM, developed by the Canadian Institute for Health Research. The methodology quality and possibility of bias of these 49 articles were examined using JBI's critical appraisal tools (2020). Trustworthiness, relevance, and results of these articles were further assessed using this tool and all articles were deemed appropriate to include in this review.

Thematic analysis was used for the data analysis which involved initial coding, generation of broader themes, and further review of relevant themes to determine their accuracy and the comprehensive categorization for all codes (Braun & Clarke, 2006).

2.3 Results and Discussion

2.3.1 Key Findings from Literature Review

Through analysis of the selected literature examining the perceptions of barriers and facilitators to community take home naloxone programs from those individuals with the lived experiences, three major themes emerged. These themes include the impact of stigma on access of naloxone, a focus on physicians and pharmacists as research participants, and a lack of focus on barriers and facilitators relevant to Ontario's community naloxone programs.

2.3.2 Stigma as Barrier to Access

Stigma is seen not only in negative attitudes towards people who use drugs and/or access naloxone at the level of the interpersonal interactions where naloxone is distributed, but it also serves as a "foundational process through which social conceptions of health and responsibility are constituted" (Fomiatti et al., 2020). Stigma is something that can exist in policies related to drug use and is something that can be kept in mind by policymakers when communicating about and implementing policy related to opioid use (Ledford, Lim, Namkoong, Chen, & Qin, 2021). This type of stigma is similar to that encountered by individuals living with dementia (Herrmann et al., 2018) and HIV (Holzemer et al., 2009) in that it can lead to deleterious health care outcomes and reduced quality of life.

Among a number of articles reviewed, stigma was cited as a known or potential barrier to accessing naloxone (Banjo et al., 2014; Edwards, Bates, Edwards, Ghosh, & Yarema, 2017; Green et al., 2017; Hammett et al., 2014; Holland, Penm, Dinh, Aran, & Chaar, 2019; McAuley, Munro, & Taylor, 2018; Tewell, Edgerton, & Kyle, 2018). Stigma surrounding naloxone and its association with reversing overdoses resulting from illicit opioid use lead to patients prescribed opioids declining naloxone offered with their prescription (Tewell et al., 2018). Lack of information or misinformation related to legal repercussions of using naloxone programs and administering naloxone was found to be a barrier to access and to contacting emergency services after naloxone had been administered (Banjo et al., 2014; Bartlett, Xin, Zhang, & Huang, 2011; Chronister et al., 2018; Deonarine, Amlani, Ambrose, & Buxton, 2016; Dwyer et al., 2016; Gatewood, Van Wert, Andrada, & Surkan, 2016; Richert, 2015; Tobin, Sherman, Beilenson, Welsh, & Latkin, 2009).

Prospective clients of naloxone programs perceived program staff to have stigmatized views towards them, while program staff perceived that clients limited their interaction with them due to their fear of discrimination by staff members (Green et al., 2017; Hammett et al., 2014; Zaller, Yokell, Green, Gaggin, & Case, 2013). Program staff members may believe that they may be enabling continued or riskier opioid use by providing naloxone to the public, or that distributing naloxone may bring clientele to their location that they consider "undesirable" (Bakhireva et al., 2018; Beletsky et al., 2007; Freeman et al., 2017; Green et al., 2013; Haggerty & Gatewood, 2018; Hammett et al., 2014; Holland et al., 2019; Rudolph et al., 2018; Thompson, Rao, Hayes, & Purtill, 2018).

Possible facilitators to access included structuring the interactions between program users and staff to allow for more indirect communication about the availability of naloxone, such as having cards available in aisles that program users can bring to a counter, in order to avoid exposing a program user as a member of the stigmatized group (Green et al., 2017). As well, there were suggestions to disseminate research findings to staff that compensatory opioid use after naloxone has been given to clients is not common (Thompson et al., 2018). Some studies mentioned the urgent need for public education about opioid and naloxone use to reduce stigma (Banjo et al., 2014; Tewell et al., 2018). Dissemination of facts about opioid use as well as "sympathetic narratives" helped to reduce stigma and increase support for take home naloxone programs (Bachhuber, McGinty, Kennedy-Hendricks, Niederdeppe, & Barry, 2015). The pervasive presence of stigma found in these studies speaks to its negative impact as a perceived barrier to naloxone access and highlights the need for identifying facilitators for addressing stigma.

2.3.3 Emphasis Primarily on Physicians and Pharmacists

Many of the studies about naloxone focused on either pharmacists (Freeman et al., 2017; Peckham, Niculete, Steinberg, & Boggs, 2018; Rudolph et al., 2018) or physicians (Gatewood et al., 2016; Lacroix et al., 2018). Increasingly, studies are selecting users of naloxone access programs as research participants (Chronister et al., 2018; Lewis et al., 2016; McAuley et al., 2018; Mitchell et al., 2017). In some cases, both pharmacists and clients are included in a single study (Green et al., 2017; Tewell et al., 2018). Outside of these three types of key informants, no other groups of stakeholders of naloxone distribution programs were involved in these previous studies. Particularly, there is room

for the sharing of perspectives of others involved in the delivery of naloxone programs including healthcare professionals such as nurses and program administrators as well as policy-makers. With a wider variety of perspectives from different types of key informants of these naloxone programs, the data collected can become more diverse and potentially identify a more comprehensive overview of barriers and facilitators to equitable access.

2.3.4 Lack of focus on barriers and facilitators relevant to the context of Ontario's naloxone programs

Many of the studies have a focus on determining barriers to the implementation of a naloxone distribution program, but they did not examine the barriers or facilitators to accessing these existing programs. For example, a study by Lacroix, Thurgur, Orkin, Perry and Stiell (2018) focused on the implementation of a take-home naloxone program in Emergency Departments across Canada. Their results indicated that barriers to implementation included a lack of allied health support for patient education, lack of time to educate patients, and not having a consistent strategy to follow up with the recipient of the naloxone kit. Another study focused on the implementation of overdose education and naloxone distribution (OEND) programs in Veteran's Affairs hospitals in the United States, and found that a lack of knowledge of OEND programs and lack of comfort distributing naloxone were barriers to the implementation of these programs (Peckham et al., 2018). While some of these findings, such as a perceived lack of time for adequate patient education and training, could potentially be seen as challenges in establishing naloxone distribution programs, many of these barriers are addressed when a naloxone distribution program is implemented (Bakhireva et al., 2018; Dwyer et al., 2016; Edwards

et al., 2017; Freeman et al., 2017; Holland et al., 2019; Lacroix et al., 2018; Nielsen, Menon, Larney, Farrell, & Degenhardt, 2016; Samuels et al., 2016) . This includes determining and maintaining a constant supply of naloxone, as well as ensuring that all personnel responsible for distributing naloxone have a high degree of knowledge of and comfort with naloxone use (Canadian Pharmacists Association, 2017). Future studies can be conducted by collecting the perspectives of different stakeholders in the existing naloxone programs to determine additional types of systemic barriers and facilitators that could influence naloxone access by program users.

Of the studies found through the literature review, none of the studies focused on the inequity in opioid-related health outcomes or how to reduce perceived barriers and promote facilitators to access for the vulnerable groups who are disproportionately experiencing opiate-related harms, including individuals without their own means of transportation (Tewell et al., 2018), and low-income individuals, particularly those without stable housing (Banjo et al., 2014). Some identified barriers that influence these groups, are a lack of transportation to community pharmacies participating in naloxone distribution programs or the loss of naloxone kits during transient housing (Banjo et al., 2014; Tewell et al., 2018). As well, potential facilitators addressing equitable access were discussed by Mitchell et al. (2017) who shared ideas relating to the placement of naloxone kits in common spaces of low-income housing. Future research can address inequities in naloxone programs by focusing on identifying them, or referencing those previously identified, and working with stakeholders to document or produce methods of overcoming these barriers.

Additionally, many of these studies were related to the specific healthcare system where the research was conducted, for example in North Carolina (Rudolph et al., 2018; Tewell et al., 2018), Massachusetts and Rhode Island (Green et al., 2017), Alberta (Edwards et al., 2017), and British Columbia (Banjo et al., 2014; Mitchell et al., 2017). The perceived barriers identified in these studies may not be relevant to advancing the understanding of equitable access to naloxone programs as they exist in the context of Ontario, for example, the need for a client to obtain a prescription from a physician or pharmacist in order to receive naloxone (Tewell et al., 2018). In Ontario, under the ONPP, no prescription is needed (MOHLTC, 2018). Another example is the cost of naloxone and/or treatment either having the potential to be prohibitive, or actively preventing clients from accessing available programs (Bakhireva et al., 2018; Bartlett et al., 2011; Dwyer et al., 2016; Gunn et al., 2018; Haggerty & Gatewood, 2018; Hammett et al., 2014; Rudolph et al., 2018; Tewell et al., 2018; Zaller et al., 2013). In Ontario, naloxone acquired through the Ontario Naloxone Program or ONPP is free of charge (MOHLTC, 2018). By conducting further research with various stakeholders of naloxone distribution programs in Ontario, findings could be specific and relevant to these regional programs with the aim of increasing our understanding about the current landscape of the opioid crisis, as it exists in Ontario, Canada**.**

2.4 Implications and conclusion

The literature review revealed that stigma surrounding opioid use and interactions with healthcare professionals were the most commonly reported perceived barriers to equitable access. The stigma regarding substance use is reflected in the general Canadian population, with 89.7% of respondents to the World Values Survey taken from 2017-

2020 stating they would not wish to have “drug addicts” as neighbours (Haerpfer et al., 2020). As well, in the research literature, there was a special emphasis on examining the perspectives of physicians and pharmacists over other stakeholder groups, and these findings were often not applicable to the current context of Ontario Naloxone Program due to the differences in other jurisdictions regarding the policies and procedures of implementing naloxone.

In regards to methodological approaches, all quantitative studies in the literature used a descriptive approach and generated responses from participants through surveys or questionnaires. The majority of these studies were limited to evaluating criteria chosen by the researchers, without mention of input from those with lived experiences. In some cases, this gap was addressed by piloting a survey or questionnaire among individuals with similar lived experience and constructing the final survey or questionnaire based on this input (Lacroix et al., 2018). Even with the inclusion of such input, the structure of surveys and questionnaires had limited ability to capture in-depth ideas, perspectives and experiences (Tuli, 2010), which necessitates the need for future qualitative research to explore the new, and emerging field of Ontario naloxone programs.

The studies using a qualitative design employed semi-structured interviews (McAuley et al., 2018), focus groups (Green et al., 2017), and community-based participatory research (CBPR) (Mitchell et al., 2017). Grounded theory was used (Gatewood et al., 2016), as well as a qualitative descriptive approach (Banjo et al., 2014), interpretative phenomenological analysis (IPA) (McAuley et al., 2018), and the use of the Health Belief Model and Harm Reduction Frameworks (Mitchell et al., 2017). Compared to the quantitative studies found in the literature review, the qualitative studies were more

effective at drawing upon the lived experiences of the participants and adding new insights to the literature surrounding naloxone programs, particularly in identifying facilitators to access (Green et al., 2017; Mitchell et al., 2017). While each approach allowed for participants to share their perspectives, semi-structured interviews with a descriptive approach allowed for the collection and dissemination of a more literal description of the participants' experiences, with less potential for distortion that can result from an approach such as IPA (Matua & Van Der Wal, 2015). A descriptive approach is particularly helpful for generating new knowledge for little researched phenomenon of interest (Matua & Van Der Wal, 2015), which is the case for exploring the lived experiences of service providers and program users within the Ontario's naloxone programs. The Harm Reduction Framework is considered the most appropriate conceptual underpinning for a study of naloxone access programs. It helps to focus the research on reducing the harm from substance use without requiring abstinence, and works to create safe, non-judgmental spaces for this to happen (Shelter Support & Housing Administration, 2017).

Chapter 3. Methods

The aim of this study is to examine the perspectives of service providers on the facilitators and barriers to equitable access to Ontario's Community-Based Take Home Naloxone (THN) programs as they exist in Durham Region, Ontario, Canada.

3.1 Research Design

3.1.1 Rationale for Exploratory Case Study Design and Social Constructivist Paradigm

This study is based on an exploratory case study design. A case study approach was chosen for its ability to attain a better understanding of experiences of individuals, bound to a specific, contemporary context (Creswell, 2013; Yin, 2009). This context defined the chosen cases including service providers who participated in either the ONP or ONPP in Durham Region, with experience distributing naloxone during the COVID-19 pandemic, through demographic questionnaires and semi-structured in-depth interviews. The selection of cases was guided by the instrumental case studies approach, with the aim of achieving a broader understanding of a phenomenon of interest (exploration of barriers and facilitators that influence access of naloxone). This design approach is appropriate in that it allowed for documenting the experiences of service providers' interactions with program users of either of Ontario's THN programs as they currently exist in Durham Region, as this population has not been included in any prior related studies.

This study was situated within an interpretive paradigm. The social constructivist framework was used because of its grounding in the ontological belief of "multiple realities constructed through our lived experiences and interactions with others"

(Creswell, 2013, p. 36). This framework is appropriate as the purpose of this research is to examine and better understand the unique perspectives of individuals who interact with THN programs and the people running or accessing them.

This study was also guided by the application of the harm reduction framework, which focuses on reducing harm resulting from substance use, and creating a safe, non-judgmental environment rather than focusing on abstinence (Bowles & Lankenau, 2019; Expert Working Group on Narcotic Addiction, 2012; Shelter Support & Housing Administration, 2017). This is accomplished by placing "the emphasis on the most immediate, achievable and positive changes, whether or not they can be shown to reduce drug consumption" (Expert Working Group on Narcotic Addiction, 2012).

The harm reduction-based approach is appropriate for the research study in that THN programs are harm reduction focused. The purpose of distributing naloxone kits is to reduce the potential harm caused by overdose. Naloxone is provided to program users with no requirements of abstinence from opioid use. Following this, in the data collection stages, interview questions were focused on the use of naloxone as a tool for harm reduction regarding opioid use and abstinence was not included as a topic in the interview guide. As well, the themes and codes generated through data analysis focused on respondents' discussion of facilitators and barriers to equitable access to naloxone for the purpose of harm reduction.

3.1.2 Study Method and Design

This qualitative study was conducted using an exploratory case study methodological approach. An exploratory case study methodology was chosen with the aim of gaining detailed insight into the underlying perceptions that exist among

individuals responsible for delivering THN programs since their perspectives about the study phenomenon have not been thoroughly examined by the existing literature. By using this methodology, the research was able to function as a precursor to future larger scale study with a more thorough examination of barriers and facilitators to equitable access to naloxone, expanding from the Durham Region to across Ontario, Canada.

A qualitative approach is appropriate for this study as the primary focus is to explore individuals' lived experiences in-depth. Through allowing participants to share narratives, the meaning associated with these experiences can be understood, and rich descriptive data can be collected, whereas quantitative methods only allow for generalized descriptions of these experiences.

For each case, data collection was completed through one-on-one, in-depth, key-informant interviews, as well as a demographic questionnaire (Appendix B) to better assess the context in which participants interact with THN programs. As well, an environmental scan questionnaire (Appendix D) was completed to inform interview questions as well as to assess the availability of naloxone through community pharmacies in Durham Region and the effect of COVID-19 on this. This research serves as a pilot study that will assist in the design of a larger study that I will complete as part of my doctoral thesis.

3.2 Setting and Participants

3.2.1 Stakeholders of Ontario's Naloxone Programs

The literature review revealed that little qualitative research was done with individuals participating in THN programs. To better understand the lived experiences of

the service providers involved in these programs, this study conducted key informant interviews to examine the study phenomenon.

3.2.2 Inclusion/Exclusion Criteria

The inclusion criteria of the study participants are: (1) individuals in Durham Region, Ontario who act as a service provider at a community organization participating in the Ontario Naloxone Program, or at a community pharmacy participating in the Ontario Naloxone Program for Pharmacies; and (2) adults over eighteen years of age because they will have more ability to access all programs as a person who is at or above Ontario's age of majority. The exclusion criteria for study participants are: (1) those who do not speak English and (2) those who are under eighteen years of age.

3.2.3 Recruitment and Sampling

Service providers were identified through a listing made available by the Government of Ontario (2021) and were contacted for recruitment by phone or email, followed up by providing a letter of information and consent if they were interested in learning more and/or participating. As well, recruitment flyers targeting service providers were posted in community pharmacies and community organizations in Durham Region, Ontario, Canada.

The study sampling process involved purposeful sampling (Palinkas et al., 2015) in order to identify and select information-rich cases, those being key informants who are service providers in either program. Convenience sampling was also used to account for recruitment issues related to the COVID-19 pandemic and lockdown. For the ONP, potential service providers included nurses, community health workers, and volunteers.

For the ONPP, these potential service providers included pharmacists or other pharmacy staff involved in the distribution of naloxone to program users.

The recruitment sites for study participants were contacted through the participating organizations of the ONP in Durham Region, such as public and community health-focused organizations, community housing organizations, and healthcare facilities including clinics and hospitals. The sites for recruitment of those stakeholders who interacted with the ONPP were through community pharmacies located throughout Durham Region. Pharmacies targeted for recruitment included national pharmacy chains such as Shopper's Drug Mart and Rexall Drugstore, those attached to the larger retail stores such as Real Canadian Superstore and Walmart, and local independent community pharmacies.

Key informant groups included service providers for each THN program (ONP and ONPP). As this is an exploratory study, two cases were completed, each with a single service provider. Rather than recruiting a larger sample and aiming for data saturation, this sample size is appropriate for an exploratory case study as the goal of this design is to "develop ideas for further study" (Yin, 2009, p. 141).

3.3 Data Collection

3.3.1 Instruments and Interviews

Semi-structured, one-on-one interviews were conducted through online videoconferencing services or over the telephone, and at a mutually agreed upon time based on participant preferences. A short questionnaire was given to participants to collect descriptive data relating to their socio-demographic information. This included length of employment, as well as their position and years of experience in the THN

program in which they work. Once the demographic data form was completed, the participants took part in a semi-structured interview regarding their experiences with the THN programs they participated in. Interviews were chosen as a data collection method for their ability to allow for open-ended answers to questions, as well as allowing for probes and follow-ups to these answers to generate detailed data that corresponds to an individual's unique experiences (Phellas, Bloch, & Seale, 2011). The interviews lasted approximately 30 to 60 minutes. The interview sessions were recorded by a digital audio recorder and field notes were taken for each participant. After the interview was completed, member checking was conducted; this was achieved by asking participants to provide their contact information in the event that clarification of the interview was needed. During member checking, the interview transcript was shared with the participant to assess its accuracy regarding their intended meaning and interpretation. Once interviews were transcribed and their authenticity was confirmed by the interviewed participants, the audio file was deleted (Creswell & Miller, 2000; Straus et al., 2004).

The environmental scan was conducted through the completion of a short questionnaire created using Google Forms by community pharmacies in Durham Region participating in the ONPP. Questions assessing naloxone availability and the experience of receiving naloxone included "How many naloxone kits are provided to the public from your pharmacy in an average week?", "How often are there no available naloxone kits when a program user requests one?", and "Is educational training provided to program users on how to use a naloxone kit?". Pharmacies were either contacted by telephone or email where a link to the questionnaire was provided along with details of the study and a

consent form. Participants from eight community pharmacies completed the questionnaire.

3.4 Data Analysis

To maintain confidentiality, all participants were given pseudonyms, recorded on a master list that is stored in a secured location. Any other identifying information was altered or removed. All interviews were transcribed verbatim prior to data analysis. Once the participants approved the transcript as having accurately reflected their thoughts, meaning, and context, the transcripts were coded and underwent thematic analysis.

Thematic analysis is the method of "identifying, analyzing, and reporting patterns (themes) within data" (Braun & Clarke, 2006, p.78) without being bound to a specific theory and epistemology. The method for data analysis was adapted from Braun and Clarke (2006). Codes and themes were identified from the transcribed interviews. Themes were found from the analysis of codes, and the codes were then sorted under their associated themes. The themes generated were reviewed first to determine that all themes fit their associated codes and revised if necessary. Secondly, the themes were reviewed from the perspective of the entire data set such that each theme works together to accurately represent the full scope of the data. Next, a detailed analysis was written for each theme with consideration for how they contributed to a larger narrative. At this point, the themes were revised until each theme had a clear scope and definition. Each theme was given a clear descriptive category that would enhance the clarity of the meaning associated with the theme.

From the environmental scan, descriptive statistical data analysis was performed using the SPSS software package, including generation of means, minimums and maximums, and percentages.

3.4.1 Establishing Trustworthiness (Reflexivity and Validity)

Reflexivity was accomplished through the use of bracketing. This was achieved through exploring my background, experiences, and preconceptions regarding equitable access to naloxone. The purpose of bracketing is to avoid assumptions and biases resulting from my preconceived notions about the research phenomenon. One method of bracketing involved my description of personal thoughts and feelings through reflection, as well as writing memos of my personal feelings related to the data collection and data analysis during the research process (Tufford & Newman, 2012).

Regarding the phenomenon of this research study, I feel that vulnerable groups who are marginalized by society including those who have low incomes, or are ethnic, or gender minorities are generally underserved by existing health programs. I believe that harm reduction is more effective than drug prohibition which focuses solely on abstinence from illicit drug use. I have no personal experience with opioid use and no one close to me has experienced opioid addiction or related harms.

Media coverage of illicit drug use, particularly before and in the early days of the opioid crisis often focused on drug use as an isolated, moral failing on the part of the drug-user, both in news media as well as fictional portrayal of drug use. While this may have affected my earlier thoughts about the topic, doing my own research and finding thoughtful, compassionate portrayals of drug use while contextualizing it within society

and culture has helped to direct my thinking and the way I approached this topic to focus on understanding the context and being empathetic to the experiences of all involved.

Assessing the quality of the qualitative data was achieved by evaluating the accuracy of data transcripts to ensure they reflected the meaning intended by the participants. This involved member checking; participants were given electronic access to transcripts and analyses to ensure the data analysis reflected the meaning of their narratives (Creswell & Miller, 2000). Peer debriefing was also used to validate and evaluate the data analysis (Spall, 1998). This involved another graduate student with no prior involvement in the study being given access to the de-identified transcripts and the existing codebook. The graduate student assessed for any potential biases that might challenge my interpretation of the data, looking for any potential disagreement regarding the codes and themes generated through my analysis (Barber & Walczak, 2009; Houghton, Casey, Shaw, & Murphy, 2013).

3.5 Ethical Considerations

A research ethics board (REB) approval application was submitted to the Ontario Tech Research Ethics Board with file number 15785 and was approved on May 15, 2020. All participants were fully informed of the study's objectives, procedures, benefits, and risks and they gave written consent before participating. Participants were informed of their right to withdraw from the study at any time, without consequences. All participants were reminded of their right to not answer a question if they were not comfortable doing so. As the interview questions regarding experience with opioid and naloxone use may cause the participant to feel emotional, they were referred to the appropriate community resources for follow-up upon their consent, and they were reminded of their right to

withdraw from their participation in the research at any time with no negative consequences. As well, all participants were given the contact information of members of the research team for any comments, questions, or concerns regarding the study.

To maintain confidentiality, the participants' identities were protected at all times both during and after the research had been completed. Codes were used in place of participants' names throughout the data analysis and research process. The data collected were stored securely, with all files encrypted and password protected and all print documents stored in a locked cabinet. Audio recordings were deleted and field notes were shredded after transcriptions had been completed. Raw transcripts were deleted after data analysis was completed.

3.6 Effects of COVID-19 on Study

The COVID-19 pandemic has affected this study in a number of ways. Interviews were originally to be done in-person whenever possible, to be accessible to those without access to a telephone or a device capable of videoconferencing capabilities and internet. For the safety of participants, study procedures were changed so that all interviews were to be done remotely. As well, recruitment was more difficult during the challenges associated with the pandemic conditions. Recruiting service providers from community pharmacies and community organizations was made more difficult with shutdowns, as well as changes in operating hours, locations, and capacities.

Chapter 4: Results

This chapter presents the results obtained from the environmental scan questionnaire conducted with community pharmacies in Durham Region, Ontario, Canada to assess participants' experiences with the ONPP. Additionally, two case studies were completed with service providers working in THN programs in Durham Region to gather their perspectives regarding barriers and facilitators to equitable access to the ONP and ONPP by program users. From these case studies, five overarching themes were generated: (1) Continuing access despite pandemic challenges; (2) No cost, no prescription as a facilitator to access; (3) Prescriber integration as a potential facilitator to access; and (4) Stigma as a barrier to access; and (5) Lack of awareness as a barrier to access.

4.1 Environmental Scan

This environmental scan questionnaire was administered to determine naloxone accessibility and availability both before and during the COVID-19 pandemic in Durham Region, to gather information regarding the length of the participants' pharmacy's participation in the ONPP, the types of education given to program users relating to the use of naloxone, and identification of opioid overdoses. A total of eight participants completed the questionnaire.

The majority of respondents worked in urban or suburban community pharmacies, all of which have been participating in the ONPP for at least six months, with most having participated for more than twenty-four months. The number of naloxone kits provided by different pharmacies both by week and year vary widely with large standard deviations, potentially due to the small sample size. No community pharmacies did not

have naloxone on hand when requested by program users. All respondents work in pharmacies carrying nasal spray naloxone kits, which appear to be more popular among program users accessing urban pharmacies, with a majority of pharmacies carrying needle injection kits as well. All pharmacies educate program users on how to use a naloxone kit as well as how to recognize an opioid overdose. There is no uniform effect of the COVID-19 pandemic on the number of naloxone kits distributed by community pharmacies, with some witnessing increases, some witnessing decreases, and most seeing no change at all. All community pharmacy respondents reported no change in access to naloxone since the beginning of the COVID-19 pandemic.

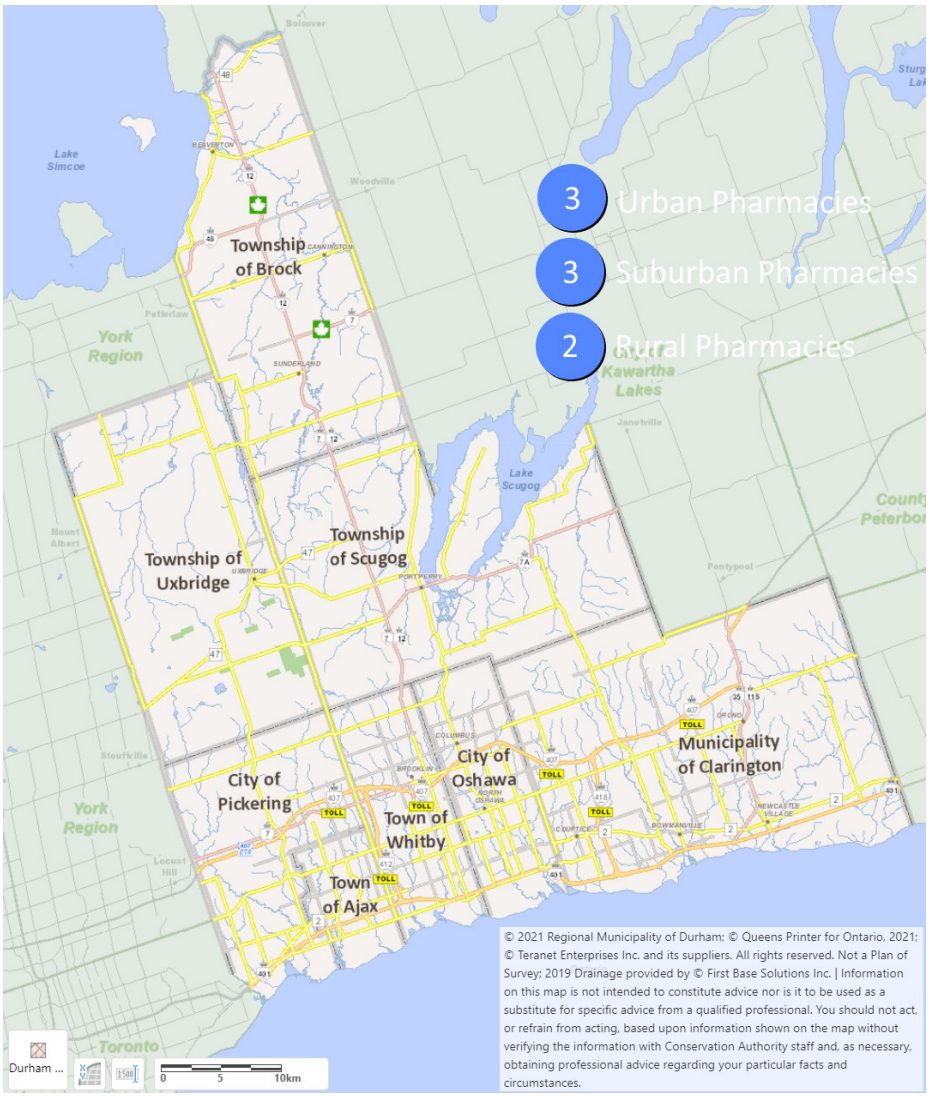

Figure 4.1. Map of respondents to environmental scan questionnaire.

4.1.1 Comparison by Location

The suburban community pharmacies surveyed had lower minimum, maximum, and mean naloxone kits distributed both in an average week and over the past year than the urban and rural community pharmacies surveyed. Rural community pharmacies had the highest average number of naloxone kits distributed over the past year. Of the three types of areas surveyed, rural areas had the highest percentage (100%) of community pharmacies participating in the program for more than twenty-four months. The only

community pharmacy that reported a decrease in distribution of naloxone during the COVID-19 pandemic was located in a rural area. Refer to Table 1 for more detailed findings from the environmental scan.

Table 4.1. Environmental scan questionnaire results.

	Urban (N = 3)	Suburban (N=3)	Rural (N=2)
How many naloxone kits are provided to the public from your pharmacy in an average week?			
Min	0.25	0	1
Max	5	1	2
Mean (SD)	2.08 (2.55)	0.67 (0.58)	1.50 (0.71)
How many naloxone kits have been provided to the public from your pharmacy in the last year?			
Min	5	5	45
Max	85	40	85
Mean (SD)	33.00 (29.70)	18.00 (19.16)	65.00 (28.28)
How long has your pharmacy participated in this program?			
Less than 3 months	0	0	0
3 to 6 months	0	0	0
6 to 12 months	0	1 (33%)	0
12 to 24 months	1 (67%)	0	0
More than 24 months	2 (33%)	2 (67%)	2 (100%)
How often are there no available naloxone kits when a program user requests one?			
More than once a week	0	0	0
Once a week	0	0	0
A few times a week	0	0	0
Monthly	0	0	0
A few times a year	0	0	0
Yearly	0	0	0
This has not happened	3 (100%)	3 (100%)	2 (100%)
What type of naloxone kit does your organization distribute?			
Injectable kit	0	0	0
Nasal spray kit	2 (67%)	1 (33%)	1 (50%)
Both types of kits	1 (33%)	2 (67%)	1 (50%)
What type of naloxone kit does your organization distribute more commonly?			
Injectable kit	0	0	0
Nasal spray kit	2 (67%)	0	0

Both types of kits are distributed equally	1 (33%)	3 (100%)	2 (100%)
Is educational training provided to program users on how to use a naloxone kit?			
Yes	2 (67%)	3 (100%)	2 (100%)
No	0	0	0
No Answer	1 (33%)	0	0
Is educational training provided to program users on how to recognize an opioid overdose?			
Yes	3 (100%)	3 (100%)	2 (100%)
No	0	0	0
Has the distribution of naloxone by your pharmacy been affected during the COVID-19 pandemic?			
Increase in distribution	1 (33%)	1 (33%)	0
Decrease in distribution	0	0	1 (50%)
No change in distribution	1 (33%)	2 (67%)	1 (50%)
No Answer	1 (33%)	0	0
Has the access to naloxone by program users from your pharmacy been affected during the COVID-19 pandemic?			
No change in access	3 (100%)	3 (100%)	2 (100%)
Increase in access	0	0	0
Decrease in access	0	0	0

4.2 Case Studies

Each case study was completed with a service provider of naloxone who was working in Durham Region. This included a demographic survey as well as a key informant interview completed by telephone. The first case study was completed with a Community Pharmacist, the second with a Community Outreach Worker working with a local community health organization.

4.2.1 Description of Case Study #1: Community Pharmacist

The first case study is a female pharmacist with less than three months of experience distributing naloxone as part of the ONPP who worked in a community pharmacy in Durham Region. The pharmacy provides the nasal spray naloxone kit; they give out approximately one per week. The pharmacist notes that the group of program users they serve are “mostly middle-aged men” and that they have “never actually

dispensed [naloxone] to a female before". The pharmacist was notified of the program through the Ontario College of Pharmacies (OCP) website updates and email communications. When receiving a naloxone kit, program users are counseled on information about when and how to use naloxone safely and correctly.

In order to receive naloxone from a community pharmacy participating in the ONPP, program users inform pharmacy staff that they are in need of a naloxone kit. Program users will be asked for their preferred naloxone formulation. Program users may also be asked to provide their Ontario health card so that its details can be used by the pharmacy to bill the Ontario government to receive reimbursement, although as of March 2018, an Ontario health card is no longer required (MOHLTC, 2018). If a naloxone kit is not already assembled, it is prepared by a pharmacist while the program user waits. Once the naloxone kit is available, a pharmacist speaks to the program user to provide education about proper use of naloxone and provides the naloxone kit with no charge to the client.

4.2.2 Description of Case Study #2: Community Outreach Worker

The second case is a female outreach worker from a community organization in Durham Region who has participated in the ONP for more than twenty-four months. As a mobile provider of harm reduction supplies, she distributes both nasal spray and needle injection naloxone kits to program users across Durham Region from a mobile van. Approximately 30 kits are given to program users each week. Program users are "mostly people who are experiencing homelessness or are underhoused". This includes those who use substances themselves and others who are "in an area where overdoses happen a lot" and need naloxone to respond to this. Outreach workers for this community organization ask program users if they need educational training upon receiving naloxone as they may

have received the training once or more in the past. This training can include explaining the differences between the two types of available naloxone kits and can help the client make an informed decision that is best suited to their needs. As well, program users are educated on "the signs of opiate overdose and how to administer naloxone and what to do after the fact".

To receive naloxone from community organizations participating in the ONP, program users inform service providers that they are in need of a naloxone kit. Service providers will ask if the program users need education on how to use naloxone to revive an individual who has overdosed, and will provide that education if needed. Based on internal or external tracking systems and reporting requirements, some organizations may require identifying information from program users while others do not. This varies depending on the funding and goals of the community organization. Once the service provider has addressed the program user's specific needs, the naloxone kit is provided at no charge.

4.3 Integrated Findings from Environmental Scan and Key informant Interviews

4.3.1 Continuing Access despite Pandemic Challenges

From both the results of the environmental scan and the conducted interviews, pharmacists did not observe a change in an individual's ability to access naloxone kits from their site of distribution since the beginning of COVID-19 pandemic in Ontario and until the time of their response. Pharmacies were deemed essential by Ontario's government and were required to quickly make adaptive changes to conform to new safety protocols. In contrast to this, the interviewed community organization worker noted that while access to their site of distribution didn't change, their naloxone

distribution greatly increased at the start of the pandemic lockdown when many other community organizations closed their doors, temporarily or otherwise. These other community organizations primarily operated indoors and were not providing naloxone kits through mobile methods or were not conducting outreach in a manner that was already safe or easily adaptable to meet the public health regulations of operating during the COVID-19 pandemic.

4.3.2 No Cost, No Prescription as Facilitator to Access

Both key informants interviewed noted the universal ability to access naloxone kits from either of their distribution settings. Describing the process of an individual receiving naloxone, the pharmacist plainly stated, “they don’t really need a prescription or anything. They just need a health card and we just fill it under the health card number and then they can get a kit”. From their perspective the ONPP is “very easy to use, it’s not very complicated”. The community organization worker stated that from their organization, “literally anybody can [get a naloxone kit]” and that, “if anyone asks we will give [naloxone kits] to them, no questions asked”. Being mobile, the community organization “just kind of [tries] to go everywhere so that no one’s left out. We go everywhere just to make sure we are available for everybody, at least if they want that option”.

4.3.3 Prescriber Integration as a Potential Facilitator to Access

One of the participants interviewed brought up the opportunity for prescribers in Ontario to discuss receiving naloxone along with prescribed opioids, “I think when prescribers write a prescription for any opioids, I think they should mention a naloxone kit. And then the pharmacist can discuss with them if they’re interested in having one on

hand. And I think most patients, if they know it's free, so they'll take it, they won't say no to it". This has been studied in the past, with participating family physicians believing that providing naloxone and overdose education would benefit patients at risk of opioid overdose, although research pre-dates the implementation of the ONPP (Leece, Orkin, Shahin, & Steele, 2015). And while opioid-related deaths are increasing due to non-prescribed opioid drugs (Public Health Ontario, 2021), discussions with prescribers about naloxone may still help to reduce some harm from opioid overdoses, and this deserves further investigation.

4.3.4 Stigma as a Barrier to Access

Stigma was mentioned in different circumstances. The community outreach worker discussed avoiding stigmatizing program users when providing supplies, "if someone asks for three or four [naloxone kits], I'm not going to badger them and ask them why they need three or four, I'm just going to give them three or four". They said their organization "[reduces] the barriers to getting a kit so you can get however many you want, whenever you want, whatever type you want, it doesn't matter. We just want to make sure that people are safe, so just trying to be out there as much as possible and getting them out". Part of this is a result of building relationships with program users who might be hesitant to take naloxone kits from someone they don't trust, since "it takes people in the populations that we work with a really long time to trust people. So, if they see a new face sometimes they don't want to ask that individual". Stigma from other organizations also prevents naloxone distribution, meaning that "there [are] places that we're not allowed to be during a certain period of day due to other organizations that are

against harm reduction. So that's a little bit difficult where there's no one handing out naloxone".

4.3.5 Lack of Awareness as a Barrier to Access

The community pharmacist stated that accessibility is hampered by a lack of public awareness of the program. From the pharmacist's experience, "[they] don't think a lot of people know about it, especially if they're [prescribed] opioids". One way the pharmacist suggested to reduce this lack of awareness is to integrate prescribers of opioids into the program by having them provide education on the use of naloxone to patients, as well as mentioning that it is available at no cost. Another suggestion was for pharmacists to talk to patients receiving opioids to "see if they would be interested in just having [a naloxone kit] on hand regardless". As well, the participant noted that there could be more awareness for pharmacists, as they themselves were only made aware of the program through emails and website updates from the Ontario College of Pharmacists. The pharmacist made a comparison to promotion done by drug reps from pharmaceutical companies, saying, "usually when there's a new drug there's a drug rep coming to the pharmacy talking to them about it". Regarding naloxone, they stated that, "no one has come in and I think it would be a good idea to [have an in-person representative come in to their pharmacy]".

Chapter 5: Discussion and Conclusions

This chapter discusses the significance of the collected results, interprets them, discusses the strengths and limitations of this study, and presents opportunities for future research. This study examined the following research questions: (1) What do service providers of the Ontario Naloxone Program in Durham Region perceive to be facilitators and barriers to equitable access; (2) What do service providers and program users of the Ontario Naloxone Program for Pharmacies in Durham Region perceive to be facilitators and barriers to equitable access? The three areas discussed include: (1) Convergence and divergence between case studies and environmental scan; (2) Continued access in pandemic conditions; (3) Reducing stigma by building trust. The findings discussed are significant for their implications for the future of harm reduction service delivery, education of community pharmacy and community healthcare workers, and health policy. Lastly, the chapter concludes with strengths and limitations of this research, a summary of the study, and potential directions for future research.

5.1 Convergence and Divergence between Environmental Scan and Case Studies

The community pharmacist interviewed as part of Case Study #1 worked in a suburban community pharmacy and reported an experience similar to respondents of the environmental scan questionnaire who also work in suburban community pharmacies. Both the interviewed suburban community pharmacist and questionnaire respondents reported low numbers of naloxone kits being distributed to program users in an average week (one or less). All suburban participants reported that there was no change in the ability of program users to access the naloxone program operating out of their pharmacies during the COVID-19 pandemic.

Findings from a previous study examining the distribution of naloxone from community pharmacies in Ontario between April 2017 and March 2018, in contrast to this study , showed a higher rate of naloxone uptake in urban rather than rural settings (Antoniou et al., 2020). As well, the community pharmacist in Case Study #1 noted that all program users accessing naloxone from their pharmacy were male. This contrasts with a study conducted by Choremis et al. (2019) that found, of the individuals accessing naloxone from Ontario's pharmacies between July 2016 and March 2018, only approximately half of program users (50.3%) were male. These disparities could result from a number of factors, including specific needs or barriers existing in the community in the surrounding area, changes in the demographics of program users since March 2018, as well as the short duration of time (less than three months), that the participant of a community pharmacy has been participating in the ONPP. As well, the ONPP itself has changed in that time, with naloxone nasal spray being publicly funded and distributed as part of the program, along with a change in rules such that a program user can receive naloxone without providing an Ontario health card, both beginning on March 27, 2018 (MOHLTC, 2018).

5.2 Continued Access in Pandemic Conditions

While enough time has passed that many community organizations have either reopened or are in the process of reopening since the beginning of the COVID-19 pandemic, the challenges experienced should be kept in mind for potential future pandemics or other similar types of crises. This is important as future crises may exacerbate the effects of the overdose crisis, as has been seen with COVID-19 (Ontario Drug Policy Research Network et al., 2020). By having plans or alternate methods for

distributing naloxone kits in similar situations in the future, services can continue uninterrupted. These methods can include mobile harm reduction services such as those used by the community organization worker in Case Study #2, as well as initiatives such as mail-based delivery of naloxone (French, Favaro, & Aronowitz, 2021), community hub models providing wraparound services (Abbotsford Hub Community Centre, 2021; Bueckert, 2021), home delivery, and increased street outreach (Collins, Ndoye, Arene-Morley, & Marshall, 2020).

5.3 Reducing Stigma by Building Trust

When program users do not have a trusting, established relationship with service providers this can prevent them from accessing naloxone programs due to the associated stigma from opioid use. Literature identifying stigma in naloxone distribution programs often focuses on overcoming this in order for initial engagement with the program users (Canadian Mental Health Association Ontario, 2018). However, little research has been done on the maintenance of these relationships in either of the settings examined in this study. While seeking naloxone in all settings can trigger either conscious or unconscious bias toward the recipient, this can be heightened in community pharmacies where program users are placed in a more visible and public facing setting than they might find themselves in when interacting with a community organization, as well as when dealing with pharmacists who are more likely than community organization-based service providers to "[reinforce] feelings of worthlessness" (Antoniou et al., 2021). Future research would need to take into consideration the impact of conscious and unconscious bias exhibited by the service providers within these settings and explore the implementation of strategies to mitigate the risk of stigmatization toward program users.

While a small number of studies examine perceptions of stigma on the distribution of naloxone, they generally focus on how stigma may contribute to an individual being less likely to access an available naloxone program (Green et al., 2017). What has not been investigated is how the stigmatizing attitudes, surrounding naloxone distribution and harm reduction in general, held by organizations or agencies may prevent other existing organizations from distributing naloxone, as seen in the narratives presented in Case Study #2. Future research could identify methods to reduce stigma so that different service organizations can operate together more harmoniously. Methods could include providing increased and/or targeted access to OEND training, which has been shown to reduce the endorsement of stigmatizing beliefs such as individuals who use drugs will engage in riskier drug use when they have access to naloxone (Winograd et al., 2020).

5.4 Study Strengths and Limitations

A strength of this study is its use of a case study methodology. This included taking a qualitative approach to data collection about a phenomenon of interest that is uncommonly studied through this lens. Through the use of interviews, qualitative methodology allowed for open-ended, in-depth perspectives from participants who can be followed up for clarification and further elaboration of ideas, which could not be achieved through the use of questionnaires alone. A case study methodology facilitated the exploring and comparing of the experiences of service providers, with differing experiences and working in diverse community settings. To further complement the qualitative methodology, an environmental scan was conducted, which allowed for further understanding of the lived experiences of those providing naloxone to program

users. Finally, this study was able to examine the impact of the COVID-19 pandemic on equitable access to naloxone from the perspective of service providers.

Another strength of this study is that it functions as a pilot study to guide the development of larger, more comprehensive research. For instance, future research can explore the lessons learned from this study to further examine the opioid crisis as it exists within the different jurisdictions in Ontario and across Canada.

There were a number of limitations with this study, particularly in the recruitment of participants. With the onset of the COVID-19 pandemic and lockdowns, shutdowns, and restrictions placed on interactions and daily life in Ontario, the ability to recruit and interact with potential study participants was greatly reduced. Many sites of naloxone distribution have been either closed or heavily modified, making recruitment more difficult. For example, posters are less effective in community organization sites with reduced or entirely absent in-person traffic. As well, pharmacies may be restricted to a certain number of individuals inside, who are also less likely to spend extended periods of time there and are less likely to notice or read recruitment flyers.

A major limitation of the study comes from a lack of recruitment of program users. They are arguably the most important stakeholders involved in the naloxone dispensing interaction and have only been able to share their experiences in a few past research studies (Antoniou et al., 2021). With only service providers recruited for this study, the representativeness of the data may be lacking. This may leave a major gap where program users are unable to share their experiences relating to barriers and facilitators to equitable access of the ONP and ONPP, and how the COVID-19 pandemic has influenced this. Further studies of either of Ontario's THN programs need to

incorporate the perspectives of program users to enhance representativeness of the study data. .

As well, recruiting service providers and program users, does not include the perspectives of those individuals who are non-users of the Ontario's THN program. Future studies can potentially recruit these individuals through methods such as snowball sampling. An example of this could be recruiting an individual who uses a THN program, and through this connection, recruiting someone they pick up naloxone for, who does not themselves access the program. Through this second participant, data can be collected regarding the perceived barriers preventing them from accessing THN programs on their own.

Chapter 6. Conclusion

In summary, this study examined the lived experiences of service providers in both the ONP and ONPP in order to better understand the perceived barriers and facilitators to equitable access of naloxone in Durham Region, Ontario, Canada. An environmental scan was completed to assess the availability and number of naloxone kits accessed in Durham Region through community pharmacies, as well as how they have been affected by COVID-19 pandemic. Respondents to the environmental scan questionnaire perceived that access to naloxone from community pharmacies did not change during this period of time. The COVID-19 pandemic was seen to negatively influence access to naloxone for some community organizations, while community pharmacies required no or minimal service delivery modifications to provide continued access during the pandemic. Naloxone kits being made available to all with no cost was seen as a facilitator to access. Stigma towards existing and potential program users and a lack of awareness of Ontario's THN programs were seen as barriers to access. Prescriber integration into the ONPP was suggested to increase access by the program users and to reduce stigma surrounding utilization of naloxone.

Future research can focus on expanding the scope of this exploratory study. This can be done in terms of geographical locations, such as examining barriers and facilitators to equitable access to the ONP and ONPP in multiple regions or the entire province of Ontario. Additional community settings can be explored with additional stakeholders including, most crucially, program users. Future research should examine strategies for building trust and maintaining effective relationships between program users and service providers. Potential research could also compare the effectiveness and

uptake of different methods of raising awareness, educating and delivering naloxone services to the users in the community, as well as the development and utilization of appropriate metrics for program evaluation.

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Appendices

Appendix A: REB Approval

Date:	*May 15, 2020*
To:	*Winnie Sun*
From:	*Ruth Milman, REB Chair*
File # & Title:	*15785 - Barriers and Facilitators to Equitable Access of Naloxone in Durham Region*
Status:	***APPROVED***
Current Expiry:	***May 01, 2021***

Notwithstanding this approval, you are required to obtain/submit, to Ontario Tech Research Ethics Board, any relevant approvals/permissions required, prior to commencement of this project.

The Ontario Tech Research Ethics Board (REB) has reviewed and approved the research study named above to ensure compliance with the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2 2014), the Ontario Tech Research Ethics Policy and Procedures and associated regulations. As the Principal Investigator (PI), you are required to adhere to the research protocol described in the REB application as last reviewed and approved by the REB. In addition, you are responsible for obtaining any further approvals that might be required to complete your project.

Thank you for adding in the appropriate review statements in the participant materials. Your study is approved in full and you may commence recruitment and data collection. We wish you success in this and all of your research endeavors. We note that within your study materials you have included modifications for your interviews to allow them to be conducted using online methodologies or telephone in order to comply with pandemic social distancing rules. As such, all aspects of your study recruitment and data collection can proceed using no direct person to person contact. When the suspension of direct person to person contact in research studies is lifted you may also revert back to in person interviews. If you do so, please submit a change request which includes materials that remove the information about the online or telephone interview procedures due to the current pandemic.

Under the Tri-Council Policy Statement 2, the PI is responsible for complying with the continuing research ethics reviews requirements listed below:

Renewal Request Form: All approved projects are subject to an annual renewal process. Projects must be renewed or closed by the expiry date indicated above ("Current Expiry"). Projects not renewed 30 days post expiry date will be automatically suspended by the REB; projects not renewed 60 days post expiry date will be automatically closed by the REB. Once

your file has been formally closed, a new submission will be required to open a new file.

Change Request Form: If the research plan, methods, and/or recruitment methods should change, please submit a change request application to the REB for review and approval prior to implementing the changes.

Adverse or Unexpected Events Form: Events must be reported to the REB within 72 hours after the event occurred with an indication of how these events affect (in the view of the Principal Investigator) the safety of the participants and the continuation of the protocol (i.e. un-anticipated or un-mitigated physical, social or psychological harm to a participant).

Research Project Completion Form: This form must be completed when the research study is concluded.

Always quote your REB file number (**15785**) on future correspondence. We wish you success with your study.

Sincerely,

Dr. Ruth Milman
REB Chair
ruth.milman@uoit.ca

Emma Markoff
Research Ethics Assistant
researchethics@uoit.ca

Appendix B: Demographic Data Questionnaire - Service Providers

Group Code	Participant Number	Date
Site	Researcher	

Please tell us the following information about yourself:

1. What is your employment status? _____
2. What is your position within your organization? _____
3. What are your professional designations, if you have any?
   _____
4. For how long have you known about this program?
   a. Less than 3 months
   b. 3 to 6 months
   c. 6 to 12 months
   d. 12 to 24 months
   e. More than 24 months
5. How long have you participated in this program?
   a. Less than 3 months
   b. 3 to 6 months
   c. 6 to 12 months
   d. 12 to 24 months
   e. More than 24 months
6. Approximately how many naloxone kits are distributed by your organization on a weekly basis?
7. What type of naloxone kit does your organization distribute?
   a. Injectable kit
   b. Nasal spray kit
   c. Both types of kits
8. Is educational training provided to program users on how to use a naloxone kit?

a. Yes
b. No

9. Is educational training provided to program users on how to recognize an opioid overdose?
    a. Yes
    b. No

Thank you very much for your time.

Appendix C: Environmental Scan Questionnaire

Group Code	Participant Number	Date
Site	Researcher	

Please tell us the following information about yourself:

10. How many naloxone kits are provided to the public from your pharmacy in an average week? _____

11. How many naloxone kits have been provided to the public from your pharmacy in the last year? _____

12. How long has your pharmacy participated in this program?

    a. Less than 3 months
    b. 3 to 6 months
    c. 6 to 12 months
    d. 12 to 24 months
    e. More than 24 months

13. How often are there no available naloxone kits when a program user requests one?

    a. More than once a week
    b. Once a week
    c. A few times a month
    d. Monthly
    e. A few times a year
    f. Yearly
    g. This has not happened

14. What type of naloxone kit does your organization distribute?

    a. Injectable kit
    b. Nasal spray kit
    c. Both types of kits

15. What type of naloxone kit does your organization distribute more commonly?

    a. Injectable kit
    b. Nasal spray kit
    c. Both types of kits are distributed equally

16. Is educational training provided to program users on how to use a naloxone kit?
    a. Yes
    b. No
17. Is educational training provided to program users on how to recognize an opioid overdose?
    a. Yes
    b. No

Thank you very much for your time.

Appendix D: Consent Form and Letter of Information

PARTICIPANT CONSENT FORM – Volunteer

Title of Research Study: Barriers and Facilitators to Equitable Access of Naloxone in Durham Region

You are invited to participate in a research study entitled, Barriers and Facilitators to Equitable Access of Naloxone in Durham Region currently being conducted by Ontario Tech University. This study has been reviewed by the Ontario Tech University Research Ethics Board [insert REB # assigned] and originally approved on [insert date].
Please read this consent form carefully, and feel free to ask the Researchers any questions that you might have about the study. If you have any questions about your rights as a participant in this study, please contact the Research Ethics Office at 905 721 8668 ext. 3693 or researchethics@uoit.ca.

Researcher(s):
Principal Investigator: Dr. Winnie Sun
Student Lead: Lucas Martignetti
Departmental and institutional affiliation(s): Faculty of Health Sciences at Ontario Tech University
Contact number(s)/email: winnie.sun@uoit.ca, lucas.martignetti@ontariotechu.net

Purpose and Procedure:
The purpose of this study is to learn about the perceived facilitators/enablers and barriers to equitable access to Ontario's naloxone programs. In this study, we will primarily collect data through in-depth interviews lasting between approximately thirty minutes to one hour. We will also make use of a short questionnaire to collect demographic information. You will participate in one interview after having completed a brief questionnaire. Over the course of the interview, you will answer a series of open-ended questions regarding your experiences of Ontario's naloxone programs. Interviews will be audio recorded and you will be given access to a verbatim transcript that you may review.

Potential Benefits:
You will not directly benefit from participating in this study. The information acquired from this study may assist in better understanding what works to enable or increase equitable access to Ontario's naloxone programs, and what factors act as barriers to equitable access to the program. It is

expected that this information will inform the further development of Ontario's naloxone programs.

Potential Risk or Discomforts:

There are minimal risks associated with the type of questions we will be asking in this study. You can stop the interview at any point and do not need to answer any questions you do not wish to answer. If the questions cause you to feel emotional or uncomfortable, and you wish to seek assistance, contact information for relevant resources is provided below.

Rapid Access Addiction Medicine (RAAM) clinics in Durham Region (through Lakeridge Health) provide access to walk-in care for people living with opioid related addictions. Services provided include medical treatment and same-day counselling services without a doctor's referral.

Contact information for RAAM Clinics:

Oshawa Hospital: Mondays and Thursdays, 9 a.m. to 11 a.m., 905-576-8711 ext. RAAM (37226)

Pinewood: Tuesdays and Thursdays, 9 a.m. to 11 a.m., 905-576-8711 ext. RAAM (37226)

Carea Community Health Centre offers services for mental health concerns and addictions, providing programs and counselling.

Contact information for Carea Community Health Centre:

Oshawa: 905-723-0036

Ajax: 905-428-1212

More services and their contact information can be found at https://www.durham.ca/en/health-and-wellness/drugs.aspx#Where-can-I-get-help

Storage of Data:

All data collected will be stored in a password-protected laptop provided by Ontario Tech University and kept in a secure location, accessible only to the researchers named above. You will be assigned a pseudonym that will be used to identify your data. Once a pseudonym has been assigned, any direct identifiers will be destroyed and disposed through appropriate shredding and secure deletion as to be non-recoverable. This non-identifiable and strictly confidential data may be kept beyond the length of this study, in the event that it could be used in pursuance of a future study surrounding the same or similar phenomenon of interest.

The results of this study may be published in a scientific journal and/or presented at a conference. Any information that would identify you will NOT appear in these publications.

Confidentiality:

Before you participate in an interview, you will be asked to complete a demographic questionnaire with the interviewer. Examples of demographic questions include your age, gender, and educational level. This information will

be paired with your interview to allow the researcher to better understand the interview data. After a pseudonym has been developed for this data, any direct identifiers will be destroyed. Throughout the study, this information will only be accessed by the researchers named above.

To safeguard your rights to confidentiality and anonymity, both verbal and written information about the objectives of this study will be available to you throughout the study period. You will be asked to provide explicit signed informed consent before participating in this study, and you will be provided with a copy of this consent form. As mentioned above, this study has received ethics approval from Ontario Tech University's Research Ethics Board. You will be notified of the use of an audio recorder during the interview and a verbatim transcript of your answers will be provided to you for review. Pseudonyms will be used to preserve your anonymity, and the data will be kept in a secure, password-protected location at all times, accessible only by the researchers named above. All study data will be aggregated and all potential identifiers will be removed to protect your confidentiality.

Your privacy shall be respected. No information about your identity will be shared or published without your permission, unless required by law.

Confidentiality will be provided to the fullest extent possible by law, professional practice, and ethical codes of conduct. Please note that confidentiality cannot be guaranteed while data are in transit over the Internet.

Right to Withdraw:

Your participation is voluntary, and you are asked to answer only those questions that you are comfortable with answering. The information that is shared will be held in strict confidence and discussed only with the research team.

You will be given information that is relevant to your decision to continue or withdraw from participation. If you withdraw from the research project at any time, you need not offer any reason for making this request. You may withdraw from the study before we have anonymized and aggregated your data. Please note it is not feasible to withdraw your results once your data has been anonymized and aggregated as it will be impossible to trace it back to you after the elimination of direct identifiers. It will also be difficult, if not impossible, to withdraw results once they have been published or otherwise disseminated. Participants can contact the researcher to withdraw via email address and/or phone number provided on the consent form.

Conflict of Interest:

There are no conflicts of interest present in this study.

Compensation
There is no compensation for participating in this study. It is expected that increased access to Ontario's naloxone programs would benefit people who use opioids.

Debriefing and Dissemination of Results:
Study results will be made available within six months of completion of the interviews. The results from this study will be used to inform further development of Ontario's naloxone programs in order to increase naloxone access and reduce opioid-related harms. If you wish to be informed of the results of this study, please feel free to contact the researchers named above at the given email addresses up to 6 months after the interview.

Participant Concerns and Reporting:
If you have any questions concerning the research study or experience any discomfort related to the study, please contact the Student Lead Lucas Martignetti at 289-634-5724 or lucas.martignetti@ontariotechu.net, or Principal Investigator Dr. Winnie Sun, RN PhD at 905.721.8668 ext. 5349 or winnie.sun@uoit.ca. Any questions regarding your rights as a participant, complaints or adverse events may be addressed to Research Ethics Board through the Research Ethics Office – researchethics@uoit.ca or 905.721.8668 x. 3693.
By consenting, you do not waive any rights to legal recourse in the event of research-related harm.

Consent to Participate:

1. I have read the consent form and understand the study being described.
2. I have had an opportunity to ask questions and my questions have been answered. I am free to ask questions about the study in the future.
3. I freely consent to participate in the research study, understanding that I may discontinue participation at any time without consequence. A copy of this Consent Form has been made available to me.
4. I allow myself to be audio recorded during the interview.
5. I agree to the secondary use of my non-identifiable data in pursuance of a future study surrounding the same or similar phenomenon of interest.

   I would like to meet a second time to review a transcript of my interview.
   □ Yes □ No

_____ _____
(Name of Participant) **(Date)**

_____ _____
(Signature of Participant) **(Signature of Researcher)**

Appendix E: Interview Guide with Tables - Service Providers

For service providers:

Information Sought	Questions and probes
Demographics	Employment and professional status Length of experience with program Number and type of naloxone kit distributed Training provided
Objective 1 How are individuals learning about and becoming involved with the Ontario Naloxone Program (for Pharmacies)?	1) Can you tell me how you first heard about the Ontario Naloxone Program (for Pharmacies)? 2) How did you become involved in the program? ***Probes*** Did you learn about the program through communication from government sources or from a professional association? 3) Can you describe the process of how the public can receive a naloxone kit from your organization? ***Probes*** What steps does someone need to take to receive a naloxone kit? Do they need to register? What are the eligibility criteria for someone to receive a kit? When someone receives a naloxone kit, is that documented or tracked? 4) Does your organization provide any educational training related to the utilization of naloxone kits or recognizing and responding to an opioid overdose? What are the education or training components? ***Probes*** What is the educational training process?

Objective 2 What are the perceived enablers/facilitators and barriers to accessing the program observed by service providers? ***Objective 3*** What perceived enablers/facilitators and barriers to equitable access to the program are observed by service providers?	What educational materials are used by service providers? What educational materials are provided to program users? Did you learn about the program through any kind of advertising or promotional materials? What were they? 5) From your experience, what program components encourage or allow people to use it? 6) From your experience, what prevents people from using this program? ***Probes*** What have you either observed yourself or learned from program users to be helpful or harmful to their participation in the program? If so, what was done to address this situation? 7) Who are the predominant groups of program users? ***Probes*** What kind of demographics do you observe accessing naloxone kits? Do you notice any trends? 8) Can you elaborate on your perspectives of any specific groups of individuals having different levels of access to the program? ***Probes*** Based on your experience, can you provide any examples of how an aspect of a person's identity, such as their culture, ethnicity, or income could affect their participation in the program? 9) In your experience, has the ability of program users to access naloxone changed during the

	COVID-19 pandemic? If so, can you elaborate on how that is happening? ***Probes*** Have you witnessed any changes to the level of access to the program during the pandemic? Has access to the program changed due to changes in rules and procedures to deal with the pandemic? What are the things that have been done to address these challenges?
Objective 4 What recommendations can service providers give to promote enablers/facilitators and to remove or reduce barriers to equitable access to the program?	10) Can you provide any suggestions for ways to improve access to the program, either for everyone or for the specific groups mentioned? ***Probes*** What do you think could be done to promote the things that make access easier? What do you think could be done to remove barriers to access? Would you recommend any changes to improve education about naloxone use or recognizing opioid overdoses?
	11) Before we finish up, do you have any final thoughts you'd like to share about your experience with access of the Ontario Naloxone Program (for Pharmacies)? ***Probes*** Is there anything else regarding what we've spoken about today that you would like to share?

Appendix F: Email Script and Letter of Information - Environmental Scan

Email Subject line:
Assistance with study: Questionnaire about access to naloxone in community pharmacy within Durham region

Dear [Community Pharmacy],

My name is Lucas Martignetti and I am a Master of Health Sciences student from Ontario Tech University. I am contacting you to request your help for our research study entitled, "Barriers and Facilitators to Equitable Access of Naloxone in Durham Region".

This study is looking at equitable access to naloxone in Durham Region. We would like to know about the experience of community pharmacies as participants in the Ontario Naloxone Program for Pharmacies. Our findings may be used to improve this program and inform policies for naloxone access.

A questionnaire is attached to this email. It asks questions about the availability and distribution of naloxone from your community pharmacy. We are hoping that you will be able to assist us by sharing your experience as part of the Ontario Naloxone Program and filling out the attached questionnaire and attaching it as a reply to this email. All responses will remain anonymous.

In the preamble of the questionnaire the details of the study are included, as well as information about the confidentiality of participants. This is so that you are able to complete the questionnaire having been fully informed of the risks, benefits, and your rights to confidentiality that come with participating in this study

If you would be interested in learning more about the study, one of our research team members will be happy to set up a time to discuss the study.

This study is being conducted by Ontario Tech University. The study has been reviewed by the Ontario Tech University Research Ethics Board [Reference number].

Thank you for your time and consideration,

Sincerely,

Lucas Martignetti

Title of Research Study: Barriers and Facilitators to Equitable Access of Naloxone in Durham Region

You are invited to participate in a research study entitled, Barriers and Facilitators to Equitable Access of Naloxone in Durham Region currently being conducted by Ontario Tech University. This study has been reviewed by the Ontario Tech University Research Ethics Board [insert REB # assigned] and originally approved on [insert date].
Please read this consent form carefully, and feel free to ask the Researchers any questions that you might have about the study. If you have any questions about your rights as a participant in this study, please contact the Research Ethics Office at 905 721 8668 ext. 3693 or researchethics@uoit.ca.

Researcher(s):
Principal Investigator: Dr. Winnie Sun
Student Lead: Lucas Martignetti
Departmental and institutional affiliation(s): Faculty of Health Sciences at Ontario Tech University
Contact number(s)/email: winnie.sun@uoit.ca,
lucas.martignetti@ontariotechu.net

Purpose and Procedure:

The purpose of this study is to learn about the perceived facilitators/enablers and barriers to equitable access to Ontario's naloxone programs. As part of this study, we will provide a short questionnaire to collect information about naloxone availability in community pharmacies.

Potential Benefits:

You will not directly benefit from participating in this study. The information acquired from this study may assist in better understanding what works to enable or increase equitable access to Ontario's naloxone programs, and what factors act as barriers to equitable access to the program. It is expected that this information will inform the further development of Ontario's naloxone programs.

Potential Risk or Discomforts:

There are minimal risks associated with the type of questions we will be asking in this study. You do not need to answer any questions you do not wish to answer. If you wish to seek assistance, please contact the researchers with the contact information provided, contact information for relevant resources is provided below.
Rapid Access Addiction Medicine (RAAM) clinics in Durham Region (through Lakeridge Health) provide access to walk-in care for people living with opioid related addictions. Services provided include medical treatment and same-day counselling services without a doctor's referral.
Contact information for RAAM Clinics:

Oshawa Hospital: Mondays and Thursdays, 9 a.m. to 11 a.m., 905-576-8711 ext. RAAM (37226)
Pinewood: Tuesdays and Thursdays, 9 a.m. to 11 a.m., 905-576-8711 ext. RAAM (37226)

Carea Community Health Centre offers services for mental health concerns and addictions, providing programs and counselling.
Contact information for Carea Community Health Centre:
Oshawa: 905-723-0036
Ajax: 905-428-1212
More services with contact information can be found at https://www.durham.ca/en/health-and-wellness/drugs.aspx#Where-can-I-get-help

Storage of Data:

All data collected will be stored in a password-protected laptop provided by Ontario Tech University and kept in a secure location, accessible only to the researchers named above. You will be assigned a pseudonym that will be used to identify your data. Once a pseudonym has been assigned, any direct identifiers will be destroyed and disposed through appropriate shredding and secure deletion as to be non-recoverable. This non-identifiable and strictly confidential data may be kept beyond the length of this study, in the event that it could be used in pursuance of a future study surrounding the same or similar phenomenon of interest.

The results of this study may be published in a scientific journal and/or presented at a conference. Any information that would identify you will NOT appear in these publications.

Confidentiality:

Throughout the study, this information will only be accessed by the researchers named above.

To safeguard your rights to confidentiality and anonymity, both verbal and written information about the objectives of this study will be available to you throughout the study period. As mentioned above, this study has received ethics approval from Ontario Tech University's Research Ethics Board. Pseudonyms will be used to preserve your anonymity, and the data will be kept in a secure, password-protected location at all times, accessible only by the researchers named above. All study data will be aggregated and all potential identifiers will be removed to protect your confidentiality.

Your privacy shall be respected. No information about your identity will be shared or published without your permission, unless required by law. Confidentiality will be provided to the fullest extent possible by law, professional practice, and ethical codes of conduct. Please note that confidentiality cannot be guaranteed while data are in transit over the Internet.

Right to Withdraw:

Your participation is voluntary, and you are asked to answer only those questions that you are comfortable with answering. The information that is shared will be held in strict confidence and discussed only with the research team.

You will be given information that is relevant to your decision to continue or withdraw from participation. If you withdraw from the research project at any time, you need not offer any reason for making this request. You may withdraw from the study before we have anonymized and aggregated your data. Please note it is not feasible to withdraw your results once your data has been anonymized and aggregated as it will be impossible to trace it back to you after the elimination of direct identifiers. It will also be difficult, if not impossible, to withdraw results once they have been published or otherwise disseminated. Participants can contact the researcher to withdraw via email address and/or phone number provided on the consent form.

Conflict of Interest:

There are no conflicts of interest present in this study.

Compensation

There is no compensation for participating in this study. It is expected that increased access to Ontario's naloxone programs would benefit people who use opioids.

Debriefing and Dissemination of Results:

Study results will be made available within six months of the study. The results from this study will be used to inform further development of Ontario's naloxone programs in order to increase naloxone access and reduce opioid-related harms. If you wish to be informed of the results of this study, please feel free to contact the researchers named above at the given email addresses up to 6 months after the completion of the questionnaire.

Participant Concerns and Reporting:

If you have any questions concerning the research study or experience any discomfort related to the study, please contact the Student Lead Lucas Martignetti at lucas.martignetti@ontariotechu.net or Principal Investigator Dr. Winnie Sun, RN PhD at 905.721.8668 ext. 5349 or winnie.sun@uoit.ca. Any questions regarding your rights as a participant, complaints or adverse events may be addressed to Research Ethics Board through the Research Ethics Office – researchethics@uoit.ca or 905.721.8668 x. 3693.

By consenting, you do not waive any rights to legal recourse in the event of research-related harm.

Appendix G: Verbal Script - Recruiting Participants

Study title: Barriers and Facilitators to Equitable Access of Naloxone in Durham Region
The information in this guide is organized as follows:

I. Incoming telephone calls about the study
II. Possible questions and answers about the study
III. Screening
IV. Verbal consent for participating in the interview
V. Booking the interview

I. Incoming telephone calls about the study

If someone calls, ascertain the following:

1. **Do they have questions about the study?** If YES, go to **Section II (below)**. After answering all their questions, ask them if they are interested in participating. If they say YES, go to **Section III (below)**.
2. **Are they interested in participating?** If YES, go to **Section III (below)**.

II. Possible questions and answers about the study

Do I have to take part in this study?

No, you are not obligated to take part in this study.

I don't understand the study; can you explain it to me? Why are you conducting this study?

The overall goal of this project is to identify and better understand both what serves as barriers to equitable naloxone access in Ontario as well as what facilitates that access, in order to make recommendations to the provincial government to improve naloxone programs.

What is expected from me?

If you want to participate in our study, you will be asked to complete a brief demographic form for descriptive purposes and then participate in a one-on-one interview lasting approximately 30 to 45 minutes. The interview will be held at a convenient time and at a place that is mutually agreed upon. We will ask you questions about your experience with naloxone programs. The interview will be audio recorded. You don't have to answer all of our interview questions.

III. Screening

I need to ask 3 questions in order to determine if you're eligible to participate in our study. **Do I have your consent to proceed?** YES or NO. If the answer is NO, thank them and end the conversation.

1. **Do you distribute naloxone or receive naloxone from a location in Durham Region?** DISTRIBUTE, RECEIVE, or NO. If the answer is NO, thank them and end the conversation.

If the answer to question 1 is YES, then ask this question:

2. **Is the program you participate in located in a community pharmacy or community-based organization?** COMMUNITY PHARMACY, COMMUNITY-BASED ORGANIZATION, or NO. If the answer is NO, thank them and end the conversation.

IV. Verbal consent for participating in the interview

Would you like to participate in a one-on-one interview for this study? We will talk about your experience participating in one of Ontario's naloxone programs and the barriers and facilitators to equitable access of naloxone. Your opinion is incredibly important to us, as it will help us to better understand the experience of individuals in a relatively new program where little research has been done. YES or NO. If NO, thank them for their time and end the call.

V. Booking the interview

If YES, proceed to booking an appointment with them.

Is there a day and time of the week of (determine week) that is usually better for you?

Is there a location of meeting that works better for you?

Can I have your address and/or email address, please?

If you need to cancel or if you will be late, call me at 289-634-5724. Please leave a message if I don't answer.

If they say YES to a reminder phone call, include their telephone number, email address and/or mailing address below in the verbal consent box. This document will be detached and stored in a locked filling cabinet.

Thank you very much for answering my questions today. I will see you on (date, time, and location).

End call.

Verbal consent for interview participation □YES →*Complete following items* □NO

Name of participant: _____

Participant's number: _____

Participant's telephone number: _____

Preferred time to be reached: _____

Participant's email address: _____

Participant's mailing address: _____

Name of person obtaining verbal consent: _____

Date: _____

Appendix H: Email Script – Study Recruitment for Community Pharmacies

Email Subject line:
Assistance with study: Sharing our recruitment flyer in your community pharmacy

Dear [Community Pharmacy],

My name is Lucas Martignetti and I am a Master of Health Sciences student from Ontario Tech University. I am contacting you to request your help for our research study entitled, "Barriers and Facilitators to Equitable Access of Naloxone in Durham Region".

This research study is conducted by Ontario Tech University. The study has been approved by Ontario Tech University's Research Ethics Board [Reference number].

This study is looking at equitable access to naloxone in Durham Region. We would like to know about the experience of pharmacists and program users participating in the Ontario Naloxone Program for Pharmacies. Our findings may be used to improve this program and inform policies for naloxone access.

Our recruitment flyers are attached to this email. They detail the basic information about the study, what is involved, who may be eligible to participate and who to contact for more information. We hope that you will be able to assist us by posting the recruitment flyers at your location.

I will be more than happy to set up a time to discuss the study with the staff or with potential study participants.

This study has been reviewed by the Ontario Tech University Research Ethics Board [insert REB assigned #] on [insert date].

If you have any questions about your rights as a participant in this study, please contact the Research Ethics Office at 905 721 8668 ext. 3693 or researchethics@uoit.ca.

Thank you for your time and consideration,

Sincerely,

Lucas Martignetti

Appendix I: Email Script – Study Recruitment for Community Organizations

Email Subject line:
Assistance with study: Sharing our recruitment flyer with your community organization.

Dear [Community Organization],

My name is Lucas Martignetti and I am a Master of Health Sciences student from Ontario Tech University. I am contacting you to request your help for our research study entitled, "Barriers and Facilitators to Equitable Access of Naloxone in Durham Region".

This research study is conducted by Ontario Tech University. The study has been approved by Ontario Tech University's Research Ethics Board [Reference number].

This study is looking at equitable access to naloxone in Durham Region. We would like to know about the experience of service providers and program users participating in the Ontario Naloxone Program. Our findings may be used to improve this program and inform policies for naloxone access.

Our recruitment flyers are attached to this email. They detail the basic information about the study, what is involved, who may be eligible to participate and who to contact for more information. We hope that you will be able to assist us by posting the recruitment flyers at your location.

I will be more than happy to set up a time to discuss the study with the staff or with potential study participants.

This study has been reviewed by the Ontario Tech University Research Ethics Board [insert REB assigned #] on [insert date].

If you have any questions about your rights as a participant in this study, please contact the Research Ethics Office at 905 721 8668 ext. 3693 or researchethics@uoit.ca.

Thank you for your time and consideration,

Sincerely,

Lucas Martignetti

Appendix J: Recruitment Flyer - Community Pharmacy

ARE YOU SOMEONE WHO USES NALOXONE KITS? ARE YOU SOMEONE WHO PROVIDES NALOXONE KITS IN THE COMMUNITY?

We would like to find out about the views of people who give out naloxone kits or receive them. We are interested in how easy or difficult it is to access naloxone programs for all people.

If you participate, you will be asked to fill out a short survey and asked questions in an interview lasting up to 45 minutes. **The entire session may take up to one hour.** The interview will be conducted **online** or by **telephone.** Participants will be given a $10 Tim Hortons gift card upon completion of the interview.

YOU ARE ELIGIBLE IF YOU ARE:

- Able to speak and understand English
- 18 years or older
- Receiving or distributing naloxone in a pharmacy setting in Durham Region, and
- Able to provide informed consent

Participants will be selected on a first come, first serve basis.

This study is being conducted by Ontario Tech University. The study has been reviewed by the Ontario Tech University Research Ethics Board #15785.

FOR MORE INFORMATION, PLEASE CONTACT LUCAS MARTIGNETTI BY TELEPHONE 289-634-5724 OR EMAIL LUCAS.MARTIGNETTI@ONTARIOTECHU.NET.
PRINCIPAL INVESTIGATOR: DR. WINNIE SUN, RN, PhD, WINNIE.SUN@UOIT.CA

For confidentially, please do not reply directly on twitter or any other social media sites. Please use contact information above. Please note that the security of email messages is not guaranteed. Messages may be forged, forwarded, kept indefinitely, or seen by others using the internet. Do not use email to discuss sensitive information. Do not use email in an emergency since email may be delayed.

Appendix K: Recruitment Flyer - Community-based Organization

ARE YOU SOMEONE WHO USES NALOXONE KITS? ARE YOU SOMEONE WHO PROVIDES NALOXONE KITS IN THE COMMUNITY?

We would like to find out about the views of people who give out naloxone kits or receive them. We are interested in how easy or difficult it is to access naloxone programs for all people.

If you participate, you will be asked to fill out a short survey and asked questions in an interview lasting up to 45 minutes. **The entire session may take up to one hour.** The interview will be conducted **online** or by **telephone.** Participants will be given a $10 Tim Hortons gift card upon completion of the interview.

YOU ARE ELIGIBLE IF YOU ARE:

- Able to speak and understand English
- 18 years or older
- Receiving or distributing naloxone in a community-based organization setting in Durham Region, and
- Able to provide informed consent

Participants will be selected on a first come, first serve basis.
This study is being conducted by Ontario Tech University. The study has been reviewed by the Ontario Tech University Research Ethics Board #15785.

FOR MORE INFORMATION, PLEASE CONTACT LUCAS MARTIGNETTI BY TELEPHONE 289-634-5724 OR EMAIL LUCAS.MARTIGNETTI@ONTARIOTECHU.NET.
PRINCIPAL INVESTIGATOR: DR. WINNIE SUN, RN, PhD, WINNIE.SUN@UOIT.CA

For confidentially, please do not reply directly on twitter or any other social media sites. Please use contact information above. Please note that the security of email messages is not guaranteed. Messages may be forged, forwarded, kept indefinitely, or seen by others using the internet. Do not use email to discuss sensitive information. Do not use email in an emergency since email may be delayed.

Appendix L: Thank You Letter

Hello,

I want to thank you for participating in the study "Barriers and Facilitators to Equitable Access of Naloxone in Durham Region". Sharing your experiences will help to add to the understanding of accessibility of Ontario's naloxone distribution programs. This may lead to recommendations that can improve these programs. If you have any questions, please contact me by email at lucas.martignetti@ontariotechu.net, or by telephone at 289-634-5724.

If you have any questions about your rights as a participant in this study, please contact the Research Ethics Office at 905 721 8668 ext. 3693 or researchethics@uoit.ca.

Thank you,

Lucas Martignetti
Master of Health Sciences Student
Ontario Tech University