Approaches to Treat Opioid Use and Concurrent Mental Health Disorders in Canada: An Exploratory Analysis of Psychedelic-Assisted Psychotherapy

By

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Supervisory Committee

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Abstract

The opioid crisis is one of the most significant public health and policy challenges facing Canadians today, with 94% of opioid overdose deaths occurring by accident, impacting not only individuals, but families, friends and communities involved. The research identified policy initiatives, legislative and regulatory approaches implemented in Canada to respond to the opioid crisis. In particular, the thesis focused on how these approaches have addressed opioid use disorders and concurrent mental health disorders. Research has identified that over 50% of those experiencing opioid use disorder also experience concurrent mental health disorders. Several studies have linked opioid use disorder to concurrent mental health disorders of post-traumatic stress disorder, anxiety and depression, which have been clinically proven to be cured by psychedelic-assisted psychotherapy and in some cases, surpassing success rates of conventional psychotherapies. Currently, psychedelic-assisted psychotherapy is not a treatment option within Canada's opioid crisis response and psychedelic substances are heavily restricted by the Government of Canada (only available for extenuating circumstances, such as end-of-life care). This research focuses on these and other policy, legislative and regulatory frameworks that could present barriers and/or opportunities for a complementary treatment option like psychedelic-assisted psychotherapy to treat opioid use disorder and concurrent mental health disorders. A comparative case study research approach was used for this research. A jurisdiction scan was conducted to explore the opioid crisis response to date by the Government of Canada and the five hardest hit provinces and territories – Alberta, British Columbia, Ontario, Saskatchewan, and Yukon. Included in this scan was the legislative and regulatory frameworks that exist in Canada related to psychedelics and psychedelic-assisted psychotherapy. In conclusion, jurisdictional successes from Saskatchewan's focus on trauma-informed practice and Alberta's recent regulation of psychedelic-assisted psychotherapy are highlighted. Recommendations on next steps for the federal/provincial/territorial governments' approach to psychedelic-assisted psychotherapy are provided, including researching the efficacy and safety of psychedelics alongside opioid agonist therapy.

Keywords: opioid crisis response in Canada; legislative and regulatory policy on psychedelics in Canada; psychedelic-assisted psychotherapy; psychedelics and substance use disorder; psychedelics and opioid use disorder; psychedelics and mental health disorders

Table of Contents

Supervisory Committee ii

Abstract iii

Acknowledgements vi

Dedication vii

1.0 Introduction 1

1.1 Background: Overview of Opioid Crisis in Canada *2*

1.2 Problem Statement *8*

1.3 Purpose, Scope and Research Questions *10*

1.4 Importance of Research *12*

1.5 Positionality Statement *13*

1.6 Structure of Thesis *15*

2.0 Methodology and Methods 17

2.1 Introduction *17*

2.2 Methodology *17*

2.3 Methods *17*

2.4 Data Analysis *19*

2.5 Strengths and Limitations *20*

3.0 Literature Review 22

3.1 Introduction *22*

3.2 Opioid Use and Concurrent Mental Health Disorders *22*

3.3 Psychedelic-Assisted Psychotherapy for Substance Use and Mental Health Disorders *24*

3.4 Summary *26*

3.5 Conceptual Framework *28*

4.0 Findings: Jurisdictional Scan 31

4.1 Introduction *31*

4.2 Government of Canada: Policy, Legislation and Regulation Related to the Opioid Crisis Response *31*

4.3 Government of Canada: Legislation and Regulation Related to Psychedelics/Psychedelic-Assisted Psychotherapy *34*

4.4 Provincial and Territorial: Policy, Legislation and Regulation Related to the Opioid Crisis Response *37*

4.5 Provincial and Territorial: Legislation and Regulation Related to Psychedelics/Psychedelic-Assisted Psychotherapy *48*

4.6 Summary *49*

5.0 Results: Policy, Legislation & Regulatory Themes 51

5.1 Introduction *51*

5.2 Main Themes and Initiatives *51*

5.3 Provincial and Territorial: Rates of Apparent Opioid Toxicity Deaths *54*

5.4 Summary *56*

6.0 Discussion and Analysis 57

6.1 Answering the Research Questions *57*

6.2 New Themes and Ideas (Unexpected Findings) *62*

6.3 Summary *63*

6.4 Revisiting the Conceptual Framework *64*

7.0 Conclusion and Recommendations 66

7.1 Introduction *66*

7.2 Strategic or Research Implications *66*

7.3 Limitations of Analysis and Areas for Further Research *67*

7.4 Recommendations *73*

7.5 Final Reflections *74*

References 76

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Dedication

This thesis is dedicated to my late dad, Ricky Johl. His life has shaped my passion for alternative healing, love for humanity and fulfillment in giving back. He is the force that continues to inspire ever element of my life. His journey and who he was will never be forgotten. Today, I know he would be proud.

"A dream you dream alone is only a dream. A dream you dream together is reality."

~ John Lennon

1.0 Introduction

The opioid crisis is one of the most significant public health and policy challenges facing Canadians today, with 94% of opioid overdose deaths occurring by accident, impacting not only the individual, but families, friends and communities involved (Government of Canada, 2019a). As more is learned about substance use disorders, there is a need to explore new and innovative treatment options to effectively respond to the underlaying comorbidities, such as mental health. Current treatment options, like methadone and psychosocial therapies may be not be sufficiently meeting the unique intersecting needs of Canadians experiencing opioid use disorders and concurrent mental health disorders. Increasingly, there has been discussion about the role psychedelic-assisted psychotherapy can play in alleviating the opioid crisis, including treating opioid use disorder and concurrent mental health disorders (University of Wisconsin, 2021; Arengeto et al., 2019; Strike et al., 2019). This thesis explores evidence-based research on psychedelic-assisted psychotherapy to address substance use and mental health disorders that are often occurring concurrently, such as anxiety, trauma and depression (Statistics Canada, 2022; Jones, et al., 2022; Fink et al., 2015; Lawson et al., 2013; Amari et al., 2011). The thesis explores the possibility of treating both the opioid use disorder and concurrent mental health disorders simultaneously, as has been recommended by the National Institute of Mental Health and other researchers in this field. Currently, opioid crisis response in Canada does not include psychedelic-assisted psychotherapy as a treatment option and psychedelic substances remain heavily restricted by the Government of Canada (only available for extenuating circumstances, such as end-of-life care). The thesis identifies current Canadian federal, provincial and territorial approaches to the opioid crisis and the policy, legislation and regulation addressing opioid use disorder that many Canadians struggle with or have died from. Opioid use disorder is defined as a chronic relapsing illness, which may involve the use of illicitly manufactured opioids or pharmaceutical opioid medications obtained illicitly or used non-medically (British Columbia Centre on Substance Use & B.C. Ministry of Health, 2017).

The research presented in this thesis identifies historical and current interventions that have been proposed and implemented by jurisdictions across Canada to address the ongoing opioid crisis. As some research has identified correlations between opioid use disorders and unmet mental health disorders (Amari et al., 2011; Fink et al., 2015; Lawson et al., 2013), the thesis further explores if and how a complementary treatment option, such as psychedelic-assisted psychotherapy could support opioid crisis interventions across Canada.

According to emerging and ongoing research, psychedelic-assisted psychotherapy has been touted for its ability to treat and cure substance use and mental health disorders (Doblin, 2019; Haden et al., 2016; Schenberg, 2018). Psychedelic-assisted psychotherapy (PAP) is a clinical approach that uses psychedelic substances and is administered by a trained therapist or two trained therapists (usually male and female team) to support the client in exploring their history,

symptoms and intentions with an emphasis on emotional and psychological growth (Reiff et al., 2020).

The thesis concludes with potential strategies to overcome identified legislative and regulatory barriers should psychedelic-assisted psychotherapy be considered as a treatment option in combating the opioid crisis in Canada.

1.1 Background: Overview of Opioid Crisis in Canada

To understand the severity and prevalence of opioid use, it is important to acknowledge the historical underpinnings and catalyst of the opioid crisis. Since the introduction of OxyContin by Purdue Pharma in 1996, following Health Canada's approval, opioids have been a challenging public health issue with many physicians in North America prescribing opioids not being fully aware of the addictive nature and the subsequent dangerous consequences it has on people's lives (Government of Newfoundland & Labrador, 2004). When OxyContin, the most high profile and popular opioid, was pulled from the shelves in 2021, other counterfeit opioid drugs infiltrated the market and other painkiller medication flooded the market given the demand for such drugs (Registered Nurses' Association of Ontario, 2022).

By 2017, it was estimated that 40.5 million people globally were dependent on opioids, with the burden of opioid use and dependence being most prevalent in North America (Degenhardt et al., 2019). Statistics Canada reported that between 2016 to 2017, life expectancy at birth did not increase for the first time in over four decades, largely due to the opioid crisis (2019). The effects of problematic opioid use have been significant and devastating for communities across Canada. From 1990-2014, the years-of-life-lost rate due to opioid related mortality increased by 142% in Canada, compared to a 10% decrease globally (Oprana et al., 2018). In addition, harms experienced by opioid users increased primarily due to fentanyl and its derivatives (i.e., carfentanil), a synthetic opioid that can either be prescribed or acquired illicitly, with trace amounts in substances sharply increasing the risk of overdose (Canadian Centre on Substance Use and Addiction, 2021; Fischer et al., 2018). As a result of opioid related deaths drastically increasing due to the overprescribing of opioid medications, a contaminated illicit drug supply (e.g., fentanyl and carfentanil), and an overall tolerance and dependence of opioids, provinces across Canada declared a state of emergency in 2016 (Fischer et al., 2018; Government of B.C., n.d.).

As mortality rates soared, the Government of Canada began working with partners in 2016 to respond and implement a number of measures across provinces and territories to address the opioid crisis, including making naloxone kits available for free (i.e., to immediately reverse harmful effects of fentanyl), increasing access to treatment services, and approving supervised consumption sites (Government of Canada, 2019). Despite federal, territorial, and provincial harm reduction efforts and other supportive interventions to alleviate the crisis, Canadians

continue to struggle with problematic opioid use and high rates of mortality from opioid-related harms (Government of Canada, 2021b), making this a challenging public health issue to address.

OPIOID USE DISORDER AND THE OPIOID CRISIS

Opioids are known as a class of drugs derived from the opium poppy plant that can produce a variety of effects on the brain, including pain relief (John Hopkins Medicine, n.d.) and feelings of well-being or euphoria (i.e., a "high") (Canadian Centre on Substance Use and Addiction, 2021). Opioids can be prescribed medically as painkillers, such as morphine and oxycodone, and/or obtained as an illicit street-drug, such as heroin (John Hopkins Medicine, n.d.). Regular use of opioids can increase tolerance and dependence, requiring higher and more frequent doses, with longer term use leading to addiction in some cases (John Hopkins Medicine, n.d.).

Statistics Canada reported that one of the most significant factors associated with problematic opioid use is fair or poor mental health and unmet needs to help with mental or emotional health or substance use (Carrière et al., 2021). The most recent data from Statistics Canada (2018) reported that approximately 9.7% of Canadians suffer from problematic use of opioid pain relief medication. Furthermore, those suffering from unmet mental health and substance use needs are 2.61 times more likely to engage in problematic use of opioid pain relief medication than their counterparts without these needs (Statistics Canada, 2022). Specific data regarding the number of Canadians presently suffering from problematic opioid use/opioid use disorder is unavailable as of January 2023. However, according to statistics on opioids and prescription drugs in Canada, 22% of Canadians over the age of 15 years use psychoactive prescription drugs in some form (Moore, 2021), with young Canadians (age 15-24 years) being the fastest growing population requiring hospitalization following opioid-related harms (Government of Canada, 2019a).

In cases where problematic opioid use emerges, individuals may access opioids outside of what is medically prescribed to experience these feelings of euphoria or being "high" (Canadian Centre on Substance Use and Addiction, 2021). Therefore, what may have been prescribed to support pain relief initially, the motivation to use opioids can evolve, the dosages prescribed may no longer be adequate and clients may seek illicit street drugs that can be contaminated with toxic substances. As mentioned, opioid harms currently being experienced are primarily due to fentanyl and its derivatives (e.g., carfentanil), where trace amounts in substances can sharply increase the risk of overdose (Canadian Centre on Substance Use and Addiction, 2021; Fischer et al., 2018).

These risks of overdose due to the contaminated drug supply is an extremely concerning reality for Canadians that use opioids. According to the Public Health Agency of Canada (PHAC), latest data indicates that there have been 26,690 apparent opioid toxicity deaths between January 2016 and September 2021 (2022). Apparent opioid toxicity deaths are known as deaths caused by intoxication/toxicity (poisoning) resulting from substance use, where one or more of the substances is an opioid, regardless of how it was obtained (e.g., illegally or through prescription) (Government of Canada, 2022b). Data on apparent opioid toxicity deaths and stimulant toxicity

deaths are not mutually exclusive (Government of Canada, 2022b). A high proportion of deaths involving a stimulant also involved an opioid (Government of Canada, 2022b). Although, PHAC's data did not identify whether individuals that experienced apparent opioid toxicity deaths were also living with opioid use disorder, one study found hospitalizations and mortality are more likely to impact those individuals living with opioid use disorder and concurrent mental health disorders (Morin et al., 2020). Regardless of PHAC's gap in demographic data, it is evident that the toxic drug supply has taken many lives in Canada. Rates of opioid toxicity deaths remain high in British Columbia, Alberta and Ontario, accounting for 88% of accidental apparent opioid toxicity deaths between January and September 2021 (PHAC, 2022), and those experiencing concurrent opioid and mental health disorders could be at greater risk (Morin et al., 2020).

COVID-19 Pandemic and the Opioid Crisis

In March 2020, another crisis emerged. The COVID-19 pandemic only perpetuated the existing opioid crisis and challenged an already struggling demographic. In a Leger poll commissioned by the Mental Health Commission of Canada and the Canadian Centre on Substance Use and Addiction (CCSA), it was reported that COVID-19-related stressors, such as financial hardships, health of family members, and social isolation, had a disproportionate impact on people with pre-existing substance use disorders and mental illness (2023). These challenges and others, including increased instances of people using substances alone and reduced access to supports and services, could be reflected in the influx of opioid-related toxicity deaths during and following the COVID-19 pandemic. For example, between April and December 2020, Canada recorded an 89% increase in opioid toxicity deaths from the same time period in 2019, for a total of 6, 214 deaths (Government of Canada, 2021a). As a result of the mental health and substance use impacts, such as increased anxiety and depression, from the pandemic, elevated rates of opioid toxicity deaths were observed in Saskatchewan and Yukon, in addition to British Columbia, Alberta and Ontario (PHAC, 2022).

The majority of emergency responses for suspected opioid-related harms in 2021 (January – December) were among those aged 20 to 49 years, with variations between provinces and territories (Government of Canada, 2022b). Young and middle-aged males continued to account for the majority of accidental apparent opioid toxicity deaths (74%) in 2021 (January – December) (Government of Canada, 2022b). For males and females, accidental apparent opioid toxicity deaths were among individuals aged 20 to 59 years (Government of Canada, 2022b).

In 2022, the Government of Canada reported that psychoactive pharmaceuticals, such as opioids, are the third most commonly used substances among youth in Canada, after alcohol and cannabis (Government of Canada, 2022a).

In the first year of the pandemic, there was a 95% national increase in apparent opioid-related deaths (April 2020 – March 2021) in the general population (Government of Canada, 2022a). Effects of the pandemic on apparent opioid toxicity deaths remained high in 2021, with

approximately 20 deaths per day in 2021 (between January and September), compared to 12 per day in 2018 and 7 per day in 2016 (PHAC, 2022).

Between April 2018 and March 2019, approximately 56% of hospitalizations for opioid use disorders were accompanied with a co-diagnosis of another mental disorder (Government of Canada, 2021b). It is noted that hospitalizations for adverse drug effects from prescribed opioids had the lowest percentage of co-diagnoses of mental disorders (15%) (Government of Canada, 2021b). This data suggests that the majority of opioid related hospitalizations are emerging from illicit opioids rather than prescribed opioids, and that those most vulnerable present with concurrent mental disorder(s).

Concurrent mental health disorders and the Opioid Crisis

It is evident that the mental wellness of Canadians has been significantly affected by the pandemic, such as increased feelings of isolation, stress, and anxiety, including changes in the availability of services for those people who use drugs (PHAC, 2022).

Multiple studies suggest that mental health challenges can perpetuate substance use disorders, such as opioid use disorder. According to Fink et al., nonmedical use of prescription opioids and major depression frequently co-occur (2015). Amari et al.'s research suggests the strongest association between nonmedical use of prescription opioids was connected with depression, followed by anxiety disorders (2011). In addition, Lawson et al., indicated that a significant number of opioid users have experienced trauma (2013), with some research identifying average responses to conventional post-traumatic stress disorder (PTSD) therapies, such as psychotherapy and pharmacotherapy, as relatively ineffective (e.g., 40-50% success from pharmacotherapies) (Steenkamp et al., 2015).

Extensive research on nonmedical prescription opioid use/disorders and mental health and pain comorbidities suggests that effective preventative and treatment interventions must consider attending to comorbidities (Fink et al., 2015; Amari et al., 2011; Lawson et al., 2013). Additionally, the National Institute of Mental Health highlights that half of individuals who experience substance use disorders during their lives will also experience a co-occurring mental health disorder, including anxiety and depression and strongly encourages treatment of the substance use disorder and co-occurring mental disorders together rather than separately (n.d.).

A common intervention to treat and reduce harms associated with opioid use disorder is opioid agonist therapy (OAT) which can prevent withdrawal and reduce cravings for opioid drugs, such as heroin, oxycodone, hydromorphone (Dilaudid), fentanyl and Percocet (Centre for Addiction and Mental Health (CAMH), 2016). The therapy involves taking prescribed opioid agonists, like methadone (Methadose) or buprenorphine (Suboxone), among others (CAMH, 2016).

A systemic review investigating conventional psychosocial interventions alongside opioid agonist therapy versus opioid agonist therapy only to treat opioid use disorder found a majority

of studies had no statistical significance in successful abstinence from opioids (Rice et al., 2020). One study utilizing thirteen different psychosocial interventions in addition to opioid agonist treatment (i.e., methadone), while the control offered standard counselling sessions and methadone treatment, those in the experimental conditions with more structured psychosocial interventions provided no additional benefit (Amato et al., 2011).

Therefore, if existing psychosocial approaches supported through the Government of Canada to treat opioid use disorder are ineffective in most cases, what more can be done? Particularly what more can be done to effectively address opioid use disorders and concurrent mental health disorders if treatment options, like methadone and psychosocial therapies, are insufficient?

Attempts to Address the Opioid Crisis in Canada

Prior to exploring alternative approaches to support individuals experiencing opioid use disorder and concurrent mental health disorder(s), it is important to recognize the policy tools and interventions the Government of Canada and provinces and territories have implemented since the opioid crisis was announced.

To date, the Government of Canada has continued to fund several projects to mitigate the harmful effects of the opioid crisis, including enforcement measures to address the tainted drug supply, initiatives to improve and provide access to treatment and harm reduction, increase awareness and prevention, and evidence building (i.e., reports, modeling, toolkits) (Government of Canada, 2022a).

In terms of treatment for opioid use disorder, the Government of Canada has supported the provinces and territories by allocating one-time emergency funding of $150 million via the Emergency Treatment Fund to improve access to evidence-based treatment services (Government of Canada, 2022a). According to the Canadian Research Initiative in Substance Misuse (CRISM) National Guideline for the Clinical Management of Opioid Use Disorder, specific opioid use disorder treatment modalities are governed by provincial regulations, therefore treatment options for opioid use disorder can vary among populations depending on the jurisdiction involved (p. 17, 2018). Specific opioid use disorder interventions in the hardest hit provinces and territories will be explored further on in this thesis.

In response to the COVID-19 pandemic, the Government of Canada increased supports for federally-funded treatment centres to enhance their virtual treatment services (Government of Canada, 2022a). The government has also supported the development of guidance for health care providers, including clinical guidelines and operational guidance for injectable opioid agonist treatment (iOAT), and national treatment guidance for opioid use disorders (Government of Canada, 2022a).

In addition, the Government of Canada has removed barriers to accessing drugs for the treatment of opioid use disorder by (Government of Canada, 2022a):

- Approving injectable hydromorphone;
- Adding diacetylmorphine to the List of Drugs for an Urgent Public Health Need to allow importation by provinces and territories;
- Facilitating the prescribing and dispensing of methadone and diacetylmorphine through regulatory amendments;
- Supporting opioid agonist therapy wraparound supports in 72 First Nations and Inuit Communities;
- Increasing the provision of opioid agonist treatment and implementing SMART (Self-management and Recovery Training) in Canada's correctional institutions.

In terms of harm reduction efforts, the Government of Canada has (Government of Canada, 2022a):

- Provided exemptions for 38 supervised consumption sites (currently operating), which have (since 2017, and as of November 2021):
    - been visited more than 3.3 million times
    - reversed nearly 35,000 overdoses without a single death
    - made over 148,000 referrals to health and social services
- Supported the *Good Samaritan Drug Overdose Act*, which provides some legal protection from possession charges for people who seek emergency help during an overdose
- Continued to improve access to naloxone, including to remote communities and isolated First Nations and Inuit communities and people experiencing homelessness
- Awarded $1 million to the winner of the Drug Checking Technology Challenge
- Opened the first Overdose Prevention Service in a correctional institution to reduce overdose incidents

Despite these various types of policy tools and initiatives, several jurisdictions in Canada are reporting higher rates of fatal overdoses and other harms (Government of Canada, 2022b), including overall declines in mental wellness as a result of the ongoing pandemic.

According to the Canadian Mental Health Association (CMHA), 54% of Canadians who reported having pre-existing mental health conditions prior to the pandemic reported further declines in their mental health during the pandemic (2021a). The CMHA called upon the Government of Canada to intervene, forecasting an "echo pandemic" whereby previously unmet mental health conditions will worsen and last long after the pandemic (CMHA, 2021b).

Consideration of psychedelic-assisted psychotherapy as a Treatment Option for the Opioid Crisis and Mental Health Crisis

One avenue of exploration for the treatment mental health disorders like depression, anxiety, trauma is psychedelic-assisted psychotherapy. Studies suggest the benefits of psychotherapy, alongside the administration of psychedelics under medical supervision, can provide increased

healing abilities in fewer therapeutic administrations compared to conventional psychotherapy (Doblin, 2019; Haden et al., 2016; Schenberg, 2018).

Different types of psychedelic substances are currently being explored for their positive impact on various mental health and substance use disorders, such as 3,4-methylenedioxy-methamphetamine (MDMA) for the treatment of PTSD (Jerome et al., 2020), psilocybin for the treatment of smoking, lysergic acid diethylamide (LSD) for the treatment of alcoholism (Jones et al., 2022), and ibogaine for the treatment of opioid dependence/use disorder (Camlin et al., 2018; Noller et al., 2018; Wilson et al., 2020). While current mainstream therapies for opioid use disorder might work in some cases, standard pharmacological treatments of methadone and buprenorphine come with a high risk of dependence, trading one addiction for another (Jones et al., 2022). Given the non-addictive chemical makeup of most psychedelics, these substances (in limited) therapeutic settings could hold promise as a potential treatment option for opioid use disorder (Jones et al., 2022). Current research, including legislative, regulatory and practice challenges of psychedelic-assisted psychotherapy is explored further in this thesis.

The Multidisciplinary Association for Psychedelic Studies Canada (MAPS Canada), a leading research organization exploring the therapeutic use of psychedelic-assisted psychotherapy states that: "a growing body of evidence from clinical research trials is showing that evidence-based, psychedelic-assisted therapies have the potential to improve the lives of millions of people who live with the impacts of complex trauma and other clinical conditions, including depression, post-traumatic stress disorder, anxiety, and substance use disorders" (MAPS Canada, 2021); clinical conditions that have been observed/diagnosed in those struggling with opioid use disorders.

1.2 Problem Statement

The broad problem that this thesis addresses is that primary existing interventions to combat problematic opioid use/opioid use disorders associated with the opioid crisis are not addressing the root of the issue (e.g., concurrent mental health disorders), and have not been able to keep up with the increasing mental health and substance use challenges that have followed the COVID-19 pandemic. The opioid crisis is a significant public health issue. Response to the opioid crisis is a multi-jurisdictional challenge, there are numerous stakeholders involved in defining and responding to the problem, as well as a number of reasons individuals engage in opioid use (i.e., pain management, self-medication, recreational, etc.) – making this issue a wicked problem. Wicked problems are defined as, "a class of social system problems which are ill-formulated, where the information is confusing, where there are many clients and decision-makers with conflicting values" (Earle & Leyva-de la Hiz, 2021, p.582) and where "sets of other problems in complex causal chains, lack clear end points, and are changed irreversibly by every intervention" (Sud et al., 2022, p.S56). Wicked problems, such as the opioid crisis and opioid use disorders, as discussed later in the thesis present their own challenges across jurisdictions in terms of uncoordinated ideas and what appropriate solutions can be (Morin et al., 2017). A challenge is

that government's opioid crisis' interventions are heavily focused on alleviating the harms and stigma associated with opioid use (i.e., naloxone kits, supervised consumptions sites, anti-stigma campaigns) and mitigating the symptoms of opioid use disorder with prescribed alternatives (e.g., suboxone and/or methadone) to improve the safety (i.e., providing a regulated substances from pharmacies) and prevent withdrawal symptoms that can lead to continued harmful illicit drug use or relapse (American Psychiatric Association, 2023). Opioid agonist therapy is encouraged to be paired with psychotherapy, however research has shown that conventional therapies are not as effective for common concurrent disorders of opioid use disorder, such as post-traumatic stress disorder (Centre for Addiction and Mental Health, 2016; Steenkamp et al., 2015). Therefore, where some treatment options (i.e., opioid agonist therapy) may not be adequately providing solutions to opioid use disorders and commonly concurrent mental health disorders, other treatment options might be helpful to consider. This thesis sets to explore what additional policy instruments and strategies can be considered in addition to the existing interventions implemented by the federal, provincial, and territorial governments to combat the opioid crisis.

Notably, while there is evidence to suggest that opioid use disorder and concurrent mental health disorders could be treated with the use of psychedelic-assisted psychotherapy, the largest barrier to implementing psychedelics as a policy initiative in the opioid crisis is that currently (April 2023) these psychedelic substances are heavily restricted by the Government of Canada. Presently, legislative and regulatory parameters in Canada limit psychedelic use, which makes it challenging to adopt as an option for the treatment of opioid use disorder. Canadian legislation restricts many psychedelics to clinical trial studies only (Government of Canada, 2022). Any sale, possession and production of psychedelics is prohibited unless authorized for clinical trials/research under Part J of the Food and Drug Regulations (FDR) (Government of Canada, 2021c). Psychedelics, with the exception of peyote, remain classified as restricted drugs in Canada under the *Controlled Drugs and Substances Act* (CDSA) (Government of Canada, 2021d). Restricted drugs are controlled substances listed under Schedule I, II, III, IV, V, or VI of the *Controlled Drugs and Substances Act* and are regulated by Health Canada (Government of Canada, 2022g). Restricted drugs discussed in this thesis include drugs under Schedule I (i.e., 3,4-methylenedioxymethamphetamine (MDMA)) and Schedule III (i.e., lysergic acid diethylamide (LSD), N,N-Dimethyltryptamine (DMT), Psilocin/Psilocybin) (Government of Canada, 2022g) and ibogaine under the Prescription Drug List (PDL) (Government of Canada, 2017). Both Schedule I and III drugs and PDL drugs are restricted whereby sale, possession or production of these substances are illegal unless authorized for medical, scientific or industrial purposes (Government of Canada, 2022e; Government of Canada, 2022i). Therefore, most therapeutic products containing psychedelics are not approved in Canada (Government of Canada, 2020c). At present, the Government of Canada has allowed access to psychedelics on a case-by-case basis for end-of-life care and some untreatable illnesses (Government of Canada, 2020c).

The thesis will identify existing policy initiatives that are responding to the opioid crisis across Canada and explore if and how existing legislation and regulation can be adapted to support the exploration of psychedelic-assisted psychotherapy to address both the opioid use disorder and concurrent mental health disorders.

1.3 Purpose, Scope and Research Questions

PURPOSE

The purpose of this thesis is to identify the policy initiatives and regulatory approaches implemented in Canada to respond to the opioid crisis, particularly how focused these approaches have been in addressing opioid use disorders and concurrent mental health disorders. In addition, the thesis will seek to identify legislative and regulatory frameworks that could present barriers and/or opportunities for the adoption of a complementary policy tool and treatment option focused on psychedelic-assisted psychotherapy. The intention of exploring such a complementary treatment option alongside existing tools and initiatives to combat the opioid crisis is to identify other evidence-based ways to support Canadians in achieving long-term substance use disorder healing and mental wellness.

SCOPE

The scope of the research focuses on the main provincial/territorial/federal responses to the opioid crisis (i.e., policy tools, initiatives, funding allocations), and if opioid use disorder and concurrent mental health disorder interventions were available in these selected jurisdictions. The research also examines legislative and regulatory challenges/barriers to accessing psychedelics and administering psychedelic-assisted psychotherapy in the Canadian-context. When available, the research explores jurisdictional experiences with psychedelics/psychedelic-assisted psychotherapy and their related interventions to address substance use and mental health disorders. Jurisdictions that were studied in this thesis are Alberta, British Columbia, Ontario, Saskatchewan, and Yukon.

RESEARCH QUESTIONS

The primary research question is:

1. How has Canada and selected jurisdictions (i.e., Alberta, British Columbia, Ontario, Saskatchewan, and Yukon) responded to the opioid crisis to date, particularly from an opioid use disorder and concurrent mental health disorder perspective?

The following secondary questions are also explored in this thesis to support and complement the answering of the main research question:

2. Are the policy initiatives, legislation and regulation in place to respond to the opioid crisis adequately addressing opioid use disorder and concurrent mental health disorders?

3. How can psychedelic-assisted psychotherapy address some of the current gaps in the treatment of opioid use disorder and concurrent mental health disorders?
4. What barriers exist in federal legislation and regulation that challenge the use of psychedelic-assisted psychotherapy as a treatment option for opioid use disorder and concurrent mental health disorders?
5. Has psychedelic-assisted psychotherapy been approved to treat other mental health or substance use disorders in the Canadian population?
    a. If so, what strategies were taken to overcome the barriers within Canada's legislative and regulatory framework?

To better understand the main concepts being used in the thesis, the following terms have been defined:

Concurrent disorders / Co-occurring mental health and substance use disorders

Concurrent disorder or co-occurring mental health and substance use disorder is a term used when a person has both a mental health disorder and a substance use disorder at the same time (Provincial Health Services Authority (PHSA), 2022). Those diagnosed with concurrent disorders often live with other challenges that can complicate their illness, such as chronic physical illness, stigma, and/or unstable housing and/or employment (PHSA, 2022).

Opioid dependence

Opioid dependence is a disorder of regulation of opioid use arising from repeated or continuous use of opioids characterized by a strong internal drive to use opioids, manifesting in impaired ability to control use and increased priority to use over other activities, regardless of harmful consequences (World Health Organization (WHO), 2021). Physiological features of dependence could be present, including increased tolerance to the effects of opioids, withdrawal symptoms following cessation, or repeated use to prevent or alleviate withdrawal symptoms (World Health Organization (WHO), 2021).

Opioid use disorder (OUD)

Opioid use disorder (OUD) is a medical condition defined by not being able to abstain from using opioids, and behaviours centered around opioid use that interfere with daily life (John Hopkins Medicine, n.d.). Being physically dependent on an opioid is characterized by withdrawal symptoms such as cravings and sweating (John Hopkins Medicine, n.d.). However, people can misuse opioids and not have physical dependence (John Hopkins Medicine, n.d.).

Problematic opioid use

Problematic opioid use occurs someone uses opioids in a way that has negative effects on their health and life, such as opioids that are not prescribed to the individual or using a prescribed

opioid in a manner not intended or instructed by the doctor or pharmacist (Government of Canada, 2019b).

Psychedelics

Psychedelics, also known as hallucinogens, are a class of psychoactive substances that work primarily on the serotonin 5-HT_{2A} receptor in the brain and can produce changes in human consciousness, perceptions, moods, emotions and cognitive processes (Alcohol and Drug Foundation, 2022; López-Giménez & González-Maeso, 2018). Commonly known psychedelic substances include, ayahuasca, peyote, mescaline, psilocybin (magic mushrooms), salvia, lysergic acid diethylamide (LSD), and dimethyltryptamine (DMT) (Alcohol and Drug Foundation, 2022).

Psychedelic-assisted psychotherapy (PAP)

Psychedelic-assisted psychotherapy (PAP) includes a spectrum of psycholytic (low to moderate dosages) and psychedelic (single or several high dosages) therapy which typically involves three types of sessions: preparatory, medication (moderate to high doses of psychedelics) and integration (Reiff et al., 2020). Generally preparatory and integrative sessions are drug-free, while the medication session involves administration of the psychoactive substance and optional engagement in psychotherapy during this time (Schenberg, 2018). Psychoactive administrations vary with MDMA requiring three administrations, psilocybin and lysergic acid diethylamide (LSD) requiring two administrations, and ibogaine requiring a single administration (Schenberg, 2018). A trained therapist or two trained therapists (male and female) are in attendance in all sessions, supporting the client in exploring their history, symptoms and intentions with an emphasis on emotional and psychological growth (Reiff et al., 2020).

Substance use disorder (SUD)

Substance use disorder (SUD) is a mental disorder that affects a person's brain and behaviour, leading to a person's inability to control their use of substances such as legal or illegal drugs, alcohol, or medications (National Institute of Mental Health, n.d.).

Toxic illegal drug supply

Toxic illegal drug supply refers to strong opioids, such as fentanyl and other toxic substances causing high rates of overdose and deaths (Government of Canada, 2022c).

1.4 Importance of Research

Governments in Canada have been grappling with how to address the growing opioid crisis in their jurisdictions with many options having been explored and implemented, yet the crisis continues to devastate Canadians. Research into how Canada has responded to the opioid crisis and particularly addressing the associated opioid use disorders and concurrent mental health

disorders is significant for not only those experiencing problematic use, but their loved ones as well. Research indicates that children and youth affected by familial opioid use disorders are more likely to experience adverse impacts, such as maltreatment and neglect (The National Child Traumatic Stress Network, 2018) and are more likely to experience substance use and mental health disorders themselves (Lander et al., 2013). This familial relationship makes this issue of opioid use disorder intergenerational and complex. In addition, some individuals close to those that have succumbed to the most fatal outcomes of opioid use disorders such as death, are having to process the loss of their friends potentially while simultaneously experiencing their own substance use and mental health challenges. Therefore, not only is this research supporting the government's response to the opioid crisis from a new and innovative way, helping those that are struggling with opioid use disorders currently, it could also prevent future substance use and mental health disorders that could be experienced by those closest the them.

In the research process for this thesis, the analysis evaluated how various jurisdictions have supported their citizens in overcoming the opioid crisis, specifically in relation to their incorporation of substance use and mental health supports to achieve long-term wellness. A number of opioid crisis response initiatives in Canada have been primarily focused on reducing mortality rates, in essence prescription monitoring and restriction, harm reduction interventions to curtail the effects of toxic illicit drug exposure, and opioid substitution therapy to stabilize and reduce substance dependence.

Despite these efforts from all levels of government, Canadians continue to experience catastrophically high levels of drug-related mortality. Investigating the available policy interventions to address the opioid crisis and potential gaps in the treatment options could improve how we approach the crisis. With growing research and evidence on the use of psychedelic-assisted psychotherapy to treat substance use and mental health disorders, two disorders which are often co-occurring, it is worth an exploration of what other options and alternatives exist. Should this complementary approach to the opioid crisis of treating the opioid use disorder be pursued in Canada, an understanding of the legislative and regulatory landscape is paramount. Overall, the thesis outlines the current state of the policy environment in the selected jurisdictions, the link between opioid use disorder and mental health disorders, how psychedelics could address this gap, and how a treatment option, like psychedelic-assisted psychotherapy would fit into the current policy environment.

1.5 Positionality Statement

I am interested in pursuing this line of research as I am frustrated with the current options for mental health disorders and substance use disorder treatment. I have witnessed close family members struggle through an often complex mental health care system and an ineffective stream of medication, psychotherapy, and rehabilitation without long lasting transformation. As a family

member trying to support my loved ones, I have been hit with the same limited resources myself as I helplessly watch them deteriorate.

The chance to research and navigate a body of work that has been replicated internationally through science and empirically published literature, and one that is being revered by a growing number of mental health workers, doctors and psychotherapists (Doblin, 2019; Haden et al., 2016), brings me joy and a sense of purpose and hope. I am extremely passionate about the future of psychedelic-assisted psychotherapy as an alternative form of treatment, that can cure individuals that have struggled to find long lasting mental wellness, free of illness. Additionally, I am driven by the promise that this is not only effective, but unlike other psychiatric medication and self-medication (i.e., biologically addictive substances), from my understanding, there is strong evidence that recovery from mental illness can be achieved in a few clinically administered sessions of psychedelics, with a very low-risk for dependence post administration (Doblin, 2019; Haden et al., 2016; Schenberg, 2018).

Alongside my personal experience with mental health and substance use disorders within my family, I have an educational background in Psychology and Corporate Social Innovation. I have worked with the British Columbia (BC) Ministry of Mental Health and Addictions and Island Health's Mental Health and Substance Use Operations, researching and understanding the lived experience of others and supporting the improvement of mental health and substance use systems. Alongside personal and provincial scope, I have worked for the Government of Canada including the Privy Council Office and Health Canada, researching and analyzing mental health data related the Canadian populations' experience of the COVID-19 pandemic and examining regulatory and compliance policy.

Therefore, my knowledge in relation to mental wellness, available medication/psychotherapy and ongoing challenges associated with untreated mental health and substance use disorders is substantiated by these ongoing narratives from communities across Canada. The recognition that there are large gaps and complex issues within Canada's mental health care system and policy barriers has become even more apparent by way of these interactions. While there have been considerable efforts recently to reboot and restructure these systems, there is still more to be done, and I believe consideration of alternative treatment methods like psychedelic-assisted psychotherapy is one way to support this work.

Therefore, my approach to research related to supporting mental health and substance use treatment through psychedelic-assisted psychotherapy, may be influenced by my frustration with current mental health and substance use treatment options and models, exposure to the complex and systemic issues in Canada's mental health care system and my positive perception of psychedelic-assisted psychotherapy as an opportunistic path to mental wellness.

Yet as I recognize this positive mindset in support of psychedelic-assisted psychotherapy, I will endeavour to be cognizant of my own biases and ensure my exploration of the literature and

knowledge sharing reflects broadly on this research topic – exploring perspectives of concern and explaining those perspectives with thoughtful consideration. This research is intended to provide knowledge, be it concerns or support of psychedelic-assisted psychotherapy that both acknowledges the research and regulations and provides consideration for further investigation – be it scientific (e.g., safety and efficacy of psychedelic-assisted psychotherapy) and regulation/policy decision-making.

1.6 Structure of Thesis

To support flow and understanding, below is an ordered outline and summary of the chapters that will be discussed in this thesis. Each chapter is intended to build on the other, with the research questions at the forefront of this exploration and a gradual narrowing in on a possible policy approach. The general form will provide an overview, what has been done, what exists now and where we are going.

1. **Introduction** – highlights the history of the opioid crisis; the emergence of opioid use disorder; concurrent mental illness; national approach to the opioid crisis; and legislative and regulatory barriers to psychedelic-assisted psychotherapy within the federal context (Chapter 1).

2. **Methodology and Methods** – draws on the literature review to determine key factors in success and challenges in legislative and regulatory policy at the federal and provincial level (Chapter 2).

3. **Literature Review** – explores existing literature related to the opioid crisis; opioid use disorder; concurrent mental health disorders; psychedelic-assisted psychotherapy to treat substance use and mental health disorders (including gaps and successes in the research) (Chapter 3).

4. **Findings** – explores the five selected provinces/territories in Canada (i.e., Alberta, British Columbia, Ontario, Saskatchewan, and Yukon) which are statistically identified as the most impacted by the opioid crisis. This chapter will highlight government policy tools and initiatives that have been implemented in these communities to mitigate the opioid crisis/support those struggling with opioid use disorders and concurrent mental health disorders, as well identify the legislation and regulatory parameters governing psychedelics and psychedelic-assisted psychotherapy (Chapter 4).

5. **Results** – identifies and collates key findings from the jurisdiction scan into main themes and summarizes the findings to be discussed and analyzed in the following chapter (Chapter 5).

6. **Discussion and Analysis** – analyzes and addresses key themes as they relate to the primary and secondary proposed research questions. Particularly utilizing a comparative analysis between jurisdictional responses to the opioid crisis, and relevant findings related to addressing opioid use disorder and concurrent mental health disorders. As identified in the jurisdiction scan, the

analysis will discuss where barriers were overcome in federal legislation and regulation related to psychedelics and psychedelic-assisted psychotherapy (Chapter 6).

7. **Conclusion and Recommendations** – summarizes and highlights the main findings, challenges, and policy initiatives and tools identified throughout the thesis. Concludes with potential pathways for future exploration and recommendations to the Government of Canada and provincial/territorial governments (Chapter 7).

2.0 Methodology and Methods

2.1 Introduction

This chapter describes the methodological research design, how the research was collected, and how the research was analyzed.

The research was conducted as a comparative case study exploring public domain sources in a jurisdictional scan of Canadian federal, provincial and territorial government responses to the opioid crisis. For additional comparative context, statistical evidence on the rate of apparent toxic opioid deaths were included in the analysis. The qualitative (policy responses) and quantitative (apparent toxic opioid deaths) data was analyzed using thematic and comparative content analysis.

Human participants were not enlisted to participate in this thesis, therefore approval from the Human Research Ethics Board (HREB) was not required.

2.2 Methodology

The research was conducted primarily as a comparative, mixed methods case study with Canada being the case and the comparative component being the opioid crisis response in the provinces and territories (qualitative) and rates of apparent opioid toxicity deaths over time (quantitative). According to Crowe et al. (2011), case study approaches lend themselves well to "capturing information on more explanatory 'how,' 'what,' and 'why' questions, such as 'how is the intervention being implemented and received on the ground?" (p. 4).

Comparative studies as described by Wenzelburger & Jensen (2022), "use cross-country comparisons to investigate whether forces of theoretical interest... are correlated with certain policy outcomes" (p. 296). A comparative analysis was conducted in the case study enabling a review of contrasts, similarities, or patterns across the jurisdictions selected, including a comparison of policy outputs (i.e., opioid crisis response initiatives and adjustments to legislation and regulation) and outcomes (i.e., rates of apparent opioid toxicity deaths). The comparative analysis thematically organized the policy outputs implemented in response to the opioid crisis and the outcome on the populations' apparent opioid toxicity death rates over time (i.e., increase/decrease).

2.3 Methods

Literature Review

A traditional literature review was conducted, which allowed for a broad overview of a topic (i.e., the opioid crisis in Canada) to be examined, alongside a range of related subjects (University Health Network, 2022), including opioid crisis response, opioid use disorder, concurrent mental health disorders, psychedelic-assisted psychotherapy, and legislative and regulatory policy in Canada. Information collected and interpreted within the traditional

literature review aims to “describe and discuss the literature from a contextual or theoretical point of view” (University Health Network, 2022). The literature review explores academic (peer-reviewed) journals to provide a fulsome scope of the themes and concepts related to this topic (opioid crisis) and its associated subjects (opioid use disorder, treatment options and legislative and regulatory policy). The traditional type of literature review was essential in grounding the thesis and exploring alternative policy options.

In general, the literature review provides an examination of the current body of research and specific to this literature review, a landscape to identify what is already known about the policy options as well as gaps in current research (Centre for Disease Control and Preventions, 2021). The literature review provides an exploration of primary opioid use disorder approaches in Canada and scientific research related to psychedelics and psychedelic-assisted psychotherapy to combat concurrent mental health disorders. Twenty-six documents were reviewed in the literature review. The search terms that were used included: psychedelic-assisted psychotherapy in Canada; mental illness and psychedelics; political perspectives of psychedelic-assisted psychotherapy; historical perspectives of psychedelics; benefits of psychedelics; barriers to psychedelic-assisted psychotherapy; MDMA; MDMA treatment for PTSD; psilocybin; psilocybin treatment; psilocybin treatment for anxiety and depression; psychedelic treatment for opioid use disorder; ibogaine for treatment of opioid use disorder; psychedelic legislation; psychedelic regulation in Canada; psychedelic policy in Canada; international psychedelics; opioid use disorder; opioid agonist therapy; opioid agonist treatment; opioid agonist treatment and concurrent mental health disorders; opioid crisis; COVID-19 and mental health and substance use; opioid use and trauma; opioid use disorder and concurrent mental health disorders.

Materials for the literature review were obtained through various research systems and databases, including the University of Victoria Libraries (Summons 2.0), Google Scholar/Google, MAPS Canada Resource database, APA PsychInfo, Medline, CINAHL Complete, Alt Healthwatch and others. Specific journals investigated included, Psychopharmacology, Psychoactive Drugs and Frontiers in Pharmacology, among others. Journal articles published within the last 10-years (i.e., 2013-2023) were of primary focus. This time period was selected as the opioid crisis in Canada and psychedelic-assisted psychotherapy research is ongoing and rapidly developing, therefore this 10-year span showcases both the current and iterative trends in approaches/therapies. Documents examined in the literature review were mainly empirical/primary and scholarly literature, which often contained original research data and were published in a peer-reviewed journal that highlighted opioid use disorder research and psychedelic-assisted psychotherapy (e.g., successful clinical administrations and limitations/need for further investigation).

JURISDICTION SCAN

A jurisdiction scan, according to Kilian et al. (2016), can “compare and evaluate options based on action taken in other jurisdictions in response to similar problems” (p. 2). The jurisdiction

scan in the thesis reviewed documents to identify historical and current responses to the opioid crisis (i.e., harm reduction, therapeutic interventions, task forces, etc.), including any concurrent mental health disorder approaches and psychedelic-assisted psychotherapy legislation and regulation implementations at the federal, provincial, and/or territorial level.

The data for the jurisdiction scan was collected using grey literature through the Government of Canada, provincial and territorial governments websites, such as published policy documents, strategic frameworks, legislative and regulatory amendments. Furthermore, given the non-regulated landscape of psychedelic therapy, government publications were limited; therefore, other forms of grey literature (i.e., newspaper articles, news broadcasts, white papers, policy literature, etc.) were explored to further contextualize this phenomenon. As the largest collective response to the opioid crisis throughout Canada began in 2016, literature throughout the thesis focused on the time period from 2016 (historical) to 2023 (current).

Material was obtained primarily through Google Scholar/Google and directly through the Government of Canada, Government of Alberta, Government of British Columbia, Government of Ontario, Government of Saskatchewan, and Government of Yukon websites. For examination of the provincial and territorial response to the opioid crisis, approximately seven official government publications were reviewed in each jurisdiction for a total of 36 documents. Certain provinces, such as British Columbia had more information, while others like Yukon had less available information on their opioid crisis response. Variations in the amount of policy publications and budget allocations in response to the opioid crisis was partly due to the duration in which each province and/or territory had experienced the crisis and how many initiatives stretched multiple areas of government. Statistical information and associated tables of each provinces'/territories' rate of apparent opioid toxicity deaths were readily available on the Government of Canada's website (Government of Canada, 2022b).

2.4 Data Analysis

Canadian jurisdictions were chosen based on their prevalence of toxic opioid-related deaths and were reviewed based on their policy responses to the opioid crisis. The provinces and territories were compared based on the policy tools (qualitative) they implemented and statistics on their populations' rate of apparent opioid toxicity death (quantitative). Two types of analysis – comparative policy and comparative statistical analysis were utilized and discussed below.

Comparative policy analysis (qualitative)

The jurisdiction scan consisted of official publications/archives, grey literature and journal articles related to the historical, current state and policy of psychedelic-assisted psychotherapy and Canadian jurisdictional interventions for opioid use disorder. The five Canadian jurisdictions explored in the scan and whose opioid response policies were analyzed thematically were Alberta, British Columbia, Ontario, Saskatchewan, and Yukon. These jurisdictions were selected as they are the provinces/territory that were reported to have experienced the highest prevalence

of opioid-related harms/deaths (Government of Canada, 2021a). Jurisdictions were compared in terms of their response efforts to combat the opioid crisis (i.e., policy initiative, legislation and regulatory amendments) and any particular efforts towards treating opioid use disorders and concurrent mental health disorders were highlighted.

Comparative statistical Analysis (Quantitative)

The statistical analysis was chosen to establish a comparative component between the policy initiatives implemented by the selected province/territory and potential correlations with the rate of apparent opioid toxicity deaths. Statistical information was obtained from the Government of Canada's website based on surveillance reporting of opioid- and stimulant-related harms in Canada and analyzed based on increases or decreases of rates of opioid toxicity deaths overtime.

2.5 Strengths and Limitations

Limitations

While clinical trials are ongoing for psychedelic-assisted psychotherapy, the most research has been conducted with MDMA and psilocybin; therefore, claiming effectiveness of other psychedelic substances to treat opioid use disorders is limited. Given that psychedelic research is ongoing and legislative and regulation is continuously changing, information in the thesis can only reflect what was available during the research period (concluding April 2023). This limitation could mean that information and subsequent legislative and regulatory approaches may be out of date. Further, given government confidentiality, research regarding policy, legislation and regulation could only be obtained from what was publicly available during the research period. Subsequently and as noted by Kilian et al. (2016), data collection methods can vary and be "inconsistent between and within jurisdictional scans" (p. 7) when using the jurisdiction scan method, presenting another limitation.

Furthermore, experiences of opioid use disorders and concurrent mental health disorders can be subjective in some studies and not clinically diagnosed, which can be present a limitation. For example, as stated in Leung et al.'s research, cross-sectional data from adults receiving outpatient opioid agonist treatment for opioid use disorders self-reported a comorbid psychiatric disorder, yet only 64% of these individuals met the clinical criteria for a psychiatric disorder (2021). Where possible the thesis identifies whether the concurrent mental health disorder had been diagnosed or self-reported. Inconsistencies related to subjective and clinical diagnoses of opioid use and concurrent mental health disorders makes it challenging to identify concrete relationships between the two disorders.

In addition, data available from Coroner's Reports/surveillance reporting does not explicitly state whether those that died from apparent toxic opioids were diagnosed with opioid use disorders, therefore this presents a limitation in identifying the rates of mortality between recreational users and frequent users/those with disordered use. Presumably opioid use disorder can increase the need and frequency of opioid use, when compared to recreational use, therefore the chances of

mortality from the illicit toxic drug supply could arguably be higher for those living with opioid use disorder. Based on this logic, an assumption can be made that those living with opioid use disorders may be exposed to the toxic drug supply more frequently (i.e., more dependent) and therefore more susceptible to opioid-related mortalities.

STRENGTHS

There is presently a tremendous amount of information related to the opioid crisis, COVID-19 (i.e., the toll on mental health and substance use), opioid agonist therapy and various opioid related interventions. Further, as psychedelic-assisted psychotherapy has built momentum, there is increasing evidence from clinical trials/research and political movement that has been documented. The robust amount of information, and the duration in which the opioid crisis has been occurring provided an exceptional landscape to draw on a variety of literature on policy, legislation and regulation.

3.0 Literature Review

3.1 Introduction

The literature review explores what is currently occurring and working well to support Canadians struggling with opioid use disorder and concurrent mental health disorders, and what, if more can be done by introducing psychedelic-assisted psychotherapy as a treatment option. The research intends to explore how to foster a holistic approach to treating opioid use disorders, by tandemly focusing on opioid withdrawal management (i.e., through OAT/iOAT) and concurrent mental health disorder(s) (i.e., through psychedelic-assisted psychotherapy) to make long-term recovery and healing even more possible.

The following themes were explored in the literature review: Opioid Use Disorder and Concurrent Mental Health Disorder Interventions and Psychedelic-Assisted Psychotherapy for Substance Use and Mental Health Disorders – and their associated subthemes below.

3.2 Opioid Use and Concurrent Mental Health Disorders

In this section of the literature review, policy tools most commonly used in Canada to mitigate opioid use disorder are explored, such as treatment/withdrawal management, harm reduction and psychosocial interventions. This section intends to provide an overview and acknowledge potential limitations in existing approaches to treating opioid use disorder.

CURRENT APPROACHES TO OPIOID USE DISORDER

Initial research on the opioid crisis response in Canada suggests that a primary policy response was treatment and harm reduction, particularly by use of opioid agonist therapy (OAT). Opioid agonist therapy is considered a form of safe supply, whereby individuals are prescribed medications, such as OAT, as a safer alternative to the toxic illegal drug supply for those at a high risk of overdose (Government of Canada, 2022c). Safer supply services build on existing approaches to treating the substance use disorder, but do not necessarily focus on stopping drug use (Government of Canada, 2022c). Yet, according to earlier research, Mattick et al. (2009) reported OAT as the best evidence based long-term treatment option for opioid use disorder. Mattick et al.'s research compared the effectiveness of methadone maintenance treatment (MMT), such as OAT versus non-opioid replacement therapy (i.e., detoxification, drug-free rehabilitation, wait-list controls, placebo medication) for opioid dependence (specifically heroin) (Mattick et al., 2009). Evidence showed that MMT/OAT was statistically significant and most impactful for patient retention and decreasing heroin use compared to non-opioid replacement therapy options (Mattick et al., 2009). There was no statistical significance related to reduced criminal activity or mortality (Mattick et al., 2009).

Further studies have explored the relationship of psychosocial interventions alongside opioid agonist treatments versus opioid agonist treatment alone. Amato et al. (2011), explored 35 studies using 13 different psychosocial interventions to support any maintenance

pharmacological treatment to standard maintenance treatment (such as opioid agonist therapy) for opioid dependence. Results showed no benefit for retention in treatment across 27 studies, no abstinence from opiates during treatment across eight studies, and no benefits to psychiatric symptoms, including depression across three studies when compared to standard maintenance treatment for opioid dependence (Amato et al., 2011). Evidence revealed no statistical significance for all comparisons and outcomes related to different psychosocial approaches (Amato et al., 2011). The duration of the studies was too short to determine outcomes of mortality (Amato et al., 2011).

According to recent evidence, hospitalizations and mortality are more likely to impact those individuals living with opioid use disorder and concurrent mental health disorders (Morin et al., 2020). In a retrospective cohort study, patients were stratified into two groups to identify the mortality outcomes of those diagnosed with concurrent mental health disorders and opioid use disorder versus those with opioid use disorder only. Of the 55,924 individuals enrolled in opioid agonist treatment, 87% had diagnosed concurrent mental health disorders (Morin et al., 2020). The study concluded that individuals diagnosed with mental health disorders were 2.25 times more likely to visit an emergency department and 1.67 times more likely to be hospitalized than those without concurrent mental health disorders (Morin et al., 2020). However, there seemed to be no association between having a mental health disorder and 1-year treatment retention of opioid agonist treatment (Morin et al., 2020). Therefore, according to this study (Morin et al., 2020), while occurrences of hospital visits increase with the presence of concurrent mental health disorders, adherence to opioid agonist treatment is not impacted.

According to the Government of Canada's Guidance on Opioid Use Disorder (OAT) Program (2021f), long-term OAT (longer than a year) is associated with better sustained outcomes, such as an increased likelihood of abstinence from illicit opioids and increased stability in comparison to shorter-term opioid agonist therapy. Research that investigated a 30-year follow up of participants in a community methadone program found that participants who remained abstinent from illicit opioids had been receiving OAT for an average of five to eight years (Government of Canada, 2021f). This research identified the long-term need for opioid agonist therapies in order for an individual to achieve abstinence and stability, which is time some users may not have.

POTENTIAL PITFALL OF OPIOID USE DISORDER POLICY INTERVENTIONS

While research suggests that OAT and similar policy initiatives have been effective, the following research has identified some pitfalls and gaps in these interventions to treat opioid use disorder and subsequently the opioid crisis more broadly. It is noted that substance dependence, such as opioid use disorder, have been and continue to be highly stigmatized, and rising to national and international policy agendas (Morin et al., 2017). Morin et al., have stated that the largest barrier is the lack of consensus on the extent of the problem and uncoordinated ideas of appropriate solutions. Inconsistent solutions have ranged from discrepancies between areas of medicine, enforcement and health policy (Morin et al., 2017). These varying solutions can

sometimes be incompatible in the complex landscape of the opioid epidemic; however, one issue that is highlighted consistently throughout the literature is the link between opioid use disorder and concurrent mental health disorder(s). According to Astals et al., in 2008, over 50% of individuals in North America with opioid use disorder had also experienced a concurrent mental health disorder. In 2021, The Public Health Agency of Canada (PHAC), acknowledged that the mental health profile of individuals who experience opioid-related harms is a priority when it comes to informing policies and interventions (Government of Canada, 2021b).

3.3 Psychedelic-Assisted Psychotherapy for Substance Use and Mental Health Disorders

In this section of the literature review, the history of psychedelics and psychedelic-assisted psychotherapy to treat various substance use and mental health disorders are explored, including identifying any challenges and gaps in the existing research. This section intends to better conceptualize the landscape of psychedelics and modalities of treatment to address aliments such as post-traumatic stress disorder and substance use disorder.

History of Psychedelics and Psychedelic-Assisted Psychotherapy

Theories surrounding the use of psychedelic substances and psychedelic-assisted psychotherapy are varied. Some psychedelic-assisted psychotherapy researchers theorize that psychedelics function to support more holistic and sustainable mental wellness in areas where conventional treatments have been ineffective and/or daily-doses of psychiatric medication and/or prolonged psychotherapy are required (Doblin, 2019; Haden et al, 2016; Schenberg, 2018). Opposing theories mentioned in the literature include concerns over psychedelic substance dependence, adverse reactions, and correlations between psychedelic use and socio-political unrest (Cottrell, 2015; Schlag et al., 2022).

Concepts that seek to explain the opposition towards psychedelics highlight social perceptions of psychedelics as constructed by compounding factors in history, such as radicalism and actions taken by American politicians in the 1970's in response to recreational use (Haden et al., 2016). Concerned individuals interpreted messaging related to psychedelics as anti-social and linked it to "disconnections from mainstream society" (Cottrell, 2015). In some cases, these socio-political influences continue to shape public perception, but with the return of psychedelic studies (as was occurring in the decades prior to the 1970's prohibition/"war on drugs"), research has undeniably revealed positive effects of psychedelics on mental wellness, particularly in clinical settings.

Favourable, and arguably more accurate historical notions of psychedelics are observed in Indigenous ceremony as pro-social, linking "spirituality, healing, and honoring seasonal and life transitions in the context of cohesive community" (Haden et al., 2016; CPHA, 2014). Hence, concepts that have emerged in regards to public health frameworks and legalization regulation draw on religious freedoms, human rights and cognitive liberties as supportive elements.

Religious freedoms and human rights have been applied when navigating drug policy issues related to the legalization of ceremonial substances such as, ayahuasca and peyote for Indigenous practices (Haden et al., 2016). Post-prohibition regulatory models in the legalization of cannabis utilized the public health framework, and current explorations of psychedelic drug policy endeavour to approach legalization through this lens as well (Haden & Emerson, 2014).

Cottrell and Haden et al., suggest potential hesitancy in supporting psychedelic research and public usage could be a reflection of the socio-political beliefs, such as stigma and political viewpoints of the 1970's "war on drugs" era and unethical psychedelic administration (2016). Historically, the reasons behind socio-political resistance, particularly relates to the politicization of psychedelics as the drug of anti-social behaviour, causing extreme hallucinations and unrest (Cottrell, 2015; Haden et al., 2016). Additionally, between the 1950s and 1970s the Central Intelligence Agency (CIA) illegally ran controversial and widely unethical experiments on human subjects using psychedelic substances, often unknowingly and without consent from participants to research torture and interrogation techniques (Lee & Shlain, 1992). These earlier studies neglected the importance of set and setting and adverse patient outcomes were often the result of unethical administrations of high dosages of psychedelics without preparation and under restraint (Schlag et al., 2022). While research linking psychedelics to mental health care began in the 1950's, it was up against this backdrop of widespread, unsupervised usage of psychedelics, which led to the illegalization, and subsequently halted advancements in clinical research (Haden et al., 2016).

PSYCHEDELIC-ASSISTED PSYCHOTHERAPY AND MENTAL HEALTH

Despite the historical underpinnings that have shaped social and political perceptions of psychedelics, psychedelic-assisted psychotherapy research reveals many promising opportunities in which psychedelic substance administration within clinical settings has resulted in long-lasting positive effects, low adverse effects and low/no drug adherence/dependence (Schenberg, 2018; Haden et al., 2016, Haden & Emerson, 2014). Summarized findings strongly suggest that psychedelic-assisted psychotherapy is a viable treatment option for mental health disorders and overall mental wellness, articulating that the implementation and legalization of psychedelic drugs in clinical settings can address the root causes of mental illness, subsequently curing the patient rather than simply managing symptoms (Schenberg, 2018; Doblin, 2019). Promising results from this research is gaining increased momentum from psychological and psychiatric professionals (Schenberg, 2018), including acknowledgment from the Government of Canada (2022d).

Scientific research exists to support psychedelic-assisted psychotherapy and its capabilities to cure various mental health disorders, including the *Food and Drugs Act* (FDA)'s support for Phase 3 trials of 3,4-methylenedioxy-methamphetamine (MDMA) to treat post-traumatic stress disorder (PTSD) (Mithoefer et al., 2019). Post-traumatic stress disorder is a common psychiatric disorder in Canada, most commonly occurring from exposure to an actual or threatened death,

serious injury and/or sexual violence, with an estimated lifetime prevalence rate of 9.2% (Van Ameringen et al., 2008). This disorder can lead to a number of intrusive and debilitating symptoms, such as distressing memories/dreams, dissociative (i.e., flashbacks) and physiological reactions to internal or external cues, and avoidance of thoughts and feelings associated with the traumatic event(s) (American Psychiatric Association, 2013). Suicidality and other negative consequences (such as substance use disorders) have been correlated with PTSD (Brake et al., 2017; Dorrington et al., 2014), with particular prevalence of suicide amongst first responders and veterans (Sareen et al., 2007).

While PTSD treatments exist, conventional administrations of psychotherapy (i.e., prolonged exposure therapy and cognitive processing therapy) and pharmacotherapies have been ineffective in treating many individuals (Koenen et al., 2017), with 40-60% of patients responding inadequately to pharmacotherapies (Steenkamp et al., 2015). According to researchers Jerome et al., the administration of MDMA alters brain activity creating subjective effects, including eliminating anxiety and distress when facing unpleasant memories (2020) and subsequently "enhancing emotional memory processing of traumatic memories with greater tolerability" (Jerome et al., 2020, p. 2493). Therefore, with the assistance of MDMA, such PTSD behaviours of avoiding feelings and thoughts associated with the traumatic event (American Psychiatric Association, 2013) could be mitigated, offering an alternative treatment for individuals with treatment resistant PTSD and those turning to opioids to manage emotional pain and experience that "euphoria" opioids can temporarily provide.

According to Phase 2 MDMA-assisted psychotherapy trials, after two to three administrations, there was a significant reduction of PTSD symptoms with 56% of participants no longer meeting the PTSD criteria post-treatment (Jerome et al., 2020). Along with continued improvement of underlying PSTD symptoms, over half of participants reported continued growth, suggesting "participants were able to successfully integrate therapeutic experiences into their daily lives to cultivate continued healing and growth" (Jerome et al., 2020, p. 2494).

3.4 Summary

While the literature acknowledged that there is an evident link to opioid-related harms hospitalizations and mortality rates among those experiencing/diagnosed with opioid use disorders and concurrent mental health disorders, there is no impact on the retention rates to opioid agonist therapy in those experiencing/diagnosed with concurrent mental health disorders (Morin et al., 2020). The research should seek to understand what Canada's federal, provincial and territorial governments have done to address the concurrent mental health disorders (approximately 50% of those with opioid use disorder (Astals et al., 2008)), as the literature points to a significant relationship between these two comorbidities and negative impacts (i.e., increased hospitalization and mortality).

Furthermore, the literature sought to explore the use of psychedelic therapies for the treatment of substance use and mental health disorders. As the literature reveals, there are a number of psychedelic substances that have shown positive impacts in addressing a variety of mental health disorders and substance use disorders. For instance, major depression, anxiety and trauma are commonly experienced in those with opioid use disorder (Fink et al., 2015; Lawson et al., 2013), which have shown to respond to psychedelic-assisted psychotherapy interventions. In addition, as mentioned in the introduction of this thesis, psilocybin has been used to treat smoking, lysergic acid diethylamide (LSD) has been used to treat alcoholism (Jones et al., 2022), and ibogaine has been used to treat opioid dependence/use disorder (Camlin et al., 2018; Noller et al., 2018; Wilson et al., 2020); therefore, based on available literature, psychedelic interventions have potential to treat opioid use disorders and its commonly co-occurring mental health disorders.

In summary the literature review provides an overview of opioid use disorder/opioid crisis and related subjects by exploring scholarly literature. Key findings from the literature review related to opioid use disorder, concurrent mental health disorders, and interventions, as well as research on psychedelic-assisted psychotherapy to treat concurrent mental health and substance use disorders are summarized below.

Below is a breakdown of the literature review themes and potential questions/issues to be explored in the jurisdiction scan:

Figure 1: Main Themes of the Literature Review

Literature Review Theme	Questions or Issues for Jurisdiction Scan
Opioid-related harms re to hospitalization and mortality increase with opioid use disorder and concurrent mental health disorders Ability to link higher hospitalizations and mortality rates to those experiencing/diagnosed with opioid use disorder and concurrent mental health disorders (Morin et al., 2020). Noted, that 50% of those experiencing/diagnosed with opioid use disordered experience a concurrent mental health disorder (Astals et al., 2008).	How are current opioid crisis interventions at federal, provincial and territorial levels of government treating opioid use disorder and concurrent mental health disorders in Canada?
	Is Canada's existing Coroner's report data able to differentiate between opioid-related harms mortality and hospitalization rates among those experiencing/diagnosed with opioid use disorder and concurrent mental health disorders? If so, this could be a useful tool to measure and monitor the impact of new complementary mental health supports in responding to comorbidities and addressing the opioid crisis.
Psychedelic drugs and psychedelic-assisted psychotherapy can treat substance use and mental health disorders	Are psychedelics/psychedelic-assisted psychotherapy being considered in Canada to

Psychedelic-assisted psychotherapy can function to support areas where conventional treatment has been ineffective and/or daily-doses of psychiatric medication and/or prolonged psychotherapy are required (Doblin, 2019; Haden et al., 2016; Schenberg, 2018). Some research notes, clinical administrations of psychedelic substances can have long-lasting positive effects, low adverse effects and low/no drug adherence/dependence (Schenberg, 2018; Haden et al., 2016, Haden & Emerson, 2014). Concerns related to drug adherence and long-term frequent administrations and dependence of opioid agonist therapy (OAT) have been noted in the literature (Jones et al., 2022; Government of Canada, 2021f). The non-addictive chemical makeup of most psychedelics, holds promise as a potential treatment option for opioid use disorder (Jones et al., 2022).	treat substance use and mental health disorders?
Negative perceptions of psychedelics perpetuated by historical socio-political resistance (Cottrell, 2015; Haden et al., 2016)	Can awareness campaigns be leveraged to increase social awareness and acceptance of alternative treatment options, like psychedelic-assisted psychotherapy?
Unethical administrations of psychedelics Central Intelligence Agency (CIA) illegally ran controversial and unethical experiments on human subjects using psychedelic substances, without consent from participants who endured torture and interrogation techniques (Lee & Shlain, 1992).	How are/how can psychedelic-assisted psychotherapies be regulated to ensure safety and ethical practices in Canada?

3.5 Conceptual Framework

Throughout the existing literature, it is evident that opioid use disorder and mental health disorders have a strong linkage, and that psychedelic-assisted psychotherapy has played a role in treating substance use disorders (e.g., smoking, alcoholism, opioid dependence/use disorder) and mental health disorders (e.g., depression, anxiety and PTSD). Yet, as the introduction of the thesis mentions, policy initiatives to combat the opioid crisis and Canada's federal regulatory and legislative frameworks do not presently support psychedelic-assisted psychotherapy.

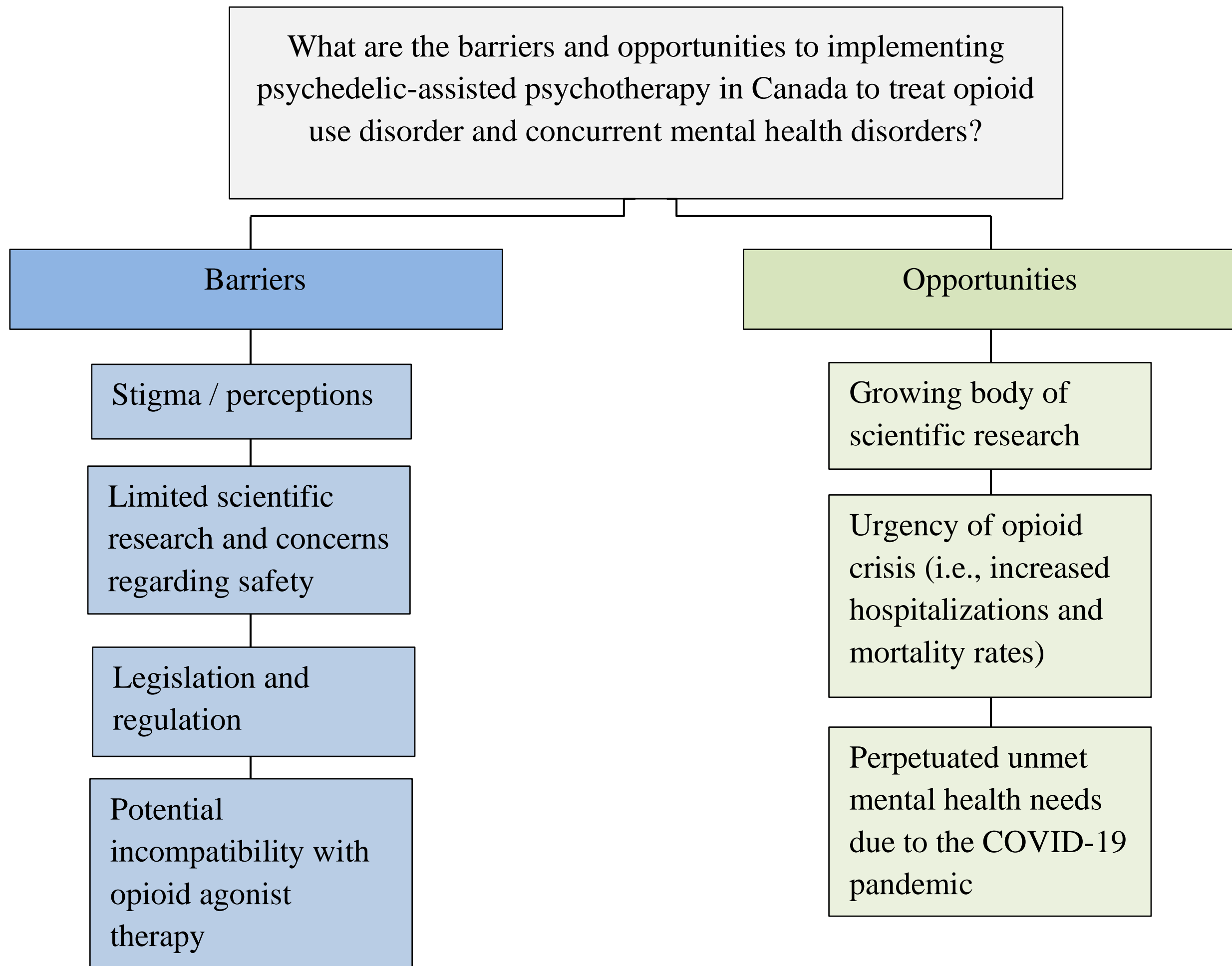
A potential theory to explain the absence of psychedelics as a treatment option to address opioid use disorder and concurrent mental health disorders, is a lack of scientific evidence,

misconceptions, and red tape associated with obtaining psychedelic medicine. The current policies to respond to the opioid crisis may be insufficient in addressing the ongoing hospitalization and mortality rates of opioid users that live with concurrent mental health disorders.

Based on what is presently known from the literature review, figure two below outlines the potential barriers and opportunities to implementing psychedelic-assisted psychotherapy in Canada to treat opioid use disorder and concurrent mental health disorders. These barriers and opportunities are as follows in no particular order and will be revisited later in the thesis:

- **Barriers**
  - Stigma and socio-political perception
  - Limited research and concerns regarding safety
  - Federal legislation and regulation of psychedelics
  - Compatibility concerns with opioid agonist therapy (OAT)
- **Opportunities**
  - Growing body of scientific research on psychedelic-assisted psychotherapy
  - Urgency of opioid crisis related to increased hospitalization and mortality from opioid-related harms
  - Perpetuated unmet mental health needs due to the COVID-19 pandemic

Figure 2: Conceptual Framework from Literature Review



4.0 Findings: Jurisdictional Scan

4.1 Introduction

This section of the thesis outlines the policy initiatives that have become available in Canada in response to the opioid crisis, including those implemented by the Government of Canada and those at a provincial and territorial level of government. This section also provides a landscape of federal legislative and regulatory policy that is in place for psychedelics and psychedelic-assisted psychotherapy.

The intention of this jurisdiction scan is to highlight the existing initiatives that address the opioid crisis/opioid use disorder, observe any gaps related in mental health supports, and better understand the regulatory and legislative barriers to accessing psychedelics.

This jurisdiction scan is intended to support the discussion and analysis section of this thesis, by identifying comparative policy tools and initiatives among the provinces/territories, potential gaps in opioid crisis response and concurrent mental health approaches, and any opportunities for new regulatory approaches among the provinces and territories in Canada.

4.2 Government of Canada: Policy, Legislation and Regulation Related to the Opioid Crisis Response

This section provide an overview of the policy, legislative and regulatory frameworks associated with opioid crisis as implemented by the Government of Canada. This section intends to provide an understanding of the regulatory environment and how the opioid crisis has been approached by the federal government to date.

Policy, Legislative and Regulatory Frameworks: Opioid Crisis

Around the time British Columbia announced the opioid crisis as a public health emergency under provincial legislation in 2016, the federal Minister of Health had made naloxone available without a prescription and issued an Interim Order under the *Food and Drugs Act* allowing for the emergency import and sale of naloxone nasal sprays (Parliament of Canada, 2016). The Government of Canada also introduced regulatory amendments to overturn the ban on the sale of diacetylmorphine (heroin) for the use of emergency treatment and allowed considerations of applications made to the Special Access Program (Parliament of Canada, 2016). In addition, Bill C-37 was introduced to streamline the application process in developing supervised consumption sites, which would allow a safe place for individuals to consume drugs, access to clean drug use equipment (e.g., needles) and in case of overdose, receive emergency medical care in a timely manner (Parliament of Canada, 2016). Bill C-37 also supported law enforcement with tools to prevent illegal drugs from being imported and manufactured in Canada, including improved enforcement at the border (Parliament of Canada, 2016). As well, the Government of Canada built capacity to support research and surveillance into evidence-based strategies to prevent, treat and reduce harms associated with addiction and drug dependency (Parliament of Canada, 2016).

Alongside prevention, treatment and enforcement, a primary intervention that was utilized across Canada to minimize the lethal impact of the toxic drug supply and increase safety for those using opioids and/or experiencing an opioid use disorder, is harm reduction (Parliament of Canada, 2016). According to the National Harm Reduction Coalition, "harm reduction is a set of practical strategies and ideas aimed at reducing negative consequences associated with drug use... [and] is... a movement for social justice built on a belief in, and respect for, the rights of people who use drugs" (2020). Key strategies that mobilized across Canada in support of reducing harm was supervised consumption sites (i.e., clean pipes, needles, staff support), increased access to naloxone kits and the introduction of the *Good Samaritan Drug Overdose Act* (Government of Canada, 2022a). The *Good Samaritan Drug Overdose Act (*Bill C-224), provides immunity to those seeking assistance (for themselves or others) and remaining at the overdose scene until emergency response arrives, preventing someone from incurring legal offences from single use drug possession, which is typically an offense under section 4 of the *Controlled Drug and Substances Act*, (Parliament of Canada, 2016).

As the Government of Canada implemented a myriad of interventions in an attempt to save lives, public pressure mounted on the federal government to declare a national emergency under the *Emergencies Act*; however, in order to declare such an emergency, the Lieutenant Governor in Council of the province in crisis must indicate to the Governor in Council that "the situation exceeds the capacity or authority of the province to manage..." and the provincial and local governments did not make this request (Parliament of Canada, 2016). In addition, the Government believed that "the crisis requires a longer term, sustained, and coordinated effort" that the *Emergencies Act* was not designed to provide (Parliament of Canada, 2016). At this time, Canada's Public Health Officer, Dr. Theresa Tam worked closely with territorial and provincial partners to support a cohesive and collaborative approach in response to the public health crisis (Parliament of Canada, 2016).

The Public Health Agency of Canada, along with territorial and provincial governments formed a Special Advisory Committee on the Epidemic of Opioid Overdose, including members from the Pan-Canadian Public Health Network Council (composed of senior public health officials from all levels of government) (Parliament of Canada, 2016). The committee's initial focus was on harm reduction, improving data and surveillance and addressing treatment (Parliament of Canada, 2016). In addition, a Health Portfolio Taskforce and a Deputy Minister Committee with Health Canada, Public Safety Canada, Global Affairs Canada, and the Privy Council Office was established to provide "strategic direction and integrate domestic and international initiatives to address the opioid crisis." (Parliament of Canada, 2016).

The Government of Canada provided territories and provinces with $36.1 billion in funding in 2016/2017 to support the delivery of health care services, including harm reduction associated with problematic opioid use and an additional $11 billion over the following 10 years for primarily home care and mental health (Parliament of Canada, 2016). While mental health and treatment fall within territorial and provincial jurisdiction, the Government of Canada

acknowledged the funding would be helpful in addressing challenges related to problematic substance use (Parliament of Canada, 2016). An additional $544 million was provided over five years to federal pan-Canadian health organization to pursue work on health innovation and prescription drugs (Parliament of Canada, 2016).

In 2017, the Government of Canada announced $65 million over five years to support the implementation of a federal strategy known as the Canadian Drugs and Substances Strategy, consisting of four pillars to address the opioid crisis and problematic opioid use: Prevention, Treatment, Harm Reduction, Enforcement, and Data and Evidence (Parliament of Canada, 2016).

Recent actions by the Government of Canada have included:

- Granting a three-year exemption under the *Controlled Drugs and Substances Act,* allowing adults 18 years and older in British Columbia to possess a personal amount of opioids, cocaine, methamphetamines, or MDMA without being criminally charged between January 31, 2023 to January 31, 2026 (Government of Canada, 2022h).
- Publicly releasing a report titled: Substance-related acute toxicity deaths in Canada from 2016 to 2017: A review of coroner and medical examiner files. The report provides an overview of the data of people who died from substance-related acute toxicity (excluding homicides) across all Canadian provinces, including the sociodemographic and socioeconomic characteristics of the people who died, substances involved, and the circumstances surrounding their deaths (Government of Canada, 2022h).
- Updating modelling projections through mid-2023 of opioid-related deaths during the COVID-19 outbreak to understand and plan for potential scenarios where opioid-related deaths may increase or decrease. As previously noted, data from several jurisdictions across Canada and the Public Health Agency of Canada have observed substantial increases in opioid-related harms and deaths since the pandemic and such modelling will support investigation into various factors responsible for the increase, such as substance use as a way to cope with stress and shifts in the drug supply (Government of Canada, 2022h, 2022k).
- Former Bill C-5 received Royal Assent on November 17, 2022, reappealing mandatory minimum penalties for drug offences in the *Controlled Drugs and Substances Act.* The adjustment forges a path for prosecutors/police to consider diverting people to treatment programs and providing warnings rather than charging and prosecuting simple drug possession (Government of Canada, 2022h).
- Launching a campaign focused on men working in trades – a disproportionally affected population in the opioid crisis – to promote help-seeking and link them to resources and supports (Government of Canada, 2022h).
- Funding investments into more generalized mental health and substance use supports, such as $500 million through the Safe Restart Agreement in response to the COVID-19 pandemic will support people experiencing challenges with substance use, mental health

or homelessness and $650 million in 2022-2023 for culturally informed and community-based wellness initiatives (i.e., substance use prevention and treatment) (Government of Canada, 2022h).

4.3 Government of Canada: Legislation and Regulation Related to Psychedelics/Psychedelic-Assisted Psychotherapy

This section of the thesis provides an overview of the federal Government of Canada's legislative and regulatory frameworks related to psychedelics and psychedelic-assisted psychotherapy, including identifying research limitations associated with psychedelics. This section intends to provide an understanding of the regulatory environment in Canada and potential areas for adjustment should psychedelic-assisted psychotherapy become a complementary treatment option for opioid use disorder.

Legislative and Regulatory Frameworks: Psychedelics/Psychedelic-Assisted Psychotherapy

There are many authors who have written about psychedelic-assisted psychotherapy within Canada, including researchers that have emerged from MAPS Canada, the British Columbia Centre on Substance Use (BCCSU), and the Canadian Public Health Association (CPHA). For purposes of this thesis, which is exploring psychedelic-assisted psychotherapy, regulatory and legislative-barriers, and potential strategies should this treatment option be widely available in Canada, pioneering authors are, Dr. Kenneth Tupper, former Director of Implementation and Partnerships at the British Columbia Centre on Substance Use (BCCSU); Mark Haden, Adjunct Professor at the University of British Columbia School of Population and Public Health, and former Executive Director of MAPS Canada; and Dr. Brian Emerson, acting Deputy (B.C.) Provincial Health Officer and Medical Consultant for Population Health Surveillance. Collectively their research explores advancements in drug policy and public health frameworks related to clinical administrations of psychedelic substances. Their recent work propelled from the Health Officers Council of B.C. proposing "a public health framework for regulating psychoactive substances" (HOC-BC, 2011), in which the highlighted authors explored "a model for the regulation and management of psychedelics" (Haden et al., 2016). Their literature illuminates key components of the research related to the positive and lasting impacts of psychedelics on mental wellness, traditional and Indigenous uses of psychedelics in ceremony, socio-political shifts in psychedelic perceptions, as well as regulatory exploration in to drug policy and psychedelic legalization within Canada. Strategies from this framework will be referenced further in this thesis as appropriate and to substantiate ways forward should such a treatment option for opioid use disorder be adopted.

Prior to exploring a model or framework of psychedelic regulation, one must understand the current barriers to obtaining authorization to administer psychedelics for use of medical, scientific, and industrial purposes in Canada. Findings reveal that Health Canada controls various psychedelic substances under the *Controlled Drugs and Substances Act*, which is a federal

statute that provides a framework for control over "substances that can alter mental processes and maybe produce harm to health or society when diverted to an illegal market or misused" (Government of Canada, 2022n). These controlled substances are listed in Schedules I-V of the *Controlled Drugs and Substances Act*, including ketamine (typically an anesthetic but at subanesthetic doses can induce psychedelic experiences (Krupitsky & Grinenko, 1997)), psilocybin ("magic mushrooms"), lysergic acid diethylamide (LSD) and MDMA which are considered illegal unless authorized for medical, scientific or industrial purposes (Government of Canada, 2022; 2022n). According to Health Canada, short-term mental health side effects from psychedelics are hallucinations, anxiety, confusion and paranoia, with some quick links mentioning connections to "bad trips" (Government of Canada, 2022). Health Canada goes on to articulate long-term [unfavourable] effects as a result of psychedelics, but it is unclear what dosage and setting is being referenced. According to Carvalho et al.'s (2014) research in crisis intervention services, it is argued such unfavourable effects most commonly occur in unsupervised settings, such as festivals and through recreational use.

Despite the absence of clarity on dosage and setting, psychedelics and psychedelic-assisted psychotherapy remain strictly regulated by the Government of Canada. However, remarkably, Health Canada does acknowledge the therapeutic exploration and potential benefits of psilocybin/magic mushrooms and MDMA on their website. In reference to psilocybin and magic mushrooms Health Canada states:

"There is increasing interest in the potential therapeutic uses of magic mushrooms and of psilocybin, one of the active ingredients in magic mushrooms. While clinical trials with psilocybin have shown promising results, at this time, there are no approved therapeutic products containing psilocybin in Canada or elsewhere. Clinical trials are the most appropriate and effective way to advance research with unapproved drugs such as psilocybin while protecting the health and safety of patients." (Government of Canada, 2022d).

In reference to MDMA Health Canada states: "MDMA is being studied for its potential to treat conditions such as anxiety and post-traumatic stress disorder. These studies use medical-grade MDMA in clinically supervised settings. Currently, there are no approved therapeutic products containing MDMA in Canada." (Government of Canada, 2022e). Health Canada has not included these statements on their ketamine and LSD webpages.

While these barriers to accessing psychedelics for medical, scientific and industrial purposes exist, a program known as the Special Access Program (SAP), has paved a path forward for individuals seeking access to psychedelic on a case-by-case basis. Historically, psychedelic-assisted psychotherapies were not available for individual use, and were only available for short periods of time through clinical trial participation (Numinus, 2022), however this has changed.

In December 2020, Health Canada published a Notice of Intent, signaling their intent to amend the *Food and Drug Regulations and Narcotic Control Regulations* to restore access to restricted

drugs through the Special Access Program (Government of Canada, 2021e). Following a 60-day comment period, targeted consultations from health care professionals, organizations, researchers, academics, licensed dealers, and the general public, a vast majority of respondents were supportive of the proposed regulatory amendments and/or increasing access to psychedelic substances more broadly (Government of Canada, 2021e). Health Canada received very little opposition to the proposal (approximately 2% of all responses) (Government of Canada, 2021e). Notably, over 80% of all respondents associated Health Canada's proposal to increase access to psychedelic restricted drugs (e.g., psilocybin, MDMA, LSD), for the purposes of treating various conditions, namely mental health disorders (Government of Canada, 2021e). Approximately 22% of respondents described having lived or living experience with a mental health disorder or other conditions, and indicated a personal interest in seeking treatment with a psychedelic restricted drug (Government of Canada, 2021e).

Particular opposition received during the noted consultation period was related to cocaine. One organization expressed concerns that regulatory changes may encourage physicians to prescribe cocaine as a first-line of treatment for individuals with stimulant use disorders, replacing addiction treatment and increasing availability of low-cost cocaine (Government of Canada, 2021e). Another organization was concerned that increased access to a safer supply of cocaine could increase rates of addiction and instead advocated for increased access to detoxification, treatment and recovery programs (Government of Canada, 2021e). The Government of Canada reaffirmed that the Special Access Program is an emergency-based form of treatment and will not enable cocaine to become widely accessible through physician prescriptions – therefore, the proposed amendment was not swayed based on these concerns (2022e).

Henceforth, in January 2022, Health Canada amended the Special Access Program regulations to permit requests for "restricted drugs", including psychedelics such as psilocybin, LSD, N,N-dimethyltryptamine (DMT) and MDMA. While authorization and sale of psychedelics remain limited in Canada, health care professionals can request a drug through the Government of Canada via the Special Access Program (Government of Canada, 2022f). The Special Access Program is regulated by Health Canada and follows regulations outlined in the *Food and Drug Regulations* (under the *Food and Drugs Act*), and can allow people access to certain medications on a case-by-case basis that are not yet authorized or available to the general public (Government of Canada, 2023; Numinus, 2022). The Special Access Program is currently available to patients with serious or life-threatening conditions in which conventional treatments have either failed, are unsuitable or are unavailable in Canada (Government of Canada, 2022f).

Patients seeking access to psychedelic-therapy via the Special Access Program can ask their physician or an appropriately licensed healthcare professional with prescribing privileges to submit a request on their behalf (Government of Canada, 2022f). In cases where requests are made on behalf of patients, the health care professional must ensure the patient is informed of possible risks, benefits and the developmental status; provide a report to Health Canada on the results of the drug, including any adverse reactions; maintain accurate and accessible records of

the quantity of drug received; and ensure prescription decisions are supported by credible evidence in medical literature or as provided by the manufacturer (Government of Canada, 2022f). Organizations and companies across Canada that offer assistance to clients/patients/physicians seeking access to psychedelic drugs through the Special Access Program are TheraPsil, Numinus, Roots to Thrive, Field Trip Health, New Earth Therapy, and the Linden Medical Centre (Psychedelic Law, 2022).

Prior to the Special Access Program, another avenue to accessing psychedelic-therapy in Canada, which is now often utilized when the Special Access Program request is denied or patients do not meet program requirements is through a section 56 exemption for drugs under the *Controlled Drugs and Substances Act*. However, according to some organizations, unlike the Special Access Program, psychedelics obtained under section 56 exemptions often take up to 300 days to obtain and patients often have to acquire substances illicitly making it more difficult to ensure safe supply for medical purposes (Filament Health, 2022).

Psychedelics/Psychedelic-Assisted Psychotherapy Research Limitations

Of note, while research has been developing to support the short and medium-term effects of psychedelic-assisted psychotherapy, long-term psychedelic effects remain limited. Concerns exist regarding long-term psychedelic effects (Aday et al., 2020), therefore, further research is required to ensure ongoing safety and efficacy of psychedelic-assisted psychotherapy. In anecdotal discussions with program leaders in the field of psychedelic medicine and a cursory review of the literature, the gaps that exist relate to social barriers which could be due to gaps in knowledge (Carhart-Harris et al., 2018) and concerns around additional substance dependence, including “generalizability and control group limitations” (Aday et al., 2020).

4.4 Provincial and Territorial: Policy, Legislation and Regulation Related to the Opioid Crisis Response

This section of the thesis provides an overview of provincial and territorial responses to the opioid crisis to date. The provinces of Alberta, British Columbia, Ontario, Saskatchewan, and Yukon will be reviewed in the scan, including implemented initiatives (e.g., harm reduction, treatment, mental health), established task forces/committees, identified funding allocations and associated agreements with or specific exemptions from the Government of Canada.

Alberta

In May 2017, as death rates rapidly increased, the Government of Alberta declared opioid abuse a public health crisis, reluctant to declare a public health emergency which carries legal implications (Bellefontaine*,* 2017). Following the announcement, the province allocated $30 million to address the crisis and established the Minister’s Opioid Emergency Response Commission to support a coordinated response (Government of Alberta, 2023a; Bellefontaine, 2017). In addition, the Government of Alberta acknowledged that opioid addiction is as a complex issue in which comprehensive and holistic approaches are required to address the crisis

(Government of Alberta, 2022a). Approaches initiated by Alberta to respond to the crisis were prevention, intervention, treatment and recovery (with acknowledgement that recovery is individualized and pathways are different for each person), enforcement and supply control, collaboration, and surveillance and analytics (Government of Alberta, 2023a; 2022a).

In 2016, Alberta was providing quarterly reports to assess fentanyl misuse, as well as the use/misuse of opioids and narcotics using existing public health surveillance (Government of Alberta, 2023b). By 2020, Alberta launched a substance use surveillance system to report the prescribing patterns, use/misuse, drug overdoses and deaths as they related to fentanyl and other opioids in Alberta (Government of Alberta, 2022b). The intention behind this surveillance was to monitor and better understand the challenges Alberta was facing in the crisis and to make informed and strategic decisions related to a recovery-oriented system of care (Government of Alberta, 2022b).

Following the conclusion of the Minister's Opioid Emergency Response Commission in 2018 (Government of Alberta, 2023a), in 2019, Alberta established a Mental Health and Addictions Advisory Council, whereby recommendations are provided to improve accessibility to recovery-orientated care and better support to get on such a pathway (Government of Alberta, 2022a). This initiative included the introduction of the Opioid Agonist Therapy Gap Coverage Program, in which individuals awaiting enrollment in a supplementary health benefit plan are provided with immediate, no-cost coverage for certain opioid agonist therapy medications for 120 days (Government of Alberta, 2022a).

One particular gap identified in the uptake of opioid agonist treatment, was a lack of transportation, in-person induction requirements, employment demands and limited childcare (Day et al., 2022). In response to this gap, Alberta launched a virtual opioid agonist treatment program, upholding their commitment to supporting individual pathways to recovery (Day et al., 2022). A total of 440 clients participated in the study and while there was rapid uptake over a period of three years, median wait days for treatment decreased going from six days to immediate access (zero days) (Day et al., 2022). Retention rates were similar to other published reports on opioid agonist treatment, however clients reported higher levels of satisfaction, an overall reduction in drug use and overdose, as well as improved social functioning (Day et al., 2022).

In addition, options for care in response to the opioid crisis include recovery housing (pre- and post-treatment), addiction treatment services (i.e., residential treatment), narcotic transition services (i.e., high-potency opioids for people with severe opioid use disorder can stabilize while transitioning to opioid agonist therapy), overdose prevention (i.e., free naloxone kits), Digital Overdose Response System (DORS) (i.e., mobile app to prevent overdose deaths in people who use alone), and other harm reduction services (i.e., needle distribution, supervised consumption services, peer and outreach support) (Government of Alberta, 2022a). Complimentary to these initiatives, the Opioid Dependency Program was created to provide methadone and suboxone

initiation and maintenance treatment to people who are dependent on opioids (Alberta Health Services, n.d.). This program's intention is to stabilize people on methadone or suboxone in an outpatient setting under close medical supervision and evaluation, allowing a person to function normally while taking these medications long term (Alberta Health Services, n.d.).

In 2018, the Government of Alberta entered into the Emergency Treatment Fund Bilateral Agreement with the Government of Canada which allocated $150 million of federal funding from April 1, 2018 to March 31, 2023 to invest in one or more of the following eligible investment areas as set out in Alberta's Action Plan (Government of Canada, 2021g):

- support initiatives that will establish, build on, or enhance existing treatment approaches;
- encourage further implementation of innovative treatment solutions; and
- recognize the importance of broader strategies to support access to treatment services by enhancing health care providers' knowledge of best practices (alcohol, cannabis, and tobacco are excluded).

Similar to the perimeters of other provinces/territories in the Emergency Treatment Fund Bilateral Agreement with the Government of Canada, the intention of this agreement is to support single or multi-year projects that would improve access to evidence-based treatment while keeping at its core, a compassionate and collaborative approach to addressing problematic substance use (Government of Canada, 2021g). In accordance with this agreement, Canada and Alberta concurred that the intention of the agreement is to provide financial support and augment treatment services in light of the opioid crisis, and that any ongoing funding for enhanced initiatives would be sustained by Alberta (Government of Canada, 2021g).

In addition, in response to the compounding effects of the COVID-19 pandemic on opioid overdoses, in 2020, the government of Alberta invested $140 million over four years to implement a new addiction and mental health strategy to improve access to services, including $40 million to address the opioid crisis and $25 million to the Alberta Recovery Plan to build five recovery communities throughout the province focused on holistic addiction recovery (Government of Alberta, 2020). This funding is complimentary to Alberta's existing approximately $1 billion investment in mental health and addictions and Budget 2022's $20 million investment over four years to further implement a recovery-orientated system of care with a coordinated network of community-based services and supports (Government of Alberta, 2022b).

BRITISH COLUMBIA

In April 2016, the Provincial Health Officer of British Columbia, declared a public state of emergency due to a significant rise in opioid-related deaths in B.C. (Government of B.C., n.d.). In 2017, the Government of Canada provided $10 million in urgent support to B.C. to assist with their emergency response efforts, including supporting the increased distribution of take-home naloxone (an antidote to opioid overdose) kits (Parliament of Canada, 2016).

In addition, in 2017, B.C. allocated $322 million over three years to save lives, address stigma, and improve access to services for people struggling with addiction, including launching an Overdose Emergency Response Centre (OERC) and providing crisis funding to hardest hit communities (Government of B.C., 2017). Specifically, B.C.'s opioid crisis response focused on six key areas: saving lives, ending stigma, building a network of treatment and recovery services, creating a supportive environment, advancing prevention, and improving public safety (Ministry of Mental Health and Addictions, n.d.). These initiatives include overdose prevention and supervised consumption services in communities hardest hit.

In 2018, the Government of British Columbia entered into the Emergency Treatment Fund Bilateral Agreement with the Government of Canada which allocated $150 million in federal funding from April 1, 2018 to March 31, 2023 to invest in one or more of the following eligible investment areas (Government of Canada, 2021h):

- support initiatives that will establish, build on, or enhance existing treatment approaches;
- encourage further implementation of innovative treatment solutions;
- recognize the importance of broader strategies to support access to treatment services by enhancing health care providers' knowledge of best practices.

Similar to the perimeters of other provinces/territories in bilateral agreements with the Government of Canada, the intention of this agreement is to support single or multi-year projects that would improve access to evidence-based treatment while keeping at its core, a compassionate and collaborative approach to addressing problematic substance use (Government of Canada, 2021h). In accordance with this agreement, Canada and British Columbia concurred that the intention of the agreement is to more rapidly ramp up or otherwise augment treatment initiatives in light of the opioid crisis, and that any ongoing funding for enhanced initiatives would be sustained by British Columbia (Government of Canada, 2021h).

To date, between January 2017 to September 2022, there have been more than 3.3 million visits to overdose prevention services and more than 22, 816 overdose responses and averted deaths (Ministry of Mental Health and Addictions, 2022). Drug-checking services have also been implemented across B.C. to help detect harmful substances, reduce drug poisoning and connect individuals to supportive services (Ministry of Mental Health and Addictions, 2022). The Lifeguard App was developed to connect people who use drugs to first responders if they become unresponsive (Ministry of Mental Health and Addictions, 2022). Between May 2020 to the end of October 2022, the app was used over 111,333 times by 13,938 users and no drug-poisoning deaths have been reported via the app to date (Ministry of Mental Health and Addictions, 2022). Despite these efforts, the BC Coroners Service Death Review Panel reported in 2022 deaths due to illicit drug toxicity were second to cancers in terms of potential years of life lost in B.C. (BC Coroners Services, 2022).

In Budget 2022, B.C. continued to enhance their response to the opioid crisis, investing $430 million over the next three years, including $22.6 million towards safe supply implementation efforts and $144.5 million in treatment and recovery beds (Ministry of Mental Health and Addictions, 2022). In 2020, B.C. was the first province to launch a program to offer prescribed safe supply, with the second phase of the program being implemented by health authorities and federally funded SAFER programs across the province (Ministry of Mental Health and Addictions, 2022). Budget 2022 will support ongoing efforts of this program, allowing health authorities to implement prescribed safe supply, while expanding and creating new programs and establishing more robust monitoring and evaluation processes (Ministry of Mental Health and Addictions, 2022). In addition, B.C. plans to develop a full-spectrum system of substance-use treatment and recovery services, including 65 new and/or enhanced initiatives with approximately 195 withdrawal management, transition and treatment and recovery beds over three years (Ministry of Mental Health and Addictions, 2022).

Other approaches supported through Budget 2022 and ongoing funding in B.C. include (Ministry of Mental Health and Addictions, 2022):

- An expanded scope of nursing practices allowing clinicians to prescribe medications for opioid-use disorder (a service which was launched in November 2021, with training support from the BC Centre on Substance Use (BCCSU));
- Opioid agonist treatment with expansions through Rapid Access to Addiction Care Clinics across the province; flexible treatment options (i.e., injectable and low-barrier tablet opioid agonist treatment);
- New teams to connect people to services and treatment (i.e., tailored services in 16 communities consisting of nurses, counsellors, social workers, and peers);
- 24/7 severe mental-health support (i.e., access to 29 Assertive Community Treatment teams across the province) and enhanced mental-health crisis lines;
- 24/7 helpline for prescribers and pharmacists;
- Community Action Teams (CAT) (i.e., growing initiative with 36 CATs across the province helping communities form partnerships and strategies to address the drug-poisoning emergency at a local level);
- Investments to support people with lived/living experience share and build peer and family support networks (e.g., Moms Stop the Harm – leading the Stronger Together initiative, a family support and development project);
- First Nations-run treatment and healing centres (i.e., supporting renovations and expansion of land-based culturally safe treatment services);
- Provincial drug-poisoning emergency response for First Nations communities;
- Métis-led mental health and wellness initiatives (i.e., Métis Nation BC developing cultural safety and wellness curriculum and harm-reduction and stigma reduction campaign);

- Gwa'sala-'nakwaxda'xw partnership (i.e., extending an Indigenous-led program for alcohol treatment and recovery in Port Hardy).

As of January 31, 2023, at request of the Government of BC, the Government of Canada granted a three-year subsection 56(1) exemption under the *Controlled Drugs and Substances Act* whereby adults (18 years and older) will not be criminally charged for personal possession up to 2.5 grams total of opioid, cocaine, methamphetamine, or MDMA or combination of, effective between January 31, 2023 to January 31, 2026 in B.C. (Government of Canada, 2022h, 2022l). British Columbia is the first province in Canada to receive this exemption (Government of Canada, 2022j). The intention of the exemption is to reduce stigma and harm, while fostering an environment for police to offer information and referrals for health and social supports rather than criminalizing those possessing small amounts of illicit substances (Government of Canada, 2022j). By modeling this approach, the hope is to decrease the barriers which prevent individuals from seeking support and obtaining treatment, and move towards ending the overdose crisis (Government of Canada, 2022j).

ONTARIO

In 2017, The Government of Ontario invested $222 million over three years to enhance Ontario's Strategy to Prevent Opioid Addiction and Overdose, allowing the province to build on previous commitments and ensure people with opioid addictions can access holistic support services (Government of Ontario, 2017). The Government of Ontario emphasized a holistic approach which would enable a full-spectrum of needs being met in those struggling with opioid addiction, such as increasing front-line harm reduction workers, expanding naloxone supplies (i.e., injectable and nasal spray options), expanding Rapid Access Addiction Medicine Clinics (i.e., addiction treatment, counselling, withdrawal management), and expanding harm-reduction services (i.e., needle exchange programs and supervised injection sites) (Government of Ontario, 2017).

In conjunction with Ontario's Strategy to Prevent Opioid Addiction and Overdose, the Ontario government also invested $20 million annually in Ontario's Chronic Pain Network over three years (Government of Ontario, 2017). The intention was to support people living with chronic pain find appropriate treatment and solutions to manage their pain (Government of Ontario, 2017). In addition, the Government of Ontario collaborated with the Ontario College of Family Physicians to mentor health care providers on appropriate prescribing of opioids for pain management and how to treat patients with addiction (Government of Ontario, 2017).

The Government of Ontario partnered with the Centre for Addiction and Mental Health (CAMH) to expand addictions treatment and family health teams throughout the province (Government of Ontario, 2017). In addition, the Government of Ontario's partnership with CAMH also supported collaborative work with Indigenous communities to enhance culturally appropriate mental health and wellness programs, including funding the expansion and creation of Indigenous Mental Health and Addictions Treatment and Healing Centres (Government of Ontario, 2017).

In 2018, the Government of Ontario entered into the Emergency Treatment Fund Bilateral Agreement with the Government of Canada, which allocated $150 million in federal funding from April 1, 2018 to March 31, 2023 to invest in one or more of the following eligible investment areas (Government of Canada, 2021i):

- support initiatives that will establish, build on, or enhance existing treatment approaches;
- encourage further implementation of innovative treatment solutions;
- recognize the importance of broader strategies to support access to treatment services by enhancing health care providers' knowledge of best practices.

Similar to the perimeters of other provinces/territories in these bilateral agreements with the Government of Canada, the intention of this agreement is to support single or multi-year projects that would improve access to evidence-based treatment while keeping at its core, a compassionate and collaborative approach to addressing problematic substance use (Government of Canada, 2021i). In accordance with this agreement, Canada and Ontario concurred that the intention of the agreement is to more rapidly ramp up or otherwise augment treatment initiatives in light of the opioid crisis, and that any ongoing funding for enhanced initiatives would be sustained by Ontario (Government of Canada, 2021i).

In 2019, Health Canada's Substance Use and Addiction Program launched a four-year project known as the Community Opioid/Overdose Capacity Building (COM-CAP), focused on supporting community-led responses to opioid/overdose-related harms in communities across Ontario (Public Health Ontario, 2022). The COM-CAP has been monitoring and evaluating the impact of existing supports, including strengthening knowledge, skills and the sharing of information across communities and networks (Public Health Ontario, 2022). This initiative works closely with organizations and networks addressing opioid/overdose harms and builds on evidence, needs and gaps to enhance their response (Public Health Ontario, 2022).

In 2020, following the COVID-19 pandemic, Ontario's monthly overdose deaths increased by 79% (Addictions and Mental Health Ontario, 2023). In 2021, the Ontario Association of Chiefs of Police (OACP), called on the federal and provincial government to invest in harm reduction initiatives and engage with partners to establish an Ontario Drug Task Force, to develop policy to manage opioids, other drugs and challenges associated with problematic use (OACP, 2021).

In 2022, Addictions and Mental Health Ontario (AMHO) welcomed the Government of Ontario's $204 million investment in mental health and addiction care as part of the provincial government's 2022 Budget commitment; however, the organization emphasized it was not enough (AMHO, 2022). In February 2022, in conjunction with member organizations, AMHO released their "No Time to Wait" budget submission and campaign, with recommendations to the Government of Ontario to implement and improve mental health and addiction response (AMHO, 2022). As it related to the opioid crisis, AMHO called on the government to restrike the Ontario Opioid Emergency Task Force, to scale up a multi-sectorial approach in light of the

escalating opioid crisis and increase in overdose deaths (AMHO, 2022). This request was made of the Government of Ontario in advance of the provincial election in June 2022 (AMHO, 2022).

In 2022, the Registered Nurses' Association of Ontario (RNAO) advocated for the Government of Ontario to amend the Ontario Drug Formulary in support of expanding safer supply initiatives in addition to those funded by the federal government, to allow for more safer supply drug options and coverage for those seeking help (RNAO, 2022). In addition, RNAO called on the Government of Ontario to lift caps on consumption and treatment services (CTS) and support and fund overdose prevention sites in every community in need (RNAO, 2022). Lastly, RNAO recommended the Government of Ontario decriminalize simple drug possession through obtaining a province-wide exemption to section 56 of the *Controlled Drugs and Substances Act* (CDSA) from the Government of Canada (RNAO, 2022).

Despite calls to action by a number of concerned organizations, the Government of Ontario's response to these calls were nominal. Aside from the Government of Ontario's investment of $204 million to build a better mental health and addiction system and requiring workplaces of known risk for opioid overdoses to provide naloxone kits and training, there was minimal mention of additional opioid crisis intervention in the province's Budget 2022 plan (Government of Ontario, 2022).

SASKATCHEWAN

In 2017, the Government of Saskatchewan established an Opioid Emergency Task Force (Task Force), co-led by the Ministries of Justice and Health with representatives from the education and social ministries focused on addressing opioid misuse and overdose in the province (Bridges, 2017). Initiatives considered and implemented by the Task Force included the distribution of naloxone kits, needle exchange programs, supervised consumption sites, treatment services (i.e., opioid substitution therapy), policing, education/public awareness campaigns, and investigating illegal trafficking and sale of opioids prescribed by physicians (Bridges, 2017). Anecdotally, Saskatoon's Health Region addiction consultant acknowledged in 2017 that the Task Force experienced "significant fiscal restraint" and the practically of initiatives would be challenging (Bridges, 2017). Despite potential fiscal restraints, by 2018, the Government of Saskatchewan had invested $7.4 million in expanding access to opioid substitution therapy.

In 2018, the Government of Saskatchewan entered into the Emergency Treatment Fund Bilateral Agreement with the Government of Canada which allocated $150 million in federal funding from April 1, 2018 to March 31, 2023 to invest in one or more of the following eligible investment areas (Government of Canada, 2021j):

- support initiatives that will establish, build on, or enhance existing treatment approaches;
- encourage further implementation of innovative treatment solutions;
- recognize the importance of broader strategies to support access to treatment services by enhancing health care providers' knowledge of best practices.

Similar to the perimeters of other provinces/territories in bilateral agreements with the Government of Canada, the intention of this agreement is to support single or multi-year projects that would improve access to evidence-based treatment while keeping at its core, a compassionate and collaborative approach to addressing problematic substance use (Government of Canada, 2021j). In accordance with this agreement, Canada and Saskatchewan concurred that the intention of the agreement is to more rapidly ramp up or otherwise augment treatment initiatives in light of the opioid crisis, and that any ongoing funding for enhanced initiatives would be sustained by Saskatchewan (Government of Canada, 2021j).

The agreement provided the Government of Saskatchewan funding to support initiatives to (Government of Canada, 2021j; Government of Saskatchewan, n.d.):

- Enhancing existing treatment approaches: building capacity through training in Trauma Informed Practice and other complementary skills to support the treatment of substance use disorders, including adjusting treatment and care plans based on client needs and root causes of problematic substance use (e.g., the impact of trauma on the lives of people with substance use disorders). This initiative included training providers in therapeutic approaches and evidence-based treatment options for patients using crystal meth (e.g., behavioural therapy and motivational interviewing and trauma-informed practices). Acknowledging that the vast majority of individuals experiencing opioid misuse and addiction have current or past experiences of trauma and violence.
- Supporting innovative treatment solutions: one-time funding to the Saskatchewan Health Authority and community-based organizations to enhance telehealth equipment and software for rural, remote and northern areas (e.g., where services are not locally available and support case managers to connect clients to health and social services they need; enhancing infrastructure/renovations (i.e., increase treatment beds, detox, transitional housing); and promote wrap-around care in the treatment of opioid or crystal meth dependence.
- Supporting strategies to enhance access to treatment services: funding regulatory agencies to recruit, train and support opioid substitution therapy.

In Budget 2022, the Government of Saskatchewan committed to a total investment of $403 million to mental health and $67 million to addictions supports, including $8 million to fund targeted initiatives that provide counselling and treatment, reduce harms associated with substance use (i.e., increasing naloxone availability in more community pharmacies) and advance preventative measures, particularly for youth (Government of Saskatchewan, 2022). In addition, the Task Force following extensive consultation with a range of partners, including people with lived experience, received an investment totaling $1 million and included (Government of Saskatchewan, 2022):

- $650,000 for development of local integrated overdose response projects;
- $150,000 for targeted stigma reduction efforts;

- $150,000 for trauma-informed practice training for front line staff to assist in identifying and appropriately responding to individuals who use substances due to past trauma; and
- $50,000 for coordinated research in areas of interest for the Task Force.

Collectively with the new 2022-23 budget, the Government of Saskatchewan has invested over $92 million in targeted initiatives focused on mental health and addictions since 2018 (Government of Saskatchewan, 2022).

YUKON

In 2017, in response to the opioid crisis, the Government of Yukon established an Opioid Action Plan consisting of four pillars (Government of Yukon, 2018):

- Harm Reduction and Take-Home Naloxone Kits: initiatives under this pillar included, hiring an opioid overdose prevention coordinator to oversee the distribution, inventory, database and training for the take-home naloxone kits; training staff in over 45 organizations (including most schools); and sought and received a Health Canada exemption to support Blood Ties Four Directions' Fentanyl Drug Checking service.
- Public Awareness and Education: initiatives under this pillar included, distributing phone and wallet "Party Safe" cards to high school students; news, social media and radio broadcasting to promote awareness of early signs of overdose, problematic substance use, and mental wellness; and sharing knowledge of psychosocial supports and treatment.
- Opioid Surveillance: initiatives under this pillar included continuing to monitor suspected opioid-related deaths, emergency visits to hospitals, distribution and use of naloxone kits and exploring other sources of information to improve understanding of opioids in the territory. Furthermore, to support this pillar, the Public Health Agency of Canada provided a public health officer from December 2017 to March 2019 to assist in a comprehensive opioid surveillance plan, including tracking opioid dispensing throughout Yukon.
- Opioid Management: initiatives under this pillar included the establishment of an Opioid Pain Management working group to convene and identify specific health and social service reforms that protect users from addiction harm and overdose; protect the community from drug diversion; help improve acute and chronic pain management; and are culturally relevant and appropriate to First Nations.

In 2018, the Government of Yukon entered into the Emergency Treatment Fund Bilateral Agreement with the Government of Canada, which allocated $150 million in federal funding from April 1, 2018 to March 31, 2023 to invest in one or more of the following eligible investment areas (Government of Canada, 2021k):

- support initiatives that will establish, build on, or enhance existing treatment approaches;
- encourage further implementation of innovative treatment solutions;

- recognize the importance of broader strategies to support access to treatment services by enhancing health care providers' knowledge of best practices.

Similar to the perimeters of other provinces/territories in these bilateral agreements with the Government of Canada, the intention of this agreement is to support single or multi-year projects that would improve access to evidence-based treatment while keeping at its core, a compassionate and collaborative approach to addressing problematic substance use (Government of Canada, 2021k). In accordance with this agreement, Canada and Yukon concurred that the intention of the agreement is to more rapidly ramp up or otherwise augment treatment initiatives in light of the opioid crisis, and that any ongoing funding for enhanced initiatives would be sustained by Yukon (Government of Canada, 2021k).

In 2021, Yukon opened the North's first supervised consumption site and expanded on the safe supply of opioids (Government of Yukon, 2022a). By Budget 2022, Yukon continued to build on the Opioid Action Plan, including the expansion of harm reduction initiatives (Government of Yukon, 2022a). Despite these efforts, in January 2022, the Government of Yukon declared a Substance Use Health Emergency in response to a surge in substance use related harms and a drastic increase in opioid related deaths (Government of Yukon, 2022b). Alongside community partners, First Nations and governments, the Government of Yukon has set to advance a range of treatment, harm reduction, prevention and awareness initiatives, including (Government of Yukon, 2022b):

- Creating a Mobile Paramedic Unit through Emergency Medical Services, including mobile paramedics and shelter paramedic dedicated to overdose response, prevention and education for those at risk of substance use harm.
- Increasing and expanding drug self-testing capability across the territory, including education and instructions on how to perform tests.
- Renovating and improving the supervised consumption site to support inhalation as a consumption method.
- Increasing access to opioid treatment services by expanding weekly physician coverage.
- Strengthening opioid treatment services by increased hiring, including nurses and people with lived and living experience as community engagement workers.
- Expanding opioid medication coverage to include Sublocade, an evidence-based, extended-release, once monthly injection of an opioid medicine called buprenorphine. Making access to treatment easier for Yukoners in rural communities.
- Launching Car 867, a mobile crisis unit that includes an RCMP officer and a trained mental health nurse. The unit provides trauma-informed, client-centered responses to mental health emergencies and wellness checks, and offers early intervention to help divert people from the criminal justice and hospital systems.

- Organizing two territory-wide public awareness and education campaigns to decrease stigma around substance use and increase awareness of the treatment, counselling and harm reduction services available from government and non-government providers.
- Gathering feedback and suggestions from Yukoners, partners and subject matter experts through several forums and gatherings, including advisory committees and working groups.
- Hosting Mental Wellness Summits to hear from leaders, partners, people with lived and living experience, and Yukoners interested in learning more about pressing mental wellness and substance use issues, initiatives and solutions.
- Increasing on-the-land healing and treatment options in the territory through engagement with Indigenous partners.

4.5 Provincial and Territorial: Legislation and Regulation Related to Psychedelics/Psychedelic-Assisted Psychotherapy

The selected provinces and territories were reviewed to determine which jurisdictions have regulated psychedelic therapy to support the treatment of mental health and substance use disorders. Among the provinces and territories of Alberta, British Columbia, Ontario, Saskatchewan, and Yukon, only one province has announced the regulation of psychedelic drugs for therapeutic use.

ALBERTA

Alberta announced on October 6, 2022, that they would become the first Canadian province to regulate psychedelics for therapeutic use, effective January 16, 2023 (Herrington, 2022; Junker, 2022). Excerpts from news releases highlight Alberta's Associate Minister of Mental Health and Addictions comment stating that, "some of the strongest supporters [of psychedelic drug therapy] are among first responders and veterans who suffer from high rates of PTSD and other mental health conditions" (Herrington, 2022; Junker, 2022). The offering of psychedelic-assisted psychotherapy in Alberta is to add to treatment options for mental health disorders and to get ahead of the curve to ensure safe use of hallucinogenic substances in a therapeutic supported environment (Dyck, 2023). According to the Government of Alberta, service providers offering treatment for psychiatric disorders using psychedelic drugs are required to meet quality and safety requirements under the *Mental Health Services Protection Regulation* (Government of Alberta, 2022c). In addition, many service providers must also to be licensed under the *Mental Health Services Protection Act* and comply with standards set in the Psychedelic Treatment Services Standards currently in development (Government of Alberta, 2022c). This regulatory framework intends to provide government oversight and key protections for patients who are receiving psychedelic drug treatment services in Alberta and includes (Government of Alberta, 2022):

- requires licensing, except in the following cases:
    - approved clinical research trials

    - ketamine used outside of psychedelic-assisted psychotherapy;
- outlines the conditions for prescribing, administering, dispensing or selling a designated psychedelic drug, and conditions for monitoring and caring for people while they are in an altered state of consciousness;
- ensures clinical oversight of licensed psychedelic drug treatment services is provided by a psychiatrist; and
- sets out the qualifications for persons conducting psychedelic-assisted psychotherapy
- ensures service providers meet quality standards such as policies and procedures for:
    - safety and security
    - employee requirements, qualifications and training
    - record creation, maintenance and retention
    - facilities or other locations where services are offered or provided;
- details requirements related to approved clinical research; and
- gives government authority to address complaints and concerns and to amend, suspend or cancel a service provider's license.

In addition to the framework, all licensed psychedelic drug treatment service providers will be required to have a complaint process, including contact information to report possible abuse to the Provincial Abuse Line, an external contact from the service provider (Government of Alberta, 2022c). Licensed psychedelic drug treatment service providers will also be required to report to the Alberta Ministry of Health regarding any serious injury or death that has occurred in relation to provided services (Government of Alberta, 2022c). Furthermore, the Government of Alberta offers an appeal process through the Appeals Secretariat (neutral government office), should citizens disagree with a decision made by the Compliance and Monitoring regarding a license issued to a psychedelic drug treatment service provider (Government of Alberta, 2022c; 2022d). The appeal panel reviewing an appeal is made up of non-government employees, who have authority and training to hear the appeal and may agree/change/reverse Compliance and Monitoring’s licensing decision (Government of Alberta, 2022d).

4.6 Summary

Through the jurisdiction scan exploring the policy, legislation and regulatory parameters of opioid crisis response and approach of psychedelic/psychedelic-assisted psychotherapy, the primary research question of: “How has Canada and selected jurisdictions (i.e., Alberta, British Columbia, Ontario, Saskatchewan, and Yukon) responded to the opioid crisis to date, particularly from an opioid use disorder and concurrent mental health disorder perspective?” – has been partially answered (more to discuss in the following chapter). Overall, a number of policy initiatives have been implemented with support from the Canadian federal government and independently at the provincial and territorial level. These types of initiatives include, naloxone kits, opioid agonist therapy and increased health supports.

The most important findings identify that two top barriers to adopting psychedelic-assisted psychotherapy as a treatment option to respond to the opioid crisis (i.e., treating opioid use disorder and concurrent mental health disorders), is Canada's federal, provincial and territorial legislation and regulation, and the lack of evidence regarding long-term effects of psychedelic-assisted psychotherapy.

These policy tools and initiatives and the legislative and regulatory amendments/exemptions will be organized thematically per province and/or territory in the next chapter.

5.0 Results: Policy, Legislation & Regulatory Themes

5.1 Introduction

This section identifies and presents the qualitative data that emerged from the jurisdiction scan related to Canada's federal, provincial and territorial response to the opioid crisis, including adjustments/amendments/exemptions to policy, legislation and regulation. Quantitative data from Canada's federal, provincial and territorial Coroner's reports documenting the rate of apparent opioid toxicity deaths 2016 to 2022 will be included as reference.

5.2 Main Themes and Initiatives

The jurisdiction scan revealed a number of policy initiatives implemented in response to the opioid crisis. The opioid crisis policy tools are sorted thematically below under harm reduction, treatment, awareness, enforcement and surveillance. These themes emerged throughout the jurisdiction scan and align with key policy tools identified in the Government of Canada's overarching actions to address the opioid crisis (Government of Canada, 2022a). Of note, opioid agonist therapy (OAT) is referenced as both a harm reduction tool, as it can reduce engagement with potential illicit toxic opioids and a treatment tool, as it can manage the withdrawal symptoms and lead to recovery overtime.

Harm Reduction

Harm reduction was a policy theme that was implemented across all provinces and territories selected for the jurisdiction scan. The most common tools that were used to address harm reduction were naloxone kits, supervised consumption sites, needle exchange/distribution programs, safer inhalation materials, and opioid agonist therapy (OAT).

Treatment

Treatment was another policy theme that was discovered to address the opioid crisis across all selected provinces and territories. The following treatments were most common throughout the jurisdiction scan to treat opioid use disorder, and include opioid agonist therapy (OAT), psychosocial therapy (optional), and counselling (optional). Funding from the Canadian federal government, provinces, and territories seemed to provide overarching commitments to generalized mental health and substance use supports for all Canadians, but not seemingly explicitly for those with opioid use disorders and concurrent mental health disorders (more on this in the next chapter). Furthermore, treatment options were adjusted in some provinces and territories to respond to treatment needs of those living in rural and remote communities, such as virtual treatment options. Alberta was the only province to regulate administration of psychedelic-assisted psychotherapy to treat a variety of mental health disorders.

Awareness and Education

The next policy initiative to be implemented in response to the opioid crisis, was awareness (e.g., potency of the poisoned drug supply and death rates) and education (e.g., how to help someone in the event of an overdose). A number of provinces and territories had personalized campaigns to promote help-seeking and resources, with a particular focus on men working in trades. In addition, other awareness and education initiatives were broadcasted using advertisements on the television and radio, on who was overdosing and how to identify an overdose and respond. Many provinces and territories took on a community-based approach and offered broad training on how to administer naloxone in the event of an overdose.

Data and Surveillance

Another key policy theme that was accelerated in response to the opioid crisis was data and surveillance, particularly related to monitoring the types and levels of fentanyl and other poisoning substances present in the toxic drug supply. The Canadian federal government, provinces, and territories accomplished these initiatives through building capacity to support surveillance into evidence-based strategies to prevent, treat and reduce harms associated with addiction and drug dependency. In addition, the federal, provincial and territorial governments improved their data collection of substance-related acute toxicity deaths (excluding homicides), including demographic characteristics, substances involved and circumstances surrounding deaths. As the COVID-19 pandemic exacerbated the opioid crisis, modeling projections of opioid-related deaths during the COVID-19 outbreak (until mid-2023) were initiated as well.

Evidence and Research

Evidence and research were primary policy theme as well in the federal, provincial and territorial governments' response to the opioid crisis, such as investing and building capacity to support research into evidence-based strategies to prevent, treat and reduce harms associated with addiction and drug dependency. In addition, the Government of Canada specifically invested in the Pan-Canadian health organization to pursue health innovation and prescription drugs research.

Legislation and Regulation

Throughout the opioid crisis, the Canadian federal government primarily made amendments/exemptions to legislation and regulation in a variety of ways in support of harm reduction and treatment efforts. In addition, the jurisdiction scan also identified if and how Canadian jurisdictions have made amendments/exemptions to legislation and regulation to allow for use of psychedelic/psychedelic-assisted psychotherapy for substance and mental health disorders. Below is a list of the legislation and regulation that were amended/exempt in response to the opioid crisis, as well as new/amended legislation and regulation related to psychedelics/psychedelic-assisted psychotherapy to date.

Opioid Crisis Response

A number of exemptions and amendments were made by the Government of Canada to policy, legislation, and regulation in response to the opioid crisis. Below is a list of the main adjustments that were made:

- *Controlled Drugs and Substances Act* exemption allowing personal possession of opioids, cocaine, methamphetamine, or MDMA or combination of (British Columbia only) to reduce stigma and barriers and encourage access to treatment (Government of British Columbia, 2023).
- *Controlled Drugs and Substances Act* reappealed allowing prosecutors/police to consider diverting people to treatment programs and provide warnings rather than charging and prosecuting simple drug possession
- Interim Order under *Food and Drugs Act* for emergency import and sale of naloxone (Parliament of Canada, 2016)
- Regulatory amendments to allow the sale of diacetylmorphine (heroin) for use of emergency treatment and considerations of applications made to the Special Access Program (Parliament of Canada, 2016)
- Bill C-37 to streamline application process for developing supervised consumption sites (Parliament of Canada, 2016)
- Bill C-37 to support law enforcement with tools to prevent illegal drugs from being imported and manufactured in Canada, including improved enforcement at the border (Parliament of Canada, 2016)
- *Good Samaritan Drug Overdose Act* to provide legal protection from possession charges for people who seek emergency help for themselves or others during an overdose (Parliament of Canada, 2016)
- Former Bill C-5 receives Royal Assent, reappealing minimum penalties for drug offences in the *Controlled Drugs and Substances Act* allowing prosecutors/police to consider diverting people to treatment programs and providing warnings rather than charging and prosecuting simple drug possession (Government of Canada, 2022h).

Psychedelics/Psychedelic-Assisted Psychotherapy

As the jurisdiction scan identifies, psychedelic substances are regulated under the *Controlled Drugs and Substance Act*, and are considered illegal substances unless authorized for medical, scientific or industrial purposes (Government of Canada, 2022). Exemptions under section 56 of the *Controlled Drugs and Substance Act* are required to access psychedelics (Government of Canada, 2021e). Another option available to access psychedelics for individual medical purposes is the Special Access Program (SAP), regulated by the *Food and Drugs Regulations (*under the *Food and Drugs Act),* which were amended allowing health care professionals (with prescribing abilities)/physicians to request psychedelic drugs on a case-by-case basis, including those drugs that are not yet authorized or available to the general public. The Special Access Program is

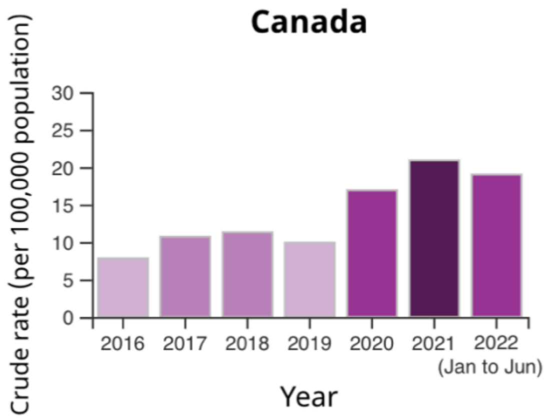
available to patients with a serious or life-threatening condition, where conventional therapies have failed, are unsuitable and/or unavailable in Canada (Government of Canada, 2022f).

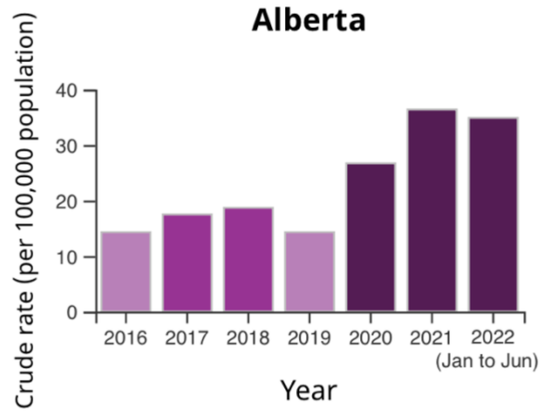
Furthermore, psychedelic-assisted psychotherapy has been regulated in Alberta and service providers offering treatment for psychiatric disorders using psychedelic drugs are required to be licensed under the Province's *Mental Health Services Protection Act,* meet quality and safety requirements under the *Mental Health Services Protection Regulation*, and comply with the Psychedelic Treatment Services Standards currently in development (Government of Alberta, 2022c). The Psychedelic Treatment Services Standards will be a framework intended to provide government oversight and key protections for patients receiving psychedelic drug treatment in Alberta (Government of Alberta, 2022c). Based on the research, the regulation and licensing of service providers and development of a framework in support of safe and quality psychedelic treatment is the first of its kind in Canada (Herrington, 2022; Junker, 2022).

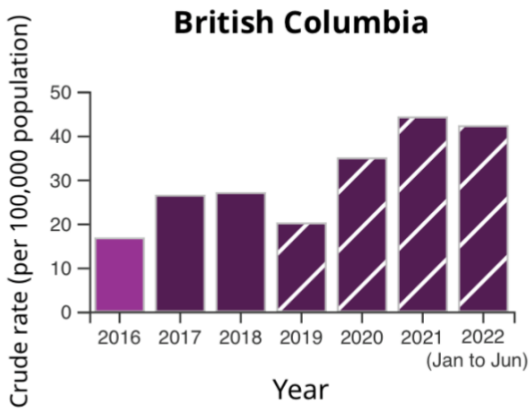
5.3 Provincial and Territorial: Rates of Apparent Opioid Toxicity Deaths

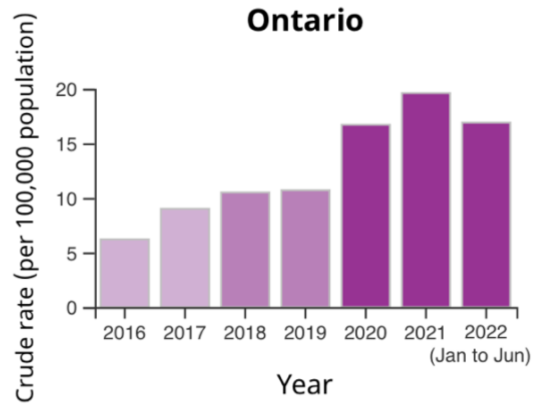
Qualitative data below represents the recorded rates of apparent opioid toxicity death across the Canada and the selected provinces and territories from January 2016 to June 2022. This data has been included to provide a comprehensive picture in light of the policy tools and initiatives implemented in each province/territory since 2017 (for most) and how this impacted the populations throughout the opioid crisis. The figures below were obtained from the Government of Canada website based on available data (2022b). The solid-filled bars represent rates of apparent opioid toxicity deaths, while the diagonal-lined bars represent rates of apparent illicit drug toxicity deaths and are inclusive of, but not limited to opioids and stimulants (Government of Canada, 2022b).

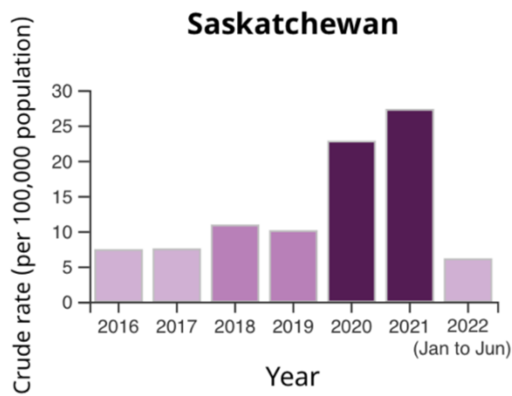
Figure 3: Rates of apparent opioid toxicity deaths across Canada

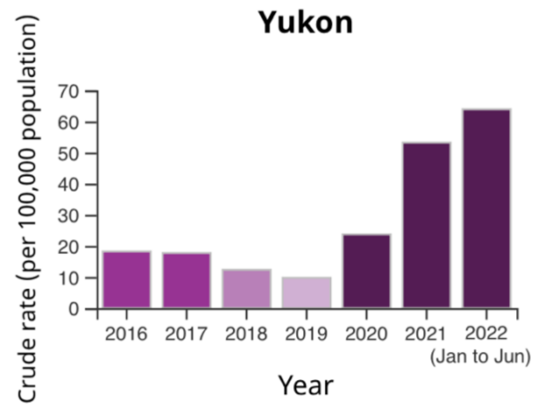












5.4 Summary

In summary, the jurisdiction scan provided a comprehensive overview of the various policy tools that were initiated by the federal Canadian government, provinces and territories and its impact on the population that experienced apparent opioid toxicity deaths. The themes explored above will be analyzed in relation to the primary and secondary thesis questions in the upcoming chapter. Prior to exploring and analyzing these themes further, attention on the areas where findings differed is worth mentioning.

Of note, from the five provinces/territories selected in the jurisdiction scan, British Columbia was the only province that requested and was granted an exemption by the Government of Canada under subsection 56(1) of the *Controlled Drugs and Substances Act* (CDSA), allowing an individual to possess personal amounts of illegal substances without being criminally charged (Government of Canada, 2022h, 20221). As mentioned earlier in the thesis, this exemption relinquishes an individual from being legally charged should they be caught in possession of a personal amount of opioids (and other substances), in support of reducing stigma and barriers and creating an avenue towards treatment rather than criminalization. It has been recorded that interested organizations have recommended other provinces and territories follow, however this has yet to occur as of March 2023 (Registered Nurses' Association of Ontario, 2022).

In addition, of the five provinces/territories selected in the jurisdiction scan, Alberta is the only province that has regulated psychedelics for therapeutic use; whereby, service providers that offer treatment for psychiatric disorders using psychedelic drugs must meet quality and safety requirements (under the *Mental Health Services Protection Regulation)* and be licensed (under the *Mental Health Services Protection Act)* to administer psychedelic-assisted psychotherapy (Government of Alberta, 2022c).

British Columbia and Alberta's provincial initiatives and lessons on the future of opioid and psychedelic-assisted psychotherapy policy in Canada will be discussed in the next chapter.

In terms of statistical evidence on the rate of apparent opioid toxicity deaths across Canada and the selected provinces/territories – overall death rates have increased, with the exception of Saskatchewan. The decreased rates of apparent opioid toxicity deaths in Saskatchewan in relation to their opioid crisis response will be discussed in the next chapter.

6.0 Discussion and Analysis

In this chapter, the results and themes revealed through the findings of the literature review and jurisdiction scan are analyzed and examined in an integrated manner. The following analysis is based on the literature review, jurisdiction scan of Canada and the five provinces and territories, and the subsequent statistical data related to each jurisdiction's apparent toxic opioid-related deaths.

Through both the findings from the jurisdiction scan and the subsequent statistical data, a number of potential answers have emerged in response to the primary research question proposed: "How has Canada and selected jurisdictions (i.e., Alberta, British Columbia, Ontario, Saskatchewan, and Yukon) responded to the opioid crisis to date, particularly from an opioid use disorder and concurrent mental health disorder perspective?" as well as the secondary questions listed below.

6.1 Answering the Research Questions

1. *How has Canada and selected jurisdictions (i.e., Alberta, British Columbia, Ontario, Saskatchewan, and Yukon) responded to the opioid crisis to date, particularly from an opioid use disorder and concurrent mental health disorder perspective?*

The Government of Canada and the highlighted provinces and territories of Alberta, British Columbia, Ontario, Saskatchewan, and Yukon have implemented a number of policy initiatives and have made several adjustments to legislation and regulation in response to the opioid crisis both in the short- and long-term. The primary themes identified throughout the jurisdiction scan and organized in the results section are: (1) Harm Reduction (e.g., naloxone kits, supervised consumption sites, opioid agonist therapy); (2) Treatment (e.g., opioid agonist therapy, psychosocial therapy, counselling); (3) Awareness and Education (e.g., targeted campaigns, how to identify and respond in the event of overdose using naloxone); (4) Data and Surveillance (e.g., evidence-based strategies, improvements on data collection of substance-related acute toxicity deaths); (5) Evidence and Research (e.g., pursuing health innovation and prescription drug research); and the overarching theme that has supported a number of these initiatives is (6) Legislation and Regulation (e.g., *Controlled Drugs and Substances Act (CDSA)* allowing prosecutors/police to defer people to treatment programs and no prosecution for simple possession, *CDSA* exemption allowing person possession of opioids, etc. in British Columbia). The majority of jurisdictions were aligned in their overall approach and response to the opioid crisis. Some jurisdictions had more available information on their public facing documents, while others did not. The reason for these variations of publicly available information is not clearly known, however one potential reason is that some provinces and territories have experienced the opioid crisis for a longer duration, like British Columbia.

In terms of treatment efforts to address the opioid use disorder, the primary form of intervention across Canada is opioid agonist therapy, whereby the use of methadone, suboxone and/or slow-release morphine (Kadian) are used to prevent withdrawal symptoms and reduce the cravings for opioids (Centre for Addiction and Mental Health, 2016). This form of treatment is both a harm reduction tool and a treatment in the sense that it allows users to use regulated substances (i.e., obtained from pharmacies) to reframe from purchasing potentially toxic opioids from the illicit market, and a treatment tool as it offers a cleaner and functional substance that manages withdrawal symptoms that keeps those experiencing opioid use disorder from returning to the illicit market. Opioid agonist therapy dosages can be gradually reduced and users are in a better position to receive additional treatment (i.e., engaging in counselling and/or psychosocial therapy). The latter, of seeking additional treatment modalities is an approach that depends on an individual's willingness to engage, noting that opioid agonist therapy is best when combined with group or individual counselling (Centre for Addiction and Mental Health, 2016).

2. *Are the policy initiatives, legislation and regulation in place to respond to the opioid crisis adequately addressing opioid use disorder and concurrent mental health disorders?*

Based on the jurisdiction scan and evidence from the literature review on the prevalence and relationship between opioid use disorder and concurrent mental health disorders, current policy initiatives, legislation and regulation do not seem to be adequately addressing both disorders. While mental health initiatives were linked as a treatment tool to the opioid crisis response, much of the funding allocations seemed to provide overarching mental health supports and did not read evidently and intentionally focused on addressing the psychosocial connection between mental health and opioid use disorders. Rather, based on the provinces/territories highlighted, most seemed to approach each disorder separately, primarily addressing the opioid use disorder with harm reduction and treatment/withdrawal management and craving reduction (i.e., opioid agonist therapy), and mental health supports (i.e., counselling, psychosocial therapy, etc.) as needed.

However, more detailed clinical information from each province and territory is required to confirm conclusively whether policy initiatives, legislation and regulation are adequately addressing opioid use disorder and concurrent mental health disorders in response to the opioid crisis. Furthermore, surveillance on rates of apparent toxic opioid deaths do not differentiate between recreational users and problematic substance users (i.e., those experiencing opioid use disorder) – this information might be helpful when monitoring the prevalence of death experienced by opioid users living with concurrent mental health disorders.

3. *How can psychedelic-assisted psychotherapy address current gaps in the treatment of opioid use disorder and concurrent mental health disorders?*

The research revealed that the benefits psychedelic-assisted psychotherapy can provide that opioid agonist therapy and conventional therapies may not is adequately treating the concurrent

mental health disorder, like post-traumatic stress disorder and depression commonly experienced by individuals with opioid use disorders.

As referenced in the key terms, opioid agonist therapy is a treatment option for opioid addiction and works to prevent withdrawal symptoms and reduce cravings for opioid drugs (Centre for Addiction and Mental Health, 2016). As identified in the literature review, long-term (i.e., five to eight years) opioid agonist therapy is associated with better sustained outcomes, such as stability and abstinence (Government of Canada, 2021f). In order to address the mental health of opioid users, counselling therapy is recommended alongside opioid agonist therapy. However, according to findings from the literature review common concurrent mental disorders experienced with opioid use disorder, like post-traumatic stress disorder (PTSD), reveal that conventional administrations of psychotherapy and pharmacotherapies have been ineffective (Koenen et al., 2017), often as low as 40-60% (Steenkamp et al., 2015).

As stated in the literature review, some psychedelic-assisted psychotherapy researchers theorize that psychedelics function to support more holistic and sustainable mental wellness in areas where conventional treatments have been ineffective and/or daily-doses of psychiatric medication and/or prolonged psychotherapy are required (Doblin, 2019; Haden et al., 2016; Schenberg, 2018). Therefore, psychedelic-assisted psychotherapy could address both the mental health disorder that opioid agonist therapy alone and conventional psychotherapy does not. Psychedelic-assisted psychotherapy utilizes three types of sessions, one of which is a medical session where psychoactive substances are administered by a trained therapist or two trained therapists (male and female team) with an emphasis on emotional and psychological growth (Reiff et al., 2020). Positive impacts of psychedelic-assisted psychotherapy are often seen following one to three administrative sessions, depending on the psychoactive substance required (Schenberg, 2018).

In addition, research on ibogaine has shown to support withdrawal management and reduce cravings in those experiencing opioid dependence/use disorder (Camlin et al., 2018; Noller et al., 2018; Wilson et al., 2020). This research is promising, and safety and efficacy of using multiple psychedelic substances to treat both opioid use disorder and concurrent mental health disorders will need to be explored further. If psychedelic substances are incompatible, opioid agonist therapy could continue to support the physiological component while psychedelic-assisted psychotherapy could address the concurrent mental health disorder associated with the opioid use disorder. Given the research identified in the thesis, there is potential that by addressing the concurrent mental health disorder associated with the substance use disorder, beneficial results could be achieved. More research is required to ensure the safety and efficacy of using both psychedelic substances and opioid agonist substances simultaneously.

4. *What barriers exist in federal legislation and regulation that challenge the use of psychedelic-assisted psychotherapy as a treatment option for opioid use disorder and concurrent mental health disorders?*

Arguably the largest barrier in federal legislation and regulation that challenges the use of psychedelics and psychedelic-assisted therapy as a treatment option in Canada is the *Controlled Drugs and Substances Act* and the *Food and Drugs Act*. Findings reveal that the Government of Canada (c/o Health Canada) controls various psychedelic substances under the *Controlled Drugs and Substances Act* which, as identified in the jurisdiction scan, is a federal statute that provides a framework for control over "substances that can alter mental processes and maybe produce harm to health or society when diverted to an illegal market or misused" (Government of Canada, 2022n). These controlled substances are listed in Schedules I-V of the *Controlled Drugs and Substances Act*, which include substances, such as psilocybin ("magic mushrooms"), lysergic acid diethylamide (LSD) and MDMA (Government of Canada, 2022; 2022n), that have been clinically proven to heal substance use and mental health disorders (Doblin, 2019; Haden et al., 2016; Schenberg, 2018; Jones et al., 2022; MAPS Canada, 2021; Jerome et al., 2020). These noted restricted substances are considered illegal unless authorized for medical, scientific or industrial purposes through a personal or physician/medical professional requested exemption under section 56 of the *Controlled Drugs and Substances Act* or a physician/medical professional request via the Special Access Program, under the *Food and Drugs Act* (Government of Canada, 2022; 2022n). The Special Access Program is currently available to patients with serious or life-threatening conditions in which conventional treatments have either failed, are unsuitable or are unavailable in Canada (Government of Canada, 2022f). As mentioned in the jurisdiction scan, according to some organizations, unlike the Special Access Program, psychedelics obtained under section 56 exemptions are often delayed (taking up to 300 days) and substances are often acquired illicitly making it more difficult to ensure safe supply for medical purposes (Filament Health, 2022).

Another barrier that was identified in the jurisdiction scan and could be attributing to the Government of Canada's legislation and regulation on psychedelics, is the lack of knowledge and understanding of the therapeutic administration of psychedelic-assisted psychotherapy. For example, Health Canada states on their website that short-term mental health side effects from psychedelics are hallucinations, anxiety, confusion, paranoia, "bad trips", and long-term [unfavourable] effects (Government of Canada, 2020), but does not state that some psychedelic like MDMA actually minimized anxiety (Jerome et al., 2020). While short-term effects stated by Health Canada may occur when using psychedelics, as by definition they are hallucinogens and can produce changes in human consciousness, perceptions, moods, emptions and cognitive processes (Alcohol and Drug Foundation, 2022; López-Giménez & González-Maeso, 2018); in some cases, the short-term impacts can lead to long-term successes. As the literature review noted, in clinical studies psychedelic-assisted psychotherapy has shown long-term cure of anxiety disorders and post-traumatic stress disorder (PTSD) by use of MDMA as it alters the

brain, eliminating anxiety and distress when facing unpleasant memories in order to engage more deeply in psychotherapy (Jerome et al., 2020). Setting in psychedelic-assisted psychotherapy is also critically important in shaping its success and ensuring clients remain comfortable and not overly stimulated as maybe the case in unsupervised settings, leading to the so called – "bad trips" (Carvalho et al., 2014). The types of administration practices are not clearly mentioned on Health Canada's website which can be significant on public perceptions of psychedelics.

Potentially, the language and generalization regarding psychedelics publicly on the Government of Canada's platforms could further perpetuate the negative socio-political perspectives historically surrounding psychedelics – which may present another barrier in public acceptance of psychedelic-assisted psychotherapy as a viable treatment option. As mentioned in the literature review, historically psychedelics have been used and explored for their therapeutic benefits, but following a sequence of events, the 1970's "war on drugs" put a quick halt to the distribution of psychedelics, restricting all access and associating these substances with anti-social, radicalism and political unrest (Haden et al., 2016). This particular politicization of psychedelics focused on extreme hallucinations conflating psychedelics with anti-social behaviour (Cottrell, 2015; Haden et al., 2016), while recent clinical research on psychedelics identifies the opposite, such as long-term cures for anxiety disorders, depression and PTSD (Jerome et al., 2020). As mentioned, Health Canada lists many short-term mental health side effects of psychedelics, including an emphasis on hallucinations and "bad trips", without reference to dosage, setting or administration practices (Government of Canada, 2022). As identified in the jurisdiction scan, some researchers in crisis intervention services, argue such unfavourable effects most commonly occur in unsupervised settings, such as festivals and through recreational use (Carvalho et al., 2014). In psychedelic-assisted psychotherapy it is administered in a controlled setting and is intentional with preparation, medication and integrated sessions (Reiff et al., 2020). Therefore, such public generalizations on Health Canada's website and lack of clarity regarding therapeutic psychedelic administration practices could possibly perpetuate inherent negative perspectives and further stigmatize Canadians from seeking and exploring this form of alternative therapy.

5. *Has psychedelic-assisted psychotherapy been approved to treat other mental health or substance use disorders in the Canadian population? If so, what strategies were taken to overcome the barriers within Canada's legislative and regulatory framework?*

While legislation and regulation in Canada has been capable of amending the *Controlled Drugs and Substances Act* and the *Food and Drugs Act* to support accessing and possessing psychedelics legally on a case-by-case basis, the federal Government of Canada has not approved psychedelics and/or psychedelic-assisted psychotherapy broadly for all Canadians. The findings revealed that the Government of Canada has approved the use of psychedelic substances, typically restricted drugs under the *Controlled Drugs and Substances Act*, to treat mental health and/or substance use disorders for Canadians with serious or life-threatening conditions where conventional treatments have either failed, are unsuitable or are unavailable in

Canada (Government of Canada, 2023; Government of Canada, 2022e; Government of Canada, 2022f; Government of Canada, 2022i). As identified in the jurisdiction scan, access to psychedelics can be achieved for these extenuating circumstances via the Special Access Program under the *Food and Drugs Act* or a section 56 exemptions under the *Controlled Drugs and Substances Act* (Government of Canada, 2022e; Government of Canada, 2020c).

As the jurisdiction scan identifies, the strategies that have been taken to overcome these federal legislative and regulatory barriers to obtain access to psychedelics and receive a section 56 exemption under the *Controlled Drugs and Substances Act* and/or access via the Special Access Program is clients working with their physician or an appropriately licensed healthcare professional with prescribing privileges and an advocacy group, such as TheraPsil or Numinus (Government of Canada, 2022f; Psychedelic Law, 2022). While participation through these organization is not essential, they can offer support and knowledge to clients throughout the request process and towards their psychedelic-assisted psychotherapy sessions.

Moreover, at the provincial level, as of January 16, 2023, the Government of Alberta is the first province to regulate psychedelics for therapeutic use to treat mental illness, including establishing quality and safety requirements under the *Mental Health Services Protection Regulation* and licensing administrators of psychedelic-assisted psychotherapy under the *Mental Health Services Protection Act* (Government of Alberta, 2022c).

As psychedelics and psychedelic-assisted psychotherapy remain illegal unless the Government of Canada (via Health Canada) provides exemptions, special access or allows access to ibogaine by prescription through the Prescription Drug List (PDL), it is unknown what other strategies have been taken to overcome the barriers within Canada's legislative and regulatory framework.

6.2 New Themes and Ideas (Unexpected Findings)

Saskatchewan Acknowledges the Relationship Between Trauma and Problematic Substance Use

As identified in the jurisdiction scan, Saskatchewan was the only province that acknowledged that the vast majority of individuals experiencing opioid misuse and addiction have concurrent or past experiences of trauma or violence (Government of Saskatchewan, n.d.). Through their Emergency Treatment Fund Bilateral Agreement with the Government of Canada (April 1, 2018 to March 31, 2023), Saskatchewan committed to enhancing existing treatment approaches and building capacity through training in Trauma Informed Practice, including adjusting treatment and care plans based on unique needs of the client to address "root causes" of problematic substance use (e.g., the impact of trauma on the lives of people with substance use disorders). In Budget 2022, the Government of Saskatchewan continued this commitment by investing $403 million in mental health, $67 million in addiction supports, including $8 million to fund targeted initiatives that provide counselling and treatment, as well as advancing preventative measures (particularly for youth), and engaging in consultation with people with lived experiences

(Government of Saskatchewan, 2022). The results section of the thesis revealed that in 2022 Saskatchewan experienced the greatest decline in rates of apparent toxic opioid deaths in comparison to the other selected provinces and territories. It is unclear if their treatment approach to the substance use disorder and concurrent past trauma played into their successful declines, but based on the evidence from the thesis treating the substance use disorder and concurrent mental health disorders together is fundamental to recovery (National Institute of Mental Health, n.d.). This could present a promising trend of approaching both the opioid use disorder and the concurrent mental health disorder(s)/trauma together towards reduced rates of toxic opioid deaths, recovery and restored mental wellness.

Enhanced Accessibility Opportunities with Psychedelic-Assisted Psychotherapy

In an effort to reduce accessibility barriers, the Government of Canada increased supports for federally-funded treatment centres to enhance their virtual treatment services (Government of Canada, 2022a). As the jurisdiction scan identified, the Government of Alberta is a strong proponent in supporting "individual pathways to recovery" and in response to treatment gaps due to transportation, in-person requirements, employment demands, and limited childcare, they launched a virtual program to support individuals entering opioid agonist therapy and experiencing accessibility challenges (Day et al., 2022). This study identified that accessibility to opioid agonist therapy can be a challenge for individuals in a variety of situations, such as those living in rural and remote areas. Therefore, this unexpected discovery could present an opportunity for psychedelic-assisted psychotherapy to be considered for those in rural and remote areas, where frequent therapy and/or virtual options may not be possible (i.e., no access to transportation or reliable internet). With psychedelic-assisted psychotherapy administered over distinct sessions, clients could attend in-patient clinics less frequently over a shorter duration in comparison to ongoing opioid agonist therapies and psychosocial therapies, which could prove helpful for rural and remote populations across Canada. Given the Government of Alberta's newly regulated psychedelic initiatives, this could be an opportunity worth exploring, either to be utilized within the virtual treatment service or as an out-patient treatment with less commitment than opioid agonist therapy and conventional psychotherapy.

6.3 Summary

The observation based on the research from the literature review and jurisdiction scan, is that the common approaches to the opioid crisis have focused heavily on reducing harms and less on mental health treatment options to address the concurrent mental health disorders which were identified earlier in the thesis to be associated often with opioid use disorder. It was observed that funding for mental health supports and resources have been generalized across Canada and tacked on to the crisis response to support a larger demographic, not holistically addressing root causes of opioid use disorder towards long term mental health and substance use healing. One exception was Saskatchewan who early on in the opioid crisis acknowledged and invested in the relationship of opioid misuse and addiction with concurrent or past experiences of trauma and

violence. According to the results section, Saskatchewan was the only province out of the five and Canada more broadly, that reported a decline in their rates of apparent opioid toxicity deaths in 2022. However, the reason for this is not clearly known.

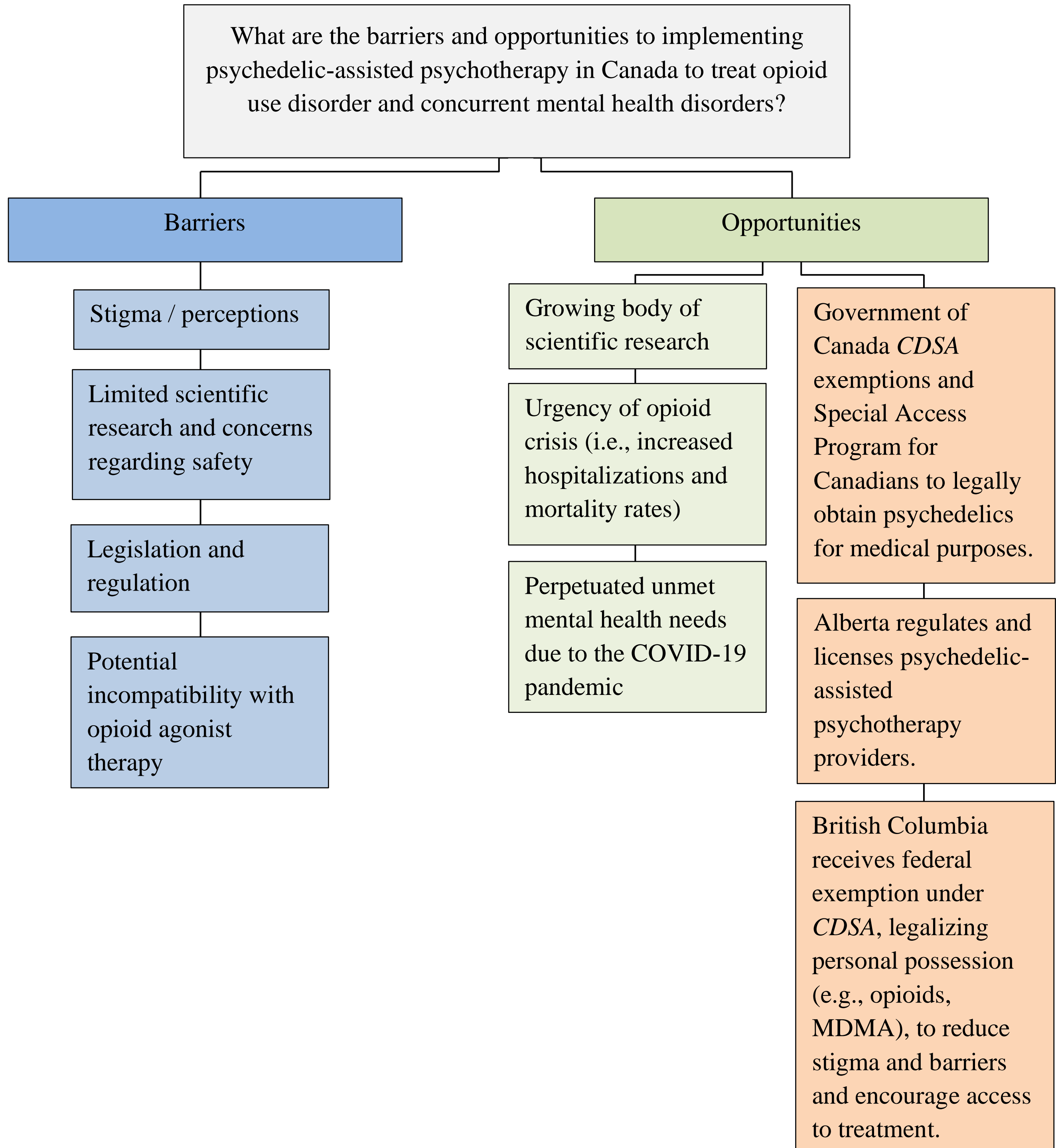
Further, Canada's federal legislation and regulation and research limitations related to psychedelic-assisted psychotherapy (i.e., long-term impacts, compatibility with other substances) are likely the largest barriers to psychedelic-assisted psychotherapy becoming a complementary treatment option to respond to the opioid crisis. Ongoing research to determine psychedelic-assisted psychotherapy's ability to work alongside opioid agonist therapy or other psychedelic-assisted psychotherapies, like ibogaine, will need to be explored. Meanwhile, the province of Alberta has begun supporting the regulation and licensing of administrators of psychedelic-assisted psychotherapy to approach mental health treatment, the first of the highlighted provinces and territories to do so.

Moving to the final chapter, we will discuss any further research implications and recommendations for consideration.

6.4 Revisiting the Conceptual Framework

As a result of the new findings from the jurisdiction scan, the conceptual framework has been adjusted accordingly below. The main barriers that remain without clearly identified opportunities from the jurisdiction scan are stigma/perceptions and research regarding safety and potential incompatibility with opioid agonist therapy. New opportunities related to provincial and federal legislation/regulation offer potential avenues for psychedelic-assisted psychotherapy becoming more widely used for the treatment of opioid use disorder and concurrent mental health disorders.

Figure 4: Conceptual Framework from Literature Review and Jurisdiction Scan



7.0 Conclusion and Recommendations

7.1 Introduction

This thesis aimed to provide a better understanding of the policy, legislative and regulatory initiatives that were implemented to respond to the opioid crisis in Canada, including how well these have supported treatment for opioid use and concurrent mental health disorders. Through both the literature review and jurisdiction scan, the findings uncovered potential answers as to what has been done and what could be done differently to meet the gaps and address the root causes of opioid use disorder for many of those that struggle.

The following sections will reflect on how this thesis has contributed to the strategic and research implications, limitations to the thesis and suggestions for future research, as well as a path forward via recommendations.

7.2 Strategic or Research Implications

Throughout the thesis, it was apparent that the literature review grounded the work and the jurisdiction scan provided an overview of what the Canadian federal government, provinces and territories initiated in response to the opioid crisis. The literature review revealed a number of connections between opioid use disorder and concurrent mental health disorders, such as depression, anxiety and particularly trauma/post-traumatic stress disorders. The literature review also provided an investigation into the clinical research on the effectiveness of psychedelic-assisted psychotherapy to treat these disorders of mental health and substance use. Most notably, MDMA is in Phase 3 trials and has shown to have long-term results on treating and curing clinically diagnosed post-traumatic stress disorders. Psilocybin or “magic mushrooms” have also been identified for their treatment impacts on anxiety, depression and smoking cessation. As well, ibogaine has been identified to support withdrawal management and reduce cravings in those experiencing opioid dependence/use disorder (Camlin et al., 2018; Noller et al., 2018; Wilson et al., 2020).

However, the jurisdiction scan identified apparent barriers that challenge psychedelics and therefore psychedelic-assisted psychotherapy to becoming a viable treatment option across Canada. One barrier being limited research on psychedelics ability to safely treat opioid use disorder while interacting with opioid agonist therapy, a treatment often used to manage opioid withdrawal. In addition, and arguably the largest barrier is Canada’s federal legislative and regulatory policies restricting drugs, like psychedelics, under the *Controlled Drugs and Substances Act* limiting exemptions and access to those requiring end-of-life care or living with untreatable illnesses.

Yet, amidst these barriers, there are a number of opportunities that have been revealed throughout the thesis, including Alberta’s support of psychedelic-assisted psychotherapy and own provincial regulations to ensure safe administrations, Saskatchewan’s acknowledgement and

emphasis on addressing both the opioid use disorder and past trauma experiences, British Columbia's receipt of a federal exemption under the *Controlled Drugs and Substances Act* to legalize personal possession of small amounts of substances, including MDMA. The Government of Canada has also publicly acknowledged the ongoing research of psilocybin and MDMA in therapeutic settings and potential benefits, and have opened the Special Access Program under the *Food and Drugs Act* making it possible for Canadians to obtain a more regulated type of psychedelic substance that may not be available within Canada.

As the thesis underscores the relationship between mental health/lived experiences and connected pathways to opioid use disorders, the compounding effects of the COVID-19 pandemic on mental health and the opioid crisis, ongoing promising research into psychedelic-assisted psychotherapy, and the federal, provincial and territorial governments' continued efforts to manage the opioid crisis and minimize the mounting rates of apparent opioid toxicity deaths – what better time than the present to open our minds to psychedelic-assisted psychotherapy to treat opioid use disorder, mental health disorders, and potentially improve our current response to the opioid crisis?

7.3 Limitations of Analysis and Areas for Further Research

Noting one limitation of the jurisdiction scan is that some provinces and territories had more publicly available information on their opioid crisis response policies, legislation and regulation than others. The reason for this is not clearly known, but presumably this could be based on the duration, extent and political focus on the issue in each province/territory. As identified in the literature review (which contributes to the wicked nature of this problem), is the lack of consensus on the extent of the opioid crisis and uncoordinated ideas of appropriate solutions (Morin et al., 2017) which might be why some provinces/territories have more available response information than others. In addition, details of specific funding allocations per policy initiative is not easily identified in the literature. Further research is required to determine where funding has been used and potentially where funding can be leveraged to support alternative and innovative forms of therapy, such as psychedelic-assisted psychotherapy. Potentially reaching out to government officials within each province and territory involved in the opioid crisis response, such as the Task Forces, could have provided more context and robust information allowing the thesis to be more conclusive regarding their specific responses to the opioid use disorder and the concurrent mental health disorders.

Furthermore, an exploration of the strategies (e.g., petitions, policy suggestions; academic research) that that have been provided to overcome Canada's federal legislative and regulatory barriers related to psychedelics is worth exploring in depth. This research could help determine what more strategically can be done and what hasn't worked in the past, if psychedelic-assisted psychotherapy is to be used more broadly across Canada as a viable treatment option for mental health and substance use disorders. Further research is required to explore what policy models, such as those mentioned in the literature review by Haden et al. (2016), proposing "a public

health framework for regulating psychoactive substances", including traditional and Indigenous uses of psychedelics and exploration in to drug policy and psychedelic legalization and regulation within Canada. In exploring potential policy navigation, it could support governments to adopt a legislative and regulatory system that is more supportive of psychedelic-assisted psychotherapy.

Based on revisiting the Conceptual Framework, as mentioned above, the main barriers that could benefit from further exploration is how to overcome stigma/perception, research on safety and potential incompatibilities with opioid agonist therapy, and government recognition and physician compensation for psychedelic-assisted psychotherapy. In addition, the relationship between the COVID-19 pandemic and the exacerbated opioid crisis, including ways to surveillance mortality outcomes of those experiencing opioid use disorder alongside concurrent mental health disorders. Another area for future research, that could present as a barrier, would be the potential safety and efficacy concern of administering multiple psychedelic-assisted psychotherapies (e.g., ibogaine-assisted psychotherapy session(s) for treatment of opioid dependence/use disorder and MDMA-assisted psychotherapy session(s) for treatment of PTSD).

Stigma and Perceptions

As the jurisdiction scan revealed, in 2020 the opposition related to the amendment of the *Food and Drug Regulations* and the *Narcotic Control Regulations* to restore access to restricted drugs through the Special Access Program was a mere two percent of responses, while 80% were in support (Government of Canada, 2021e). The two percent of respondents were concerned that the amendment would include cocaine, expressing that physicians may prescribe cocaine as a first line of treatment for stimulant use disorders and depend on safe supply instead of advocating for detox, treatment and recovery (Government of Canada, 2021e). There was no opposition for psychedelics. More research on these types of public and organizational perceptions, could be useful for future policy.

An example of exploring this topic, surveying Canadians on their perception of psychedelics and psychedelic-assisted psychotherapy and their comfortability and reasons for engaging or not engaging in this type of healing. Demographics could include a mix of people with lived experience, front-line workers, physicians, relevant organizations, similar to respondents consulted in Health Canada's Notice of Intent. By researching the level of engagement participants are willing or unwilling to have with psychedelics, or their perceived effectiveness, this information could provide the Government of Canada and provinces/territories knowledge on public perception, level of therapeutic understanding, and appetite for alternative healing among their unique populations. In better understanding the level of engagement, perceptions, knowledge, and potential stigma of using psychedelics, this could help support policy and decision makers decide whether building a psychedelic framework could work to meet the needs of Canadians/provinces/territories.

Psychedelic-Assisted Psychotherapy to Treat Opioid Use Disorders

Another addition, while there was evidence-based literature on psychedelic-assisted psychotherapy to treat mental health disorders, such as anxiety, depression and PTSD, and substance use disorders, such as smoking, alcoholism and opioid dependence/use disorder, there was a recognition of limited evidence on psychedelics treating mental health and substance use disorders concurrently, except early research on ibogaine and depression, which should be explored further (Wilson et al., 2020). Further clinical research of the short- and long-term success of psychedelic-assisted psychotherapy on opioid use disorders would be helpful, including investigating any negative long-term impacts of psychedelic use.

Moreover, although rare, some instances of adverse reactions related to genetics and other risk factors have been identified from psychedelic use (Li et al., 2015; Schlag et al., 2022); therefore, if legalization of psychedelic-assisted psychotherapy is to be widely implemented and used to treat substance use and mental health disorders, such as opioid use disorders and concurrent mental health disorders, relevant screening protocols and physician/administrator training will need to be developed to ensure continued patient safety. If opioid agonist therapy is to be used in addition to administrations of psychedelic-assisted psychotherapy, research on compatibility, safety and efficacy is important to explore. Further, if multiple psychedelic substances, such as MDMA for PTSD and ibogaine for opioid dependence/use disorder are administered in psychedelic-assisted psychotherapy sessions, compatibility, safety, and efficacy will need to be explored as well (e.g., dosage, simultaneous sessions or intervals).

COVID-19, the Opioid Crisis and Opioid Use and Mental Health Disorders

Another area worth exploring is the relationship between and surveillance of rates of apparent opioid toxicity deaths, opioid use disorders and declines in unmet mental health needs perpetuated by COVID-19 pandemic related stressors. As the literature identified, correlations between mental health and substance use are significant, particularly with opioid use disorder and mental health disorders (Amari et al., 2011; Fink et al., 2015; Lawson et al., 2013). As discussed, one study found increased hospitalization and mortality among those living with opioid use disorder and concurrent mental health disorders (Morin et al., 2020) and another found that adverse drug effects from prescribed opioids have the lowest percentage of co-diagnoses of mental health disorders (Government of Canada, 2021b). The data suggests that the those most vulnerable to opioid related hospitalization and mortality are from those accessing illicit opioids rather than prescribed opioids, and that those with unmet concurrent mental health disorders are more susceptible. Given the impact the COVID-19 pandemic has had on mental health, its important these challenges continue to be monitored and responded to efficiently. Current Public Health Agency of Canada (PHAC) modelling suggests (until June 2023), rates of apparent opioid toxicity deaths are not expected to decline and reach pre-pandemic levels with current approaches (Government of Canada, 2022m). As governments work to address these unmet mental health needs and the increasingly concerning rates of apparent opioid toxicity

deaths in many provinces and territories, it would be helpful to explore how these variables relate and if surveillance methods can be adapted or leveraged from other databases to monitor these relationships. By monitoring the relationship of toxic drug use and increases in opioid use disorder and concurrent mental health disorders following the COVID-19 pandemic we could potentially better understand how to intervene. Increased monitoring could also measure successes and challenges should an alternative treatment option like psychedelic-assisted psychotherapy be introduced as an opioid crisis response initiative.

Psychedelic-Assisted Psychotherapy Physician Compensation

Other provinces and territories would be interesting to explore in terms of their approach to the opioid crisis and subsequent opioid use disorders and concurrent mental health disorders. Of note, while not identified within parameters of the jurisdiction scan, Quebec became the first province in Canada to pay doctors for psilocybin-assisted therapy (Dunne, 2022). Following a medical exemption provided by Health Canada in June 2022, two doctors received monetary compensation from the Government of Quebec for providing the psychedelic treatment to a patient (Dunne, 2022). The Government of Quebec has recognized psilocybin as a therapeutic treatment option and covers the cost of psilocybin sessions for patients who have been granted medical access (Dunne, 2022). As the findings reveal of Alberta, physicians/administrators should receive licensing, have regulatory oversight, but in addition – as Quebec has formalized – be compensated appropriately by acknowledging psychedelic-assisted psychotherapy as a viable medical option. If psychedelic-assisted psychotherapy is to be considered a medical option to treat opioid use disorder and concurrent mental health disorders, appropriate compensation could be explored to incentivize physicians. Future research could investigate if other provinces and territories have followed in Alberta and Quebec's footsteps that were not highlighted in this thesis.

Summarized below is the information identified in the above section, including examples of how this research could be explored and the benefit/purpose it could have on the future of opioid crisis response, overall substance and mental wellness, and how Canadian governments can leverage this knowledge for decision-making.

Figure 5: Areas for Future Research, Examples and Purpose

Areas for Further Research	Examples of Approach and Purpose
Opioid Crisis Response	• Detailed breakdown of funding allocations to each policy tool and initiative within each jurisdiction. Potentially identify where funding could be leveraged for innovative treatment options like psychedelic-assisted psychotherapy. • Conversations with government officials/front-line services to identify and fill gaps of opioid crisis response that was not readily available online. Perhaps better understand perceptions on the extent of the problem and coordination of appropriate responses. • Further exploration of Saskatchewan's decrease in rates of apparent opioid toxicity deaths and their prioritization of trauma informed care. • Explore monitoring and surveillance capabilities related to opioid toxicity deaths, such as recording those with concurrent opioid use and mental health disorders to better understand this relationship. • Information could further identify and respond to treatment option and evaluation gaps, and identify funding streams to support options like psychedelic-assisted psychotherapy.
Strategies used to Overcome (Psychedelic) Drug Policy in Canada	• Explore and identify how citizens and advocacy organizations have influenced or attempted to influence psychedelic drug policy in Canada. • Lessons learnt and successes could be leveraged to support future legislation and regulation amendments in Canada if psychedelic-assisted psychotherapy becomes a treatment option in the opioid crisis response.
Appetite for Psychedelic Therapy in Canada	• Survey Canadians on their perceptions, stigma, knowledge and understanding of psychedelics as a form of medicine.

	• Engage in focus groups with people with lived experience of opioid use disorders and/or mental health disorders to determine their willingness to participate in a Pilot Program for example. • Information identified could help support governments to make informed decisions based on social acceptance and where gaps in knowledge could be supported by education.
Psychedelic Substance Compatibility with Opioid Agonist Therapy and/or Ibogaine	• Clinical research and/or jurisdictional exploration of the safety and efficacy of psychedelics alongside opioid agonist therapy. • Clinical research and/or jurisdictional exploration of the safety and efficacy of psychedelic compatibility with other psychedelics, like ibogaine. • Information could help inform governments on appropriate next steps, mitigation strategies to ensure safety, and overall comfortability for citizens who wish to engage with a psychedelic-assisted psychotherapy treatment option for opioid use disorder.
COVID-19 and the Opioid Crisis, Opioid Use Disorder and Mental Health Disorders	• Deep dive into the relationship between COVID-19 and its impact on those with opioid use disorders and concurrent mental health disorders. • Information can determine how and where governments should respond to support those living with concurrent disorders and if alternative treatment options like psychedelic-assisted psychotherapy could support these demographics.
Psychedelic-Assisted Psychotherapy, Regulation and Legislation and Physician Compensation	• Explore how and where jurisdictions (i.e., nationally and internationally) have adopted psychedelic-assisted psychotherapy as a mainstream treatment option for substance use and mental health disorders. • Explore what legislative and regulatory frameworks exist in these jurisdictions and how/if physicians are compensated similar to other forms of medical treatment administration.

	• Information for this research could support governments of Canada to determine and develop legislative and regulatory approaches and physician compensation to encourage medical participation if psychedelic-assisted psychotherapy becomes a new regulated treatment option.

7.4 Recommendations

Based on the research from the literature review and jurisdiction scan, the following recommendations have been proposed to the Government of Canada and the provincial and territorial governments for consideration. In no particular order these are:

Recommendation 1: Government of Canada and provinces/territories partner to develop a Pilot Program for those living with opioid use and concurrent mental health disorders.

The Government of Canada could adopt a pilot program in relationship with provinces/territories to support candidates that have been deemed untreatable of their opioid use disorder and concurrent mental health disorder(s). Access to psychedelics for use of psychedelic-assisted psychotherapy via the Special Access Program could be fast tracked and participants can be screened by their physician for any potential medical concerns that have been linked to adverse psychedelic reactions prior to applying. Funding could be provided by the Government of Canada, through a relationship similar to that created between provinces/territories in the Emergency Treatment Fund Bilateral Agreements identified in the thesis to respond to the opioid crisis. Participants can sign appropriate consent and cohorts can be followed, documenting successes and challenges with this model of treatment. This pilot could support identifying the compatibility, safety and efficacy of opioid agonist therapy alongside psychedelic-assisted psychotherapy to address the concurrent mental health disorder treatment gap. Further, where deemed safe and possible (e.g., dosage, administration intervals), ibogaine-assisted psychotherapy alongside another psychedelic-assisted psychotherapy (e.g., MDMA for PTSD), could be administered to identify compatibility and efficacy in addressing both the opioid use disorder and concurrent mental health disorder. Findings from these cohorts could inform and support future policy, legislation and regulation adaptations related to psychedelic-assisted psychotherapy at the federal, provincial and territorial levels.

Recommendation 2: Government of Canada and provincial/territories establish a regulatory framework and body to ensure the safety and efficacy of administration methods of psychedelic substances for purposes of psychedelic-assisted psychotherapy.

To ensure efficacy and safety of psychedelic-assisted psychotherapy in support of opioid use disorder and concurrent mental health disorder treatment, thorough training of administrators (informed by both traditional Indigenous and clinical practices), building a regulatory body for

trained professionals and recognized traditional healers, and investing in experienced psychedelic substance growers and distributors to ensure quality control should be considered. Early exploration of safety, resources and compatibilities to treat opioid use disorders could pave a path forward for psychedelic-assisted psychotherapy being recognized as a viable medical option. Experiences can be leveraged and modelled from the Alberta Government and other international jurisdictions that have successfully implemented psychedelic policy initiatives, legislation and regulation.

Recommendation 3: Government of Canada and provincial/territories leverage reputable partners to reduce stigma, increase awareness/ education and autonomy associated with psychedelics/psychedelic-assisted psychotherapy.

As identified in the thesis, anecdotal discussions with program leaders in the field of psychedelic medicine and a cursory review of the literature, barriers to psychedelic use in society could be related to gaps in knowledge (Carhart-Harris et al., 2018) and concerns around additional substance dependence, including "generalizability and control group limitations" (Aday et al., 2020). Canadians should be made aware of psychedelics/psychedelic-assisted psychotherapy as a form of healing to support their recovery, while still acknowledging potential gaps in research related to long-term impacts and incompatibilities. Key partners could be the Government of Canada/Provincial/Territorial (e.g., promoting the cohort research approach), the Canadian Mental Health Association (CMHA), the Canadian Counselling and Psychotherapy Association (CCPA), the College of Family Physician of Canada (CFPC), and the various psychedelic organizations that have been supporting Canadians through the process of requesting exemptions through Health Canada. By engaging and enlisting a variety of reputable entities, awareness can be increased and Canadians could become more hopeful and comfortable in exploring, requesting and accessing these alternative forms of treatment.

7.5 Final Reflections

Psychedelic-assisted psychotherapy has gained momentum and support in recent years across the world as citizens and governments search for alternative therapies where conventional therapies have been inadequate. With the onset of the COVID-19 pandemic, coupled with the ongoing opioid crisis, Canadians faced an immense decline in their mental health, including increased rates of substance use disorders. Modeling developed by the Public Health Agency of Canada (PHAC) projects that opioid-related deaths through to June 2023 will remain high or may decrease slightly, however, they are not expected to reach lower levels seen prior to the COVID-19 pandemic (2022m). As the Government of Canada, provinces and territories have allied together to respond to the opioid crisis with much needed harm reduction, treatment, awareness/education, enforcement and surveillance, it is not enough and rates of apparent opioid toxicity deaths continue to soar. With research frequently connecting the relationship between substance use and mental health disorders, we cannot ignore the incontestable importance of addressing both ailments holistically and addressing the root causes of opioid use disorder.

Examples from Saskatchewan could be a guidepost for other Canadian jurisdictions, as their acknowledgement of this connection could potentially be reflective of their decreased opioid toxicity mortality statistics. While there is more research required to ensure the safety and efficacy of psychedelics from an opioid agonist therapy compatibility standpoint or a multi-psychedelic-assisted psychotherapy approach, we must remain open to psychedelic-assisted psychotherapy as an option for those that need it most. Psychedelic-assisted psychotherapy has been proven to heal anxiety, depression, post-traumatic stress disorder, smoking, alcoholism, and opioid dependence/use disorder – why not use these substances to simultaneously treat opioid use disorder and the concurrent mental health disorder(s) that accompany them? Policy initiatives implemented across Canada in response to the opioid crisis over the past seven years have not been able to contain and reduce the crisis. By adopting informed guidance, policy frameworks and appropriate legislation and regulation, psychedelic-assisted psychotherapy has the potential to be the change Canadians need for the opioid crisis and their overall mental wellness.

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