A Review of Prescribed Safer Supply Programs Across British Columbia: Recommendations for Future Action

A Report from the Office of the Provincial Health Officer

December 2023

Purpose: To provide information on implementation of the provincial Prescribed Safer Supply (PSS) policy, and recommendations to improve benefits and minimize harms.

Background: In 2016, a public health emergency was declared in response to a sharp increase in drug related deaths in British Columbia (BC). Deaths due to drug toxicity are primarily due to harmful contaminants in the unregulated supply, including potent opioid analogues such as fentanyl or carfentanil; benzodiazepines; and other potent contaminants such as xylazine. The drug poisoning crisis has continued to escalate with increasing numbers of deaths annually, despite ongoing health interventions to enhance access to harm reduction, treatment, and recovery. The crisis has also been exacerbated by the pandemic, when shutdowns resulted in significant barriers to accessing medical and harm reduction services while at the same time the global drug trade was disrupted leading to rapidly changing availability and toxicity of drugs on the illicit market.

Addressing this complex public health emergency requires a suite of interventions along a continuum of care, including:

- prevention (e.g., education, mental health supports, appropriate pain management etc.)
- intervening early (e.g., integrated child and youth teams, community counseling etc.);
- reducing risk to save lives (e.g., overdose prevention sites, naloxone kits, drug checking etc.);
- connecting people to care where and when they need it (e.g., outreach, treatment, withdrawal management, opioid agonist therapy (OAT), acute care services etc.); and,
- creating pathways to recovery and wellness so people can live healthy lives (e.g., building connections, peer support, housing, community recovery sites etc.).

PSS - the prescribing, dispensing, and administration of pharmaceutical-grade alternatives to the poisoned supply – is part of this continuum. PSS was implemented as an approach to reduce substance use related harms including toxicity-related injuries (e.g., anoxic brain injury) and deaths; enhance connections to health and social supports; support titration, stabilization and engagement onto treatment; and improve overall health and wellness for people who use substances.

In the early stages of the pandemic, once the compounding impacts on people who use drugs (PWUD) from the poisoned supply and the measures taken to control the transmission of COVID became clear, guidance was developed to support access to pharmaceutical alternatives for people who access the unregulated supply. Called *Risk Mitigation in the Context of Dual Public Health Emergencies (RMG),* these provided clinical guidance on how to prescribe hydromorphone tablets and other medications (e.g., stimulants) as well as regulated drugs such as alcohol, tobacco and cannabis.

The purpose of this guidance was to support healthcare providers to mitigate their patients' compounded risks of COVID-19, withdrawal, cravings and overdose risk. In July 2021, the Ministry of Mental Health and Addictions announced a new initiative expanding on learning from RMG, *Access to Prescribed Safer Supply in British Columbia: Policy Direction*. This policy was designed to address the drug poisoning crisis by improving access to prescribed pharmaceutical alternatives (i.e., PSS) to help separate people from the unregulated and poisoned supply.

During implementation, serious concerns have been raised regarding the benefits and harms of the PSS approach for both individuals accessing PSS and the broader population. Potential benefits include preventing toxic drug poisonings and deaths, improving access and engagement in health and social services as well as reducing associated healthcare costs. However, harms of the PSS approach may include potential population level harms such as diversion to non-intended populations, expanded access and availability of opioids for youth, and normalization of this access leading to risky use, and reduced incentives for recovery. Other concerns include public acceptance, and uncertainty over long-term population-level effects (e.g., increasing the prevalence of substance use disorders).

It is critical through this process to affirm the inherent rights and title of B.C. First Nations, and we recognize the right to health and wellness of all First Nations, Métis, and Inuit people living in the province. Indigenous Peoples and communities continue to be disproportionately impacted by this crisis that compounds the harms of colonial history, anti-Indigenous racism in the health system and intergenerational trauma. We must uphold our foundational obligations to Indigenous Peoples provided by the *BC Declaration on Rights of Indigenous Peoples Act* (BC DRIPA) by fully realizing First Nation, Metis and Inuit peoples' right to: 1) to the highest attainable standard of physical and mental health 2) access without discrimination to all social and health services and 3) access to traditional medicines and maintaining their health practices (*BC Declaration on Rights of Indigenous Peoples Act*, Article 24). This work involves actively identifying policies, regulations and structures that affirm white supremacy and racism and actively dismantle them and champion a trauma/violence informed, anti-racist and culturally safe policies and programs.

In light of the concerns raised and to find ways to maximize the benefits, and minimize the harms of PSS, including amongst Indigenous peoples, the Provincial Health Officer (PHO) was asked to review the provincial policy and implementation. This review aimed to better understand challenges faced by PSS prescribers and by people who accessed or tried to access PSS, as well as the broader societal impacts of current PSS policies and programs. Ultimately, the purpose of this review is to advise on whether this policy should be continued, and if so, what recommendations should be considered to improve benefits and minimize harms.

The recommendations and advice in this document support a public health approach to PSS that endeavours to 1) respect the autonomy and right to self determination of people who use drugs (PWUD), 2) support health care providers and others caring for people who use drugs, 3) address the underlying determinants of health, stigma, discrimination, racism and health inequities experienced by PWUD. In addition, we endeavoured as much as possible to be informed by those with lived and living experience and, be pragmatic and evidence-based.

Process: This office approached this review as follows.

1) **Review of documents and evidence** on issues of PSS and other harm reduction services.

The following documents were reviewed:

- Risk Mitigation in the Context of Dual Public Health Emergencies ("Risk Mitigation Guidance"), BC Centre on Substance Use
- Opioid Use Disorder Practice Update, BC Centre on Substance Use
- Stimulant Use Disorder Practice Update, BC Centre on Substance Use
- Opioid Use Disorder Guidelines, BC Centre on Substance Use (forthcoming)
- Access to Prescribed Safer Supply in British Columbia: Policy Direction, Ministry of Mental Health and Addictions/Ministry of Health
- Alternatives to the Toxic Drug Supply: An Ethical Analysis, Dr. Eike-Henner Kluge for the Ministry of Mental Health and Addictions

Additionally, a review of implementation challenges and evidence from the BC Centre on Substance Use, summarizing published literature, public and internal provincial monitoring data, and clinician concerns was developed to inform my review. This **BCCSU evidence scan** is enclosed (Appendix A).

2) **Consultation with Key Stakeholders** including clinicians (from the Downtown Eastside (DTES), urban outside DTES, and rural, with representation from all health authorities including First Nations Health Authority (FNHA), and clinicians working with First Nations communities and Indigenous peoples), people with lived and living experience (PWLLE) of substance use, families and caregivers of people who use substances, and academics researching and evaluating prescribed safer supply. Clinicians included physicians in a range of specialties from addictions medicine, psychiatry, family practice, emergency medicine, intensivists, hospitalists, pediatrics as well as nurse practitioners, registered nurses and registered psychiatric nurses. Further details on this engagement process are available in the enclosed **Engagement** report (Appendix B).

3) **Ethical Analysis** of PSS using a population and public health lens, conducted by the Provincial Health Ethics Advisory Team. A population health ethical analysis differs from a clinical ethical analysis in that it considers how benefits may accrue to one group while harms may be experienced by a different group, as opposed to clinical ethics where the patient is the one experiencing both potential benefits and harms. Analysis was conducted in supplement to the earlier provincial ethical analysis, which took a largely clinical ethical analysis approach and was also conducted prior to release of some of the newer monitoring and evaluation findings. The **Ethical Analysis** is enclosed for your review (Appendix C).

My recommendations are based on a public health approach to substance use, incorporating a synthesis of the findings of the evidence review, the engagement process, and the ethical analysis.

Key Considerations:

The *BCCSU evidence scan* highlights that the evidence base of benefit for PSS is quite limited. This is appropriate and not surprising for a new intervention: high quality research takes time, and the peer-review process, though sometimes lengthy, ensures a degree of quality which is important to the creation of evidence.

Evidence for PSS is promising as it is largely positive, but not at this point strong enough for this intervention to be described as fully evidence-based. Most of the limited published peer-reviewed studies lack a control or comparison group and the actual intervention received by study participants is in most cases a combination of broader access to wrap around health services including PSS, Opioid Agonist Treatment (OAT), and primary care, making it difficult to attribute any benefits to PSS alone.

The evidence scan demonstrates that more needs to be done to investigate the potential for harm at the population level. Some diversion is occurring; however, the extent and impacts are unknown. Diversion to people at risk of drug poisoning may be of benefit, while diversion to people who would otherwise not use unregulated drugs is harmful. The BC Coroners Service and the BC Centre for Disease Control have each produced some helpful analyses and, although they have limitations, these analyses are reassuring. In particular, data show there is no increase in Opioid Use Disorder (OUD) diagnoses amongst youth, or in any age group, since the RMG guidance were released in 2020 and PSS was initiated in 2021. However, primary data collection with youth is limited aside from a pre-publication analysis from the At Risk Youth Study. Additionally, policing data (e.g., drug seizures), while also reassuring, have not been systematically explored.

There are many strengths to the community-based mixed methods evaluation currently underway through the contracted PSS evaluation team. However, the small number of participants accessing PSS has made it difficult to complete the quantitative studies and

more time is needed for data collection. In addition, systematic evaluation of potential unintended consequences is outside the scope of the current evaluation.

Finally, the evidence scan describes significant operational challenges to implementation of PSS and outlines substantial issues with implementing access to alternatives to the unregulated market through a prescriber-based system. The evidence scan highlights PSS as an intervention has had a very limited reach compared to the estimated number of eligible participants, and one which has been delivered almost exclusively to people with diagnosed opioid use disorder. Conversely, past diagnoses of OUD are relatively uncommon among people dying of drug poisoning. The evidence scan notes that implementation of PSS is placing strain on a health care system already in distress. And the reviewed literature demonstrates that the available medication options are not providing viable alternatives to the unregulated market for many people, undermining their effectiveness at separating people from the toxic supply, and increasing the potential for diversion.

The *Engagement report* highlights the substantial and very real fear that people who use drugs (PWUD) are experiencing about the potential for the PSS policy to be discontinued or for clinicians to choose to discontinue prescribing independent of a policy change. Their experience is that policy and prescribing decisions are being made based on anecdotal concerns about harm, and without real evidence. They expressed very clearly the distress being felt that un-quantified potential harms to others may be deemed more important than the potential of PSS to decrease deaths from toxic drugs, which they experience among their friends and community on a monthly basis. These fears in and of themselves are leading to harms in this community.

Clinicians in my consultations described a diverse set of experiences with and perspectives on PSS, from having seen patients experience life-changing benefit to having seen patients face substantial harm. Many described an experience of “clinical futility”, i.e., that most of their patients receiving tablet hydromorphone in particular, were not experiencing improved health outcomes, including not experiencing lower drug poisoning risk. However, they contrasted the experience of limited effect for many with descriptions of situations in which substantial benefit was achieved for select patients, and generally urged that they do not lose the ability to prescribe PSS, including hydromorphone, as an option in those patients for whom they think clinical benefit could be achieved.

In these consultations it became clear that what was referred to as PSS was a spectrum of use of prescribed medications (most of which was tablet hydromorphone) along a continuum from harm reduction (i.e., providing PSS alone to people at risk of death from the toxic drug supply) to use of PSS medications in medical models, especially to support initiation and maintenance on OAT. Data support this as over 90% of those who accessed PSS had a prior diagnosis of OUD and most had received or were receiving OAT within weeks of receiving prescriptions for PSS. In discussing PSS, clinicians described use to

titrate people more rapidly on OAT, to manage withdrawal symptoms, to maintain PWUD when they were in hospital in order to continue treatments, as well as initiating PSS as a means of connecting people to treatment and other social services.

There was substantial variation in experience depending on the area clinicians worked and the population they served; specifically, clinicians who provided services in the DTES or to people who had severe substance use disorders and regularly used toxic street drugs (containing fentanyl and other synthetic opioids with high levels of other contaminants including benzodiazepines, hence this patient population has extremely high tolerance) did not find benefit of prescribing tablet hydromorphone and many had stopped or substantially reduced their prescribing. The moral distress experienced by this group of clinicians cannot be overstated. There was hope when the PSS program started that this would be able to support people during the uncertainty of the pandemic, however, it became clear from a prescriber perspective the limited medications available and dosages were not sufficient to make a difference in this high risk population.

Compounding the distress experienced by many clinicians and PWLLE was witnessing the worsening of the situation in general for PWUD, particularly people who were living in poverty and experiencing homelessness. The pandemic radically changed the drug landscape globally and in BC, leading to increased toxicity of drugs and adulteration with many agents including xylazine and benzodiazepines. This has resulted in overdose presentations worsening and becoming increasingly complex to manage, including complicating engagement in treatment. In addition, clinicians reported increased stimulant use among PWUD often for reasons of unmet basic needs; for example. to stay awake, to avoid violence, or to reduce feelings of hunger.

Stakeholders we listened to across the province expressed their distress that the impact of the pandemic and the economic pressures that have arisen in the past three years has led to a demonstrated worsening of people experiencing housing insecurity and homelessness, income insecurity, food insecurity and worsening of mental health and substance use, especially amongst PWUD, leading to an increasing sense of helplessness for clinicians and for PWLLE and their families. A small number of clinicians expressed their very strong feelings that this general worsening of conditions was in part due to the negative impact of the PSS policy.

Clinicians also expressed concerns about lack of evidence-based guidance for benzodiazepine withdrawal, increased time required to manage withdrawal from benzodiazepines as well as opioids leading to increased waiting for detox, lack of supports in the community after detox, lack of availability of a range of recovery supports and pharmacy support as key issues that compounded their concerns about PSS.

Clinicians universally sought more access to data about PSS implementation and impact, particularly population level impacts. They described a desire for renewed clinical

guidance, but with two conflicting needs identified (sometimes by the same person): (1) guidance with more room for clinical discretion and adaptation to the unique needs of their individual patients and (2) stricter guidance with less room for discretion, in order to ensure consistency between prescribing patterns. In considering this seeming contradiction, I reflect that an approach of greater clinical discretion and patient-centred care is more aligned with our obligations to provide culturally safe care to Indigenous patients; additionally, there was no consensus about the prescribing approach that should be taken if stricter guidance was developed. Additionally, it was identified that many groups of prescribers had already developed their own guidance for their patient populations, based on available evidence and experience to date.

There was general consensus among those consulted that additional medication options and distribution systems need to be developed. For medication options, powdered fentanyl and various forms of diacetylmorphine were supported by both PWLLE and clinicians. The strong evidence base for diacetylmorphine as a form of treatment of opioid use disorder was highlighted. The need for smokeable options was also highlighted. There were significant risks described if stimulants are not included among the options available. Other points of consensus were the need for medical models that are not dependant on an individual prescriber (e.g., access though health authority Supervised Consumption Sites, multidisciplinary clinics with wrap around supports, including peer support, where patients have a relationship with the clinic versus an individual provider) and non-medical access models (e.g., compassion clubs). Particularly in rural areas the need for innovative partnerships between clinicians, pharmacists and peer supports and access to virtual care models were identified as ways to provide access and support both to PWUD and clinicians.

Other key themes in my consultations, as described in the *Engagement* report, were the need for a strong substance use system of care and treatment options for those who desire them; the importance of mental health care for PWUD and the difficulty in accessing it; the need for a variety of options (or “tools in the toolbox”) when offering prescribed safer supply; and the need for specific approaches to care for Indigenous peoples, youth, people with chronic pain, and people working in the trades.

In addition, it was illuminated in these consultations that the understanding what recovery means or what stability means differs for many. In particular some clinicians describe recovery as a person being off all drugs and see use of PSS or OAT as being contrary to recovery; while PWUD describe stability and recovery as being able to live in safe housing, care for their family and have meaningful employment regardless of use of PSS or long-term OAT. I believe evidence both in the literature and the data from BC and elsewhere supports that recovery must be understood as a process (not a false dichotomy of use or abstinence). Recovery is rather a process through which people improve their health and wellness, live self-directed lives and strive to reach their full potential. This process is individually defined, and abstinence may be a cardinal feature for many, but the process is

non-linear and relapse is common. To make a difference in this toxic drug crisis we must be prepared to engage and support people at all stages in their process and recovery journey.

The *Ethical Analysis* is based on engagements of the Provincial Health Ethics Team (PHEAT) with more than 350 interested parties representing a very diverse range of stakeholders.

Four ethical questions were considered:

1. How should we balance the risks and benefits of PSS to individuals eligible for PSS and those not eligible for PSS in the broader population?
2. How should the benefits of PSS for some individuals be balanced with the impacts of diversion?
3. What ethical considerations are relevant when the needs or preferences of individuals accessing PSS come into tension with prescriber preferences or practices?
4. What is an ethical approach to addressing concerns about PSS?

Interested parties shared diverse perspectives about potential benefits and harms of PSS, concerns about the current state of PSS, and equity issues. PHEAT articulates a number of values that are important to decision-making about prescribed safer supply, namely: cultural safety and cultural humility; distributive justice (equality and equity); duty to care; effectiveness; efficiency; flexibility; integrity; procedural justice (fair process); respect; solidarity; and utility (weigh harms and benefits).

Although I encourage you to read the full ethical analysis, I will share PHEAT's conclusions on the first ethical question, as it provides very helpful guidance. I take heed of their conclusion that the ethical defensibility of PSS depends on the strength of evidence of benefit and harm, and therefore the imperative provincially to realistically assess the evidence base and collect additional evidence where gaps exist.

Key messages:
A. When harms to individuals are certain/severe, there is ethical justification to implement effective interventions that reduce or eliminate those harms even when it means there may be some uncertain risks to other individuals in the broader population.
B. When there are uncertain risks to other individuals or the broader population simultaneous action must be taken to identify these risks and reduce them as much as possible.
C. Any intervention that is deemed ineffective and harmful to individuals and/or those in the broader population should be replaced with a new or re-designed intervention that is maximally beneficial and least harmful.

Recommendation:
1. At present, a PSS policy can be defensibly prioritized, as it is reasonable to attempt to mitigate risks for individuals who face certain and severe harm, even if the intervention results in some risk of harm to others in the broader population.
2. Based on the available evidence, action must be taken to maximize benefits and reduce harms related to the unregulated drug emergency and safe supply policy, including consideration of expanded access to safe supply, culturally safe programs and services, substance use treatment and recovery programs, mental health services, and initiatives to address other social determinants of health (e.g., housing, food security) for youth and adults.
3. Alternative safer supply models and protocols (e.g., different substances, adjusted doses, modified criteria for access for those not currently eligible who may benefit, different delivery methods) should be considered and implemented on the basis of being effective to reach the goals of PSS.
a. Evaluations of effectiveness should be based on review of available evidence and input from interested parties, including PWUD and healthcare providers (HCPs).
4. As harm to others must be reduced, action must be taken to identify and address such harm.

The Ethical Analysis also highlights the need for a fair and transparent process of decision-making about PSS, with an ongoing mechanism for concerns to be raised and addressed. Stakeholders attending our engagement sessions voiced appreciation for the opportunity to share their concerns, and I believe an ongoing or periodic process of engagement would not only be important for supporting clinicians and PWLLE but also would address this ethical recommendation.

Integrating the components of my review from a public health perspective has been a challenging task, as the stakes are high, emotions are strong, and evidence is incomplete. I have attempted to identify points of agreement among diverse parties and to recommend reasonable courses of action based on evidence and ethics when decisions were required.

I hope you will find value in the following advice, which I am available to discuss at your request.

Advice and Recommendations

1. Based on the multiple components of my review the following are general recommendations:
    a. The term prescribed safer supply should be retired. I recommend "prescribed alternatives" to the toxic supply instead. Use of this term should situate prescribing in the context of off-label use of prescription medications, which is a routine part of clinical practice.

    b. Substance use must be understood as a public health issue and through a social determinants of health lens. Income equality, access to safe and secure housing, decolonization and reconciliation, require investment alongside investment in prescribed alternatives to the toxic drug supply.

    c. Provincial housing policy should include provisions for substantial increases in supportive housing and low-income independent housing, recognizing that poverty and homelessness worsens problematic substance use.

    d. The Province should continue to build a robust primary health care system, that is inclusive of an evidence-based substance use system of care including prevention, treatment, and harm reduction approaches that is readily available to all people in British Columbia, including youth and people living in rural and remote communities.

    e. Diversion should be understood as indicating unmet needs for PWUD (both medical and social needs) and therefore efforts to mitigate diversion should begin with efforts of the health and social service system to better meet those needs.

    f. Changes to the prescribed safer supply policy should be made with the recognition that the unregulated supply is rapidly changing, and prescribed alternatives should be acceptable as alternatives.

    g. Tapering or discontinuation of opioid medications to people who consume opioids regularly, when the change to prescribing occurs without their consent, results in significant harms as patients may then compliment a tapered dose with toxic, illicit substances. Changes to policy must be accompanied by improved access to treatment services and to prescribed alternatives to the illegal market for people who would not choose or are not eligible for treatment of substance use disorder.

    h. The Province should build on models of care where prescribed alternatives are provided as part of holistic, integrated care. Patients with an opioid use disorder or other substance use disorder should be supported in being co-

prescribed medications to treat substance use disorders, including OAT, or transitioned seamlessly to these medications should they desire to do so. Greater care should be made to communicate in a way that recognizes that the distinction between prescribed alternatives (i.e.,PSS) and other medications to treat substance use disorders, including OAT, is not always clear and is subject to change over time as evidence of impact accumulates as well as subject to the patient's individual recovery journey.

i. A substantial investment should be made in evidence-based youth health promotion and wellbeing. This should include, but not be limited to, recreational opportunities, economic opportunities, educational opportunities, mental health services, and connection to cultural programming and Elders for Indigenous youth. While supports should be accessible to all youth, specific focus must be on improving the mental and physical wellbeing of youth in care, Indigenous youth, 2S/LGBTQIA+ youth, and youth from racialized communities.
    i. This investment should be accompanied by development of a monitoring system for youth wellbeing that is inclusive of monitoring youth substance use at the population level over time. A review of existing data sources should be conducted to identify gaps and make recommendations. Consideration should be given to delegating a single ministry or agency responsibility for moving this monitoring work forward, given the number of organizations with overlapping responsibilities in this area.

2. I recommend the following changes to clinical guidance documents:
    a. The current Risk Mitigation Guidance should be retired. In its place, I recommend a guidance document on prescribing for people who use substances in short term emergencies (e.g., fires and floods).

    b. The BCCSU Opioid Use Disorder Practice Update should be retired, as its content has largely been incorporated into the new Opioid Use Disorder Guidelines as well as recommended Risk Mitigation Updates and other practice support tools.

    c. The BCCSU Stimulant Use Disorder Practice Update should be modified to more clearly delineate the potential role of prescribed psychostimulants as both a treatment and/or a harm reduction intervention, and to better situate this within the treatment continuum.

    d. A separate BCCSU collection of documents related to off-label prescribed alternatives should be created. These documents should emphasize the importance of clinical discretion in prescribing and should include:

i. A regularly updated review of relevant academic literature;
ii. An analysis of the potential benefits and risks of providing prescribed; alternatives to unregulated drugs, with the risks described to include a discussion of the risks of diversion;
iii. Recommendations on monitoring patients for benefit and for evidence of diversion; and,
iv. Practice updates and prescribing considerations for specific medications.

Practice support tools and guidance specifically for non-addiction specialist physicians (i.e., emergency medicine, urgent care, primary care) should be developed. People with lived and living experience, Indigenous rightsholders, prescribers, pharmacists, mental health and addiction specialists, ethicists, and College regulators should be included in the development process. Consideration should be given to integrating these materials into standard curricula, accreditation, and licensing processes.

e. Tablet hydromorphone should be maintained as an option for ongoing use for select patients, with clinical guidance as outlined above to include a description of the populations that may be most likely to benefit, and considerations in monitoring for benefit.

3. Regarding the Access to Prescribed Safer Supply in British Columbia: Policy Direction document, I recommend the following:
    a. This policy should be continued, with modifications and supportive changes as described in my other recommendations.

    b. The document should be amended to clarify that that purpose is to provide patients with prescribed alternatives to unregulated substances, and that its purpose is not to increase access to regulated medications for people who are not patients (i.e., clarify that the mechanism of impact is intended to be through the prescriber-patient relationship, rather than broadly enabling diverted medications to enter the illegal market).

    c. The Evaluation and Monitoring Framework should be complemented with additional components:
        i. A greater emphasis should be placed on monitoring for unintended consequences. Monitoring should include primary data collection with youth about their use of substances generally and their access to diverted medications specifically (e.g., regular surveys of youth substance use; this should leverage broader monitoring of youth wellbeing as recommended above).
        ii. Accountability for monitoring using law enforcement data should also be described in the revised framework.

iii. A strength of the current evaluation plan is its emphasis on identifying unmet needs among people accessing prescribed alternatives; this should be continued.
iv. Where possible, evaluation activities with primary data collection – particularly those engaging PWLLE - should be facilitated by PWLLE of substance use.
v. Provisions should be made to encourage research and knowledge generation from multiple agencies and research groups, and for those results to be routinely shared with the Province (the Decriminalization Research and Evaluation Working Group may provide a model).
vi. The revised Evaluation and Monitoring Framework should be taken to the Public Health Assessment and Surveillance Special Advisory Committee (reporting to Public Health Executive Committee) for endorsement.
vii. Implementing the revised framework will require significant new resources and may require a new RFP in addition to the funded evaluation.

4. I recommend the following in order to better operationalize access to prescribed alternatives to the toxic drug supply:
    a. The Province should work with manufacturers and distributors to expand opioid medication options available to people at risk of opioid overdose, with prioritization of DAM and fentanyl in a variety of formulations, including smokeable formulations.
        i. This direction is outlined in the current policy but has not been implemented widely. An analysis of barriers (including legislative, regulatory barriers) should be conducted to identify feasible strategies for expanded access.
        ii. The Province should take a clear role in supporting the supply chain, with a goal of ensuring medication options that provide adequate alternatives to the unregulated supply are not prohibitively expensive for program operations and can be accessed by a variety of types of clinics and pharmacies.
        iii. At this time, the default provision of these additional medications should be witnessed dosing, with unwitnessed dosing (carries) available for select patients where the prescriber-patient relationship supports a low and managed risk of diversion.
        iv. A strong evaluation plan with assessment of objective outcomes should be in place to ensure that benefits are accruing from any novel therapeutic options.

b. Additional consideration should be given to expanding the range of stimulant options, including smokeable formulations, recognizing the prevalence of polysubstance use and the contamination of the stimulant supply.

c. Consultation should occur with Indigenous rightsholders to identify immediate and long-term opportunities to increase Indigenous communities' self-direction on substance use care, including prescribed alternatives where desired.

d. The Province should fund clinics that use a multi-disciplinary approach, with funding available to health authority and (particularly in areas where HA clinics do not exist such as much of the North) non-health authority affiliated clinics, that can demonstrate the following:
    i. Creation of comprehensive supports for people at risk of drug poisoning, including medication options and protocoled models of prescribed alternatives (e.g., the patient has a relationship to the clinic not just an individual prescriber)
    ii. Wrap around services such as primary care, pharmacy support, social work, peer support and wound care.
    iii. Engagement of peers as part of care team. Support and protect peer navigator involvement in primary care where patient consent is given.
    iv. Engagement and collaboration with regional public health and mental health and substance use teams.

    Of note, the approach taken for clinics serving Indigenous clients could be substantially different from other clinics, and my advice to fund multidisciplinary clinics should not be seen as overriding BC's legal and ethical obligation to ensure self-direction, responsiveness, and cultural safety in health care for Indigenous peoples.

e. Virtual models of substance use care should be supported as much as possible. Rather than stand-alone clinics for prescribed alternatives, these should be clinics offering multidisciplinary support for substance use issues, including the full spectrum of medication supports, allied health services, and peer navigators.

f. Opportunities for enhancing access to on-site consumption of prescribed alternatives at existing harm reduction sites, for example at overdose prevention and supervised consumption sites, should be considered and supported.

g. Centralized storage, distribution, and delivery of prescribed alternatives substances should be considered in order to account for geographical challenges with access.

h. Secure e-prescribing (to replace triplicate prescription pads) should be enabled across the province to reduce the administrative burden on prescribers and facilitate patient access.

i. Remuneration for substance use care and support for PWUD including screening for drug use should be further strengthened in the Longitudinal Family Physician payment model.

j. The Province should invest systematically in making witnessed dosing easier on patients including:
    i. Creating financial incentives (e.g., fee codes) for community pharmacies to provide fentanyl patch changes and witnessing of other opioid formulations (i.e., diacetylmorphine).
    ii. Working with BC Housing, to implement and evaluate patient centred prescribing (inclusive of OAT and prescribed alternatives) based in supportive housing facilities.
    iii. Exploring mechanisms to enable virtual witnessing technology to be used by health authority clinics and community pharmacies.
    iv. In order to improve continuity of care for patients receiving OAT or other prescribed alternatives to the toxic supply (including those receiving witnessed dosing), working with the College of Pharmacists of BC to amend Professional Practice Policy-71 to enable routine delivery of controlled substances by pharmacy employees who are not regulated health professionals, where appropriate safety measures are in place and record keeping is maintained.

k. Specific training opportunities should be created and offered to people (including peers and clinicians) involved in programs and clinics offering prescribed alternatives.

5. I recommend the following measures to improve transparency and accountability around this policy direction:
    a. The Province should regularly communicate with the public about its response to the unregulated drug poisoning emergency, with the purpose of increasing public knowledge of and support for provincial interventions.

    b. The communications strategy should include public surveys to assess public understanding of the emergency and identify where targeted communications might help overcome barriers to implementation of

response activities, including prescribed alternatives. Consider how BC Stats might be involved in this process.

c. Monitoring and evaluation results related to prescribed alternatives should be made public on an ongoing basis.

d. There should be sustained and meaningful engagement of people with lived and living experience of substance use in changes to policy and in decisions about allocation of funding. Expanding funding and support for peer-based organizations allows more capacity to meaningfully engage and provides other direct benefits, as these organizations provide services to many who are not reached by the health care system.

e. A process should be created whereby people who use substances, clinicians, and others can raise concerns about implementation of prescribed alternatives and be sure they will receive thoughtful consideration. (One option could be a formal review committee with representation from the provincial ethics committee, PWLLE, College of Physicians and Surgeons, College of Nurses and NPs and College of pharmacists, representative of researchers in the field, the PHO or delegate, supported by the MMHA that periodically undertakes updated reviews of the risks and benefits of the policy and its implementation and provides advice to MMHA on any concerns)

6. The Province, in broad consultation with stakeholders, should regularly review the policy of prescribed alternatives to the toxic supply to ensure adjustments are made as needed, including updating the ethics review and as evidence is generated from the evaluation framework. Results of this review should be made public. As above, a formal review committee could functionally support this recommendation.

7. The Province should provide a mandate to MMHA staff to develop policy options for implementation of additional medical models not based on individual prescribers and non-medical models of access to regulated alternatives to the toxic drug supply.

Appendix A

A Targeted Scan of Evidence on Prescribed Safer Supply Programs for the Provincial Health Officer

Dec 8, 2023

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Background

This scan of available information on prescribed safer supply (PSS) programs has been prepared on the request of the Provincial Health Officer in order to support a review of PSS programs in BC. In keeping with this request, key areas of focus for this scan requested include 1) the reach and accessibility of current PSS services in BC and other jurisdictions, 2) limitations of commonly prescribed safer supply medications, and 3) PSS medication diversion and its impact on adults and youth (see methods section below for additional detail).

Anecdotal information and emerging evaluations of PSS programs since 2021 have revealed key challenges concerning the accessibility of prescriber-based safer supply models, the appropriateness of the medications offered and risks associated with diversion, including specific considerations for youth. These findings are presented below in a brief overview of available evidence. A list of published policy and guidance documents pertaining to PSS is also provided at the end of this document.

While this evidence scan is focused on exploring specific aspects of the prescriber-based models of safer supply provision, it is important to note that preliminary reviews of PSS in BC and Ontario[1] have yielded some early insight into the benefits of these emerging services as well. Key benefits identified by these reviews include reduction in the rate of drug poisoning events, decrease in emergency department visits, some reduction in reliance on the toxic unregulated drug market, improved sense of community and wellness, and enhanced connection to wrap-around care and support services.[1-4] These findings are partly based on early evaluations of Risk Mitigation[2] prescribing in response to the COVID-19 pandemic, which was mainly limited to hydromorphone prescribing and preceded the development of PSS protocols. Most available analyses are limited by the absence of control groups and the inclusion of multiple interventions (prescribed safer supply, primary care, and often OAT co-prescribing), which make it difficult to delineate outcomes attributable to prescribed safer supply. However, more robust data is emerging in support of Risk Mitigation prescribing as an early model of safer supply provision. For example, a forthcoming Vancouver-based controlled retrospective cohort study involving individuals dispensed Risk Mitigation prescribing (from March 27, 2020 to August 31, 2021) found that receiving Risk Mitigation opioids was associated with reduced all-cause and drug-poisoning-related mortality in the following week.[5]

As such, the critical review of current prescriber-based safer supply programs presented in this document should be considered in the context of the utility of safer supply provision as a means of reducing drug poisoning and related harms. Overall, it is emphasized that considerably more data is needed to identify the strengths and limitations of existing PSS programs and to guide future programming and policy.

[1] Although some safer supply programs exist outside of BC and Ontario, available published data pertains to programs in two provinces.

[2] Risk Mitigation prescribing refers to the prescription of pharmaceutical substitutes to unregulated substance during the COVID-19 pandemic in order to to support quarantine and isolation while minimizing the risk of drug-related harm among people who use drugs.

Methods

Information for this scan was gathered during June–July 2023 through a search and review of academic and grey literature using broad search terms to capture articles that may concern different models and aspects of safer supply provision. For the purposes of this report, a scan of evidence and clinical experience was chosen rather than a structured or systematic literature search in the interest of rapidly establishing a foundation for further targeted inquiries, and in view of the fact that evidence pertaining PSS programs is currently sparse and largely localized in BC and Ontario. This scan should not be viewed as a comprehensive evidence review.

The periodically-updated repository of PSS program evaluations and reports housed on the website of the National Safer Supply Community of Practice was identified as a central resource that supplied the majority of sources pertaining to existing PSS programs. Additional targeted academic and grey literature searches were conducted for topics relating to each section of the scan.

Reach and accessibility of prescribed models

Key Findings

- Only 4,331 BC residents are PSS recipients while it is estimated that 115,000 people live with OUD in this province
- Only 16.5% of Harm Reduction Client Survey respondents reported ever having received PSS.
- Survey findings show that the reach of PSS is largely limited to people with OUD who are already connected to the healthcare system, which excludes at risk populations facing marginalization
- PSS services often exclude people who do not engage in daily opioid use, which means the majority of people at risk of drug poisoning are not eligible for PSS

According to data from the BC Centre for Disease Control (BCCDC) and Health Sector Information, Analysis and Reporting (HSIAR) branch of Ministry of Health, there are 4,331 opioid PSS recipients in BC as of September 2023. This is a fraction of the estimated 115,000 BC residents[3] who live with opioid use disorder (OUD).[6] Two hundred and fifty-six patients received stimulant PSS in September 2023, and 4,441 received any type of PSS (some patients received more than one medication type). The number of patients receiving PSS per month has been decreasing since April 2023. People who use unregulated opioids but do not have OUD are also at risk for drug poisoning death and could be eligible for PSS; however, the size of this population is unknown. A 2023 cross-sectional survey study of people who accessed a harm reduction service (n=491) between March 2021 and January 2022 found that only 16.5% of respondents, all of whom were eligible for receiving PSS, had ever received prescribed safer supply.[7]

[3] There are multiple estimates of people living with OUD in BC. The estimate cited in this document was published in 2018 and has been widely cited. A 2020 analysis estimated that 83,000 people in BC met the criteria for OUD, while in a 2022 interview, BC's chief coroner indicated that the estimated number of people with OUD in BC was 90,000.

This BCCDC study also found that people who accessed drug checking services (odds ratio [OR]:1.67 [95%CI: 1.00-2.79]), overdose prevention sites (OR: 2.08 [95%CI: 1.20-3.60]), and opioid agonist treatment (OR: 4.48 [95% CI: 2.13-9.40]) had significantly higher odds of PSS receipt compared to people who did not.[7] These findings clearly suggest that the prescriber-based safer supply model is likely primarily reaching people with an OUD diagnosis with a pre-existing connection with the healthcare system.[7] The study authors concluded that strategies and service models were needed to reach people who are not already connected to the healthcare system and harm reduction services. An example of such a strategy can be found in the peer-led model implemented at one of the participating sites in Northern Health, where people with lived and living experience of substance use supported connection to a prescriber and low-barrier delivery of medications.[7,8] The study also found that, largely due to this peer-led site, the Northern Health Region had the highest rate of access to PSS.[7] Although this site adheres to a prescriber-based model, its relative success in reaching community members in need of a safer supply of drugs demonstrates that involving peer navigators, designing a less "medicalized" program-client interface, and adapting programs to rural and remote regions can have a critical role in reducing barriers to access.

Many prescriber-based safer supply services only accept clients who meet the criteria for OUD or use opioids daily, precluding others who are at risk of opioid poisoning (e.g., many have another substance use disorder) but do not engage in daily use. Additionally, some prescribers limit PSS to individuals who are eligible for and prescribed OAT, although the frequency of this occurrence is unknown. For example, the Safe Opioid Supply (SOS) program in Toronto reports reserving program admission for individuals who report daily fentanyl use (and with daily use of fentanyl, a diagnosis of OUD is presumed).[3] This limitation in access excludes a significant portion of BC's at-risk population. According to a 2018 report by VCH, only 39% of those who had died of opioid poisoning had documented daily opioid use, while the majority either did not engage in daily substance use (17%) or had another substance use disorder (45%),[9] which may mean that the majority of people at risk of death from opioid poisoning would not qualify to receive PSS.

Internal preliminary data from the BCCDC and the Ministry of Health (Health Sector Information, Analysis, and Reporting (HSIAR)) confirms the limited reach of PSS programs.[7] Nearly all PSS opioid recipients (>90%)[4] had an opioid use disorder diagnosis prior to or on the first day of their PSS dispense.[7] Additionally, anecdotal information and qualitative research findings from individual PSS programs also note the limited reach and somewhat selective accessibility of their programs. For example, a Health Canada-funded evaluation of 10 federally funded PSS programs included qualitative data on the experience of PSS service providers; many respondents found that, in the prescriber-based models of safer supply, "the most 'treatment-resistant' and highly marginalized people fall through the cracks."[4] Some program staff members emphasised that requiring people with OUD to "formally engage with the health care system to have access to safe[r] drugs" was a major barrier.[4]

[4] Data supplemented by preliminary information received from HSAIR through written personal communication; August 20, 2023.

From the observation that current PSS models predominantly serve clients with OUD and with pre-existing connections with the healthcare system or affiliated psychosocial support services, it can be extrapolated that a significant proportion of individuals who "fall through the cracks" may belong to communities that have historically faced barriers to accessing the healthcare system. For example, existing data has demonstrated that Indigenous individuals[10-12] and members of 2SLGBTQ+ communities[13,14] are less likely to access care for substance care due to the intersecting systemic stigma and discrimination within the healthcare system. People experiencing homelessness are also among populations with disproportionately high rates of substance use and sporadic access to healthcare.[15]

Evaluations of individual programs also highlighted long waiting lists, lack of space, and staff shortages as barriers to program access. Long medication pick-up wait times at pharmacies have also affected client access to safer supply services, as have challenges with attending booked appointments.[3,4] In the survey conducted for a review of 10 PSS sites in Canada, a small proportion of participating staff strongly agreed that they were meeting client needs in terms of wait times (33%), hours of operation (25%) and the physical space to provide services (15%).[4] Most of the interviewed program staff reported that the process of adhering to regulatory requirements of a prescriber-based model of safer supply, as well as the need for frequent medical assessment and check-ins, has "made the work of staff significantly more difficult."[4] Like staff in many other healthcare fields in BC, multiple interviewed program operators reported staff burnout and shortage across the 10 programs in BC and Ontario. The SOS program in Ontario reported having had to close its sites to new intake multiple times due to shortage of trained staff.[3]

Qualitative evaluation results involving PSS clients echo staff's frustrations concerning the high-barrier and labour-intensive nature of these programs. Interviewed clients cited multiple program features that functioned as a significant barrier to sustainable participation; these included long wait times, the requirement of frequent medical assessments and check-ins (including urine drug tests), short prescription durations, daily visits for medication pick-up and witnessed consumption, and restrictive missed dose protocols. While some clients appreciated the structure and support they were receiving from periodic check-is and pharmacy visits,[1,16] many clients reported struggling to maintain a routine or employment due to these requirements. Clients who did not live near the PSS site reported having difficulties with daily transportation.[3,4] One respondent described the experience of adhering to PSS requirements as being "shackled to the healthcare system" while trying to be safe.[4]

Limitations of currently available PSS medications

Key Findings

- Qualitative findings suggest that hydromorphone does not meet the needs of PSS clients with high opioid tolerance and presents a considerable medication burden to meet client needs.
- According to data from a Risk Mitigation hydromorphone prescribing service in Victoria, only 24% of clients remained in the service at 60 days post-initiation.
- Prescribed safer supply clients commonly listed powdered fentanyl as their drug of choice; some emphasized that an injectable and smokeable option is necessary for them.

To support the implementation of the province's Access to Prescribed Safer Supply in British Columbia: Policy Direction, the BCCSU has released two practice updates[5] that include prescribed safer supply guidance for opioids (hydromorphone and M-Eslon) and stimulants (dextroamphetamine and methylphenidate):

Opioid Use Disorder Practice Update (January 2022)

- Individuals may be co-prescribed hydromorphone to support opioid agonist treatment initiation or maintenance.
- Individuals who actively use opioids and are at high risk of drug poisoning or other harms due to reliance on the unregulated drug supply may be prescribed hydromorphone and/or M-Eslon. Individuals do not have to receive opioid agonist treatment to be eligible.

Stimulant Use Disorder Practice Update (June 2022)

- Individuals who actively use stimulants and who are at high risk of drug poisoning or other harms related to unregulated stimulant use may be prescribed dextroamphetamine SR and/or dextroamphetamine IR or methylphenidate SR and/or methylphenidate IR.

Currently available PSS evaluation reports largely pertain to tablet hydromorphone, as this is by far the most common medication provided by PSS programs. Many program clients—particularly those who do not engage in daily fentanyl use and those who use hydromorphone as an adjunct to other OUD medication or support—report having benefitted from hydromorphone. [2-4,11,12] However, anecdotal information and qualitative findings from PSS clients and staff to date overwhelmingly and consistently suggest that hydromorphone is inadequate for wholly meeting the needs of clients with high opioid tolerance due to daily fentanyl use. For these clients, hydromorphone may have limited benefit in terms of managing cravings and withdrawal symptoms, necessitating their continued use of the unregulated drug supply.[1,3,4,16-19] Examples of comments reflected in qualitative evaluations include:

[5] Practice update guidance was based on clinical experience and preliminary data from a year of Risk Mitigation prescribing. Risk Mitigation is considered a separate category of guidance as its scope was limited to prescribing in the context of COVID-19.

> "*For those who have been using fentanyl, their tolerance is such that even maximal doses of Dilaudid have little effect except withdrawal management. This leads people to continue to use street fentanyl, as the Dilaudids do not approximate the effect they get from fentanyl."* [3]
>
> *"I barely feel it [hydromorphone]; it's like taking an aspirin after morphine."*[4]
>
> *"It's not effective. I don't feel it. It barely helps with dope sickness and cravings."*[4]

Program staff and clients also indicate that prescribing dosages in accordance with existing guidance may not meet client needs. For example, an evaluation of PSS programs reports that initial doses of 4–12 8mg hydromorphone tablets per day are prescribed, as per existing guidance. However, this dosage is inadequate for the majority of clients, with some programs reporting prescription dosage increased to 16–40 8mg hydromorphone tablets per day to meet their needs.[4] This presents a considerable medication burden for clients seeking to alleviate withdrawal symptoms and manage cravings.

Evidence that tablet hydromorphone may be an inadequate alternative to high-potency unregulated opioids for a significant portion of people at risk of opioid poisoning has been emerging since early evaluations of Risk Mitigation prescribing. For example, an evaluation report on Risk Mitigation prescribing practices (i.e., clients received opioids, stimulants, or both) at Victoria's Cool Aid Community Health Centre (n=313) between March and August 2020 found that only 76 (24.2%) of clients had remained engaged in the service at the 60 days post-initiation.[20] Reasons noted in the report for cessations included hydromorphone-negative urine drug screens, physician concern related to diversion, and clients finding hydromorphone unhelpful. As discussed in the section below, signs of diversion may also indicate that the medication has not addressed client needs.

Clients commonly listed powdered fentanyl as their drug of choice; some emphasized that an injectable and smokeable option is necessary for them.[3,4] Program staff participating in a survey for the national evaluation of PSS suggested that access to the following medication should be facilitated or expanded included[4]*:*

- Fentanyl (predominantly fentanyl powder, but also buccal tablets [Fentora] and fentanyl patches [250, 500 and 1000mg])
- Diacetylmorphine
- Injectable morphine
- High dose injectable hydromorphone

In response to this need for a broader range of medications, the BCCSU in partnership with the provincial government has been developing Prescribed Safer Supply Protocols for providing fentanyl patches, Sufentanil, and Fentora within a phased framework. However, as these protocols demonstrate, the provision of these medications is resource-intensive and pose a range of medication-specific challenges:

Fentanyl patch

- Fentanyl patch programs are resource-intensive to operate and access. Clients require patch changes every 48–72 hours.
- People wearing fentanyl patches could be subjected to physical violence and/or theft if their patches are visible or if they are known to be wearing patches.
- Many clinicians do not consider fentanyl patches as a prescribed safer supply, but rather as off-label OAT, which requires further research, as it:
    - Delivers a consistent, long-acting dose of medication similar to methadone or slow-release oral morphine
    - Is highly protocolized in both dosing and the clinical settings
    - Is carefully regulated to ensure patches are not diverted or not used as intended
    - Does not give clients an experience of short-term euphoria or other effects
- Medication coverage
    - Special Authority coverage must be secured for each patient enrolled in a fentanyl patch program. Once Special Authority is approved, coverage is available through PharmaCare, including Plan G and Plan W for those eligible. Approval for Special Authority coverage lasts for one year, at which point it must be renewed. Note: Tegaderm occlusive dressing (a requirement for covering and protecting applied fentanyl patches to reduce the risk of early removal or augmentation by the client) is not covered by PharmaCare.

Sufentanil (intravenous or sublingual medication)

- The provision of Sufentanil, according to existing protocols, can be disruptive, time-consuming, and resource-intensive for clients and providers. Clients may need to access up to 4 doses per day; program hours of operation and staffing capacity will influence the number of doses clients can access in a single day, and the total number of clients who can access the program.
- According to clinical experience, a prohibitively high volume of Sufentanil is often required to meet the needs of clients who have very high opioid tolerance due fentanyl use. These barriers to access have negatively impacted the favourability of this medication among clients and providers.
- Medication Coverage
    - Sufentanil does not require Special Authority coverage. This is a regular benefit drug and coverage is available through PharmaCare Plans, including Fair PharmaCare, Plan G, Plan C, and Plan W.

Fentora (buccal tablets)

- As per existing protocols, clients have to attend the PSS site or pharmacy twice or more daily with three or more hours between doses.
- Clients who have high tolerance due to regular fentanyl use often require a high number of Fentora tablets to avoid withdrawal.
- This barrier to access has negatively impacted the favourability of this medication among clients and providers.
- Medication Coverage
    - Special Authority coverage must be secured for each participant enrolled in a fentanyl tablet program. Once Special Authority is approved, coverage is available through PharmaCare, including Plan G and Plan W for those eligible. Once approved, the approval period lasts for one year, at which point coverage must be renewed annually.

Diversion and its impact

Key Findings:

- Diversion of hydromorphone is reported by PSS program staff and clients as a common occurrence, likely due to the undesirability of this medication among people with high opioid tolerance.
- Some PSS clients report diverting hydromorphone in order to obtain other substances that better meet their needs or to support others who may not be able to access prescriber-based safer supply.
- Anecdotal reports have suggested that youth may increasingly be accessing diverted hydromorphone; however, current BC data does not indicate an increase in OUD diagnoses among youth

While quantitative data is currently lacking, diversion of PSS hydromorphone is identified by clients and staff of reviewed PSS services as a common occurrence[6], likely due to the undesirability of this medication among people with high opioid tolerance.[1,3,4,16-19] It should be noted that, to date, hydromorphone tablets have consistently comprised a small proportion of law enforcement-seized opioid samples in BC, with an increase noted from March 2020, reaching 1.5% in 2020 and 4.4% in 2021.[21]

Some clients who participated in the evaluation of PSS programs reported selling hydromorphone in order to obtain fentanyl or other substances that adequately address their withdrawal and cravings. Other participants report giving away a portion of their medication to support someone else.

> "*People trade their Dilaudid because they want the fentanyl that is strong enough to overpower the fentanyl that they were using before the Dilaudid program. The Dilaudid program only offers 30 pills maximum [per day], which is nowhere near as high an amount as the fentanyl is*."[1]

A body of research on research on motivations for using diverted opioid medications for OUD shows that people choose these medications for reasons consistent with therapeutic use, including the management of withdrawal symptoms, cravings, self-treatment of existing opioid use disorder, and reducing reliance on unregulated opioids with unknown and potentially dangerous contents.[19,22-26] In addition, a significant proportion (33–51%) of individuals who have used diverted OAT medications report barriers to accessing treatment and harm reduction.[22,23] No research is currently available on reasons for accessing diverted prescribed safer supply. While research suggests individuals use diverted opioids for therapeutic reasons, serious consequences related to diversion remain a concern. Prescribers must continue to consider individual and public safety, including increased access to opioids, drug poisoning, and death, when prescribing safer supply medications.

The impact of using diverted prescription opioids on people at current risk of unregulated drug poisoning remains unclear. A 2021 prospective cohort study based in Vancouver's Downtown Eastside involving 1,151 participants who use drugs found that people who used diverted opioids had a decreased risk of exposure to fentanyl, which is presumed to decrease the risk of drug poisoning because diverted opioids

[6] Cited data is from urban centres only. Diversion is not likely to be uniform across urban and rural settings, though the extent to which it may differ is unknown. Clinical experience suggests that diversion may be more common in urban settings compared to rural settings.

provide a more predictable dose[7] (adjusted odds ratio [AOR] = 0.70, 95% CI: 0.52–0.94).[17] This protective function of diverted medication in the absence of sufficient access to a safer supply was expressed by a number of PSS clients as well[18,19]:

> "*If somebody's trying to look for fentanyl, but they can only find Dilaudid, it's going to be a lot safer for them."*[16]

> *"I'll give one or two away if somebody's hurting. Of course I will... I hold no shame in that*." [16]

While the drug poisoning death rate in BC during January–September 2023 was slightly (5.6%) higher than in the corresponding period in 2022, the BC Coroner's Service has not found any evidence that PSS programs have contributed to this increase.[27] Earlier data collected following the implementation of Risk Mitigation prescribing supports this conclusion. Between March 2020 to May 2021, hydromorphone was detected in 5.9% of unregulated drug poisoning deaths, and the monthly proportion of hydromorphone detected in post-mortem toxicology has remained relatively stable, ranging from 0 to 8.2% between Jan. 1, 2019 and Fe. 28, 2020, and from 2.7% to 9.3% between March 1, 2020 and May 31, 2021.[28] In addition, of the 5.9% of deaths where hydromorphone was detected, the vast majority included both hydromorphone and fentanyl while hydromorphone without fentanyl or fentanyl analogues was detected in less than 2% of total deaths.[28] These findings suggest that Risk Mitigation prescribing, hydromorphone in particular, was not a direct contributor to the rising rates deaths due to the unregulated drug supply.

Relevant research on diverted prescription opioid use among youth

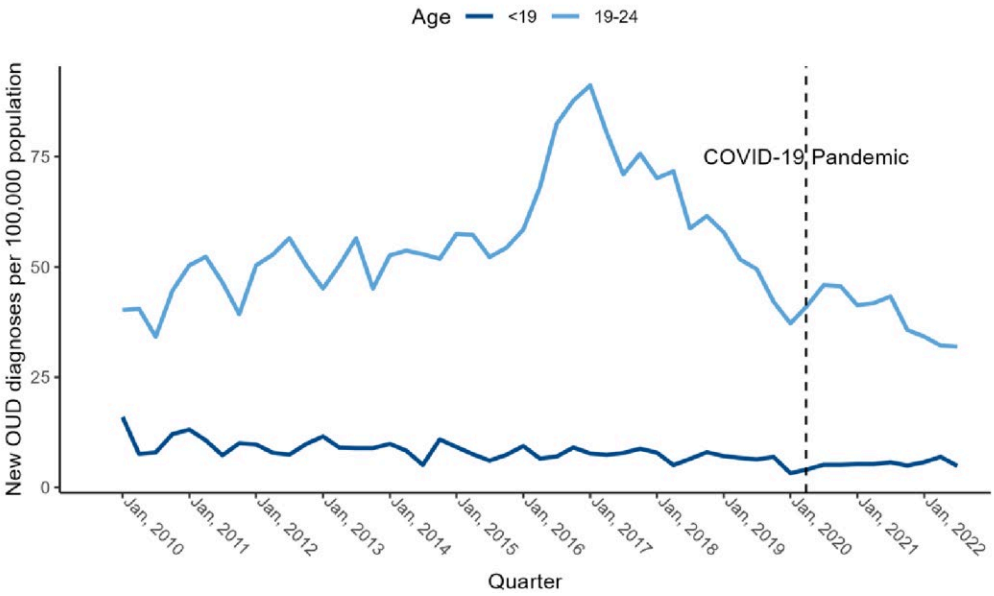
Given that early initiation of opioids is associated with the development of OUD later in life,[30] and that OUD in youth is associated with higher risks of morbidity and mortality compared to other substance use disorders,[31] there is a need to understand how youth initiate and obtain opioids, and how PSS impacts these processes. While data are limited in BC, national survey data from the US suggest that most youth obtain opioids from friends or family for free (33.5% of adolescents, 41.4% of young adults), or from a single prescriber (19.2% of adolescents, 24.0% of young adults), and less often through unregulated sources such as drug dealers (6.5% of adolescents, 7.8% of young adults).[32] This corresponds with anecdotal reports that many youth who would not consider obtaining fentanyl or other opioids from the unregulated drug market may feel safer using opioids that come in a prescription bottle available through acquaintances.

The use of diverted prescription opioids by youth is a potentially significant concern that can lead to continued opioid use.[33] A 2016 BC-based longitudinal study (n=462) found that non-medical prescription

[7] It should be emphasized that this study involves participants who use drugs regularly (i.e., participants in Vancouver Injection Drug Users Study [VIDUS] and the AIDS Care Cohort to Evaluate access to Survival Services [ACCESS] cohorts.) There are currently no dedicated studies on the prevalence and impact of diverted PSS medication use by opioid-naïve individuals or people who use drugs occasionally.

opioid use was a significant predictor of subsequent initiation of injection opioid use among street involved youth.[33] It is noted, however, that a small portion of youth who try opioids develop OUD.[34] It is also acknowledged that the province's representative for children and youth, Jennifer Charlesworth, reported that there is no indication from available monitoring data that youth have been using diverted safer supply medications at a significant scale.[35] Current data from the BCCDC demonstrates that there has been no increase[8] in the rate of new OUD diagnoses among youth since March 2020 when prescribed safer supply was implemented in BC through Risk Mitigation prescribing (see figure below).[36] The rate of new OUD diagnoses among youth under 19 years of age has remained stable and low since 2010, while new diagnoses among youth aged 19–25 has decreased since 2017.[36]

Incidence rate (new cases) of opioid use disorder diagnosis among youth under 25 in BC



Nevertheless, research has demonstrated that the impact of opioid prescribing trends on rates of unregulated drug use and new OUD diagnoses are generally established in the long term.[37] Given the reports of the wide availability of prescription hydromorphone diverted by PSS clients who find them inadequate, the broader possible risks of offering this medication as the primary PSS option should be considered with great care. These include risks to youth and opioid-naïve community members.

[8] Note: This data is descriptive; additional research is needed to fully examine an association between new OUD diagnoses and prescribed safer supply. Additionally, these findings are limited to people who received a diagnosis of OUD and does not include people without a formal OUD diagnosis who had health care contact for a drug poisoning event. The addition of drug poisoning codes can increase the rate of cases, but does not change the overall trend.

Available published policy and guidance for PSS

Below is a briefly annotated, chronological list of guidance documents that are guiding the development of prescribed safer supply programs and practices in BC.

1- Access to Prescribed Safer Supply in British Columbia: Policy Direction (July 2021)

A policy direction released by the Ministry of Mental Health and Addictions, the Ministry of Health, and the Office of the Provincial Health Officer that urges and facilitates the development of procedures and programs for the prescription of pharmaceutical alternatives to the toxic unregulated drug supply as a means of reducing the risk drug-related harms, including drug poisonings. It provides the fundamental components for offering prescribed safer supply through existing regional health authority-run and federally-funded programs, including overarching principles and service delivery requirements (e.g., eligibility, medications).

2- Risk Mitigation in the Context of Dual Public Health Emergencies (January 2022)

Initially released in April 2020 and subsequently updated in 2022, this interim guidance document was developed by the BCCSU, the Ministry of Mental Health and Addictions, and the Ministry of Health in response to the compounding impact of the COVID-19 pandemic on the harms of the toxic unregulated drug supply and the overdose emergency in BC. In addition to outlining measures to support ongoing access to care during the COVID-19 pandemic, the document includes guidance on prescribing pharmaceutical alternatives to unregulated drugs in order to help individuals at risk of withdrawal or overdose to safely self-isolate to reduce COVID-19 transmission; this practice has been termed *Risk Mitigation* prescribing. For people who use opioids, medications supported by this document for *Risk Mitigation* prescribing include hydromorphone tablets and sustained-release oral morphine (M-Eslon). The current (2022) edition of this document includes a review of emerging evidence and clinical experience with Risk Mitigation prescribing as well as offering updated guidance for this intervention.

3- Opioid Use Disorder: Practice Update (January 2022)

To facilitate up-to-date clinical management and harm reduction interventions for individuals with opioid use disorder, this document outlines new evidence and clinical experience published since the 2017 release of the BC Provincial OUD guideline. Among the new information provided in this practice update document is an overview of preliminary evaluation findings and clinical experience from over a year of *Risk Mitigation* prescribing of pharmaceutical alternatives to unregulated opioids. This document also provides further guidance on prescribing hydromorphone and M-Eslon as harm reduction options outside of the context of COVID-19 (i.e., prescribing to individuals who are not at risk of or infected with COVID-19) to help reduce individuals' reliance on the toxic unregulated drug supply and to decrease the risk of drug-related harms.

4- Stimulant Use Disorder: Practice Update (June 2022)
Provides an overview of evidence-based treatment options and introduces emerging practice options not considered evidence-based practice for those who use unregulated stimulants. Among the new information provided in this practice update document is an overview of preliminary evaluation findings and clinical experience from over a year of *Risk Mitigation* prescribing of pharmaceutical alternatives to unregulated stimulants. This document also provides further guidance on prescribing dextroamphetamine and methylphenidate as harm reduction options outside of the context of COVID-19 (i.e., prescribing to individuals who are not at risk of or infected with COVID-19) to help reduce individuals' reliance on the toxic unregulated drug supply and to decrease the risk of drug-related harms.

5- Prescribed Safer Supply Protocols: Fentanyl Patch (October 2022)

As the first phase of the implementation of *Policy Direction* to provide access to prescribed safer supply in British Columbia, this document was developed by the BCCSU to provide a standardized clinical protocol for the provision of fentanyl patches to reduce reliance on the toxic unregulated drug supply and associated harms. This protocol was adapted from the Fentanyl Patch Policy by PHS Community Services Society.

6- Prescribed Safer Supply Protocols: Fentora (August 2023)

This document provides a standardized clinical protocol for the provision of Fentora both as a maintenance medication and a PRN (as needed) option to reduce reliance on the toxic unregulated drug supply and associated harms.

7- Prescribed Safer Supply Protocols: Sufentanil (August 2023)

This document provides a standardized clinical protocol for the provision of sufentanil to reduce reliance on the toxic unregulated drug supply and associated harms. This protocol is adapted from PHS Community Services Society's Sufentanil Policy.

8- Prescribed Safer Supply Operational Resource: Considerations for Implementation (Forthcoming, 2023)

This operational resource is intended to provide guidance and support to programs seeking to implement PSS programs. This resource seeks to assist operators in developing models and selecting interventions that best balance the limitations, capacity, resources, needs, and opportunities of their program.

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Appendix B

Appendix B: Engagement Report

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1. Introduction

The Provincial Health Officer (PHO) is the senior public health official in British Columbia (BC), with responsibility for monitoring population health and providing independent advice to public officials on public health issues. In the context of the ongoing toxic illicit drug public health emergency, the PHO was asked to review BC's prescribed safer supply (PSS) initiative and provide recommendations to the Province on how to proceed.

PSS enables clinicians to prescribe pharmaceutical alternatives to the toxic unregulated drug supply to people at risk of drug-related harms. PSS is a form of harm reduction, though some PSS medications may also be prescribed in the context of substance use treatment. Individuals, including clinicians and PWUD, have many differing views on what constitutes PSS and that is reflected in this report.

The goal of the PHO's PSS review is to support prescribers and people who use drugs (PWUD) by ensuring that BC's PSS program meets the needs of people at risk of harm or death due to the toxic illicit drug supply, while also considering the health and safety of the community.[9] The PHO's review responds primarily to concerns raised about the prescribing of hydromorphone (HDM) tablets.

Between July and September 2023, the PHO engaged with physicians, nurse practitioners, family members impacted by substance use, and people with lived and living experience (PWLLE) of substance use. Engagement sessions occurred province-wide to capture a diversity of experiences and perspectives from rural and remote areas, urban contexts, and the Downtown Eastside (DTES). Additionally, the PHO had conversations about PSS with individuals and organizations across the province, and while not every voice is directly reflected in this document, all informed the PHO's broader report and recommendations.

This Engagement Report summarizes key themes captured during the engagement process. Perspectives on PSS varied widely, and clinicians practicing in the DTES had notably different experiences from participants in other regions. The intention of the report is to reflect the broad and diverse range of perspectives and experiences gathered during the engagement process rather than to synthesize these views into a single unified position.

The findings of the Engagement Report should be interpreted with several caveats in mind. Efforts were made to protect the anonymity of participants. In some cases, this limited the amount of contextual information that could be provided. Engagement sessions were not intended to constitute rigorous qualitative research, but rather to gain a broader understanding of stakeholders' experiences and views regarding PSS. Moreover, it is not always possible to isolate the effects of PSS, as it is often co-prescribed with opioid agonist treatment (OAT) or provided in conjunction with other health and social services. In some cases, perceived benefits may be attributable to co-interventions.

[9] This report uses the term "people who use drugs" (PWUD) to describe people who are currently using substances. It also uses the term "people with lived and living experience" (PWLLE) to denote people with current or former experience of substance use.

Considerable research, evaluation and monitoring of PSS is underway, and the PHO has met with many researchers to learn more about PSS-related data. However, PSS research findings and data interpretations discussed are out of scope for this Engagement Report. Instead, these data are reflected in the BCCSU evidence scan. This Engagement Report is by design limited to perspectives expressed during the engagement sessions.

2. Background

BC is the first province in Canada to develop a provincial policy framework to enable PSS provision. As a harm reduction intervention, PSS aims to provide a safer supply of medications to separate people from the toxic drug supply and thus reduce risk of death and harms. People have been accessing PSS since March 2020, when the Province introduced Risk Mitigation in the Context of Dual Public Health Emergencies. This document enabled the provision of PSS medication during the COVID-19 pandemic to reduce risk of overdose for those with, or at risk of contracting, COVID-19. In July 2021, BC released Access to Prescribed Safer Supply in British Columbia: Policy Direction (PSS Policy), which enables prescribing more broadly for those at risk of death from accessing the toxic drug supply.

In addition to provincial policies, PSS in BC is supported by clinical guidance and protocols developed by the BC Centre on Substance Use (BCCSU) and informed by experts across the province. These include:

- Opioid Use Disorder Practice Update (2022)
- Stimulant Use Disorder Practice Update (2022)
- Fentanyl Patch PSS Protocol (2022), Sufentanil PSS Protocol (2023), Fentanyl Tablet PSS Protocols (2023)

While BC's PSS initiative enables access to select opioids, stimulants, and benzodiazepines, most PSS recipients have received opioid medications, the large majority of which were tablet hydromorphone. As of June 2023, approximately 4,619 individual people have been prescribed opioid PSS medications. Of note, while PSS can be prescribed as a standalone harm reduction-oriented intervention, it is frequently used clinically as an adjunct to OAT. The line between PSS and augmented OAT is not clear, and individuals have a variety of perspectives and experiences.

As PSS is a novel and innovative intervention, ongoing monitoring and evaluation of its outcomes are crucial components of the PSS policy. Existing research indicates that PSS improves engagement and retention in healthcare, as well as people's overall physical and mental health and well-being. The BC Coroners Service reports that there is no indication that PSS is contributing to unregulated drug deaths in the province.

3. Summary of Key Themes

3.1 PSS is a Valued Intervention

PSS is a necessary life-saving health intervention for people at risk of harm or death due to the toxic illicit drug supply. While participants spoke to the current limitations of PSS, most agreed that it is a necessary intervention in the context of the ongoing toxic drug emergency. Overall, participants shared that the concept of PSS is sound (i.e., offering medications of known quality and quantity to reduce

reliance on, and risks of harms from, the toxic drug supply), but implementation has been the primary challenge.

Clinician Perspectives:

Physicians and nurse practitioners (clinicians) appreciate having PSS (primarily tablet hydromorphone and to a lesser extent fentanyl patches and injectable HDM) as one of the 'tools in their toolkits' to support people who use drugs. Several clinicians expressed their view that the key benefit of PSS has been increased initiation and retention of patients with an opioid use disorder (OUD) on opioid agonist treatment (OAT), particularly for clients who might not otherwise engage with the health care system. Others described PSS as a useful tool to engage and retain clients in other substance use treatment programs, or to otherwise support clients to achieve their substance use care-related goals (e.g., minimizing reliance on street drugs).

> *"[Is our goal to] get them to stop [our clients] using the toxic street supply or to keep them engaged in care that we know will keep them alive? That's why I still prescribe [to clients] who are using the illicit supply… because I get to keep seeing them and keeping them on OAT."*

Although participants generally understood that PSS was not intended to be a conventional form of substance use treatment, they discussed the ways in which PSS provision can overlap with treatment. Several clinicians described using PSS medications as an adjunct or extension to opioid agonist treatment. Others, however, pointed out that the use of PSS exclusively as a vehicle to achieve treatment and recovery sits in tension with the intended purpose of PSS as a harm reduction initiative.

> *"Safer supply is an opportunity for generating evidence for treatment engagement and retention for those with OUD, but this is at odds with the spirit of PSS as a public health intervention."*

Clinicians shared that PSS helps some clients achieve the level of stability needed to access other health and social services, such as treatment, employment, or housing. Clinicians also believed that PSS may be helpful for addressing public drug use and disorder. They likewise noted that offering PSS in different settings (e.g., hospitals, police holding cells, detention centers) may help reduce violence in these settings while improving health outcomes.

Some clinicians were concerned that access to tablet HDM – one of the most accessible and widely prescribed PSS medications so far – may be withdrawn without suitable alternatives being made available for their clients. While clinicians expressed signification trepidation about long-term HDM prescribing, there was broad agreement that HDM can be a valuable PSS option – especially in relation to OAT titration and to relationship-building with for example, youth who were using illicit substances.

Clinicians acknowledged that stigma and mistrust of people who use drugs (PWUD) in the medical system hinders individuals' ability to seek out and receive appropriate, patient-centred care. Some clinicians urged their colleagues to recognize the value and insight PWLLE have to offer. Clinicians are deeply invested in the health and wellbeing of their patients, and many noted that building trusting patient-provider relationships leads to better outcomes. For example, some clinicians have found that providing "carries" (i.e., take home doses of PSS) can be safe, effective, and empowering for stabilized patients, helping them attain a greater sense of control and responsibility in their lives.

PWLLE Perspectives:

Individuals who accessed PSS shared that these medications have improved their lives by providing them with the safety and stability needed to seek employment, pursue housing, care for their children, and build healthier relationships. Family members of people accessing PSS also highlighted improved safety and stability as benefits of this intervention. One family member shared that once their loved one started receiving PSS, the chaos in their life was reduced and they were better able to manage their health and their responsibilities.

> *"I've overdosed 12 times, but I've had no overdoses since starting PSS."*

> *"What saved my life was having my NP listen to me and asking me what I needed."*

PWUD also noted that PSS has served as a helpful entry point into substance use care, providing them with access to a clinician who later helped them transition to OAT or other forms of care that aligned with their goals. Of note, client goals can be diverse, and do not always include abstinence or opioid agonist treatment (e.g., some clients may aim for greater life stability, not abstinence/OAT; some clients expressed the benefit they experienced from using PSS to support their OAT).

Overall, PWLLE were pleased that PSS was designed to meet people where they are at, with many noting that it helps marginalized people access care and establish trusting relationships with clinicians and other care providers. This feature was noted as particularly important for those who have been harmed by racism or colonialism within the Western medical system, and for those who have endured other traumatic experiences in medical contexts. PWLLE also highlighted that PSS has the potential to be more accessible than other substance use care modalities.

However, PWLLE also underlined PSS access and retention issues, noting that these overlap with existing barriers to OAT access. These challenges include high PSS program barriers, such as eligibility requirements, cost, geographical distance to travel for witnessed dosing, daily witnessing requirements, stringent appointment requirements, urine testing, and limited pharmacy hours/unexpected pharmacy closures. PWLLE also discussed the limited treatment options available for individuals with more complex needs such as developmental challenges or disabilities (e.g., fetal alcohol spectrum disorder).

Other challenges discussed include the lack of facilities where individuals can titrate onto OAT if they so choose, as well as the lack of suitable PSS medication options. PWLLE also highlighted prescriber-related barriers to access, including the overall lack of PSS providers (which is especially acute in certain regions), and the lack of continuity between prescribers. Relatedly, PWLLE emphasized that PSS has not been scaled up nearly enough to meet community needs.

PWLLE and their families want to be recognized and valued as experts with regard to the mental health and substance use system. PWLLE emphasized the need to engage them as partners at every stage of PSS service design and delivery, including policy and program development. "Nothing about us without us" was a commonly shared sentiment among PWLLE and their family members, and there was a commonly held feeling that government engagement often feels perfunctory. Significant effort is required to earn and maintain trust with PWLLE.

3.3 Gaps in the Substance Use System of Care

PSS is one service within the continuum of interventions that constitute BC's broader substance use system of care. Participants described several gaps within the current system, proposing areas where the system could be improved.

Clinician Perspectives:

Clinicians described how gaps in the substance use system of care impacted their ability to care for their patients. The limitations of the treatment and recovery system were discussed at length. For example, clinicians shared that they find it challenging to connect patients to withdrawal management (detox) or treatment in a timely manner, with the process being labour-intensive and often futile.

> *"Addiction is not just a biological, medication, receptor-based problem."*

Clinicians expressed concern with stringent admission requirements at treatment facilities, many of which are abstinence-based and will not accept individuals who are on PSS or OAT. This disincentivizes clinicians from providing PSS to patients who may want to seek treatment in the future. Transitioning patients off PSS to support their entry into treatment was identified as a destabilizing process that can have negative client outcomes (e.g., loss of care, return to use of the toxic street supply and increased risk of drug poisoning harms and death).

Clinicians are also concerned about the limited supports available to clients once they are released from withdrawal management or other treatment services into the community with reduced opioid tolerance. This was recognized as a gap that results in people being lost to care, increasing the risks of toxic illicit drug-related harms and death. These concerns were particularly salient among clinicians in the North, where withdrawal management, treatment and recovery facilities were described as highly limited and difficult to access.

PWLLE Perspectives:

PWLLE noted significant gaps in the substance use system of care, highlighting issues such as barriers and "gatekeeping." More specifically, PWLLE described their frustrations with the treatment and recovery system, including extended wait times between withdrawal management and other ongoing treatment services, long wait lists for treatment beds, poor discharge practices (e.g., discharging clients back onto the street without housing), and the limited efficacy of many of these programs based on personal experience or the experience of people around them. One DTES resident discussed how returning to the community after an in-patient treatment program hindered their recovery process, underlining the need for more abstinence-based/sober living facilities outside of the DTES.

Some participants spoke to the poor quality of many bed-based treatment and recovery programs, noting that compulsory treatment is not evidence-based and can be detrimental to the health and well-being of PWUD. It was also suggested that the outcomes of substance use treatment need to be evaluated and monitored, in addition to (but independently from) the evaluation of PSS outcomes. PWLLE likewise expressed concerns about the lack of government oversight and standards of care for

the treatment and recovery system and highlighted the need to regulate privately-run treatment facilities.

Of course, it should be noted that PWLLE are not calling for PSS merely because of barriers to accessing treatment and recovery programs. While such barriers do exist, not all PWUD who would benefit from PSS are seeking to enter treatment and recovery programs. PWLLE consistently identified the importance of having options across all components of the substance use system of care.

Beyond the substance use-specific system of care, participants also highlighted that many PWUD face inequitable mental health care access. One participant shared that the root cause of their substance use is trauma and post-traumatic stress disorder (PTSD); however, they have been unable to access a psychologist or psychiatrist to receive appropriate care for these underlying conditions, thus exacerbating their substance use and reliance on the toxic illicit supply.

Finally, families and loved ones represent an important source of support for individuals experiencing substance use-related challenges. However, participants discussed the general lack of supports available for family members across the continuum of care.

3.4 Connection to Social Supports

Participants discussed how the social determinants of health influence substance use, and how providing relevant supports can improve the health and well-being of PWUD.

Clinician Perspectives:

Clinicians acknowledged that while health interventions such as PSS can promote short-term stability, other supports are needed to enable longer-term stability. Several clinicians identified appropriate housing as an important and often necessary precursor to achieving longer-term stability; however, they explained that connecting their patients to housing supports was nearly impossible. One clinician observed that providing supports for basic social determinants of health (i.e., hotels/motels, food, and basic income allowances) in addition to onsite PSS and OAT provision during the COVID-19 pandemic resulted in better health outcomes among PWUD, when compared to OAT treatment alone.

Social workers were highlighted as an important part of health care teams able to connect clients to social supports, and by extension, to help them achieve their substance use-related goals. Clinicians also discussed the importance of being kind and fostering positive and respectful patient-provider interactions, in order to retain individuals in care and enable other social system connections to be established.

Clinicians reflected on substance use as a social problem requiring solutions that effectively address poverty, marginalization, trauma, and other root causes of substance use. One clinician reflected that PSS can keep people alive, it was questionable whether it could help them achieve the ultimate goal of improving their quality of life. Other clinicians asserted that the solution to the toxic drug crisis lies with PSS in combination with addressing the social determinants of health. DTES clinicians acknowledged that many of their clients lived in extremely challenging conditions and noted that any substance use-related

progress may be short-lived in the absence of additional supports for key social determinants of health (e.g., income, housing, food security, employment).

PWLLE Perspectives:

PWLLE and their family members also discussed the need to address social determinants of health, including mental health, housing, poverty, and food insecurity. The COVID-19 pandemic exacerbated many of these challenges, which disproportionately affect PWUD. PWLLE likewise concurred with many of the sentiments expressed by clinicians surrounding the need for supportive housing and other social supports. Furthermore, participants discussed notable gaps in supports for families whose loved ones are experiencing substance use-related challenges.

3.5 Expanding the Continuum of Options

Participants discussed the benefits and limitations of different PSS medication options from the perspective of both providers and recipients. Overall, participants agreed that different medications work for different populations and regions, confirming the need for an expanded range of medication and formulation options to better meet the needs of diverse PWUD. The absence of inhalable or smokeable PSS options was highlighted as a gap by both clinicians and PWLLE.

Clinician Perspectives:

Clinicians described an urgent need to increase the range of available PSS medications. They suggested that expanded options may improve PSS engagement and retention, reduce toxic drug related harms and deaths, and potentially reduce the incidence of diversion. Some conceptualized PSS as a continuum of different (drug) molecule offerings available in different formulations and potencies, depending on client needs (e.g., tablet HDM, injectable HDM, smokable DAM, smokable fentanyl, fentanyl patch, iOAT with DAM). In general, clinicians welcomed having as many 'tools in their toolkit' as possible to support their clients, although some felt that efforts and resources should be diverted away from PSS options that are not working in favor of those that are.

Clinicians discussed the benefits and limitations of specific PSS medication options in terms of client demand and the feasibility of provision, with clinicians from different regions expressing varied perspectives. Citing recent research on drug use patterns and preferences among PWUD as well as their own clinical observations, clinicians discussed the need for more inhalable or smokeable PSS options. Urban clinicians noted that powdered fentanyl, fentanyl patches, and DAM are in greatest demand and are most likely to reduce opioid use. Rural and remote clinicians noted that all PSS medications should be made available across these regions.

The following sections describe clinicians' perspectives on specific PSS medications.

Hydromorphone

Clinicians noted that HDM is one of the most accessible and widely prescribed PSS medications so far. Several challenges related to HDM tablets as a PSS option were discussed, including the clinical complexity of HDM prescribing, the risk of diversion, the resource intensive nature of daily dispense programs, and HDM's limited benefits for clients with higher opioid tolerance.

> *"HDM is [like bringing] a knife to a gun fight. [It] is not the right medication, but it has its place. As a hospitalist I use it all the time – [it is very effective as PRN]."*

Some clinicians expressed that although HDM may be a useful short-term tool (e.g., PRN), they failed to see how it could offer long-term benefits to clients. One clinician found that HDM was more useful for clients who are not experiencing poverty, as these clients are less incentivized to divert their medication. Clinicians also reflected on whether recent negative attention on HDM has made it difficult to focus on how it may be beneficial for different populations of PWUD.

Despite these challenges, clinicians spoke to several scenarios where the ability to prescribe HDM as a PSS option has been useful. HDM is valued as a means to engage and retain clients in substance use treatment or other forms of care (e.g., in acute care settings). HDM is also believed to be impactful when used as an adjunct to OAT, whereby HDM is used to manage a patient's cravings and/or withdrawal symptoms while initiating or titrating onto OAT.

Multiple clinicians shared that they have seen their clients benefit from HDM, with some reducing their illicit drug use and others seeking employment or achieving personal substance use goals (e.g., abstinence) with the aid of HDM. Clinicians shared that HDM remains useful for clients with lower opioid tolerance levels, those who use opioids intermittently, and those who have used Tylenol 3 (i.e., T3s) over extended periods of time and require an alternative to reduce their acetaminophen exposure. Rural clinicians shared that, in the absence of other options, HDM has tended to work well in their communities. Clinicians also shared that some clients tend to prefer the shorter acting effects of HDM relative to other, longer acting medications.

Overall, perspectives on the benefits and drawbacks of HDM were mixed. Many clinicians were opposed to ending HDM-based PSS prescribing without other effective options in place. Indeed, this was an area of concern and focus for clinicians who feared that there were plans to end access to HDM as PSS. Generally, clinicians acknowledged that HDM is useful for some but not all clients and maintained that the decision to prescribe should be based on individual clinical judgement and discussions with patients (rather than at a population level). However, many expressed support for reducing HDM prescribing once more appropriate and effective medication options are readily available.

Fentanyl

Clinicians were generally supportive of fentanyl PSS options, with wide support for the use of fentanyl patches once scaled up. Clinicians that currently offer fentanyl patches shared that they tend to work well for most but not all patients, with some feeling few to no effects from the patches. These clinicians expressed that current fentanyl patch formulations are not strong enough to meet patient needs and raised logistical and operational challenges with offering them (e.g., supporting staff to complete patch

changes, often involving multiple patch applications on individual clients). Some clinicians felt that fentanyl patches would be more appropriately offered as an emerging form of OAT, rather than a safer supply option.

Clinicians discussed fentanyl powder, which is currently available at some programs in the DTES. Despite limited access, powdered fentanyl is in high demand due to its flexible formulation which can be smoked, injected, or snorted. One clinician noted that fentanyl powder tends to work well for those who can access it due to its high potency. On the other hand, clinicians recognized that some patients preferred lower potency options over fentanyl powder.

Overall, clinicians expressed support for expanded availability of different fentanyl formulations. Some raised the witnessed and resource-intensive nature of existing programs, and urged exploration of take-home models of fentanyl PSS for some patients based on trusted relationships.

Diacetylmorphine

Clinicians discussed the high viability of diacetylmorphine (DAM) as a PSS medication option, particularly for older clients who prefer its effects over more potent medications such as fentanyl, or for individuals who use recreationally. Some clinicians cited the rigorous evidence base and success of existing injectable opioid agonist treatment programs offering DAM through both witnessed and carries-based models (e.g., British model), and reflected on how these programs may be adapted for PSS DAM.

Clinicians cautioned that while DAM is preferred by older clients, they have found that it generally does not meet the needs of younger clients who prefer to smoke fentanyl rather than inject DAM. Though not currently available in BC, an inhalable or smokeable formulation of DAM would provide a novel option for PWUD.

Stimulants

Clinicians discussed how stimulants have generally been overlooked, despite posing comparable risks to fentanyl due to the lack of supports and resources for people who use stimulants. Some clinicians described a need for a safer supply of methamphetamine to support clients who use stimulants. It was noted that there is a strong stimulant prescribed in the United States but currently unavailable in Canada.

Despite participants' limited discussion of stimulant prescribing under the Risk Mitigation Guidance, several clinicians shared that prescribing Lisdexamfetamine (Vyvanse), a common ADHD medication, helped their clients stop using crystal methamphetamine and speculated about the potential benefits of a safer supply of stimulants for individuals with undiagnosed ADHD and a SUD.

Benzodiazepines

Clinicians shared that although benzodiazepine prescribing under the Risk Mitigation Guidance does occur, it is uncommon and carried out in a highly cautious manner due to the clinical complexity of co-occurring opioid, alcohol and/or benzodiazepine use. Clinicians cited research from other countries (e.g., Germany, Switzerland) which may provide some insight into best practices for benzodiazepine prescribing.

PWLLE Perspectives:

PWLLE and their family members agreed that more PSS medication options were needed to meet the needs of PWUD and separate them from the toxic illicit supply. PWUD who were able to receive PSS explained that the right medications and formulations have helped them reduce, and in some cases eliminate, their illicit drug use. Others spoke to the challenges they experienced while attempting to access different PSS medication options.

> *"I had to commit to tapering down [my drug use] in order to receive a prescription, [even though] I was experiencing trauma at the time."*

PWLLE expressed concern that the speed with which the illicit supply is changing is outpacing the ability of PSS to provide viable options. One participant noted that the window of viability for PSS was closing, as the adulteration of the illicit supply was going to reach a point where a medical-based PSS system would not be able to provide viable alternative. For example, they pointed to the increasing presence of "cattle tranquilizers" (Xylazine) in the illicit supply and noted that clinicians will never prescribe these as PSS. PWLLE also shared frustration with the slow roll-out and adoption of new PSS medication options. For example, PWLLE pointed to new injectable options being made available only after the preference on the street had shifted to inhalable options. This sense of the government and medical system being several steps behind was seen to indicate a lack of urgency around the toxic drug crisis.

> *"We have the right to choices."*

Many participants expressed concerns with the inflexibility of some PSS programs, which required them to reduce their illicit drug use to receive PSS. Due to the medical nature of PSS, they shared that having to identify a treatment goal or reduce the amount of PSS they are on over time was a paternalistic practice that belied contempt for them as drug users, while clashing with the patient-centred philosophy of PSS. Further, some pointed out that titrating PSS doses down without full client engagement could put people at risk of accessing the unregulated supply to meet their needs, placing them at increased risk of drug poisoning.

Some PWLLE felt that the clinicians they encountered were stigmatizing or mistrusting and urged care providers to listen to their clients and their needs. PWLLE of PSS shared that their clinicians sometimes made decisions about whether a PSS medication was effective without adequate consultation, and without taking the time to understand clients' own goals or definition of success. PWUD maintained that their feedback should be a key consideration when determining whether a medication is beneficial or harmful.

> *"The meaning of stability [and recovery] may be different for patients than for clinicians."*

Hydromorphone (HDM)

PWLLE expressed a high-level of concern that HDM will be removed as a PSS option. There was fear that such a sudden shift would put people at increased risk of harms from the toxic illicit drug supply. While participants agreed that HDM lacked the potency to meet the needs of many PWUD, it was widely recognized as a lifesaving intervention for some. One participant described HDM as a "stepping-stone to stability and safety."

> *"I would be dead without Dilaudid."*

Fentanyl

PWLLE advocated for greater access to fentanyl products, especially inhalable options. Fentanyl PSS is viewed as a viable long-term option for some PWUD, as well as a valuable support for titration on to other medication options.

> *"I am stable on fentanyl patches after lobbying for a year to get them in my region."*

Diacetylmorphine (DAM)

PWLLE view DAM as a PSS option with significant potential for stabilizing substance users and separating them from the toxic illicit supply. They noted that access to DAM is currently limited to small injectable OAT (iOAT) programs in urban areas and advocated for expanded access to DAM iOAT and PSS across all regions of BC.

> *"Currently, it's like winning the lottery to get into [a DAM program]."*

Stimulants

PWLLE expressed concern that stimulant users are being overlooked in discussions about PSS despite the increasing risk of a toxic supply. They advocate for expanded PSS options for stimulant users, including fast-release medications with higher peaks (e.g., faster onset of action). PWLLE noted the need for access to pharmaceutical alternatives to methamphetamine (meth) and suggested that Canada is behind the United States in approving such options.

> *"I shouldn't have to use opioids to get treatment."*

Benzodiazepines

PWLLE also expressed the need for increased access to benzodiazepines as a PSS option. It was noted that while some people use benzodiazepines intentionally, others develop dependence on benzodiazepines by using other illicit drugs which have been contaminated with benzodiazepines. PWUD want clinicians to understand these complexities and help them navigate their options, including to help them avoid withdrawal when transitioning to PSS.

3.6 Emotional and Moral Distress

In the context of a toxic illicit drug crisis, PSS access and provision raises a variety of moral and emotional challenges for stakeholders. Clinicians expressed concerns pertaining to issues such as medical ethics, client well-being, and prescriber isolation. PWLLE voiced their moral distress, grief, and loss, as well as their fears that PSS services might be cut. Families also expressed a great deal of moral distress.

Clinician Perspectives:

The constraints, conflicts, dilemmas, and uncertainty of providing a novel intervention like PSS within the context of the toxic illicit drug public health emergency is taking a toll on clinicians. Throughout the engagements, clinicians raised many ethical questions, including:

- How do I know if I am doing good?
- What if my patient stays on PSS forever?
- What are the long-term social impacts of PSS?

Clinicians are experiencing significant moral distress when providing care to vulnerable clients with limited guidance and a lack of training in harm reduction. It was evident throughout the engagements that clinicians are strongly bound to the ethical principle of "do no harm," and that PSS creates an unusual dilemma for care providers who feel ill-equipped to balance the potential risks of the toxic illicit drug supply against the risks of high-dose prescribing.

> *"[Physicians] want to see people get better, and to us, that looks like people getting off drugs […] [Physicians] are not against PSS, but I need government to understand that that's not why I became a doctor. I don't work on a population level; I work on an individual level."*

Clinicians expressed discomfort with the notion that some people may be on PSS forever. Keeping patients alive is a primary focus for clinicians, but concerns remain about the "endgame" or "exit strategy" for PSS. This highlights the tension between clinicians' training to screen, assess and treat substance use disorders, and PSS as a harm reduction initiative. Clinician discomfort regarding possible long-term PSS use also sits in tension with the fact that not all PWUD aim to stop using PSS or other drugs. Some clinicians also emphasized that they had not been trained to provide PSS and felt unsure of their ability to make clinical decisions around PSS or to help their patients. At the same time, one doctor highlighted the need to trust their patients and decolonize their clinical practice.

Many clinicians have lost patients to the toxic illicit drug supply, and for some, this has resulted in an urgent desire to separate their clients from the toxic illicit supply through PSS. These clinicians shared that they experience moral distress because they know they are not able to meet their client's needs with the available PSS medication options. One clinician described it as bringing a knife to a gun fight, because available PSS options are unable to match the potency of the fentanyl products on the street. Another clinician shared that they had lost patients to care that might have been retained if they had felt comfortable enough to prescribe them benzodiazepines.

> *"I am just trying to keep people alive, and it sucks."*

Moral distress was particularly pronounced in the DTES, with clinicians expressing grief and frustration that their patients seemed to be getting more unstable and unwell despite herculean efforts to support them. Clinicians observed that patients sometimes do not progress in their recovery or may discontinue proven effective treatment in order to access PSS. Likewise, patient tolerance continues to push higher and higher, leaving clinicians wondering if they are contributing to the solution or the problem.

PSS providers in rural and remote areas were particularly likely to express a sense of isolation and helplessness. This was attributed to their lack of connection to other clinicians offering PSS, and the sense that local health care colleagues may not support PSS. They shared that this contributes to feelings of isolation in their PSS practice and/or a sense of shouldering the burden of clinical substance use care alone.

In the North, some clinicians shared their distress that people seeking PSS were being turned away every day and were subsequently at risk of illicit drug poisoning. Clinicians expressed frustration that PSS is not more widely accessible and that practitioners providing PSS are in the minority. One clinician said they felt like the responsibility for separating people from the toxic illicit drug supply was being downloaded onto physicians even as it was becoming increasingly politicized.

> *"The majority of doctors don't prescribe OAT let alone PSS. Rapid access clinics are basically ERs for substance use."*

Conversely, some clinicians felt that they were being pushed to offer PSS despite being uncomfortable with it as an intervention or lacking the appropriate medications to do so. This pressure was described as coming from the government as well as from clients. A few clinicians shared that they have felt threatened by clients who felt that they have a right to access PSS.

> *"It feels [like] we are [being] coerced as physicians to participate in evidence building without our consent."*

We also heard from clinicians who struggle to support patients in relationships where there is an imbalance of power or intimate partner violence, and where there is an immense amount of pressure for the vulnerable partner to obtain safer supply. This leads to moral distress about the impact that changes in prescribing may have on a patient's safety. The overall effect can be a sense of paralysis, where any action or inaction by prescribers may cause harm.

Clinicians also expressed significant concerns about (primarily) men who are housed and employed and at high risk of toxic illicit drug related harms or death. It was observed that many men who use stimulants are unaware of the risks they face, and it was suggested that awareness campaigns and access to fentanyl test strips would be helpful. Clinicians felt that this population was difficult to reach and worried that their care providers often do not recognize them as an at-risk population. Some urge that more effort should be made to educate family physicians to recognize men's alcohol and cocaine use as risk factors for toxic illicit drug harms. Further, it was suggested that take-home doses could be appropriate and effective for this type of "weekend warrior."

> *"I am concerned about the growing division among people practicing addictions medicine."*

Clinicians' distress is also related to fears about creating or deepening conflicts within clinical and broader communities. One clinician likened it to practicing abortion care in the years after abortion was decriminalized.

> *"It's not just the intervention that is politicized. We are politicized too as prescribers, and it doesn't feel good."*

Teamwork within the clinical settings was noted as an important factor in preventing feelings of distress and isolation. Nevertheless, clinicians also expressed distress in relation to concerns for their colleagues well-being. Some clinicians were concerned that providing PSS to a new client could drive a wedge between them and an existing provider. Similarly, clinicians are distressed by the uncertainty around whether their Colleges will support them offering PSS.

There are some settings in which PSS was less likely to cause distress to clinicians. For example, clinicians providing PSS in hospital settings had comfort in seeing their patients every day. In fact, hospitalizations

were often seen as a window of opportunity to stabilize patients who otherwise were not having success in treating their SUD. Some clinicians shared that while they would not provide PSS in their regular practices, they are confident providing PSS in hospital settings. Other clinicians felt that the best conditions for PSS were in outpatient settings, where long-term relationships had already been established with clients. These conditions enabled care providers to observe the longitudinal impacts of PSS on their patients, which for some served to build their confidence in the intervention.

PWLLE Perspectives:

PWLLE also expressed their experiences of acute grief, pain, and loss amidst the toxic illicit drug crisis. They highlighted their experiences of feeling undervalued and disposable, and likewise shared their fears that lifesaving services would be reduced or eliminated. Meanwhile, family members of PWUD expressed a great deal of moral distress.

3.7 Practicing Public Health

Many participants understood PSS as an emergency public health measure enacted in response to dual public health emergencies: the COVID-19 pandemic and the toxic drug crisis. This understanding of PSS as a public health intervention sits in tension with the ways clinicians are used to practicing individualised medicine, which leads to questions about where the access points and delivery of PSS is best situated in the health care system. There was strong consensus amongst clinicians that prescribers (i.e., NPs and MDs) should not be the only access point for safer supply.

Clinician Perspectives:

Clinicians shared the view that PSS is a public health-oriented harm reduction intervention rather than a form of treatment. Some clinicians highlighted conflict between the harm reduction approach of PSS and traditional medical paradigms. Physicians described feeling inadequately equipped to deliver a public health intervention like PSS. For some, PSS challenged their medical training and/or professional values. Some physicians felt that PSS should be provided through the public health system (as is the case with vaccines) rather than by individual physicians, thus alleviating strain on physicians and providing the structural support necessary for PSS to have a population-level impact.

3.8 Diversion of PSS

Diversion of PSS surfaced as a multidimensional issue of significant interest and concern to participants. The potential impacts of diverted PSS, especially HDM, on youth was a source of major apprehension. Discussions also highlighted how the fear of PSS diversion creates barriers to accessing PSS.

Clinician Perspectives:

Many clinicians are distressed about the risk of diversion and potential downstream impacts of PSS. The key concerns clinicians shared were the risk to opioid-naïve individuals who might overdose on diverted PSS, as well as the long-term impacts of people, especially youth, accessing diverted HDM on the street and transitioning to fentanyl and/or developing OUD or SUD. Clinicians also voiced their concern over diverted safer supply enriching organized crime networks. The worry around diversion and the potential for their actions as a clinician to do

> *"Youth access drugs that are available and cheap, so if HDM is available and cheap then that is a concern."*

harm is amplified by the fact that prescribers' names are on prescriptions and medication bottles, establishing a clear line of responsibility and potential liability for the medication and any potential harms it may cause if diverted.

Ongoing monitoring of diversion provides some comfort for clinicians, but dissemination of monitoring data needs to be made more accessible. The majority of evidence of diversion is anecdotal, which contributes to uncertainty around the issue. As a result, there is a diversity of perspectives and varying degrees of concern expressed by clinicians. For some clinicians, concern over diversion stops them from offering PSS entirely, whereas for others, diversion is a lesser concern in comparison to the risks of the illicit drug supply.

Some clinicians expressed the view that diverted PSS is itself harm reduction, as diverted pharmaceutical alternatives are still safer than the toxic illicit supply (due to known drug quality and potency). In this view, diverted PSS was seen as beneficial rather than harmful. Several clinicians expressed concern that the system-wide apprehension about diversion was driving the creation of a high-barrier system that made it difficult for PWUD to access PSS, thereby putting them at risk of toxic illicit drug harms and death.

> *"Diversion addresses a variety of unmet needs."*

While perspectives on diversion vary, there was broad agreement amongst clinicians that diversion is more likely to occur when PSS options are not meeting patient needs. When patients are prescribed a strength and quantity of medication that meets their needs and that can be consumed in a way that meets their preference (e.g., inhalable and injectable options), there is little motivation to divert PSS. Further, clinicians suggested that providing housing, other social supports and access to PSS in this setting would also lower the risk of diversion.

PWLLE Perspectives:

The unpredictability and toxicity of the illicit supply loomed large in discussions with PWLLE on diversion. Deep frustration was expressed about the heightened focus on diversion of PSS. A few PWLLE remarked that the concern about diversion felt disingenuous given the well-documented and ever rising death toll related to the toxic illicit drug supply. More pointedly, some PWLLE felt that the anxiety around diversion is evidence of discrimination against PWUD within the health care system and that issues around liability were being given more weight than their lives.

> *"Without my medication I will die, and my children will be orphaned. I'm happy and have a great job. But a policy makes or breaks whether I continue to breathe."*

Participants also discussed how public narratives that are critical of PSS are harmful to PWUD. They described how the low level of PSS prescribing to date is unlikely to be of sufficient scale to cause the population-level health impacts of diversion (e.g., increased incidence of overdoses and opioid use disorders) as speculated in the media. There was also concern that the heightened focus on diversion in BC would discourage PSS expansion in BC, as well as the implementation of PSS programs in other parts of the country.

While PWLLE recognized that diversion was not unique to PSS and happened with all kinds of medications, they broadly shared the view that diversion of PSS was a direct result of PSS medications not meeting the needs of PWUD. They believed that if people could access more PSS options in formulations (e.g., inhalable) and strengths that mirrored what was available on the street, diversion would decrease significantly.

> *"Diversion of HDM has always happened – I was buying it 25 years ago."*

PWLLE expressed the view that diversion, while not ideal, could save lives. To illustrate the point, one participant shared that they would rather their child use diverted HDM than use toxic street drugs and die. Others shared that they seek out diverted PSS because they are unable to access PSS directly (e.g., due to deprescribing, limited pharmacy hours, distrust of medical professionals, daily witnessing requirements), or if they are in withdrawal but trying to avoid street drugs. They pointed out that increased access to PSS may shrink the market for diverted medications and therefore decrease the incentives that lead to diversion in the first place.

> *"I have used diverted PSS for two years and these two years have been the best of my life. I consider myself in recovery. People conflate recovery with abstinence, but I'm in recovery from the chaos. Treatment does not equate to abstinence."*

3.9 Deprescribing

In the context of PSS, deprescribing is the process of a supervised reduction in medication dosage or a termination of prescribing. For PSS, the clinical goals can include discontinuing medications or lowering doses, where the prescriber has determined that potential harms outweigh potential benefits or where benefits are unclear. Deprescribing of PSS appears to be a result of concerns about the effectiveness of PSS, medication nonadherence, possible diversion, and a breakdown in trust with a patient (often due to urine screening results).

Clinician Perspectives:

As with diversion, clinicians have a range of perspectives on deprescribing. Some clinicians felt strongly that health care providers should not deprescribe without offering an alternative PSS medication. These clinicians see deprescribing as a significant risk factor for toxic illicit drug poisoning. One clinician suggested that it would be useful to track drug poisoning injuries and deaths that occur after an individual is deprescribed PSS.

Clinicians shared examples of how deprescribing has damaged relationships and resulted in fragmented or complete loss of care. In these cases, any stability that had been gained through PSS was believed to have been lost. Some clinicians reported that deprescribing can result in violent and abusive behaviour against them.

While some clinicians saw deprescribing as harmful or morally wrong, many others saw it as an ethical imperative in certain circumstances. Some clinicians deprescribe automatically if they find a patient is, not taking their PSS and are suspected of diversion. In these cases, the risk of continuing to provide PSS is determined to be too high to continue. Some clinicians also deprescribe automatically if they find their patients are taking illicit fentanyl in addition to their PSS therefore negating the benefits.

Clinicians also deprescribe in cases where they believe that PSS is not benefiting the client. How client benefit is assessed appears to vary. Clinicians shared that there can be a lack of a unified approach, and if they deprescribe a patient, another clinic may (re)prescribe.

PWLLE Perspectives:

PWLLE reported that deprescribing is increasingly common and emphasized how dangerous the practice can be. They also noted that clinicians sometimes force patients to choose between OAT or PSS, even though some clients have found that PSS and OAT work well in tandem. Although current PSS prescribing options remain limited, they cut out the worst and most dangerous impacts of the illicit market. One participant spoke about a situation where an individual had been deprescribed PSS and died from the illicit supply shortly thereafter. In light of this risk, PWLLE urge prescribers not to deprescribe their patients without consent. Some PWLLE also warned that deprescribing would increase demand for PSS medications in the illicit market, fueling sales of counterfeit substances cut with dangerous adulterants.

> *"Public opinion shouldn't dictate what medications I get for my disease."*

There was a general feeling among PWLLE that deprescribing is happening because of the current political context. They observed that stigma against PWUD and the backlash against PSS, other forms of harm reduction, and decriminalization playing out in the media may be impacting prescribers' decision-making. One participant lamented how even their community's strongest advocates and success stories are losing access to PSS and turning back to street drugs as a result of what they perceived to be the politicization of the issue.

> *"The [health] system doesn't meet our needs, and we get punished for it."*

Furthermore, some PWLLE added that limited PSS prescriber numbers, the pressures prescribers face from colleagues, and the fear of audits by regulatory colleges are contributing to deprescribing and overall prescriber hesitancy.

As with diversion, PWLLE believe that deprescribing is a result of PSS medication options that are not meeting the needs of PWUD. PWLLE argue that even if an individual's PSS is not meeting their needs, they see a benefit in replacing some of their toxic illicit supply with PSS. While it would be preferable to completely separate people from the illicit supply, that isn't always possible with the currently available PSS options. As such, deprescribing is generally experienced by PWUD as punitive and life-threatening. Indeed, one participant noted that the constant urine screening required in some PSS programs was humiliating, and that these screens, which often preceded deprescribing, made them feel like they had "one foot in the criminal justice system instead of the health system."

3.10 Clinicians Need More Support

PSS can be complex and challenging for healthcare providers, and clinicians need additional supports to implement PSS successfully. Clinicians identified a variety of supports that would enable them to provide PSS more effectively and with more confidence. PWLLE also highlighted the need for greater supports and guidance for healthcare professionals.

> *"Supporting PSS prescribers is supporting PWUD."*

Clinician Perspectives:

Access to PSS Data

Currently there is no clear mechanism for monitoring, evaluation, and research findings to be disseminated to clinicians in a timely manner to influence practice. Clinicians want access to timely monitoring and evaluation data, as well as data around quality-of-life improvements enabled by PSS. The availability of quantitative and peer-reviewed research will help clinicians refine their approach to PSS and build confidence in the intervention. Some clinicians expressed that while new research will be beneficial, there are also benefits to be gained by more effective dissemination of existing data – especially between MMHA and health authorities and health authorities and clinicians. Evidence summaries, which include implications for practice where appropriate, were recommended as an accessible mode of dissemination.

Some clinicians said they want access to more population surveillance data, whereas other clinicians felt that they were ill equipped to interpret population-level data to inform their individual-level practice. Clinicians believe that they are practicing evidence-generating medicine but expressed feeling disconnected from the findings of their work.

Clinicians were aware of the benefits of PSS noted in early research findings (e.g., in reducing overdoses). However, many clinicians believe the existing research is biased and are unconvinced that PSS has reduced illicit drug related deaths. They expressed skepticism noting that the preliminary benefits that have been identified may be due to other factors, such as income supplementation through the federal government's Canada Emergency Response Benefit (CERB) program during COVID-19. One clinician noted that PSS further complicates the typical 'clinical math' associated with providing care to people who use drugs and felt that clients would derive greater benefit from social supports (e.g., housing) that are outside their scope of care.

Some clinicians expressed concern that the politicization of PSS could drive bias in data collection and interpretation, as well as negatively impact the monitoring of unintended consequences. It was recommended that PSS data should be presented with a high level of transparency, including regarding data limitations, to dispel distrust.

Clinical Guidance

Clinicians want clear and objective clinical guidance that promotes patient-centered care and permits some clinical discretion. Clinicians expressed a need for clinical guidance around a variety of elements of their practice, including dosage guidance with expanded ranges, more specific scales, and monitoring. Some clinicians shared frustration with the length of time that guidelines and protocols were taking to develop and urged that this work be prioritized.

Clinicians described the need for additional practice support tools including a "cheat sheet" to support conversations with patients about potential risks and benefits of PSS. Such resources would be useful to clinicians with a range of experience offering PSS. Clinicians shared that consultations with clients are often complex, and that a tool to support consistent practice would take some pressure off prescribers. Clinicians shared that clinical guidance and support for consistent PSS practices could also come in the

form of communities of practice or other groups where clinicians could learn from each other, as prescribing individually can cause challenges.

Regulatory College Support

Clinicians were clear that they want more support from their regulatory Colleges around the provision of PSS. Many clinicians believed that the College of Physicians and Surgeons of BC (CPSBC) and the BC College of Nursing Professionals (BCCNP) do not fully support PSS. The perceived disapproval of the Colleges in relation to PSS was identified by clinicians as a key source of anxiety.

Discussions revealed that clinicians have wide-ranging interpretations of College direction and expectations. For example, some clinicians believed that the College required them to conduct urine screens at every visit and that deprescribing was mandatory if screening was negative for PSS. Other clinicians understood urine screens and deprescribing as falling within their clinical discretion. This lack of certainty, combined with the potential for clinicians' practice to be reviewed by the College and the threat of discipline, adds significant complexity to already challenging clinical decision making. Clinicians want clarity on how, when, and why PSS-related decisions are reviewed, and on what is required of them to remain in compliance.

> *"The College weighs on [us] – we are always thinking about how they will see our prescribing."*

The fear of College review and discipline appears to be a barrier to the successful implementation of PSS. Clinicians shared that the perceived need to justify their PSS prescribing to the College represented an additional burden in the context of an already unmanageable workload. The perception of CPSBC scrutiny of prescribing practice appeared to disincentivize some clinicians from providing PSS. Additionally, those who had had their practice reviewed highlighted the immense burden of unpaid time that was required to comply with College processes and procedures.

Payment

Clinicians underlined factors that de-incentivize PSS provision, including the workload required and limited billing mechanisms. Clinicians identified the fee-for-service model as inadequate and noted that while the new longitudinal payment model is beneficial, it doesn't fit well with substance use care. Financial stressors related to payment also make it difficult for clinics to engage allied health professionals to improve retention and enhance patient outcomes.

PWLLE Perspectives:

PWLLE also recognized that clinicians need greater support and guidance surrounding PSS. Some PWLLE noted a lack of understanding of PSS, harm reduction, and substance use among clinicians. There were calls for the creation of mandatory trainings on the toxic drug poisoning crisis, harm reduction, and PSS for all prescribers and healthcare professionals, to be developed with in concert with PWLLE.

3.11 One Size of PSS Doesn't Fit All

Each region of the province has a unique culture and context, and there isn't a single approach to PSS that will work everywhere. Any changes to PSS policy or service delivery should allow prescribers the necessary flexibility to use their professional clinical judgment.

Clinician Perspectives:

Access to PSS is currently concentrated in urban areas, creating inequities across the province. Clinicians identified multiple barriers to PSS service delivery in rural and remote communities, including the need for patients to travel long distances to access services, as well as limited staffing due to recruitment and retention issues. These challenges were compounded by a perceived lack of support from municipalities, health system partners including certain pharmacies, and in some instances health authorities.

> *"In the North, it's easier to find a dealer than a doctor."*

Pharmacies were raised as critically important for ensuring access to PSS. Likewise, pharmacy-related issues were identified as contributing to inequities in PSS access across the province and across regions. Clinicians noted that some pharmacies are reluctant to support PSS prescribing or even to allow PWUD inside their storefronts. There was also a concern expressed from some clinicians that a small number of pharmacies are exploiting abusing the system for profit. On the other hand, some participants discussed innovative models and partnerships with pharmacies, highlighting relationships as an important success factor in PSS service provision.

Clinicians felt that regional heath authority support for PSS was inconsistent across the province. In some regions, the health authority was viewed as a barrier to PSS implementation and clinicians recommended that the province fund non-health authority programs to ensure access to PSS for people who need it.

The infrastructure and resource needs in rural and remote settings are significant. Clinicians expressed concern that in the context of scarcity, some colleagues and community members believe that money spent on harm reduction means less money for treatment beds. This perspective may contribute to a lack of interest in providing PSS. Clinicians noted that in small communities, losing a prescriber can be catastrophic as there are rarely other providers locally that can take on their patients. As a result, people lose access to PSS and its benefits and are forced to turn to the toxic illicit supply.

> *"My provider went on vacation, and I had to explain my story to a stranger who wanted me to be sober. This is why people stockpile drugs.*

Funding for outreach and delivery services are necessary to overcome the geographic distance between PSS programs and clients. Clinicians noted that in some regions, daily pick-up of medication and/or witnessed dosing are hindered by pharmacies that close on weekends or have other limited hours, lack of staffing, lack of public transit, and inclement weather impacting travel. One clinician practicing in a remote area noted it was widely accepted that patients on the fentanyl patch go into withdrawal on Sundays when they are unable to access a patch change, and therefore prescribing HDM to create a bridge to the next fentanyl patch is common practice. To avoid withdrawal, patients are known to stockpile HDM.

PWLLE Perspectives:

PWLLE and family members of PWUD were unequivocal about the need to improve access to the substance use continuum of care, including PSS, in rural and remote communities. They identified the need for expanded access to video interviews for intake and assessment, and virtual prescribing to help with reach and access. Further, they noted the need to address transportation challenges by increasing access to carries, medication delivery, mobile pharmacists or other access points for PSS.

> *"People are dying because they are not able to access their prescription."*

The need for enhanced services and supports for youth, 2S/LGBTQIA+, and racialized communities was also identified. PWLLE strongly advocated for increased engagement with these communities around OAT, PSS, and harm reduction to better understand their unique needs. Participants called for increased funding to enable more safe spaces for youth to explore their relationship to substances (e.g., by-and-for-youth drug user meetings).

PWLLE also stressed the need to acknowledge and address the trauma and poor treatment of youth in, and aging out of, the foster care system, and to significantly increase the supports available to them – including for those who have lost parents to the toxic drug supply.

Supporting Indigenous People

Clinicians identified several enabling factors for supporting Indigenous clients, including medical practitioners with appropriate cultural safety and cultural humility training, experience working with First Nations communities/Indigenous clients, and incorporating more Indigenous health professionals into the substance use workforce. These enabling factors also include a nuanced understanding of the roots of Indigenous people's substance use in the intergenerational trauma of colonization, as well as the negative impacts of forced treatment.

Clinicians also recognized the importance of relationship building with Indigenous patients to overcome their distrust of a medical system that has too often been characterized by anti-Indigenous racism. Some clinicians likewise expressed the need for a reflexive examination of their own cultural biases and colonial training, in order to be able to provide culturally responsive care.

Supporting Youth

Clinicians recognize that youth without a stable home or in the foster care system are most likely to use drugs. Clinicians also shared that they see many young people who have lost a parent to toxic illicit drug poisoning and are themselves at risk of illicit drug related harms. Limited supports are available for young people dealing with trauma, and clinicians feel they have limited options for supporting them.

> *"When people shout, 'what about the children' they only mean the children who don't use drugs."*

Clinicians report that youth are often scared to access supervised consumption or overdose prevention sites, and therefore are not connecting to many community-based harm reduction services. Clinicians see this as a significant advantage of PSS: it is getting young people "in the door" in ways other harm reduction services aren't currently equipped to do. Some clinicians were hopeful that more youth are coming forward for support because PSS and decriminalization are enabling them to feel more trust in the healthcare system.

> *"Without safe supply that includes youth they will die. I was at a funeral for a 16-year-old. The kids who need HDM are not getting it."*

Supporting People Living with Pain

Some clinicians expressed concern that patients living with pain are being politicized, which is creating uncertainty among medical practitioners. Clinicians are regularly seeing pain patients who are desperate for support. Clinicians described low-income seniors and people living with chronic pain who have turned to the toxic illicit drug supply after being deprescribed opioids. This puts them at risk of toxic illicit drug poisoning.

Clinicians observed that the CPSBC practice standard *Safe Prescribing of Opioids and Sedatives* released in 2016 led to a decreased in opioid prescribing for people with pain, resulting in significant long-term impacts. Some clinicians argued that family physicians need to re-engage in the treatment of pain so that people suffering are not put at greater risk.

Supporting People Working in Trades

Clinicians expressed significant concern about men working in the trades and the need to recognize them as a high-risk population. Clinicians described two different profiles they observe commonly with this population. One group are men who work in trades during the week and use illicit drugs on the weekend. These "weekend warriors" may not recognize the risks inherent in the illicit drug supply, which makes them more likely to use alone.

The other group clinicians identified are tradespeople who were injured on the job, prescribed opioids to manage their pain, and then deprescribed, resulting in them seeking illicit supply. An urgent primary care clinician shared that men fitting this profile were the most common group of people seeking PSS Further, it was reported that these men are difficult to get into PSS clinics due in part to stigma. This led another clinician to urge for the reconsideration of what is meant by "low barrier" access to PSS, as PSS is currently only low barrier for certain groups (e.g., urban street entrenched drug users).

3.12 Envisioning the Future of PSS in BC

Throughout the engagement workshops, participants were asked to share their visions for what an ideal safer supply program should look like in BC. The discussions that ensued were rich and varied, but all shared the thread of care and compassion for PWUD.

Clinician Perspectives:

Many clinicians expressed the need for a new name to describe the provision of pharmaceutical alternatives through the medical system. Clinicians felt that "PSS" did not accurately reflect the intervention they are trying to deliver, and some worried that the term implied a level of safety that can be misleading for young people. Many clinicians indicated this feedback was provided to government prior to the PSS policy release in 2021. Language matters, and the current vocabulary around PSS is limited and, in some cases, problematic. The challenges around defining PSS as an intervention and a policy are compounded by the politicization and stigmatization that characterizes public discourse. One clinician commented that PSS has a communications problem as a novel intervention.

> *"The term safer supply makes it sound safe for teens – they know fentanyl is dangerous but think 'dillies' [HDM] are safe."*

Clinicians agree that the ideal state of PSS in BC would be characterized by a non-stigmatized, culturally safe program, accessible across the province for all those at risk of toxic illicit drug related harms. Perceptions of how to achieve this vary. Many believe that more medication and access options and fewer barriers are needed to reach those people who do not feel safe to disclose their substance use. Others feel that the benefits of PSS can only be achieved through highly structured programs with witnessed dosing or short-term carries as the default provision method.

Despite the noted benefits of PSS, clinicians recommended several changes for future implementation. They recommend scaling up programs that are working and increasing supports for communities that are under-resourced to offer PSS. Finally, some clinicians urged caution that the utility of PSS is impacted by the evolving drug supply, which is increasingly being adulterated with new types of drugs (e.g., "tranq dope").

Prescribers have been feeling the burden of responding to the toxic drug crisis, and they are concerned that they are expected to outpace drug dealers and 'gatekeep' access to PSS. To meet the need for PSS in the province, clinicians urged an exploration of options that are less resource intensive and don't require 1:1 prescribing. Some clinicians feel that their focus should be on treatment and that safer supply should be de-medicalized.

Most clinicians agreed that there should be a continuum of safer supply provision methods in BC, from PSS through to a regulated supply. Many felt that this would take pressure off prescribers while enabling them to retain PSS as a tool in their toolbox. A regulated supply was viewed as a way to expand access to safer supply at a population level. Many clinicians envisioned a regulated supply similar to cannabis, whereas others talked about compassion clubs as a more desired model.

PWLLE Perspectives:

PWLLE echoed the calls of clinicians to find a more appropriate name for PSS. They encourage people-first language and would like to see the end of terminology such as 'safer supply' to describe current pharmaceutical alternative options. For example, one participant argued that prescribed HDM isn't a substitute for anything on the street and that calling it PSS was confusing.

> *"Recovery should be based on what the patient wants and not what the provider wants."*

Overall, PWLLE want to be able to access patient-centered substance use care that recognizes and respects the diversity of their needs and goals. They emphasize the need for enhanced services and supports for youth, 2S/LGBTQIA+ and racialized communities, and family members of PWUD. PWLLE also advocate for significantly enhanced services and supports for rural and remote communities through options like telehealth.

PWLLE are acutely aware of stigma in their communities and in the health care system. There was broad agreement that seeking support in the current substance use system of care means navigating around too many barriers. PWLLE recommend expanded support for peer navigators and other peer-driven initiatives.

PWLLE also discussed the potential for enhancing and diversifying safer supply models. This could include initiatives such as peer navigator services and different delivery models. Some PWLLE also want safer supply decoupled from the medical system. They view a non-medical community-based model as the only way to remove barriers to safer supply and to turn the tide on the toxic illicit drug supply. At the same time, some PWLLE also noted that non-medicalized options should coexist with – not entirely supersede – medicalized PSS models. They explained that access to PSS in a clinical setting suits some clients best as long as those settings are supportive and non-stigmatizing. Several examples of clinics or services involving partnerships with clinicians, pharmacists, peers and other supportive services were described.

Most importantly, PWLLE would like a system that does not require them to continually advocate for and defend the value of a lifesaving intervention.

4. Conclusion

This report summarizes key themes captured during the Provincial Health Officer's engagements with physicians, nurse practitioners, family members, and PWLLE regarding PSS in BC. Throughout the discussions, it was clear that PSS is a valued intervention in the context of the ongoing toxic drug emergency. Clinicians view PSS as an important 'tool in their toolkits' to support people who use drugs, not only by separating them from the toxic supply but also because of its power to bring people in the door and facilitate connections to other health and social supports.

Many PWLLE described the successes they have had with PSS, demonstrating through their own lived experiences the benefits that such programs can offer. PSS has helped them enjoy stable employment, housing, healthier relationships, and connection to loved ones, including care for their children. Critically, PSS also reduces the harms of accessing an unregulated street market.

PWLLE recognize PSS as an intervention with potential to reach more people than other substance use care modalities. However, PSS is currently inaccessible to the majority of people who use drugs. Examples were shared of individuals in rural and remote communities having little to no access to prescribers and experiencing compounding barriers related to stigma, community discrimination, and transportation. Access to PSS is also limited in urban areas – several PWLLE described gaining access to a PSS program as akin to winning the lottery.

PWLLE also described the need for a broader range of supports not only for PWUD but also for their family members. Moreover, family members of PWUD concurred with PWLLE that PSS represents a lifesaving intervention, yet one that is currently inaccessible to many of the people at risk of toxic drug poisoning.

Clinicians agreed that significant barriers and gaps exist in the substance use system of care, and that it is confusing how PSS fits within this continuum. These uncertainties leave people at risk of significant harms, including fatal overdoses and being lost to care. Challenges accessing withdrawal management, treatment and recovery programs were a source of concern for all participants. Similarly, there was wide agreement that key social determinants of health, especially housing, are necessary precursors to long-term stability, leading to calls for greater investments in social supports. Participants also reflected on the need to address poverty, marginalization, trauma, and other root causes of substance use.

For PSS to be successful, participants identified the need for an expanded continuum of medication options. PWUD emphasized the importance of personal agency and choice in selecting the medications and formulations that are right for them. While perspectives on the benefits and drawbacks of HDM were mixed, there was overwhelming opposition to ending access to tablet HDM prescribing under PSS, recognizing that it was an important medication for many. PWLLE want access to more fentanyl products and DAM, especially in inhalable and smokable formulations. Pharmaceutical alternatives for stimulants and benzodiazepines are also required to meet the needs of PWUD.

Meanwhile, clinicians are experiencing significant moral distress regarding providing a novel intervention like PSS amidst a toxic illicit drug public health emergency. Prescribers described feeling inadequately equipped to deliver a public health-oriented intervention like PSS. Many clinicians expressed concerns regarding the unintended consequences of PSS, including diversion and negative population-level health impacts. For some, PSS challenged their medical training and/or professional values. PWLLE and family members are also facing emotional and moral strain, and family members of PWUD need more support.

The optimization of PSS service delivery requires improved support for clinicians, including from their regulatory Colleges and health authorities. Clinicians want increased and timely access to PSS data and research findings. Clinicians also want clear and comprehensive clinical guidance. Some clinicians want more directive guidance and protocols, whereas others want more clinical discretion to determine the best option for their individual patient.

When it comes to PSS, one size doesn't fit all. There are diverse needs regionally and across the unique populations of PWUD in BC. Notable gaps in PSS access were identified for Indigenous peoples, youth, individuals living with pain, people working in the trades, and intermittent and recreational drug users. To understand the diversity of existing needs, PWLLE emphasized the importance of sustained, meaningful, partnered engagement. To meet this diversity of needs, clinicians advocated for flexibility to use their professional judgment.

For many, the ideal PSS model would include a continuum of safer supply delivery models, ranging from PSS through to a regulated supply. For others, a highly structured medical-based approach is the way forward. Looking to the future, many clinicians and PWLLE articulated a shared vision for non-stigmatizing, patient-centered, culturally safe, accessible PSS program as part of a continuum of care (including harm reduction, treatment including OAT, withdrawal services, and a spectrum of recovery services) that support PWUD across BC and respects the diversity of client needs and goals.

Appendix C

Ethical Analysis of the Prescribed Safer Supply Policy in British Columbia:

Final Report and Recommendations

BC Provincial Health Ethics Advisory Team
November 3, 2023

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Executive Summary

Who we are

PHEAT is BC's Provincial Health Ethics Advisory Team. Our team includes ethicists and other healthcare providers working in BC health authorities, including First Nations Health Authority.

Background

In August 2023, the Public Health Officer of BC asked PHEAT to look at ethical issues related to Prescribed Safer Supply (PSS). Safer supply programs are intended to reduce harms related to drugs and connect people to healthcare and social supports. Ethics focuses on determining the best way to respond to a problem.

Our Approach

We reviewed research, government reports, and media stories about PSS in BC. We connected with people who use drugs (PWUD), Indigenous leadership, healthcare providers, policy makers and others interested in PSS about the pros and cons of the current PSS policy in BC.

What we learned

People shared many different opinions about PSS, including:

Benefits	PSS can improve quality of life, stability, physical health, and mental health
	PSS is life-saving and life changing for some PWUD
	PSS can reduce harms, including from overdose and involvement with police
	PSS can support increased engagement in work, school and healthcare
	PSS supports dignity, autonomy, self-determination and client-centred care
	Diversion of PSS may have beneficial impacts, including access to safer supply for PWUD without PSS and other unmet needs
Concerns	BC may not provide enough support for PWUD or prescribers
	It is difficult to access PSS, particularly for youth and people in rural and remote areas
	Current delivery methods may increase stigma and do not meet the needs of many people who use drugs
	PSS may increase tolerance, making detox and opioid agonist therapy more difficult
	Diversion of PSS may have harmful impacts, such as contributing to increased substance use, dependence, overdose, and trauma
	PWUD may not have basic needs met, such as access to housing, food, and healthcare
	More substance use treatment, recovery programs or mental health services are needed
	Some groups are more affected by the toxic drug emergency as a result of systemic inequities and/or racism, such as: Indigenous peoples, people with mental health issues, people living in poverty, youth, and people living in rural and remote areas
	Safer supply decisions are made without enough consultation with PWUD, prescribers
	Partnership with Indigenous leaders and communities is inadequate
	There is not enough research on safer supply, including PSS

Values and Principles

The following ethical values and principles are important when making decisions about public health: Cultural safety and cultural humility; effectiveness, efficiency, integrity, procedural justice (fair process), solidarity, distributive justice (equality and equity); duty to care; respect; utility (weigh harms and benefits)

Ethical Questions

We asked four ethical questions. We carefully considered how to balance the values and principles. We made recommendations based on our analysis of these questions:

1. How should we balance the real and potential benefits and harms of PSS?
2. How should the benefits of PSS be balanced with the impacts of diversion?
3. How should we address tensions between the needs of individuals accessing PSS and prescriber practices?
4. What is an ethical approach to addressing concerns about PSS?

Recommendations

We conclude that safer supply is an ethical way to reduce harms for PWUD. At present, based on available evidence, a safer supply policy can be ethically defended and prioritized.

We recommend that the BC government and health authorities:

1. **Support PSS delivery within healthcare systems**. PSS policy should aim to reduce inequities and not place unfair burdens on particular individuals and/or populations. Policies should not perpetuate stigma and/or systemic or structural inequities. Partnership with Indigenous leaders is essential to ensure culturally safe supply options.
2. **Partner with PWUD, prescribers and Indigenous leaders** in developing, implementing and revising safer supply policies and services to ensure they are maximally effective.
3. **Recognize and address the disproportionate impact of the unregulated drug supply on Indigenous populations.** Partner with Indigenous leaders and communities in the development of culturally safe supply options that address systems of oppression, Indigenous specific racism and ongoing colonialism in the healthcare system.
4. **Recognize and address the unique needs of youth.** Partner with youth to develop strategies to decrease risks from the unregulated drug emergency**,** such as tailored mental health resources and harm reduction services.
5. **Invest in services to improve health and reduce harms from substance use for PWUD**. For example: access to safer supply, prevention services, treatment services, culturally safe services, mental health services, housing, and food.
6. **Evaluate safer supply program effectiveness (including cultural safety)** by drawing on available and emerging evidence, including quantitative and qualitative research. Implement ethically sound evaluation and reporting mechanisms. Be prepared to adapt interventions based on emerging evidence.
7. **Consider diverse safer supply models including providing safer supply in non-healthcare settings**. This may include different substances, doses, and criteria for access, as well as a range of delivery methods.

8. **Ensure strategies to address diversion[10] reduce negative impacts of diversion <u>without</u> disrupting benefits** to those accessing PSS, including benefits of diversion for those who rely on diverted PSS to avoid unregulated drugs.
9. **Ensure strategies to reduce diversion address unmet needs of people who divert PSS.**
10. **Provide appropriate supports for prescribers of PSS.** Prescribers should be provided with education and supports necessary to ensure PSS is accessible to all who need it. Safer supply policies should be aligned with prescribers' standards of practice and regulatory requirements. This must be done with input from prescribers, regulatory bodies and other interested parties.
11. **Develop processes for people to raise concerns about safer supply policy and services**. Processes should be put in place for PWUD, Indigenous leaders, prescribers, and other interested parties to raise concerns, including issues related to cultural safety and humility.
12. **Regularly update this ethical analysis** to incorporate new evidence. Partner with Indigenous leadership to ensure cultural safety and humility.

[10] For this review, we consider diversion as a circumstance where some or all of the prescribed supply end up with someone other than the person for whom the prescription was intended.

Acknowledgement

This work was conducted on the traditional, ancestral and unceded territories of many First Nations across the province colonially known as British Columbia (BC). We wish to acknowledge the distinct rights and title of these First Nations, including their unextinguished land rights and rights to self-determination, health and wellness within these territories. We also recognize that there are over 200 First Nations in BC, all of which have their own distinct cultures and voices in this conversation.

We also recognize the individual and collective rights that extend to all Indigenous Peoples (First Nations, Métis, and Inuit) who reside in BC but whose ancestral territories are outside of BC.

The issues addressed in the ethical analysis here have impacted all communities across BC. Many people have directly experienced suffering and loss in the unregulated drug emergency. This analysis strives to provide an ethical lens to an evaluation of one policy, Prescribed Safer Supply (PSS)[i]. Throughout this work we honour and reflect on the difficult and often devastating experiences of those impacted by the ongoing unregulated drug emergency. We thank those who took the time to share their voices and experiences to inform this analysis.

We wish to draw attention to the intersecting factors, including Indigenous-specific racism, colonialism and intergenerational trauma that have led to a disproportionate impact of the unregulated drug emergency on First Nations, Métis and Inuit peoples and communities in BC. This disproportionate impact has led to a death rate from the unregulated drug emergency that is 5.9 times higher for First Nations individuals compared to non-First Nations British Columbians, and 11.2 times higher for First Nations women compared to other BC women[ii]. Throughout this ethical analysis we strive to highlight our commitments to honour Indigenous human rights, including the Indigenous Right to Health.

We seek to recognize and uphold the rights of Indigenous Peoples outlined in the United Nations Declaration of the Rights of Indigenous People (UNDRIP), the B.C. Declaration on the Rights of Indigenous Peoples Act (DRIPA), the Truth and Reconciliation Commission of Canada Report: Calls to Action, the National Inquiry into Missing and Murdered Indigenous Women and Girls: Calls for Justice and the In Plain Sight Report.[iii,iv,v,vi,vii] These foundational documents recognize and define universal Indigenous rights and Indigenous human rights, including the Indigenous Right to Health. Specific rights recognized within these documents include: the highest attainable standard of physical and mental health; access healthcare without discrimination; be actively involved in developing health programs; and access traditional medicines and maintenance of traditional health practices.

Background

The unregulated drug emergency in BC was declared a public health emergency in 2016 in response to a sharp increase in drug-related deaths in the province. Over 13,000 British Columbians have died since the emergency was declared, with an estimated 225,000 people continuing to be at risk of injury or death[viii]. The immediate driver of these deaths is the increasingly volatile, inconsistent, toxic unregulated drug supply dominated by fentanyl[ix]. In addition to volatility and inconsistency in potency, drug checking results have found much of the opioid supply is contaminated by fentanyl analogues such as fluorofentanyl as well as benzodiazepines and other sedatives[x,xi].

As part of several other broader initiatives and policies aimed at reducing harms related to unregulated drug supply, BC introduced the *Access to Prescribed Safer Supply in British Columbia: Policy Direction*[xii] in 2021. Prescribed Safer Supply (PSS) is the provision of pharmaceutical-grade alternatives for people who are at risk of adverse events (e.g. injury, death) from the unregulated drug supply. Approximately 5,000 British Columbians have access to prescribed safer supply on any given month, with hydromorphone being the most frequently prescribed opioid medication[xiii].

There are many models for safer supply[11], including prescribed (PSS) and non-prescribed models, that use a diverse range of drugs and delivery methods. The goals of safer supply programs generally include: reduce or eliminate unregulated drug supply-related injuries (e.g. anoxic brain injury) and deaths; enhance connections to health, social and cultural supports; and improve overall health and wellness for PWUD[xiv,xv]. These programs aim to ensure service equity and provide care that helps address stigma faced by PWUD[xvi].

In August 2023 the Public Health Officer (PHO) of BC requested that BC's Provincial Health Ethics Advisory Team (PHEAT) conduct an ethical analysis on the PSS policy and implementation. The aim of this analysis is to identify and examine the emerging and ongoing ethical implications of PSS at the individual and population level as well as provide recommendations for BC's response to ethical challenges related to PSS.

This ethical analysis applies to the current BC context and BC's current PSS policy. PSS is the prescribing, dispensing, and administration of pharmaceutical-grade alternatives for people who are at risk of substance overdose events and death. Within BC's current PSS model, there are several options, including various drugs, delivery methods, and practices for witnessing consumption. This analysis focuses on ethical issues with respect to how PSS is currently offered in BC. The ethical analysis is part of a larger provincial effort under the PHO to evaluate the evidence for PSS, engage with impacted groups and explore options.

[11] According to the Canadian Association of People who Use Drugs, "safe supply refers to a legal and regulated supply of drugs with mind/body altering properties that traditionally have been accessible only through the illicit drug market". Canadian Association of People Who Use Drugs. (2019). *Safe Supply: Concept Document,* p.4. https://vancouver.ca/files/cov/capud-safe-supply-concept-document.pdf

At the request of the PHO, we have considered issues related to diversion in this ethical analysis. Diversion of medications is not unique to PSS or PWUD. We recognize that discussions about diversion of PSS can perpetuate stigma towards PWUD. In this analysis, we consider diversion broadly as a phenomenon that occurs when some or all of a medication prescribed to an individual ends up with someone other than the person for whom the prescription was intended. It may be used as a strategy to meet needs (e.g. access to adequate drugs, food, housing, connection; helping a friend in withdrawal) or be unintended (e.g., stolen). Diversion commonly happens within the context of intersecting systemic factors, including: lack of access to harm reduction services, treatment services, recovery programs mental health services, housing, shelter and food; poverty; gender-based violence; disparities in resources for Indigenous people, youth and those in rural and remote areas; and limited culturally safe and trauma-informed care.

This ethical analysis is informed by a review of sources related to the unregulated drug supply and PSS including: a literature review of published and grey literature, media reports, BC Coroner data and BC Centre for Disease Control (BCCDC) reports; and engagement with over 372 interested parties via survey and interviews.

Literature Review

Conducting a comprehensive literature review was beyond the scope of this project. We have therefore drawn from a literature review commissioned by the PHO conducted by the Canadian Institute for Substance Use Research. We recognize that research on safer supply and PSS is nascent, and therefore consider the evidence with its limitations in mind. Furthermore, we recognize that western medical-model research has historically been oppressive and has taken an extractive approach of doing research to and at the expense of marginalized populations rather than respecting people as the experts of their own experiences. Based on existing literature and available data [xvii], we proceed with the following understanding:

- There are many models for safer supply, including prescribed and non-prescribed models.
- Significant and ongoing harms are attributed to the unregulated drug supply. These include high mortality (approximately six people are dying each day in BC at the time of this report) and morbidity[xviii].
- Existing ethical analyses of PSS interventions have determined the interventions can be ethically justified in this current context[xix,xx]
- The majority of research on PSS programs is qualitative and focused on people receiving prescriptions under this model[xxi].
- From the research that exists, PSS programs are associated with reduced risk of death, reduced or eliminated use of unregulated drugs, increased engagement in health and social services, sustained retention in the safer supply program, improved mental and physical health and improved social and economic wellbeing. PSS may also reduce healthcare use and costs[xxii].
- From research reviewed, we acknowledge there is limited evidence on potential harms and benefits of PSS to populations who are not receiving prescriptions or are not eligible for PSS.
- Research on topics such as diversion and the role of social determinants of health in implementation of PSS is limited.

Engagement with Interested Parties

We conducted a survey and interviews in September of 2023. We received 366 survey responses. We conducted six interviews (via phone or Zoom) and two focus groups (via Zoom). The same open-ended questions were asked in the survey and interviews. These questions related to: perceived harms and benefits of PSS in its current form; people and groups most impacted by PSS and the unregulated drug supply; concerns about how PSS is currently delivered, including what would address these concerns; perceived harms and benefits of diversion; the future of PSS; and whether involvement in PSS created value conflicts (Appendix A).

The following interested parties from across BC were represented in this engagement process: PWUD; youth accessing mental health, substance use, and related services; family members of and people who support PWUD; drug user organizations; regional health authorities; First Nations Health Authority (FNHA); departments and organizations serving Indigenous people who use drugs; community-based organizations serving PWUD; physicians; nurse practitioners; other healthcare providers; medical health officers; regulatory colleges; organizations representing health professionals; researchers; and police and public safety representatives.

Interested parties who responded reported a broad range of roles, including: people accessing PSS prescriptions; family members of PWUD; prescribers; nurses; support workers (including peer workers); social workers; those in program coordination and leadership roles; and researchers. Interested parties were engaged with PSS in urban, suburban, rural and remote areas, with just under 1/3 of respondents having some involvement in rural and remote areas.

Through the engagements, we aimed to elicit perspectives and beliefs related to PSS, as well as interested parties' ideas of ways to proceed in regards to PSS. There was significant diversity in the beliefs and experiences of the interested parties. A wide range of opinions emerged through this engagement process, relating to benefits of PSS, harms associated with PSS, concerns about the current state of PSS in BC, and equity issues. Of note, while the engagement and literature review were accommodating of the range of PSS options made possible by the PSS policy, responses from engagement focused mainly on prescribed opioids.

Benefits of PSS

- Identified benefits of PSS for **recipients**: improved quality of life and stability; reduced reliance on the contaminated and volatile unregulated drug supply; improved physical and mental health; reduced involvement in risky activities (e.g., survival sex work); reduced overdoses and harms related to the unregulated drug supply; increased involvement in social and occupational activities (e.g., work, school); increased engagement with healthcare and substance use supports; and recognition of autonomy, self-determination and client-centred care.
- Identified benefits of PSS for **clinicians**: improved relationships with recipients; recognition of and respect for dignity and client-centred care; and a new way to support clients with substance use.

- Identified benefits of PSS for the **broader population**: increased availability of regulated drugs in the illicit market (due to diversion) such that PWUD who do not have access to PSS (e.g., due to age, lack of prescribers in the area, type of substance use) are able to benefit from safer supply; reduced influence of organized crime and criminal activity; and advancement of strategies to address the unregulated drug emergency.

Harms related to PSS

- **Recipients** of PSS may experience the following harms: increased opioid tolerance that makes opioid agonist treatment (OAT) and detox more difficult; increased substance use, addiction, overdose, and trauma; reduced likelihood of becoming abstinent; harms such as dangerous withdrawal associated with unexpected prescription discontinuation or unwanted diversion (e.g. theft); and experiences of stigma and harm related to PSS use within the medical system.
- For **clinicians**, potential harms included: pressure and scrutiny in prescribing practice; lack of support (e.g. lack of material supports such as funding and staffing, or lack of support to address their other concerns such as questions over program surveillance or limited guidance); conflict with clients and other providers; as well as moral distress (for some, when faced with pressure to implement PSS; for others, when they felt limited in how they could implement).
- For the **broader population**, possible harms identified include: greater availability and accessibility of prescribed opioids that are perceived as safe, leading to increased use of opioids; escalation of use to more potent opioids; and subsequent harms such as increased dependence rates, overdoses and trauma. Rural/remote and youth populations were of particular concern in relation to diversion. Other possible harms included: increased influence of organized crime; higher burden on healthcare; perpetuation of a stigmatizing and medicalized approach to drug use; and that the current limited and particular delivery of PSS may lead to overgeneralized conclusions about harm reduction and safer supply.

Concerns about the current state of PSS

- Concerns related to research **evidence**: deficiencies in the amount and quality of evidence for the PSS model; and a lack of evidence on the effectiveness of PSS in improving health and reducing reliance on the illicit supply. Some concluded this should lead to the program being paused or shut down, while others cited emerging evidence and supported continued evidence-gathering amidst ongoing, adaptable implementation.
- Concerns related to **implementation**: inadequate monitoring, accountability, and regulation of PSS; limited types, doses, and forms of drugs currently available; inadequate infrastructure and supports for PSS implementation; and limited engagement with affected populations for planning and implementation (e.g., physicians and nurse practitioners or PWUD).
- Concerns related to substance use service **access**: lack of additional supports for substance use prevention, early intervention, and treatment; limited/no access to PSS; increasingly reduced access to PSS.
- Concerns related to **equity**: groups that were identified as being disproportionately impacted include youth, Indigenous people, people with mental health issues, people living in poverty and rural and remote populations, gender diverse individuals; high barriers to access associated with

PSS being delivered within a medical model; the polarization and politicization of PSS due to stigma related to drug use; lack of access to treatment and recovery services, mental health services, housing, safety from gender-based violence and food security.

- **Moral distress** may be experienced when prescribers feel that PSS: may increase the number of people who develop drug dependency and addiction; lacks safety measures (e.g., strategy for safely de-prescribing); is addressing needs related to underlying healthcare system deficits (e.g., lack of treatment and recovery programs). Moral distress was also experienced when prescribers felt they could not meet the needs of clients due to limited funding and resources, inadequate medication options or scrutiny from and conflict with colleagues.
- Inadequate **infrastructure**, including lack of prescribers, lack of supports for prescribers and lack of funding, are leading to increased health care provider (HCP) burnout.
- Those providing feedback emphasized the broader **context** PSS has taken place in which includes: a lack of access to and existence of appropriate healthcare resources; the COVID-19 pandemic; high levels of mental health struggles amongst youth; poverty; racism; colonialism; an ongoing 'war on drugs'; high levels of stigma towards PWUD; and the ongoing unregulated drug emergency.

Ethical Analysis

This analysis focuses on ethical issues related to PSS in BC. First, we clarify the scope of the analysis. Second, we describe how public health ethics differs from clinical ethics. Third, we highlight the ethical values and principles that guide this analysis. Lastly, we analyze ethical questions related to PSS policy in BC.

Scope of Analysis

1. The analysis highlights ethical tensions with PSS and how they ought to be considered under specific circumstances.
2. Determinations of effectiveness of the PSS policy broadly fall outside the scope of this Ethical Analysis.
3. The intent of the analysis is not to defend PSS or recommend ending PSS. Instead, it seeks to provide insight into the ethical questions emerging from PSS so as to support decision making about how safer supply strategies should be implemented. We are sensitive to the complex nature of PSS, the wide range of potential harms and benefits to different groups of people, and the many ways to decrease the harms from the unregulated drug emergency. The input shared through the engagement process is contextualized and weighed carefully.

Public Health Ethics

Public health interventions and decisions should seek to reduce harms to both individuals most at risk of harm and the broader population. Where the harms to either individuals or the broader population are unbalanced such that one group faces a higher level of risk (e.g., an individual has a higher risk than the broader population vs. the broader population has a higher risk than individuals), a rationale for prioritizing either individuals or the broader population should be provided.

While ethical decisions and interventions in clinical ethics focus on the health and interests of the individual client, interventions in public health should consider the health and interests of a population to inform decisions. Interventions should only be offered if it is determined that they are likely to be more beneficial than harmful for a specific population. Physical, emotional, psychological, social, and cultural harms and benefits should be considered.

Ethical Values and Principles

Public health ethics involves a systematic process to clarify, prioritize and justify possible courses of public health action based on ethical principles, values and evidence. This analysis explores ethical questions by drawing on established public health ethics frameworks and literature[xxiii,xxiv,xxv,xxvi]. The specific values and principles utilized in this analysis include: cultural safety and cultural humility; effectiveness; efficiency; flexibility; integrity; procedural justice (fair process); solidarity; distributive justice (equality and equity); duty to care; respect; and utility (weigh harms and benefits) (Appendix B).

In general, the principles and values used in this analysis fall into two categories: procedural (i.e., how we make decisions and work together, relating to the decision-making process) and substantive (i.e., what goals or ends we should pursue and how we weigh these principles and values against one another, relating to the decision or outcome itself). Substantive values and principles may conflict when addressing ethical considerations in relation to PSS. When it is not possible to uphold all values (e.g., values are in conflict with one another), justification is provided for trade-offs that must be made and values that are prioritized.

Cultural safety and cultural humility are cross-cutting values that are both procedural and substantive in nature, are relevant to each of the other values and principles, and should be applied throughout each analysis.

Ethical Questions

1. How should we balance the real and potential benefits and harms of PSS?
2. How should the benefits of PSS be balanced with the impacts of diversion?
3. How should we balance the needs or preferences of individuals accessing PSS with prescriber practices?
4. What is an ethical approach to addressing concerns about PSS?

Question 1: How should we balance the real and potential benefits and harms of PSS?

This question assesses the impact of PSS on the population as a whole. Within that population we recognize that there are: PWUD who have access to PSS; PWUD who do not have access to PSS; people who have used drugs in the past and may use drugs in the future; people who are currently opioid naïve but who may start using drugs in the future.

Values and Principles

Cultural safety and humility, effectiveness, efficiency, flexibility, solidarity, duty to care, and utility.

Analysis

There is limited research on PSS[12]; however, qualitative studies affirm PWUD experience a range of benefits from these programs (as outlined above). For some individuals, PSS is both life-saving and life changing. It reportedly allows a restored sense of dignity and enables quality of life e.g. in terms of being able to go to work and care for loved ones. When scientific evidence and knowledge base about an environmental or human health hazard is underdeveloped, and the consequences of the hazard are severe, the precautionary principle encourages decision makers to adopt precautionary measures[xxvii]. In light of the high likelihood of serious or irreversible harms from the unregulated drug supply (e.g., major morbidity, mortality), lack of scientific certainty of the benefits of PSS or safer supply should not be used as a reason to refrain from implementing measures to prevent these harms. In this context, a precautionary approach recognizes that action is currently needed to save lives[xxviii]. In addition to saving lives, the precautionary principle recognizes the ethical justifiability of actions to decrease morbidity risks (e.g. reducing unwanted use of benzodiazepines), to reduce stigma, improve dignity and quality of life for PWUD. Such action upholds the **duty to care**.

When harms to individuals are certain, severe or irreversible, there is ethical justification to implement effective interventions that reduce or eliminate those harms even when it means there may be some uncertain harms to other individuals. Drawing on the value of **utility**, the certain, serious or irreversible harms related to the unregulated drug supply that PSS can reasonably be expected to address (for some individuals) can ethically be prioritized over harms that are uncertain (e.g., harms from diversion). In

[12] Our review of literature on safer supply did not evaluate heroin assisted treatment programs, and was focused on medical models. Thus, our appraisal of quality and content of the evidence is specific to those interventions more closely aligned to PSS as it is currently implemented (e.g., such as with prescription hydromorphone tablets).

light of emerging evidence that the unregulated drug supply is becoming increasingly adulterated and dangerous and deaths are increasing, the risk of inaction is even further greater[xxix,xxx,xxxi].

Any intervention that is deemed ineffective and harmful should be re-designed or replaced with a new intervention that is maximally beneficial and least harmful. This work should be done in partnership with Indigenous leaders and approached with **cultural humility**, in order to foster **cultural safety** for Indigenous people and acknowledge the disproportionate impact of the unregulated drug supply on Indigenous populations. While programs and services are the substantive goal, **cultural humility** and **cultural safety** are both substantive and procedural principles. As such, respectful engagement with Indigenous leaders and communities regarding safer supply options in the broader continuum of care, inclusive of wholistic perspectives on wellness, are necessary for the development of culturally safe options that address systemic oppression, Indigenous-specific racism and ongoing colonialism in the healthcare system.

This analysis is predicated on PSS being reasonably effective and not placing unfair burdens on individuals or groups. The strength of the justification for accepting uncertain harms decreases as the **effectiveness** of harm-reducing or risk-mitigating interventions is unclear (i.e. if PSS does not clearly reduce the risk to the individuals accessing PSS). The **effectiveness** of PSS, or how well it reaches the policy's intended goals, should be assessed in an ongoing manner, including whether PSS decreases exposure to the unregulated drug supply. This evaluation requires ongoing analysis of emerging evidence, inclusive of the experiences of PWUD.

When there are uncertain harms to other individuals or the broader population, simultaneous action must be taken to identify these harms and reduce them as much as possible. Therefore, while building effective responses to the harms of the unregulated drug supply, it is necessary to simultaneously identify potential or uncertain harms (e.g., harms from diversion). Evidence of who is harmed and the degree of severity and probability of harm should guide actions to **efficiently** reduce these harms as much as possible.

Individuals accessing, or who would potentially benefit from accessing, PSS have the most to gain or lose if changes are made to PSS. As noted, PSS has been described as life-saving and life changing for some individuals. Based on evidence and in **solidarity** with interested parties, it may be appropriate to adapt or change the current PSS approach to better meet needs of PWUD and the broader population. Expansion of current services or different interventions may be warranted to achieve the intended effect of BC's current PSS policy. This points to the importance of **flexibility** to continue to assess, respond, and change the intervention as needed to ensure the most ethically justifiable route is undertaken.

Conclusions

- Safer supply is currently an ethically defensible way to reduce harms for PWUD. It is reasonable to attempt to mitigate harms for individuals who face certain and severe harm, even if the intervention results in some risk of harm to others in the broader population.
- The current PSS model should be reviewed and potentially modified to ensure the intervention is maximally effective in terms of reducing morbidity and mortality from the unregulated drug supply while simultaneously addressing and mitigating harms to others.
- Evidence-based interventions must be implemented to maximize benefits and reduce harms related to the unregulated drug emergency. Evaluations of effectiveness should be based on review of robust evidence (including qualitative and quantitative research). Interventions should be considered with input from interested parties, including PWUD, Indigenous leaders and prescribers and must be developed with cultural humility and ensure cultural safety.
- Decision-makers should:
    - Consider diverse safer supply models and protocols (e.g., different substances, adjusted doses, different delivery methods, non-prescribed models). Expansion of safer supply to Indigenous communities and rural and remote areas must be done in partnership with local leaders, communities and FNHA, especially in the context of lack of access to treatment and recovery programs as well as limited infrastructure to support PSS implementation.
    - Expand other programs and services including: substance use treatment and recovery programs, mental health services, and initiatives to address other social determinants of health (e.g., housing, food security) for youth and adults.
    - Be prepared to adapt interventions based on emerging evidence related to the increasingly dangerous drug supply. Efforts must be made to adapt to the new knowledge and modify strategies, while continuing to ensure alignment with ethical principles and values.

Question 2: How should the benefits of PSS be balanced with the impacts of diversion?

As noted, for this review, we consider diversion as a circumstance where some or all of the prescribed supply end up with someone other than the person for whom the prescription was intended.

Values and Principles

Cultural safety and humility, procedural justice, distributive justice (equity and respect), and utility (weigh harms and benefits).

Analysis

Based on review of the literature and engagement with interested parties, this analysis is informed by emerging indications that some diversion of some PSS is currently occurring in BC. In some cases, diversion is a consequence of people attempting to address unmet needs as a result of the social determinants of health (e.g. related to poverty or stigma). The impacts of diversion of PSS may be beneficial (e.g. access to safer supply for a PWUD who does not have a HCP to provide PSS; known/measured dosing of substances; means to meet basic needs) or harmful (e.g. if the diverted drug

reaches an opioid naïve individual and triggers new onset opioid use disorder, or becomes an additional substance used by an individual). There is a lack of data identifying exactly who is, or may be, harmed or helped by diversion.

We balance the benefits of PSS with potential harms of diversion, drawing upon the public health principle of **utility** that seeks to uphold a positive balance of overall benefits to harms; making decisions that promote health and minimize harms as much as possible. Effective interventions to address the certain and severe harms from the unregulated drug supply (e.g., PSS) take priority at this time over the potential and even likely (but not currently quantifiable) harms to the population from diversion. Recognizing there are potential harms to the population, the precautionary principle and **utility** also require simultaneous efforts be put in place to mitigate potential harms from diversion of substances as much as possible.

Public health issues are social and structural, while interventions are often targeted at the individual level. There may be perceived or actual conflicts between the fit of a public health intervention in a context that is individual-focused, such as prescribed interventions. Strategies used to address diversion often include: observed administration, daily dosing, urine drug testing, and expanding drug options. These strategies aim to increase the ability of individuals who access PSS to follow treatment recommendations (thereby maximizing benefit of PSS) and to require engagement with prescribers, health care teams and health systems. However, such measures (e.g., witnessed consumption) may be regarded as overly restrictive and/or as an unwanted intrusion. They may result in harms to PWUD and create barriers to PSS. This is particularly relevant from a **cultural safety** perspective as services may be unsafe due to historical and present day harms experienced by Indigenous people in the healthcare system. These harms can be compounded as intrusive approaches are amplified by racism and stigma in the healthcare system.

Attention should be paid to how diversion reduction strategies create ethical tension between the values of **utility** (i.e., minimizing harms and maximizing benefits) and **distributive justice** (equity). Health decisions should not place unfair burdens on some individuals or populations, nor perpetuate or exacerbate systemic or structural inequities. We recognize that strategies to reduce diversion and increase connections with health care providers and systems may impact some individuals more than others (e.g., Indigenous persons when culturally safe services and trauma informed practices are not adequately provided). When implementing, expanding, reconsidering and/or redesigning public health interventions, **equity** considerations (including **cultural safety and cultural humility**) are important in order to address the needs of, and avoid further burdening, those who are underserved and marginalized. Ethically acceptable interventions are those that are least restrictive.

Interventions to mitigate diversion can be justifiably implemented if they are both **effective** in reducing the harms they seek to address and align with the principles of **procedural justice, respect, cultural safety** and **cultural humility**. Interventions that seek to reduce diversion should ensure **cultural safety** and **cultural humility** as well as meeting five additional ethical criteria: (1) effective; (2) least restrictive/intrusive; (3) more beneficial than harmful; (4) fair; and (5) acceptable to interested parties who are impacted by the interventions.[xxxii]

Diversion reduction strategies should focus on both ensuring access to appropriate safer supply for PWUD and effectively addressing other unmet needs such that need to divert PSS is minimized. Procedural justice ensures fair process throughout planning and implementing of decisions through transparency, inclusiveness, accountability, reasonableness, and consistency. Procedural justice also recognizes reciprocal accountabilities with First Nations, and the need for inclusion of Indigenous voices throughout all these phases of the process. Mechanisms to address diversion must be voluntary and informed by respectful engagement inclusive of interested parties including PWUD, Indigenous leaders and prescribers. **Cultural safety** and **cultural humility** are essential for developing and maintaining respectful processes and relationships with Indigenous leaders and communities throughout the planning and implementation of PSS policies. This includes ensuring **equity** in access to healthcare, without discrimination, and actively partnering with Indigenous communities in the development of health programs. Furthermore, respecting Indigenous cultural rights involves facilitating access to traditional medicines and supporting the continuation of traditional health practices that are integral to Indigenous well-being and self-determination[13].

Finally, it is important to recognize that issues of diversion and diversion mitigation result in moral distress for some prescribers. Diversion is a complex issue, influenced by individual, social, and structural factors. The measures prescribers currently have to address diversion (e.g. witnessed consumption, daily dosing) are largely focused on individual PWUD, and may be experienced as ineffective and/or inappropriate by PWUD and prescribers. Further, the professional standards and requirements of prescribers are sometimes in perceived or actual conflict with practices that could enable or mitigate diversion. This may result in conflicts between what prescribers feel obliged to do at clinical and public health levels.

Conclusions

- As emerging evidence indicates diversion of prescribed substance(s) is occurring and may be causing harms, decision makers should consider:
    - A range of evidence-based safer supply models (e.g., different substances, adjusted doses, modification to existing access, different protocols, delivery methods).
    - Mechanisms to address the unmet needs of people eligible for PSS. These unmet needs should be construed broadly and include: providing culturally safe and trauma-informed care; providing access to safer supply that is appropriate to the individual; and consideration of expanding access to safer supply (e.g., non-prescribed models), and improving accessibility to other effective harm reduction services, treatment and recovery programs, mental health services, primary care, housing, food security, and community connection. This needs to be consultation in consultation with those with lived and living experience.

[13] These rights are outlined in the following foundational documents: The United Nations Declaration of the Rights of Indigenous People (UNDRIP), the B.C. Declaration on the Rights of Indigenous Peoples Act (DRIPA), the Truth and Reconciliation Commission of Canada Report: Calls to Action, the National Inquiry into Missing and Murdered Indigenous Women and Girls: Calls for Justice and the In Plain Sight Report.

  - Strategies to reduce diversion that do not disrupt benefits to those accessing PSS (this includes benefits to individuals who may rely on diverted PSS to avoid the unregulated drug market).
  - Strategies to address the needs of those in the population at greatest risk of developing problematic opioid use.
- Strategies to address diversion should consider how PSS prescribing and diversion mitigation measures fit within prescribers' standards of practice and regulatory requirements. Where perceived or actual conflicts exist, efforts should be made to better accommodate and support PSS within healthcare, or consider adaptations to enable provision of safer supply in non-healthcare settings.

Question 3: How should we address tensions between the needs of individuals accessing PSS and prescriber practices?

Values and Principles

Cultural safety and cultural humility, integrity, solidarity, duty to care, distributive justice (equality and equity), respect, and utility (weigh harms and benefits).

Analysis

Tensions arise when individuals seeking to access PSS are not able to have their needs met for a variety of reasons (e.g., lack of access to a prescriber; lack of access to adequate safer supply through PSS; stigmatizing or non-trauma informed care; unconscious bias and Indigenous specific racism). HCPs may be unwilling or unable to meet their client's needs due to: limitations in PSS options; fear of "enabling" or worsening a client's drug use; questions regarding effectiveness and utility of PSS; discordance with colleagues; inadequate PSS guidance; and lack of support from specialists. Additional challenges experienced by providers include conflict with patients and other prescribers about PSS, conflict between PSS and a HCP's training or beliefs about standard of care; scrutiny from regulatory bodies; and feelings of moral distress. **Distributive justice** (equality and equity), **respect** and **solidarity** may not be upheld due to HCP preferences, practices or interpretations of the **duty to care**.

HCPs have a fiduciary **duty to care** towards all individuals in their care, meaning they are obligated to act in the best interests of their clients by addressing health-related needs to the best of their ability[xxxiii]. Some people may interpret these obligations as the extent of the HCPs' duty to their clients; however, others see the **duty to care** as also preventing harm and doing good for others in the population or communities who may be harmed by a policy or intervention. In the PSS context, PSS policy encourages qualified health care providers to prescribe safer supply, but recognizes that prescribing occurs at their discretion.

PSS is currently delivered via a medical model, which requires licensed physicians and nurse practitioners to prescribe drugs and pharmacists to dispense them (there are many variations of implementation within these medical models). In our engagements, while some interested parties believed the current PSS model meets the needs of PWUD, others saw many of the programs stemming

from the PSS model as high barrier to access and out of step with **respect**, patient-centered care, trauma-informed care and **cultural safety** for PWUD. Barriers to PSS may disproportionately affect and harm some PWUD, raising further concerns related to **distributive justice** (equality and equity) and **cultural safety**.

Healthcare provision and safer supply policy should uphold the principle of **utility** by balancing non-maleficence (do no harm) and beneficence (promote good). It is recognized that individual prescribers may weigh potential harms and benefits differently than the ethical analyses informing policy decisions, which can lead to tensions with clients and other providers. Ultimately, some HCPs may be comfortable providing PSS while others may not. Policymaking and implementation conducted with **integrity** can enhance trust of PWUD and HCPs. This is achieved by upholding ethical values and principles in policy and implementation and addressing causes of moral distress among HCPs. It is also important to recognize how **utility** and **integrity** intersect with **cultural safety** and **humility**, in order to promote respectful engagement processes and relationships with Indigenous leaders and communities throughout the planning and implementation of PSS policies. This is essential to upholding Indigenous rights to the highest attainable standard of physical and mental health.

HCPs should be provided with education and supports (e.g. with resources, clear policy, clinical guidance) necessary for BC's healthcare systems to ensure PSS is accessible to all who need it. Consistent with other types of healthcare, HCPs opting out of PSS (e.g. due to discomfort with harm reduction) may be accommodated, provided that they are not discriminating against particular individuals or groups and that their refusal to prescribe PSS not become a barrier to safer supply for eligible PWUD. While navigating the complexities and uncertainties associated with PSS policy can be challenging, inaction has significant consequences. **Distributive justice** (equality and equity), **respect**, **solidarity** and the **duty to care** can be supported through strengthening the capacity of BC's healthcare system to ensure access to PSS for those who need it.

Conclusions

- HCP preferences and decisions related to PSS should not be a barrier to accessing PSS.
- HCP decisions related to PSS should be non-discriminatory.
- HCPs should be provided with education and supports (e.g. with resources, clear policy, clinical guidance) necessary for BC's healthcare systems to ensure PSS is accessible to all who need it.
- Education and support for HCPs on PSS is needed in the following areas:
    - how stigma and unconscious bias against PWUD may inform decisions
    - medical (individualistic) models versus public health (community and population) models
- Efforts should be made to reduce barriers and mitigate potential harms for PWUD accessing PSS in the current medical system (e.g., via enhancing trauma-informed care).
- Non-healthcare models of PSS (i.e. non-prescribed models) should be considered in part to address limitations of current PSS delivery.
- Safer supply services should be designed and implemented in ways that promote cultural safety and cultural humility, distributive justice (equality and equity), effectiveness, integrity, respect, solidarity, and utility.

Question 4: What is an ethical approach to addressing concerns about PSS?

Values and Principles

Cultural safety and cultural humility, effectiveness, efficiency, flexibility, integrity, procedural justice, solidarity, distributive justice (equality and equity), duty to care, utility (weigh harms and benefits).

Analysis

An ethical approach to addressing concerns related to PSS should incorporate both procedural and substantive values and principles.

Procedural justice incorporates a set of fundamental principles, which are applied in resolving ethical issues. Fair process means transparency, inclusiveness, accountability, reasonableness and consistency should be upheld throughout the planning and implementation of decisions. This includes recognition of reciprocal accountabilities with First Nations, and inclusion of Indigenous leadership through all phases of policy planning, implementation and evaluation. Outcomes are more justifiable, equitable and fair when processes are inclusive of interested parties and varying viewpoints. Decision-making processes should be **effective**, **efficient**, and **flexible**. Those engaged in creating and implementing policies related to safer supply should act with **integrity** and in **solidarity** with PWUD, Indigenous people, other persons facing systemic or structural inequities, and prescribers who are needed to implement safer supply services.

Through **distributive justice**, issues of equality and equity are addressed, including systemic inequities and intersecting factors that result in disproportionate impacts of the unregulated drug supply on equity-deserving groups such as (but not limited to) Indigenous populations and communities, women, gender diverse people, youth and those living in rural and remote communities. The **duty to care** includes addressing social determinants of health that drive these health inequities. The principle of **utility** is applied in weighing the harms and benefits of various approaches.

Ethical approaches uphold **respect** for interested parties through honouring culture, dignity, patient preferences, and self-determination. This work must be approached with **cultural humility**, in order to foster **cultural safety** for Indigenous people. Respectful engagement that minimizes power imbalances can support environments where Indigenous people feel safe accessing healthcare. Culturally safe and trauma informed care are necessary to support delivery of basic health care and safer supply programs.

Conclusions

- Ongoing evidence-gathering and careful assessment of the intended and unintended impacts of PSS on all parties is needed in tandem with ongoing action to address the emergency. This process should be carried out systematically, using procedural justice principles to reach impacted populations and inform careful assessment of both harms and benefits of PSS.

    - Research processes with First Nations, when gathering evidence, also need to be culturally safe and should include consideration of the Ownership, Control, Access and Possession (OCAP) principles[xxxiv].
    - In addition to the scientific evidence base, make equitable space for expanded source(s) of information regarding effectiveness (e.g. diverse and experiential ways of knowing, such as Indigenous knowledge, teachings, oral histories, community knowledge and lived experiences, groups with knowledge about needs of specialized populations).
- Interested parties, including those with lived and living experience, Indigenous groups (including leaders, communities and FNHA), HCPs (e.g., prescribers, pharmacists, mental health and addiction specialists), and ethicists, researchers, College regulators and decision makers, should be included in safer supply policy and guideline development.
- Consultation with interested parties, inclusive of PWUD, Indigenous leaders, cultural knowledge keepers, researchers, and others will enrich discussion about what strategies are aligned with cultural safety and humility, harm reduction, trauma-informed practices and Wise Practices[xxxv]. The decision to conduct engagements should be made thoughtfully. Further burdens of consultation should not be placed on communities disproportionately negatively impacted by the unregulated drug supply when existing knowledge from past engagements and research is available and yet to be actioned. Further, in recognizing that engagements can be tokenistic and further harm, efforts need to be taken to ensure any engagements follow principles of ethical engagement with PWUD, such as those put forth by the BCCDC and the Vancouver Area Network of Drug Users[xxxvi,xxxvii]
- Engagement should be conducted with prescribers and potential prescribers who have concerns related to PSS to better understand and address their concerns. Appropriate supports, including education, should be put in place for prescribers.
- Clear mechanisms and pathways should be established for raising concerns on individual and policy levels.
- Culturally safe pathways to raise quality concerns are necessary to ensure harms including racism and lack of cultural safety, are being reported and addressed for continuous quality improvement[xxxviii].
- This Ethical Analysis should be reviewed on a regular basis and recommendations adapted as evidence regarding safer supply evolves. In recognition of the many intersecting influences of the unregulated drug emergency, revised or additional ethical analyses focusing on other factors should be considered (e.g., how PWUD are engaged in decision-making over the unregulated drug emergency, ethical concerns over current treatment centers).

Recommendations

We conclude that safer supply is an ethical way to reduce harms for PWUD. At present, based on available evidence, a safer supply policy can be ethically defended and prioritized. We recommend that the BC government and health authorities:

1. **Support PSS delivery within healthcare systems**. PSS policy should aim to reduce inequities and not place unfair burdens on particular individuals and/or populations. Policies should not perpetuate stigma and/or systemic or structural inequities. Partnership with Indigenous leaders is essential to ensure culturally safe supply options.
2. **Partner with PWUD, prescribers and Indigenous leaders** in developing, implementing and revising safer supply policies and services to ensure they are maximally effective.
3. **Recognize and address the disproportionate impact of the unregulated drug supply on Indigenous populations.** Partner with Indigenous leaders and communities in the development of culturally safe supply options that address systems of oppression, Indigenous specific racism and ongoing colonialism in the healthcare system.
4. **Recognize and address the unique needs of youth.** Partner with youth to develop strategies to decrease risks from the unregulated drug emergency**,** such as tailored mental health resources and harm reduction services.
5. **Invest in services to improve health and reduce harms from substance use for PWUD**. For example: access to safer supply, prevention services, treatment services, culturally safe services, mental health services, housing, and food.
6. **Evaluate safer supply program effectiveness (including cultural safety)** by drawing on available and emerging evidence, including quantitative and qualitative research. Implement ethically sound evaluation and reporting mechanisms. Be prepared to adapt interventions based on emerging evidence.
7. **Consider diverse safer supply models including providing safer supply in non-healthcare settings**. This may include different substances, doses, and criteria for access, as well as a range of delivery methods.
8. **Ensure strategies to address diversion reduce negative impacts of diversion without disrupting benefits** to those accessing PSS, including benefits of diversion for those who rely on diverted PSS to avoid unregulated drugs.
9. **Ensure strategies to reduce diversion address unmet needs of people who divert PSS.**
10. **Provide appropriate supports for prescribers of PSS.** Prescribers should be provided with education and supports necessary to ensure PSS is accessible to all who need it. Safer supply policies should be aligned with prescribers' standards of practice and regulatory requirements. This must be done with input from prescribers, regulatory bodies and other interested parties.
11. **Develop processes for people to raise concerns about safer supply policy and services**. Processes should be put in place for PWUD, Indigenous leaders, prescribers, and other interested parties to raise concerns, including issues related to cultural safety and humility.
12. **Regularly update this ethical analysis** to incorporate new evidence. Partner with Indigenous leadership to ensure cultural safety and humility.

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Appendix A: Survey and Interview Questions

The following questions were asked of people who responded to an online survey and those who took part in interviews.

Welcome

Please answer the question based on your experience. All questions are optional

We are asking these questions to evaluate Prescribed Safer Supply (PSS) as it is currently being implemented, as well as prescriber-based safer supply interventions as they could be*. PSS: Prescribed Safer Supply (PSS) is a policy put in place in 2021 by the BC Government. It allows physicians and nurse practitioners to prescribe drugs to people who are getting drugs from the illicit (street) market (e.g., hydromorphone as an alternative for "down," Ritalin as an alternative for cocaine). PSS aims to reduce the risk of poisoning and death due to the toxic drug supply.*

Introductory questions:

1. Please describe your role and/or experience of PSS.
2. Where have you been involved with PSS (e.g. urban or rural or remote settings or all of these settings)? Please describe.

Questions about risks and benefits of PSS:

3. What are the benefits of prescribed safer supply?
4. What are the risks of prescribed safer supply?
5. Are there groups of people/ populations who you think are particularly affected by the toxic drug supply and PSS? How? What special considerations do you believe are owed to this/these group (s)?
6. What are you worried about in continuing PSS in how it is currently being delivered/practiced?
7. What could be done to help address or resolve these concerns:
8. Has your involvement with PSS ever left you feeling like you were unable to act according to what is important to you/your values/beliefs)? If so, can you please elaborate?

Questions about diversion:

Diversion in the context of PSS is when the medications that have been prescribed to a certain person go somewhere else after they have been given out. (e.g. the medications are sold, traded, shared, lost or stolen).

9. Please describe what diversion means to you
    a. What do you see as the risks and benefits of diversion? Please explain
    b. Do you have specific examples or evidence regarding diversion that you could share with us?
    c. How should we (if at all) address diversion?

Questions about the future of PSS:

10. Are there potential benefits or risks of PSS that have not yet occurred?
11. What steps should be taken to better understand the benefits and risks of PSS? For example, research or quality improvement projects.
12. Do you have other ideas for the future of prescribed safer supply?
13. Who else should we talk to? & contact information
14. If you would like to receive information on the results of this project please provide your email address here:

Appendix B: Ethical Values and Principles

Public health ethics involves a systematic process to clarify, prioritize, and justify possible courses of public health action based on ethical principles, values, and beliefs of impacted parties, and scientific and other information. The principles and values selected for this analysis were informed by multiple recognized approaches to support everyday ethical practice and respond to ethical challenges in public health. In general, the values and principles used in this analysis fall into two categories: procedural and substantive, and are defined and applied below. Cultural safety and cultural humility are cross-cutting values that are both procedural and substantive in nature, are relevant to each of the other values and principles, and should be applied throughout the ethical analysis. Under each principle and value listed below is a definition followed by a description of the application of healthcare ethics in the context of healthcare ethics.

Cultural safety & Cultural humility[14]

Cultural safety definition: Cultural safety is an outcome based on respectful engagement that recognizes and strives to address power imbalances inherent in the healthcare system. It results in an environment free of racism and discrimination, where Indigenous people feel safe when receiving health care.

Cultural humility definition: Cultural humility is a process of self-reflection to understand personal and systemic biases and to develop and maintain respectful processes and relationships based on mutual trust. Cultural humility involves humbly acknowledging oneself as a learner when it comes to understanding another's experience.

Application in healthcare ethics: Refers implicitly to the relationships between Indigenous and Settler peoples and social systems. Cultural humility is a practice that can lead to cultural safety, which is an outcome that can only be measured by Indigenous people.

Procedural Values and Principles

How do we make decisions and work together?

Note: All procedural values and principles must be upheld through the decision-making process.

Effectiveness

Definition: Assess how well something produces an intended goal(s).

A*pplication in healthcare ethics:* Assess the extent to which desired outcomes or objectives are achieved as a result of an intervention or initiative intended.

Efficiency

Definition: Maximize the benefit of available resources and avoid waste.

[14] First Nations Health Authority, Creating a Climate for Change Cultural Humility Resource Booklet. https://www.fnha.ca/Documents/FNHA-Creating-a-Climate-For-Change-Cultural-Humility-Resource-Booklet.pdf

Application in healthcare ethics: Streamline local, regional, and provincial infrastructure to ensure there is no duplication of work and the personnel, with the appropriate authority and expertise, are in place.

Flexibility

Definition: Adapt to new knowledge and evidence.

Application in healthcare ethics: Adapt to new knowledge and evidence by modifying strategy in response to healthcare system needs (considering client, public and healthcare provider needs).

Integrity

Definition: Align decision-makers' prioritized values with their decisions and actions.

Application in healthcare ethics: Promote trust by implementing decisions that uphold prioritized values. Address moral distress and provide support for well-being for decision makers and those carrying out the decisions.

Procedural Justice (fair process):

Definition: Ensure a fair and transparent process throughout the planning and implementation of decisions.

Application in healthcare ethics: Uphold:

1. *Transparency:* Act openly and honestly, in a manner that ensures decision making and actions can be understood by people not involved in these activities. Any planning, policy and actions is transparent and open to participants' input as well as available to the public as much as possible.
2. *Inclusiveness:* Involve interested individuals to the greatest extent possible, address barriers that may impede engagement and promote trust.
3. *Accountability:* Accept responsibility for one's actions and document and describe the rationale for the decisions made or not made.
4. *Reasonableness:* Confirm decisions are rational, free as possible of bias, evidence-informed, defensible, guided by appropriate process, timely, practical, and open to review and appeal.
5. *Consistency:* Respond in the same manner to similar circumstances and justify any changes to the ethical decision-making process, guidance, analyses, or rationale.

Procedural justice includes recognition of reciprocal accountabilities with First Nations, and inclusion of Indigenous leadership through all phases of the process.

Solidarity

Definition: Adopt collaborative approaches to understand each other's needs, and cooperate in formulating strategic responses.

Application in healthcare ethics: Promote cooperation among communities and between local, regional, provincial, and federal decision makers to promote fair and just responses.

Substantive Values and Principles

What goals or ends should we pursue and how should principles and values be weighed against one another?

Note: When it is not possible to uphold all substantive values, it is necessary to justify, communicate and document trade-offs and prioritizations.

Distributive Justice

Definition: Promote equitable distribution (fairness): Everyone matters equally, but not everyone may be treated the same.

Application in healthcare ethics: Consider the two factors in equitable delivery of care and services that must be balanced based on the issue under consideration:

1. *Equality*: Individuals ought to be treated with equal concern and respect such that those with similar situations should have similar access to health-care resources. Resource allocation decisions must be made with consistency across populations and among individuals regardless of their human condition (e.g., race, age, disability, ethnicity, ability to pay, socioeconomic status, pre-existing health conditions, perceived obstacles to treatment, past use of resources, etc.); and
2. *Equity*: Health measures should not place unfair burdens on particular individuals and/or populations; should not perpetuate systemic or structural inequities (e.g. underserved populations who face systemic or structural health inequities, social policies or processes and/or geographic obstacles that create barriers to accessing resources, etc.); and should attempt to reduce inequities**.**

Duty to Care

Definition: The healthcare provider's professional responsibility or legal obligation to provide care to all individuals in their care.

Application in healthcare ethics: Uphold the health-care provider's duty to care as the situation requires and as circumstances reasonably permit.

Respect

Definition: Promote, consider, and recognize culture, autonomy, and perspectives of people, as much as possible.

Application in healthcare ethics: Uphold:

1. *Cultural respect:* Approach all individuals, families, and communities with respectful inquiry of their unique identity, culture, worldview, and lived experiences. Environments should strive to be socially, spiritually, physically, emotionally, and psychologically safe. Ensure that individuals are respected, supported and will not be judged for their beliefs, values or way of being.
2. *Dignity:* Respect the intrinsic worth of every person and community
3. *People-centered care:* Provide care that responds to individual preferences, needs and values

4. *Self-determination*: Engage in the process of an individual or community guiding their future through engagement in responsible and informed decision-making, that supports autonomy and independence.

Utility (Weigh harms and benefits):

Definition: Uphold a positive balance of overall harms and benefits.

Application in healthcare ethics: In general, make decisions that promote health and minimize the overall harms as much as possible.

Appendix C: List of Abbreviations

BC – British Columbia

BCCDC – BC Centre for Disease Control

DRIPA - BC Declaration on the Rights of Indigenous Peoples Act

FNHA – First Nations Health Authority

HCPs – Health care providers

OAT – Opioid agonist treatment

OCAP – Ownership, Control, Access, and Possession

PHEAT – Provincial Health Ethics Advisory Team

PHO – Provincial Health Officer (currently Dr. Bonnie Henry)

PSS – Prescribed Safer Supply

PWUD – People who use drugs

UNDRIP - United Nations Declaration of the Rights of Indigenous People

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