Toolkit for Substance Use and Addictions Program Applicants

Stream 2 – Increasing Access to Pharmaceutical-Grade Medications

AUGUST 2019

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The use of pharmaceutical medication to treat opioid use disorder is supported by extensive evidence in Canada and around the world. While oral medication (e.g., methadone and buprenorphine-naloxone) is the predominant form of opioid agonist treatment (OAT), international and domestic studies also support the supervised use of injectable medication (iOAT) (e.g., diacetylmorphine; hydromorphone) for certain individuals struggling with severe, chronic, opioid use disorder.

More recently, Canadian programs are providing services that build on the established OAT and iOAT models. These innovative projects provide prescription opioids to treat substance use disorder, with appropriate prescriber oversight, through models that provide more flexibility for patients (e.g., less restrictive eligibility requirements; more medication options).

Recognizing the scale of the ongoing opioid overdose crisis, and the need to support the development of new evidence-based approaches, Health Canada has launched an anticipatory call for pilot projects. As noted in the Guide for Applicants, applications submitted under this stream must demonstrate: linkages to provincial and/or territorial health systems; health care provider oversight; plan for ethics review; involvement of people with lived and living experience of past or current substance use; and commitment to participate in and contribute to an independent, third-party evaluation, coordinated by Health Canada, which will include common outcome and performance indicator measures across projects. This robust evaluation will help determine if the new models deliver the expected results for people struggling with opioid use disorder.

To assist you in applying for pilot project funding, Health Canada asked a group of experts to bring together research, best practices, as well as regulatory and public health considerations, and develop a set of reference resources that represent current expert opinion in this developing field. This Task Team consisted of public health practitioners, researchers, people with lived and living experiences, pharmacists, and people who work in harm reduction and community health organizations from across the country:

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- Wendy Muckle, Chief Executive Officer, Ottawa Inner City Health, Inc.; and
- Jordan Westfall, co-founder Canadian Association for Safe Supply, major contributor to *Safe Supply: A Concept Paper*.
- *Toolkit written on behalf of the Task Team by Rebecca Penn*

They assembled the attached resources that you may wish to consider, as you complete submissions for this funding stream. We have also included a copy of the recently published British Columbia Centre on Substance Use "Guidance for Injectable Opioid Agonist Treatment for Opioid Use Disorder", as well as a selection of references where you can obtain further information.

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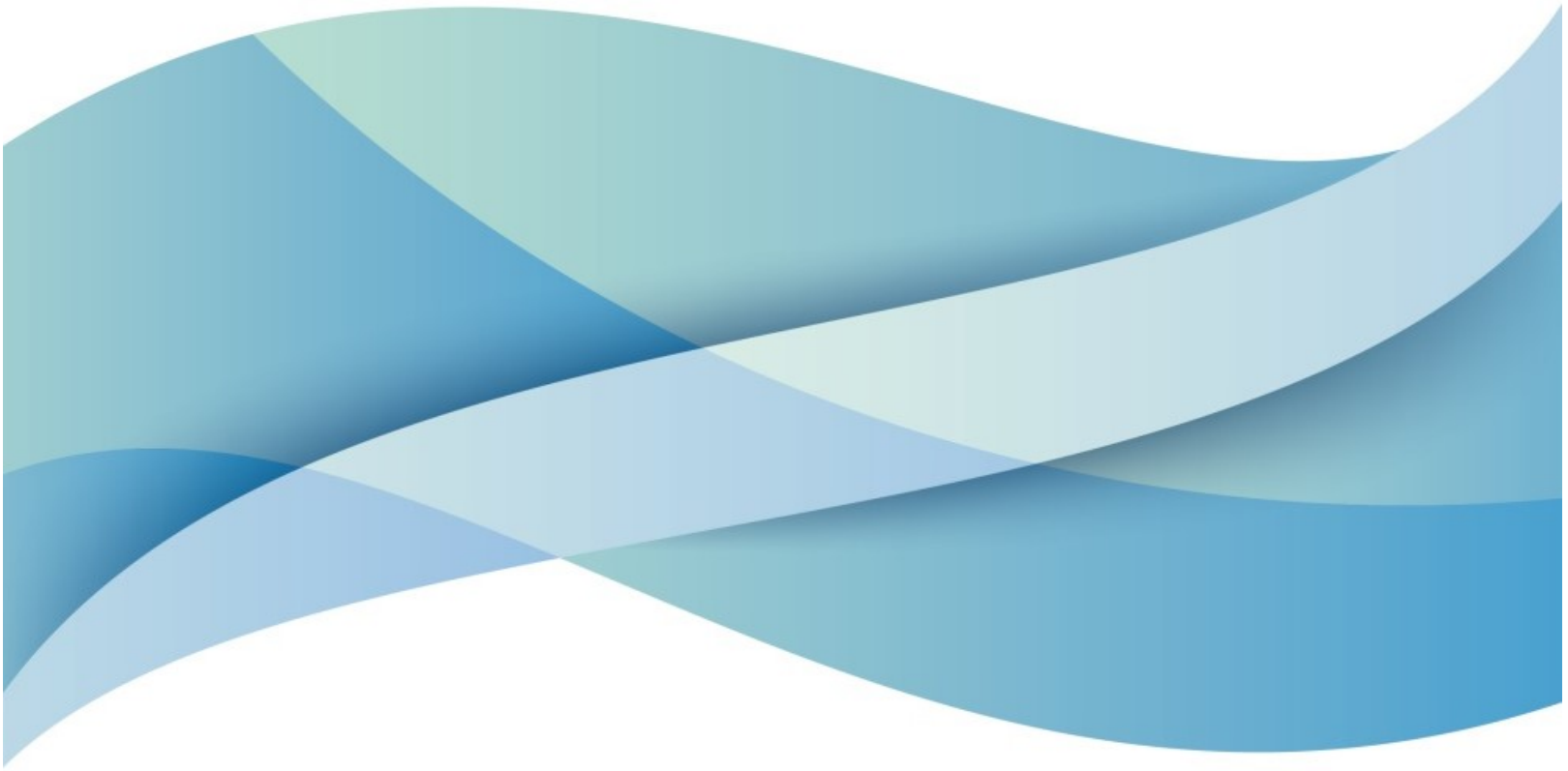
Section 1
Safer Supply: A Continuum of Care for People Who Use Drugs



1. Safer Supply: A Continuum of Care for People Who Use Drugs

There is a continuum of care for addressing social and health concerns related to the use of substances that ranges from harm reduction approaches to addiction treatment approaches, and safer supply programs exist along this continuum. Similarly, safer supply models exist along a continuum, anchored at one end by programs designed with as few barriers as possible (e.g., flexible eligibility requirements, unobserved dosing), and highly-clinical models of opioid agonist treatment (OAT) on the other end (e.g., multiple witnessed daily doses, illegal drug abstinence). The options for safer supply that are explored in this document are those that could be implemented rapidly, in accordance with current legislation and regulations.

Operationalizing safer supply programs at this time will build on medical models that require prescriptions and some degree of monitoring and care from authorized health professionals and that operate within the parameters set by the current legislation and regulations. The medical models discussed represent a diverse range of programmatic and pharmaceutical alternatives for people who use drugs who are dependent on the contaminated and unpredictable illegal drug market. In particular, "flexible" models are highlighted as offering emerging practices for safer supply.

A continuum of care for safer supply models

Models provide a way of categorizing approaches and describing characteristics and goals of programs. In reality, programs may draw on aspects of different models to address the needs, cultures, and drug supply contexts of their community. The models suggested here are 'ideals'. We provide examples of programs that best fit as representative of a model, but acknowledge that they may also include characteristics of other models. The models are not mutually exclusive; together they offer a continuum of approaches for providing regulated alternatives to illegal drugs. Ideally, people who use drugs will have access to services from different models, and be able to move between models according to their needs and goals, as requested. The models provide a continuum that recognized that everybody, from people with a substance use disorder to the person who uses occasionally, is at risk of an overdose when consuming substances that may be contaminated with fentanyl or similar toxic substances.

A variety of models in many different settings are critical to meet the diverse needs of the broad population. Appropriateness of models is dependent upon factors such as community context, need, jurisdiction-specific regulations, existing services, available resources, and drug scene. Models need to be tailored to these factors and reflect the commitment to a public health and harm reduction approach and the provision of low-threshold accessible services.

Table 1.1 provides an overview of three broad approaches for offering safer supply programs:

Traditional approaches, such as the provision of opioid agonist therapies, are embedded in the treatment system and are largely oriented towards treating opioid use disorder rather than safer supply. However, when needed, the focus of OAT can be shifted to the provision of safer supply, rather than treatment, by lowering eligibility requirements, focusing on patient-centered goals, focusing on reducing use of illegal drugs (and related harms), and by employing a low-threshold/harm reduction approach to providing access to regulated opioid alternatives to the illegal drug supply. Traditional approaches provide an increasingly wider range of service designs, as well as pharmaceutical options that can be used alongside safer supply prescribing. For example, safer supply prescribers of pharmaceutical opioids (across all models) may prescribe slow-release oral morphine (Kadian®) as a 'backbone'[1], alongside Dilaudid® tablets or injectable hydromorphone[2].

Enhanced models expand on OAT to offer lower-barrier access to treatment of opioid use disorder *and* to safer supply, i.e., pharmaceutical alternatives to illegal opioids. Injection opioid agonist treatment (iOAT) programs are finding ways to reduce the barriers to access and retention for people who use opioids by expanding eligibility criteria to opioid use (rather than opioid use disorder) and offering a harm reduction approach to drug use. Enhanced models provide observed consumption, similar to traditional OAT models. There is a strong evidence base for iOAT that is continuing to be developed. There are examples of enhanced models currently being piloted in settings such as overdose prevention sites and supportive housing.

Finally, *flexible models* refer to the growing number of community-based initiatives that seek to provide pharmaceutical alternatives to the illegal drug supply, with as few barriers as possible and without expectation of transition to treatment. Flexible models seek to provide a nimble, responsive, and less treatment-intensive and less medicalized approach to providing safer supply programs. In general, these models offer daily-dispensed drugs, prescribed by a doctor or nurse practitioner, which may be consumed unobserved or observed, as needed and appropriate. However, flexible models may take a variety of forms, including buyer's club models as long as there is appropriate prescriber oversight and that activities remain within the parameters set by the current legislation and regulations. Although these flexible models are evidenced-informed in their design, there is currently limited guidance for prescribers and therefore prescribers may need to extrapolate from evidence and iOAT and other prescribing guidelines, and consult with their clinical peers to provide care. *Flexible* models have strong potential for scaling up and are highlighted here as a promising model for pilot projects and evaluation.

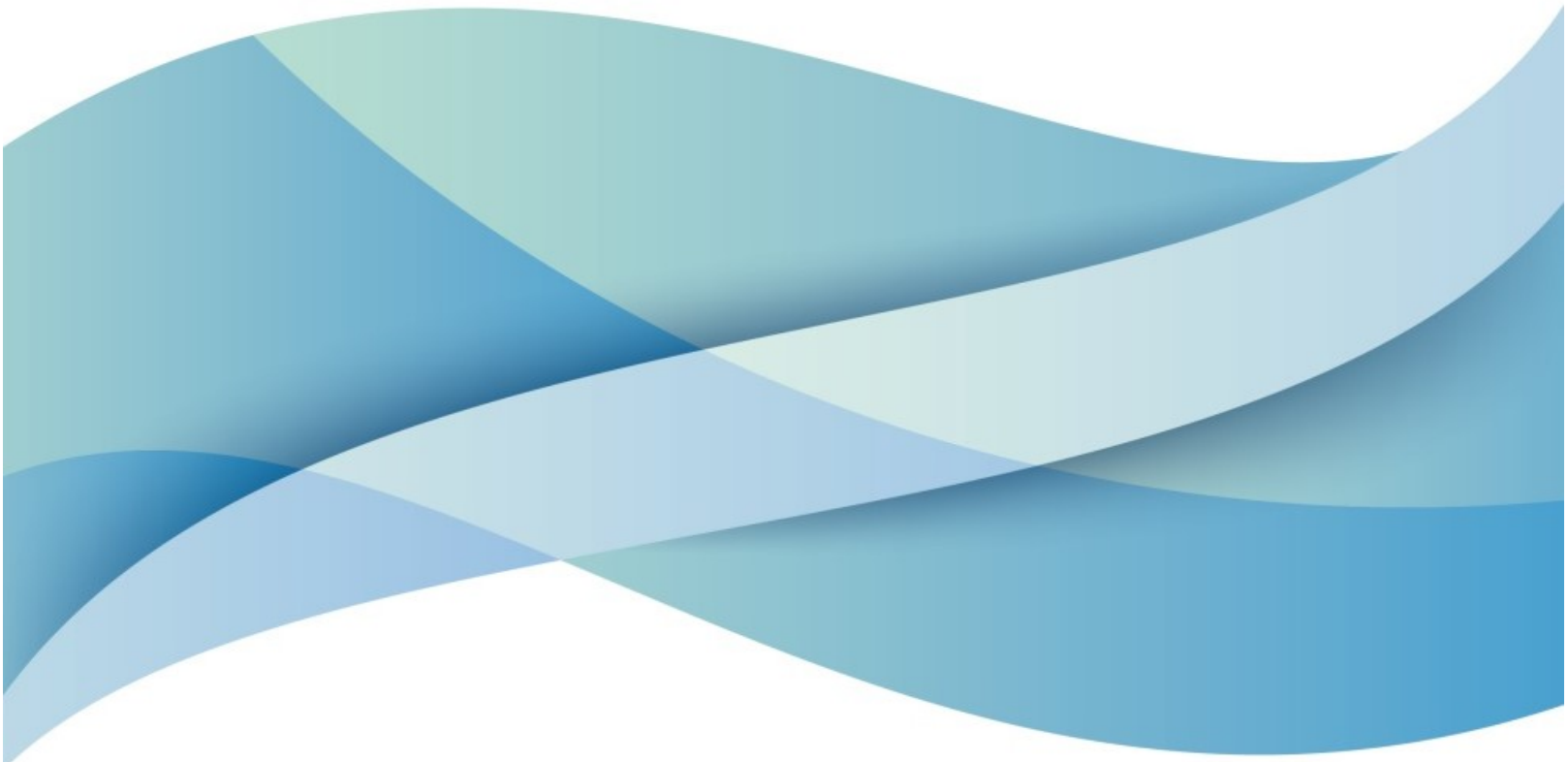
All approaches, from *Traditional* to *Flexible* models, can provide a regulated alternative to the illegal drug supply for people who use drugs, and are necessary to address the ongoing opioid crisis. While the Task Team acknowledges the importance of *Traditional* approaches that are founded on well-established OAT models (e.g., buprenorphine/naloxone, slow-release morphine, and methadone), these approaches will not discussed in detail here. A detailed analysis of *Enhanced* and *Flexible* models are presented in **Section 3.1**.

[1] Slow release oral morphine (SROM, brand name Kadian®) is considered an appropriate 'back bone' because of its long acting pharmacological properties.
[2] Hydromorphone (brand name Dilaudid®) are short acting.

Table 1-1 - Approaches to safer supply programs

	Models that can be implemented within existing legislative framework			Other models (out of scope)
	Traditional	**Enhanced**	**Flexible**	**Without prescriber oversight**
Target Population	People with substance use disorder who are seeking treatment.	People with substance use disorder, for whom traditional treatment has been unsuccessful.	People who use illegal substances, whose needs are not met by highly-structured models.	People who use opioids or stimulants.
Models	OAT; iOAT Multiple models.	Adapted iOAT/Tablet iOAT (TiOAT) for safer supply. Multiple options: 1. Comprehensive/dedicated (Crosstown) 2. Integrated/embedded (PHS, MOP); 3. Pharmacy model; Observed consumption. Lower threshold entry to iOAT model of safer supply. These may also include the prescription of regulated stimulants.	Daily dispensed; low threshold; self-titrated; observed and unobserved consumption; hub and spoke (rural areas). Already being done informally in private and primary care practices. Any proof of concept project that meets the requirements of appropriate prescriber involvement (e.g., a medical model) and permissible within the current regulatory and legislative frameworks.	Non-medicalized buyers clubs / compassion clubs.
Evidence	Adheres to current clinical guidelines.	iOAT as treatment has a strong evidence base; TiOAT as lower barrier treatment is being piloted. iOAT and TiOAT as safer supply models require further evaluation.	Requires pilot testing and evaluation to develop an evidence base.	
Characteristics	Medicalized; embedded in addiction treatment and primary care systems; uses contingency management.	Medicalized; embedded in addiction treatment and primary care systems; can require multiple visits a day for observed dosing; contingency management; wrap-around care.	Low threshold, harm reduction and public health informed approach. Embedded in primary care, SCS/OPS/CTS, or housing with pathways to health, social, and addiction treatment services.	Non-medicalized; public health approach.
Goals	Patient led goals: e.g. reduce/stabilize drug use, work towards abstinence.	Patient led goals around reducing illegal drug use or stabilizing use, if desired.	Reduce illegal drug use and related risks.	Provide safer supply of regulated drugs.
	Reduce risks of overdose and harms; Increase engagement with health, social services; provide primary care; reduce petty crime, sex work; reduce reliance on illegal market. Engage with highly marginalized/at risk people who typically do not access health and social services.			

Section 2
A Review of the Evidence



2. A Review of the Evidence

Given that safer supply programs are only just beginning, the evidence for safer supply interventions has yet to be established. However, the foundation of safer supply programs is built on the strong evidence available for the effectiveness of reducing harm through the provision of regulated pharmaceutical-grade opioids to people who use illegal opioids under the supervision of health providers (referred to as managed opioid programs, maintenance therapies, opioid-agonist treatment [OAT], or injection opioid agonist treatment [iOAT]). This evidence is reviewed here.

Opioid Agonist Treatment

A brief review of the evidence supporting oral OAT is provided here because it is an evidence-based approach for treating opioid use disorder[1] (OUD) and a critical tool for addressing the opioid overdose crisis[2]. In addition to the treatment goals of OAT (i.e., reducing and/or stabilizing drug use), OAT may be used for safer supply goals, i.e., reducing illegal drug use. OAT may be offered through oral formulations (e.g., methadone, buprenorphine-naloxone) or injectable formulations (e.g., diacetylmorphine, hydromorphone). Studies are also examining the potential harm reduction and protective effects of OAT, for example, improving social integration, increasing HIV treatment adherence, and possibly reducing hepatitis C infection[3] [4], and reducing initiation into injection drug use[5].

Studies[6] suggest that diversified opioid-agonist treatments are needed for people with opioid use disorder. Opioid agonist treatments have evolved to include pharmaceutical options beyond methadone, such as buprenorphine-naloxone (brand name Suboxone®), and slow-release oral morphine (SROM - brand name Kadian®). A study in Switzerland found that with the addition of new OAT alternatives, demand for methadone had decreased, yet methadone remained the most commonly used OAT[4] and is considered a second-line treatment for OUD[1]. Current Canadian guidelines[1] recommend buprenorphine-naloxone as a first line treatment because of its superior safety profile (6 times safer than methadone in terms of overdose risk) and its potential for flexible take-home dosing and fewer required medical appointments.

While methadone and buprenorphine have been most prominently used for people with more stable opioid use disorder, slow-release oral morphine may show promise for those with less stable OUD[7]. There is a growing evidence base for SROM that suggests that SROM has efficacy rates similar to methadone, but with a better safety profile, including fewer drug-drug interactions, and greater improvements in patient-reported outcomes, such as tolerability, alleviation of cravings and withdrawal symptoms, and treatment satisfaction. Canadian guidelines recommend that SROM be prescribed by specialists and as daily witnessed doses because of the potential patient and public safety risks[1].

In addition to an expansion in the pharmaceutical options for OAT, injectable opioid agonist treatment (iOAT) provides an approach for those who prefer to inject. Diacetylmorphine (heroin) and hydromorphone (brand name Dilaudid®) are prescribed in iOAT programs.

Heroin-assisted treatment

For over a century, unsupervised prescription injectable diacetylmorphine has been available in the United Kingdom[8] [9] [10], and Switzerland has provided supervised prescription diacetylmorphine as a standard drug treatment for opioid use disorder since 1999[11]. Supervised prescription diacetylmorphine is now provided in Germany, Denmark, the Netherlands[10,] and increasingly in Canada, primarily for those who have had a poor response to methadone treatment. The prescription of diacetylmorphine, also known as heroin-assisted treatment (HAT) has been demonstrated to be effective and cost-effective in Europe and Canada[12] [13] [14]. A study conducted in Canada (NAOMI) involved participants in Montreal and Vancouver who had failed methadone-based treatment. They were randomized to receive either heroin assisted treatment or methadone maintenance treatment. Corresponding to the results found in studies in England, Spain, Germany, Switzerland, and the Netherlands[10] [12] [13] [14] [15], this Canadian study[16] found that overall, HAT is more effective than methadone. More specifically, it found:

- Those receiving HAT reduced their use of illegal drugs more significantly than those receiving methadone;
- The HAT group showed significantly greater improvements in their medical and psychiatric status, economic status, employment situation, and family and social relations compared to the group receiving methadone;
- Other positive benefits of HAT, such as reduced mortality, reductions in needle sharing, increased treatment retention, reduced risk of acquiring HIV, hepatitis B and C, improved housing and employment stability, and dramatic reductions in criminal activity.

Hydromorphone: an effective and acceptable alternative to diacetylmorphine

A Vancouver-based study[17] examined whether injectable hydromorphone was an effective and acceptable alternative to diacetylmorphine prescription for iOAT programs. Injectable hydromorphone was found to be non-inferior to diacetylmorphine; additionally, retention in treatment was high (over 80%) and there were fewer side effects among people receiving hydromorphone. The study authors conclude that hydromorphone is a suitable alternative to diacetylmorphine prescription, particularly in jurisdictions where diacetylmorphine is not easily available. Guidelines are now available in BC[18] [19] and nationally[20] for both forms of opioid agonist treatment programs that use injectable opioids.

Harms and recommended practices for injecting oral opioids

Recently, prescribers have begun prescribing hydromorphone tablets as a regulated alternative opioid. There are groups of people who use drugs who have expressed a strong preference for

tablets over injectable formulations. For example, in Quebec, crushing and injecting tablets is a common practice and first choice for at least a 40 per cent of people who inject drugs[21]. Further, access to injectable high-potency hydromorphone is hampered by provincial formulary caps and/or exclusions, thereby making tablets a more affordable and accessible option. However, health care providers may have concerns for their patients about potential health risks associated with injecting crushed and dissolved tablets, as well as liability concerns about prescribing and dispensing a tablet that has not been approved for injection.

Literature addressing the injection of opioids manufactured for oral consumption highlights the specific health issues that can occur, which include[22 23]:

1. skin and soft tissue injuries (e.g., skin ulcers and cellulitis)
2. lung, heart and other conditions related to blood vessels (e.g., blood clots, endocarditis)
3. local and generalized infections (e.g., abscesses around injection sites and generalized blood infections)

These health issues can be caused by viral, bacterial, or other matter introduced by injecting in non-sterile conditions. They can also be caused by the drug itself, but more commonly, by ingredients in the drug (such as bulking agents, coatings, waxes or gels) that are included to make the oral formulation work as intended, for example to maintain its stability, or to control the release of the drug once it is swallowed, as well as prevent tampering. These ingredients may have adverse effects on the body whey they are dissolved into solution and injected. They can clog needles or filters, become lodged within the skin or other blood vessels, and cause medical complications[24 25].

The available research on the beneficial effects of filtering opioids manufactured for oral use prior to injection provides a number of harm reduction practices that address the harms introduced by both non-sterile conditions as well as from excipients, these include[21 22]:

- handwashing prior to injection and alcohol swabbing at the injection site;
- using sterile water to prepare the solution to be injected;
- use of sterile injection equipment;
- filtering the solution using a combined Sterifilt® brand filter and cotton filter.

With proper filtration, much of the expedients are excluded, leaving primarily the active component of the drug[22 24]. A study[21] in Quebec found that the combination of a Sterifilt® brand filter and cotton filter makes it possible to optimize the filtering capacity of Sterifilt® while maintaining a good amount of active ingredients in filtered solutions. Based on this research, oral drugs injected using harm reduction practices may be a better alternative to illegal drugs procured from the illegal market[22 23 24]. Another recommendation based on this research could be that if oral hydromorphone tablets were to be provided to people who may

inject them (or use them intra-nasally or smoke them), it would be best to prescribe hydromorphone tablets with the least amount of excipients in them, or the least amount of excipients that are harmful if injected[22]. For example, immediate release tablets are likely to have less (or less harmful) excipients compared to sustained released tablets. This recommendation also coincides with the reported preference of people who use drugs for Dilaudid® over generic formulations of hydromorphone.

Stimulant Substitution Programs

Thus far emphasis has been placed on a safer supply for opioids because of the unpredictable and toxic opioid supply on the illegal market. There are some reports that illegal stimulants may also be vulnerable to contamination, and polysubstance use is common. This supports the need for safer supply of stimulants. Research evidence for stimulant substitution treatment is currently not as strong as that for opioid substitution treatment, and further research is needed[26] [27].

Existing treatment options for stimulants almost exclusively focus on abstinence-based approaches, and operate on appointment-based schedules that can be difficult for people to comply with. Further, many may not offer counseling and social supports appropriate to the situations of people who use stimulants[27] [28]. The integration of a harm reduction approach in managed stimulant programs makes it an appealing alternative to many of the existing treatment options for stimulant use.

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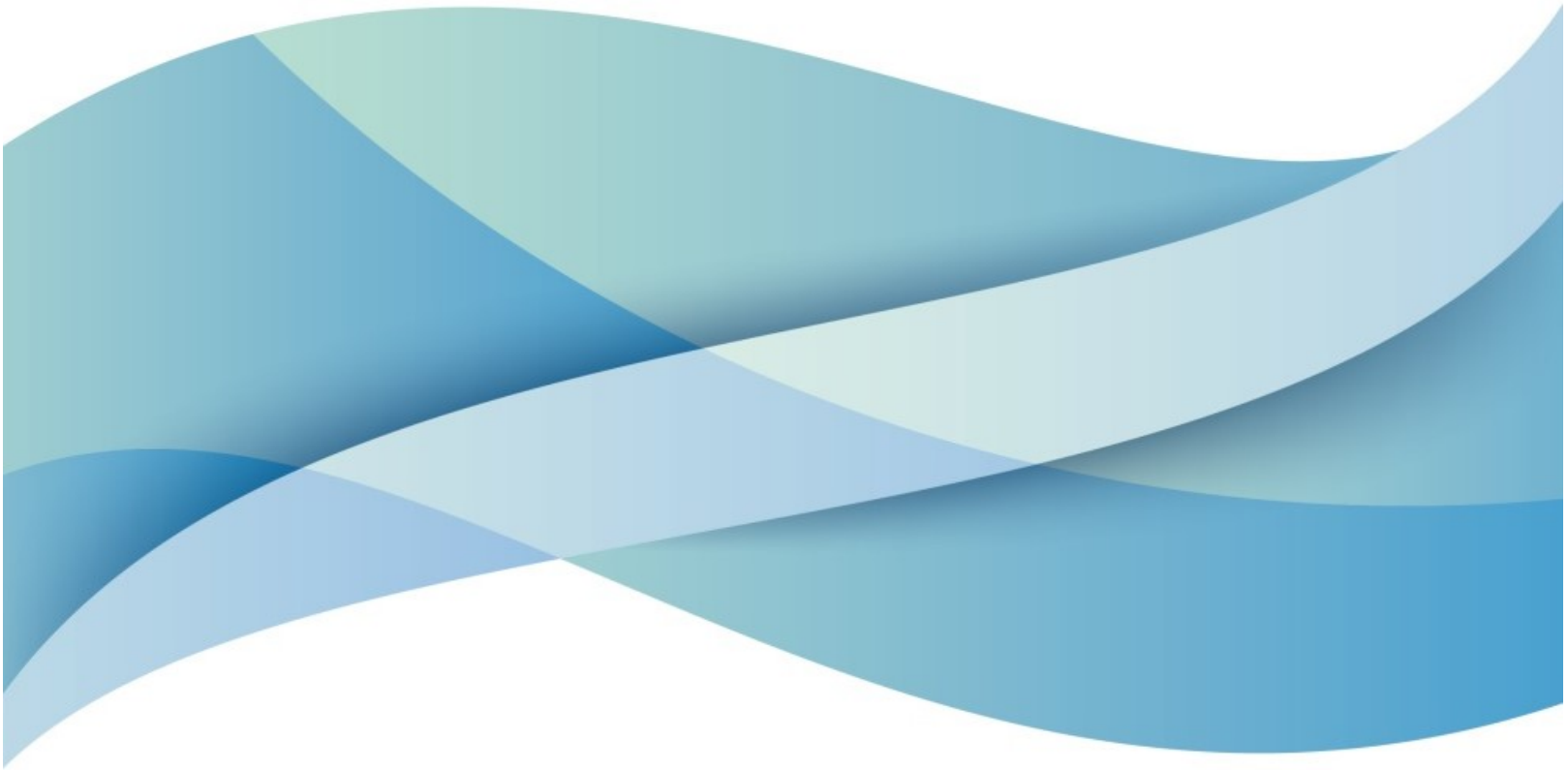
Section 3
Establishing Safer Supply Programs



3. Establishing Safer Supply Programs

The following tools are intended to support decision-making for program design considerations. They include:

- **3.1** Service model design
  - **3.1.1** Comparison of flexible and enhanced models of safer supply
  - **3.1.2** Considerations for observed and unobserved dosing models
  - **3.1.3** Considerations for rural and remote areas
  - **3.1.4** Case studies of current programs
- **3.2** Selecting and obtaining regulated pharmaceutical drugs for these models
  - **3.2.1** Regulated pharmaceutical-grade opioids used in safer supply programs
  - **3.2.2** Regulated pharmaceutical-grade stimulants used in safer supply programs
  - **3.2.3** Map: Process for acquiring controlled substances via existing regulations
- **3.3** Considerations for creating operational and clinical protocols
- **3.4** Site requirements and staffing considerations

3.1 Service Delivery Design

A critical element of service delivery design is to engage with people who will use the program: i.e., people who use drugs. By consulting with and including people who use drugs in the design, services are more likely to meet the needs of the target population.

There are different service delivery models that can be adapted to meet the needs and cultures of the local context in which the program will operate. There are also legislative and regulatory considerations for service delivery design.

This section guides a safer supply program design team through considerations for service delivery models by:

- **3.1.1** Presenting a comparison of Enhanced and Flexible models
- **3.1.2** Presenting the regulatory considerations for observed and unobserved dosing
- **3.1.3** Service delivery design considerations for rural and remote areas
- **3.1.4** Providing case studies of programs currently being piloted

3.1.1 Flexible and enhanced safer supply program models

In Section 1, a continuum of care for safer supply programs for people who use drugs was introduced. This continuum of care ranges from *Traditional* approaches (e.g., OAT), to *Enhanced* models, and to *Flexible* models (see **Table 1-1** in Section 1). A detailed analysis of *Enhanced* and *Flexible* models is presented below, including key characteristics, settings, strengths, limitations, anticipated benefits, potential harms, and strategies for mitigating harms.

Enhanced Models

Enhanced models provide observed consumption and contingency management, similar to traditional OAT models, however, they are adapted to provide a lower barrier approach to delivering regulated alternatives to illegal drugs, i.e., safer supply. Injection opioid agonist treatment (iOAT, and TiOAT – tablet injection opioid agonist treatment) may be used as either treatment for opioid use disorder or for providing a safer supply of regulated alternatives to opioids purchased from the illegal market. The focus of enhanced models is on the latter goal: *iOAT and TiOAT as an approach for providing a regulated supply of opioids and/or stimulants*. Existing iOAT and TiOAT programs are finding ways to reduce the barriers to access and retention for people who use opioids, such as offering programs in supervised consumption sites, overdose prevention sites, and supportive housing; by changing eligibility criteria to opioid use (rather than opioid use disorder); and offering a harm reduction approach to drug use.

The British Columbia Centre for Substance Use (BCCSU) identified three models of care in their iOAT guidance document (BCCSU 2017), which may be adapted to have a safer supply focus on reduced *illegal* drug use and related harms, rather than a treatment focus on reduced drug use:

A. Comprehensive and dedicated supervised injectable opioid agonist treatment program (iOAT) – adapted to deliver safer supply

Example: Crosstown Clinic in Vancouver BC

- Provides a comprehensive model of care alongside supervised iOAT;
- Often located in hospitals or clinics, or as a standalone facility;
- Services are co-located at the clinic (e.g., pharmacy, primary care health providers, social workers) or are referred to community services; and
- Services include addictions care, primary care, mental health care, chronic pain management, and psychosocial services such as housing, employment, trauma therapy and specialized services for women, youth, and Indigenous peoples.

Strengths: Offers continuity of care, "one-stop shop"; preferred option for people who lack clinical and social stability; few/no barriers to wrap-around services; solid body of evidence supporting iOAT. Has potential to pilot lower threshold approaches such as unobserved dosing and unobserved titration, permitting polysubstance use, and offering stimulant substitution treatment.

Limitations: Resource-intensive; requires on-site pharmacy that is compliant with compounding regulations; not appropriate for community with lower demand or capacity for iOAT; there may be challenges in de-intensifying treatment.

Anticipated benefits: Reduces clients' use of illegal drugs and reliance on illegal market, increases engagement with primary health care and social services, decreases mortality related to overdose and other related harms; reduced involvement in crime and sex work.

Potential harms: Maintains clients' use of injection if other modes of consumption are not permitted (e.g., many sites do not have inhalation facilities); maintains dependence on illegal market if optimal dose or optimal drug is not provided.

Mitigation strategies to reduce potential harms: Provide a range of drugs and formulations (e.g., stimulants, opioids; pills, injectables); work closely with clients to determine their optimal dose and offer alternatives such as slow release oral morphine, e.g., Kadian®, as a 'backbone' in addition to their regulated opioids; have smoking facilities; permit polysubstance use and multiple modes of consumption (i.e., intranasal, oral ingestion, injection, inhalation).

B. Integrated or embedded supervised injectable opioid agonist treatment program - adapted to deliver safer supply

Examples:

- *Ottawa Inner City Health's Managed Opioid Program is located within supportive housing and supervised injection site.*
- *Portland Hotel Community Services Society has an existing iOAT program and is piloting a tablet injectable (TiOAT) program at their Molson overdose prevention site in Vancouver BC.*

- iOAT program, adapted for safer supply, is integrated with existing services at community health centres (CHC), harm reduction programs (including supervised consumption sites, overdose prevention sites), or supportive housing;

- Extends the range of services to existing clients, and also might attract new clients who would also benefit from the broader range of health and social services and addictions treatment offered on site, or through referral pathways to providers in the community; and
- Offers both pharmaceutical opioids and/or stimulants as regulated alternatives to the illegal contaminated market.

Strengths: Lower resource requirements compared to comprehensive/dedicated iOAT or traditional OAT models; provides continuity of care; low barriers to additional services; appropriate for locations with lower demand for iOAT, e.g., rural areas; growing body of evidence supporting embedded iOAT. Has the potential to pilot lower threshold approaches such as unobserved dosing and unobserved titration, permitting polysubstance use, offering the full continuum of care of OAT and referral to recovery services, and offering stimulant substitution treatment.

Limitations: Requires on-site pharmacy or pharmacy delivery (compliant with College regulations for compounding); requires additional staffing and dedicated space.

Anticipated benefits: Reduces clients' use of illegal drugs and reliance on illegal market, increases engagement with primary health care and social services, decreases mortality related to overdose and other related harms; reduces involvement in crime and sex work.

Potential harms: May maintain clients' use of injection if smoking or intranasal consumption are not permitted; maintains dependence on illegal market if optimal dose or optimal drug is not provided.

Mitigation strategies to reduce potential harms: Provide a range of drugs and formulations (e.g., stimulants, opioids; pills, injectables); work closely with clients to determine their optimal dose and offer oral opioid agonist treatment options such as slow-release oral morphine (Kadian®) as a 'backbone' in addition to other prescribed pharmaceutical opioids; have smoking facilities; permit polysubstance use alongside observed dosing; and permit multiple modes of consumption.

C. Pharmacy-based supervised injectable opioid agonist treatment program – adapted to deliver safer supply

Example: PHS Community Services Society in Vancouver was piloting this model.

- This model may be more appropriate for settings in which the first two models are not feasible (e.g., in rural settings);
- Primary care and addiction services are offered in existing clinics, and observed dosing is undertaken by trained pharmacists in select community pharmacies; and

- Referrals are made to community agencies for services such as mental health care, chronic pain management, and psychosocial services (e.g., counseling, employment, housing) and specialized services for women, youth, and Indigenous peoples.

***Strengths*:** Appropriate for communities with low demand for iOAT; appropriate for clients on a stable dose; lower resource requirements.

Limitations: Requires community pharmacy with appropriately trained staff to dispense, supervise, and respond to adverse events, with dedicated space for supervised consumption, and facilities compliant with College regulations for compounding. There may be higher barriers to additional services. Although barriers to treatment are reduced, it is still high treatment intensity in that clients have to attend pharmacy multiple times per day for dosing.

***Anticipated benefits*:** Reduces clients' use of illegal drugs and reliance on illegal market, decreases mortality related to overdose and other related harms; reduces involvement in petty crime and sex work; lower treatment intensity enables more time to participate in other activities (child care, work); increases access in communities that have few social services locally.

Potential harms: Maintains clients' use of injection in the absence of inhalation facilities; maintains dependence on illegal market if optimal dose or optimal drug is not provided; complicates connections to social and health services because they are not onsite.

Mitigation strategies to reduce potential harms: Provide a range of drugs and formulations (e.g., stimulants, opioids; pills, injectables); work closely with clients to determine their optimal dose and offer other OAT alternatives such as slow release oral morphine, e.g., Kadian®, as a 'backbone' in addition to their regulated supply of opioids; have smoking facilities; permit polysubstance use alongside observed dosing; have outreach workers attend community pharmacies to provide support and referrals; prescribers, support workers, and pharmacists work together to provide care.

Flexible Models

Examples:
- *The Liverpool model (1980s UK)*
- *London Intercommunity Health Centre's model (Ontario)*
- *Dispensing machine model (yet to be piloted)*
- *BCCDC low barrier oral hydromorphone feasibility pilot (upcoming)*

Flexible models refer to the growing number of community-based initiatives that seek to provide regulated alternatives to the toxic illegal drug supply with as few barriers as possible, in a flexible and responsive manner. In general, these models offer daily-dispensed drugs,

prescribed by a doctor or nurse practitioner, which are consumed unobserved, as needed, or frequently dispensed drugs for observed dosing. Flexible models may involve a mix of observed and unobserved titration and dosing, according to the needs of their clients. Flexible models have strong potential for scaling up and are highlighted here as an emerging model for pilot projects and evaluation.

- Primary care providers at community health centres or community clinics prescribe hydromorphone to select clients at high risk of overdose or harm.
- Clients are seen daily at first, then weekly, then monthly or as appropriate by the prescriber to monitor health and wellness, and clients pick up daily-dispensed prescription at a community pharmacy, clinic, or potentially, a dispensing machine. Consumption is not observed, except for those for whom there are health and safety concerns (e.g., those who are consuming alcohol and/or benzodiazepines).
- Additional services (wrap-around care) may be provided on-site with few/no barriers, or referred to community providers through directed pathways.

Strengths: Lower resource requirements; leverages existing relationships between prescribers/primary health care teams and clients. Less treatment intensive (i.e., observed dosing is not required, unless indicated for specific clients) and so less demanding on clients (e.g., do not have to attend clinic/pharmacy multiple times per day). Provides flexible and responsive care to people who use drugs (not necessarily those with opioid use disorder), including those who use stimulants; have the potential to be scaled up and to reach a wider group of people who use drugs.

Limitations: Evidence-informed – requires proof-of-concept piloting. Current practice suggests improved health benefits and greater stability, but it is unclear that these positive outcomes are due to safer supply because consumption is not observed. Current practice demands prescribers carefully document their rationale, including how their decision-making is evidence informed and in line with practices of their peers. This approach may add additional burden to already over-stretched organizations and primary health care teams.

Anticipated benefits: reduces clients' use of illegal drugs and reliance on illegal market; decreases mortality related to overdose and other related harms; reduces involvement in petty crime and sex work; lower intensity approach enables more time to participate in other activities (child care, work); increases connection to health and social services.

Potential harms: The biggest concerns are the potential for diversion, and prescriber liability should a client overdose or experience harm. Diversion is a concern in areas where the drug supply is contaminated with carfentanil, which increases people's tolerance; the volume for the prescribed dose that would be needed to match a very high tolerance may not be appropriate or desirable. This might encourage people to exchange or sell their prescribed medications for fentanyl, carfentanil or other illegal drugs. By adding additional service demands to already under-resourced organizations, this may limit access to services

across the organization; i.e., existing resources are deployed for new flexible safer supply programs at the expense of other programs.

Mitigation strategies to reduce potential harms: provide a range of drugs and formulations (e.g., stimulants, opioids; pills, injectables); work closely with clients to determine their optimal dose and offer opioid alternatives such as slow-release oral morphine, Kadian®, as a 'backbone' in addition to their prescribed opioids; permit polysubstance use; prescribers, support/outreach/peer workers, and pharmacists work together to provide care. Organizations require sustainable and adequate funding to effectively provide a full range of services.

Table 3-1 – Summary of considerations related to *Flexible* and *Enhanced* models for safer supply

	Flexible	**Enhanced**		
	Embedded and integrated Daily dispensed HDM	**Pharmacy - iOAT/TiOAT**	**Embedded or Integrated iOAT/TiOAT**	**Comprehensive and dedicated iOAT**
Examples	London InterCommunity Health Centre (ON); Liverpool Model (UK 1980s).	Portland Hotel Society (PHS), Vancouver, was piloting this model.	PHS, Vancouver (TiOAT); Managed Opioid Program (MOP), Ottawa (iOAT).	Providence HC Crosstown clinic, Vancouver; Sheldon M. Chumir Health Centre, Calgary.
Setting	CHCs / Housing	Community pharmacy	SCS/OPS/CTS; Supportive housing	Hospital/clinic
Observed dosing requirements	Unobserved or observed. Tiered.	Observed. Tiered.	Observed. Tiered.	Observed. Tiered.
Prescribing model	Individual prescriber-patient. Daily dispensed.	Individual prescriber-patient. Frequently dispensed, with set minimum time between doses.	Individual prescriber-patient. Frequently dispensed, with set minimum time between doses.	Individual prescriber-patient. Frequently dispensed, with set minimum time between doses.
Type of drug and mode of consumption	Hydromorphone injectable/tablets; Dexedrine, Adderall, Vyvanse. Injection, oral, intranasal consumption.	Hydromorphone injectable/tablets. Injection, oral, intranasal consumption.	Hydromorphone injectable/tablets (exploring fentanyl). Injection oral, intranasal consumption.	Diacetylmorphine (only Crosstown), hydromorphone injectable. Injection, oral, intranasal consumption.
Pharmacy support	Community pharmacy, with compounding for multi-dose vials.	Community pharmacy with compounding for use of multi-dose vials.	Community compounding pharmacy; RN compounds multi-dose vials as needed, as permitted by regulatory colleges.	On site compounding pharmacy.
Wrap-around care	Available with low barriers. Embedded in primary care, with other health and social services available, but not required. Low barriers to additional services.	Available. Connected to primary care and referrals to other health and social services when needed.	Available with low barriers. Connected to primary health care, direct pathways to health and social services, but not required.	Available with low barriers. Direct pathways to primary health and social services; “one stop shop”.
Evidence-base	Safer supply approaches are extrapolated from the evidence for iOAT. No current guidelines. Requires proof of concept pilot projects.	Safer supply approaches are extrapolated from the evidence for iOAT. No current guidelines. Requires further piloting.	Safer supply approaches are extrapolated from the evidence for iOAT. No current guidelines. Requires further piloting.	Strong evidence. iOAT Guidelines have been established. Requires continued evaluation as an approach for safer supply.
Resources required	Observed dosing requires room, staff. Unobserved dosing requires fewer resources.	Need infrastructure for observed dosing (e.g., room, staff) and need pharmacy buy-in.	Expand existing infrastructure for observed dosing (room, staff).	Resource intensive; requires a sustainable supply of diacetylmorphine (or hydromorphone).
Implementation considerations	Cost: Need hydromorphone listed in formularies at appropriate concentrations; availability of single use vials or compounding pharmacy for multi-dose vials. Regulatory issues with Colleges (e.g., off-label injection use of oral medications; compounding, prescribing and assessment frequency).			1. Considerations for securing diacetylmorphine supply. 2. Cost of infrastructure. 3. Needs of the community.
Comments	Lower cost requirements, especially for unobserved dosing models, or off-site observed models (i.e., pharmacy-model).	Potential option for settings such as rural/remote and Indigenous communities. Scalability based on pharmacy support and capacity. Appropriate for patients on a stable dose. Less intensive treatment requirements. Lower cost requirements than enhanced models.	Lowering barriers to iOAT. Lower cost requirements than comprehensive models. **Vision:** SCS/OPS/CTS models supply hydromorphone (with limits on dose and frequency) to clients, after medical assessment.	Lowering barriers to OAT.

3.1.2 Regulatory considerations for observed and unobserved dosing

Table 3-2 – Regulatory considerations for observed and unobserved dosing

Question	Observed	Unobserved	Legislation/ Regulation and Oversight

What do the guidelines say?	Currently, there are no guidelines for prescribing stimulants or opioids as a pharmaceutical alternative to the illegal drug supply. The lack of guidelines creates a grey area. Prescribing off-label and outside of existing guidelines has left some prescribers concerned that they will be held to criminal, professional, and medicolegal liability should harm come to their patient, or to the community. Key stakeholders who are prescribing safer supply reported feeling ethically-bound to respond to the harms that they see arising for patients who have a substance use disorder and/or are experiencing harms (e.g., overdose) related to the toxic illegal drug supply.		• Professional regulatory colleges.
			• Current guidelines that may inform safer supply practice:
			  • iOAT guidelines,
			  • OUD guidelines,
			  • Stimulant prescribing guidelines for ADHD.
			• Needed: guidelines for prescribing controlled substances as safer supply.

	OAT and iOAT guidelines provide guidance for observed safer supply prescribing, including contingency management.	In the absence of guidelines for prescribing controlled substances for safer supply, prescribers document how they: • follow standards of care; • use the evidence-base; • follow research protocols approved by an ethics board; and/or • consult with and follow practices of their peers.	
Infrastructure considerations:			
(1) What are the security and storage requirements?	Observed dosing requires having controlled drugs on site. The CDSA-NCR regulations establish minimum security requirements s for Licensed Dealers:[1] • Secure area for storage and preparation of the medication that is not accessible to patients or outsiders, including bolted safes, locked narcotic cabinets) • Documentation and inventory management systems.	N/A for programs where prescriptions are dispensed at a community pharmacy. For those that have on-site dispensing but do not observe consumption, see *Observed* column.	• Controlled Drugs and Substances Act (CDSA)-Narcotic Control Regulations (NCR), • Regulatory Colleges, • Provincial/ Territorial Health and Safety Regulations, • iOAT guidelines[3].

Table 3-2 – Regulatory considerations for observed and unobserved dosing

Question	Observed	Unobserved	Legislation/ Regulation and Oversight
	In addition, Health Canada has developed guidance for community pharmacists to minimize the potential diversion of controlled substances from their establishments[2], including: • security measures, destruction procedures, inventory and reconciliation, and record-keeping.		
(2) What other spatial considerations are there?	Consumption and chill out areas: • Dedicated room with controlled entry that has space for supervised injection, • Table/bench space with cleanable surface (i.e. not wood), • Seating that is easily moved and cleaned, • Storage area for clients' belongings to prevent diversion, • Comfortable area for post-consumption monitoring. Storage area for injection equipment.	Storage area for tourniquets, Steri-wipes; filters; needles of various gauges; and other safer injection equipment. Refer clients to supervised consumption services/ overdose prevention services, provide education on safer use practices.	• Provincial/territorial health and safety regulations. • iOAT guidelines. • Best practices for harm reduction[4].
(3) How are the doses prepared?	For injectables, a pharmacy is required either onsite or in the community that meets professional and jurisdictional requirements for compounding. Onsite preparation requires authorized health practitioners. The question of who crushes and prepares tablets for injection must be addressed. Currently, nurses are only permitted to do this when following an approved research protocol. Monitoring system needed to ensure minimum time between doses.	Doses of injectables are prepared at a compounding pharmacy compliant with jurisdictional regulations. Tablets can be dispensed at a community pharmacy that does not do compounding. Clients prepare their dosage of tablets for consumption (e.g., for injection, inhalation, intranasal use).	• CDSA-NCR-New Classes of Practitioner Regulations (NCPR). • Professional regulatory Colleges.

Table 3-2 – Regulatory considerations for observed and unobserved dosing

Question	Observed	Unobserved	Legislation/ Regulation and Oversight
(4) Who administers doses?	Clients administer their own dosages. Under circumstances in which a client cannot inject themselves, nurses may be permitted to administer intramuscular or subcutaneous injections – *check with jurisdictional regulatory Colleges.*	Clients administer their own doses.	• CDSA-NCR-NCPR. • Professional regulatory Colleges.
(5) What staffing requirements are there?	Qualified health professionals or supervised trained staff for pre- and post-assessment, administration of correct dose, and supervision of self-administered injections. Access to qualified health professionals and trained staff 7 days per week, 365 days per year. Support workers, such as peer workers, harm reduction workers, community outreach workers, case managers.	Access to a safer supply prescriber, including a backup to provide continuity of care should primary prescriber be absent. Programs do not need to operate 7 days per week, 365 days per year. Must make sure that the pharmacy has a prescription for days when the program is closed. Support workers, such as harm reduction workers, peer workers, community outreach workers, case managers.	• CDSA-NCR-NCPR. • iOAT guidelines (can be adapted for safer supply goals). • Best practices in harm reduction services[5].
Other considerations:			
(1) Titration	Observed titration is consistent with observed dosing programs. Not everyone needs a full titration program, however.	Some flexible models permit self-titration, others follow an unobserved titration protocol.	• Professional regulatory Colleges. • iOAT guidelines may be adapted for safer supply.
(2) Dosing schedule	Can offer a fixed dosing schedule or flexible timing with a defined minimum amount of time between doses (e.g., up to 5 times per day, at least 1 hour between doses). Dosing schedules are linked to program hours of operation.	Unobserved dosing provides clients with a flexible dosing schedule, with recommended periods of time between doses. Clients pick up their daily supply and use as needed. Doses are not connected to program hours of operation.	• Professional regulatory Colleges. • iOAT guidelines may be adapted for safer supply.

Table 3-2 – Regulatory considerations for observed and unobserved dosing

Question	Observed	Unobserved	Legislation/ Regulation and Oversight
(3) Diversion	Observed dosing is thought to reduce diversion, in conjunction with security procedures (e.g., secure storage, separate area for clients to store belongings). Please see above: *Infrastructure considerations #1. Security and storage requirements*	Diversion concerns are greater for programs with unobserved dosing.	• CDSA and NCR • Professional regulatory Colleges • Provincial/Territorial Health and Safety Regulations • iOAT guidelines may be adapted for safer supply
(4) Individual client needs	Clinical judgment should be used to determine if observed dosing is required, for example, for clients who are also using alcohol or benzodiazepines, who have complex health issues, or who struggle with stability.	Clinical judgment should be used to determine if unobserved dosing is appropriate for clients. Unobserved dosing may support clients' engagement with employment, education, and childcare.	• Professional regulatory Colleges. • iOAT guidelines may be adapted for safer supply.

[1] Health Canada. Directive on Physical Security Requirements for Controlled Substances (Security Requirements for Licensed Dealers for the Storage of Controlled Substances) Retrieved from: https://www.canada.ca/en/health-canada/services/health-concerns/reports-publications/controlled-substances-precursor-chemicals/directive-physical-security-requirements-controlled-substances-licensed-dealers-security-requirements-storage.html

[2] Health Canada (2019). *Recommended guidance in the areas of security, inventory reconciliation and recordkeeping for community pharmacists*. Retrieved from: https://napra.ca/sites/default/files/2019-04/CS-GD-022%20Recommended%20guidance%20for%20community%20pharmacists_EN.pdf

[3] British Columbia Centre on Substance Use (2017). *Guidance for Injectable Opioid Agonist Treatment for Opioid Use Disorder.* Retrieved from: http://www.bccsu.ca/wp-content/uploads/2017/10/BC-iOAT-Guidelines-10.2017.pdf

[4] Strike C, Hopkins S, Watson TM, Gohil H, Leece P, Young S, Buxton J, Challacombe L, Demel G, Heywood D, Lampkin H, Leonard L, Lebounga Vouma J, Lockie L, Millson P, Morissette C, Nielsen D, Petersen D, Tzemis D, Zurba N. (2013). *Best Practice Recommendations for Canadian Harm Reduction Programs that Provide Service to People Who Use Drugs and Are at Risk for HIV, HCV, and Other Harms: Part 1*. Toronto, On: Working Group on Best Practice for Harm Reduction Programs in Canada. Retrieved from:: https://www.catie.ca/en/programming/best-practices-harm-reduction#part1

[5] Strike C, Watson TM, Gohil H, Miskovic M, Robinson S, Arkell C, Challacombe L, Amlani A, Buxton J, Demel G, Gutiérrez N, Heywood D, Hopkins S, Lampkin H, Leonard L, Lockie L, Millson P, Nielsen D, Petersen D, Young S, Zurba N. (2015). *The Best Practice Recommendations for Canadian Harm Reduction Programs that Provide Service to People Who Use Drugs and Are at Risk for HIV, HCV, and Other Harms: Part 2.*Toronto, ON: Working Group on Best Practice for Harm Reduction Programs in Canada. Retrieved from: https://www.catie.ca/sites/default/files/bestpractice-harmreduction-part2.pdf

3.1.3 Service delivery design considerations for rural and remote areas

Patterns of substance use, the illegal drug market, the availability of services and resources, and socio-cultural responses to substance use may be significantly different in remote and rural areas. Some communities and their leadership may benefit from education about the role of safer supply programs to reduce the harms related to use of illegal drugs. A critical component for the success of a program in some rural and remote communities is gaining the approval and support of leadership, and attending to the cultural and social determinants of health.

Access to harm reduction and primary care services may be more difficult in rural and remote areas. Many rural areas report service shortages that result in significant barriers to care. In resource-scare areas, the pharmacy-model of iOAT (supervised consumption in a pharmacy, similar to community pharmacy based oral OAT access) and flexible (i.e., unobserved consumption) models may prove most effective.

Some other models to consider, often in conjunction with the pharmacy model or flexible models, include:

Hub and spoke model: The hub and spoke model of service delivery arranges service delivery assets into a network consisting of an anchor establishment (hub) that offers a full array of services, complemented by secondary establishments (spokes or satellites) that offer more limited services[1]. Those individuals who require more intensive services attend the hub (e.g., for initial assessment and titration), and ongoing support and services (such as observed consumption) is offered at spoke sites. Spoke sites could offer group appointments, as well as individual follow-up. This works in a similar manner as the pharmacy model, but the spokes would offer broader support and services than that offered by a pharmacy alone. This model may also adopt a mobile component, where the 'spokes' are mobile satellites.

Telehealth: Telehealth offers a promising tool for providing services in rural areas where there is a lack of specialized providers and services. Telehealth uses technology to provide access to services across distance by connecting clients with providers for screenings, counseling, and other services. Multiple technological platforms are being used: telephones, smart phone applications, and video conferencing, for example. This approach is useful not just for barriers related to distance from providers, but also for privacy concerns, lack of access to transportation, and concerns about missing time from work and childcare. A study[2] of people engaged in opioid agonist therapy across 48 clinics in Ontario found that patients who were treated via telehealth were more likely to be retained in therapy than patients treated in person, and the group that used both telehealth and in person treatment also had higher retention rates than those only receiving care in person. This model may be used alongside the pharmacy-model.

Mobile services: Mobile services offer the possibility of bringing services, medications, health professionals to localities where a fixed site could not be sustainably supported. Research[3]

suggests that mobile services mitigate barriers such as distance, social isolation, lack of time, and childcare issues, and are cost-effective ways of improving health outcomes in underserved communities. Mobile services may be used alongside telehealth and pharmacy-models.

Peer support services: Trained, employed peer support workers can maintain presence, support, and service provision in areas lacking local health and social services. In addition to filling the service gap, they may also enhance program legitimacy and acceptability. Employing peer workers contributes to their social determinants of health (see Section 4.5) by providing income and employment, and it may expand the reach of services to community members previously unconnected to services. Peer workers from the local community will understand and share cultural similarities that may contribute to greater trust and willingness to engage in services.

[1] Elrod JK and Fortenberry Jr JL. (2017). The hub-and-spoke organization design: an avenue for serving patients well**.** *BMC Health Services Research, 17*(Suppl 1):457. https://doi.org/10.1186/s12913-017-2341-x

[2] Eibl JK, Gauthier G, Pellegrini D, Daiter J, Varenbut M, Hogenbirk JC, and Marsh DC. (2017). The effectiveness of telemedicine-delivered opioid agonist therapy in a supervised clinical setting. *Drug and Alcohol Dependence*, *176*, 133-138. https://doi.org/10.1016/j.drugalcdep.2017.01.048

[3] Stephanie W.Y. Yu, Caterina Hill, Mariesa L. Ricks, Jennifer Bennet, and Nancy E. Oriol. (2017). The scope and impact of mobile health clinics in the United States: a literature review**.** *International Journal for Equity in Health, 16*, 178. 10.1186/s12939-017-0671-2

3.1.4 Case study of current safer supply pilot project

Portland Hotel Society (PHS) Molson Overdose Prevention Site program – an example of an *Enhanced* iOAT model

TiOAT Program - Tablet Injectable Opioid Agonist Treatment Program
A treatment program that includes safer supply goals, i.e., the provision of a pharmaceutical opioid to reduce illegal drug use.

PHS has started a program for people with opioid addiction who have not responded well to oral opioid agonist treatments like Methadone, Suboxone®, or Kadian®. The program is located at the Molson Overdose Prevention Site (OPS). The hours are from 1pm-10pm.

The program: Participants receive 2 crushed hydromorphone 8 mg tablets to inject or take orally at Molson OPS up to 5 times per day as needed, with 1 hour minimum between doses. There are no take home doses. This is a pilot program and is being evaluated.

To qualify, people must:

- Be diagnosed with Opioid Use Disorder
- Have tried methadone formulations, Kadian®, or Suboxone® in the past without success
- Be willing to follow up with the doctor and clinical team
- Be willing to sign consent forms

Program rules:

- Must inject/take at the MOPS
- No mixing with other street drugs (has to be separate hits)
- No jugging or injecting in the groin
- No doctoring (assisted injection)
- Be respectful of clients and staff
- Provide regular urine drug tests

To sign up, people must:

- Fill out paperwork at MOPS and provide a urine sample.
- See a doctor at MOPS to assess medical eligibility
- Get approved and start (space permitting)

3.2 Selecting, Obtaining, and Dispensing Regulated Drugs for Safer Supply Programs

This section provides information about selecting and obtaining regulated pharmaceutical-grade opioids and stimulants as alternatives to the toxic illegal drug supply. While the decision of which drug may be most appropriate for an individual is made between a prescriber and the client, issues such as accessibility, formulations, cost, compounding and dispensing, and preferences all influence which drugs may be used. This section offers:

3.2.1. A comparison of regulated pharmaceutical-grade opioids used in safer supple programs, including how to obtain them

3.2.2. Information about pharmaceutical-grade stimulants used in safer supply programs

3.2.3. A map of the regulatory landscape for acquiring controlled substances via existing regulations

3.2.1 Regulated pharmaceutical opioids used in safer supply programs

A range of regulated pharmaceutical opioids are currently in use across the range of *Enhanced* and *Flexible* models of safer supply. In programs that rely on injectable opioids, diacetylmorphine and hydromorphone are both evidence-based medication choices (based on patient choice and prescriber judgment); however, hydromorphone is most commonly prescribed due to the significant difficulties in accessing a sustainable supply of diacetylmorphine (BCCSU 2017). Considerations related to these two medication options are discussed below, and a summary comparison of different options and their respective regulatory considerations are presented in **Table 3-3**.

Access

- Diacetylmorphine is not manufactured domestically, and can be difficult to access because of importation challenges, and insufficient supplies; however, Health Canada has recently added diacetylmorphine (brand name Diaphin I.V.) to the *List of Drugs for Urgent Public Health Need* for severe opioid use disorder (as of April 25, 2019)); with this recent listing, practitioners across Canada can now prescribe diacetylmorphine, which has been approved in a foreign jurisdiction, but that is not approved in Canada.
- Health Canada recently (May 1, 2019) approved supervised injectable opioid agonist therapy (siOAT) as an indication for one brand of injectable hydromorphone (10mg/ml, 20mg/ml, 50mg/ml, and 100mg/ml); however, most provincial formularies only list low-potency hydromorphone (e.g., 10 mg/ml) and hydromorphone tablets, making cost a barrier for some.
- Hydromorphone tablets are available in both brand name (Dilaudid®) and generic. Dilaudid® is preferred by most people who use drugs because it is easier to crush and prepare than generics.

Formulation

- Injectable high-potency hydromorphone (e.g., 50mg/ml, 100mg/ml) has been indicated for opioid use disorder, and is the preferred option among stakeholders.
- Medically, higher dosing strengths are preferred as it is always safest to inject lower volumes intravenously.
- Off-label prescribing of hydromorphone tablets for injection is being piloted and evaluated.

Compounding & dispensing

- Injectable hydromorphone is dispensed either by single-use ampules delivered by a local pharmacy, or through advanced compounding by a trained pharmacist compliant with jurisdictional professional College requirements.
- Nurses can draw up doses from single-use ampules.
- Single-use ampules come in a limited range of concentrations, making it difficult to provide accurate doses without resulting wastage.
- Advance compounding, which uses multi-use vials, reduces wastage and the potential for diversion; however, the compounding infrastructure requirements may not make this

feasible for organizations without embedded pharmacies, or for community pharmacies that do not meet jurisdictional professional requirements.
- Tablets need to be crushed and, if to be injected, prepared using best practice recommendations, i.e., using high quality pill crusher (e.g., Silent Knight[1]) and filtration using a combination of a Sterifilt® and cotton filter[2].
- Current pilot projects provide a research protocol that enable nurses to prepare tablets for injection. The issue of who prepares tablets for injections will need to be clarified with professional regulatory colleges and/or through the establishment of safer supply guidelines.

Cost

- Most provincial formularies only list low-potency hydromorphone (e.g., 10 mg/ml), and programs have found that clients require very large volumes to meet their optimal dosage, or to use tablets.
- There are considerable differences in costs for prescription drugs depending upon who is purchasing. Hospitals are able to negotiate purchase agreements, and so are able to purchase at much lower rates than community pharmacists.
- Multi-dose vials requiring advanced compounding are often cheaper, and reduce wastage and the potential for diversion; however, this option is not available to those sites that lack an on-site pharmacy, unless they have health care professionals on site whose provincial regulations permit compounding.

Health risks

- Oral hydromorphone tablets (that are then crushed, prepared, and injected) are considerably cheaper than injectable hydromorphone; however, regulatory Colleges have expressed concerns about injecting a drug that is intended for oral consumption only, due to unclear health risks, though studies[9] are now suggesting that combined filtration using Sterifilt® filter and cotton filter is an effective harm reduction practice (see **Section 2**: Review of the evidence).
- People who inject hydromorphone tablets report a preference for Dilaudid® (name brand) over generic tablets, saying that the Dilaudid® is easier to crush and prepare. Immediate release tablets are preferred to extended release tablets. Extended release tablets have a waxy coating and often produce a jelly-substance, which may increase health risks of injecting these tablets compared to Dilaudid®.
- There are preferred types of equipment for preparing tablets for injection: a pill crusher and filters that are being piloted to see if in controlled environments, injection of tablets is not as risky as previously thought (e.g., risks of endocarditis, abscesses, vein damage).

Diversion

There are concerns that oral tablets are more easily diverted. A current Vancouver-based pilot study of an observed tablet injection program requires nurses to crush and prepare the tablets for injection and add 8-10 drops of sterile water to moisten the powder (to prevent diversion), as per the research protocol. As stated above, the issue of who prepares tablets for injection

must be addressed through the establishment of guidelines, and/or by professional regulatory colleges.

Obtaining hydromorphone *(the following information is adapted from the BC iOAT Guidelines 2017)*

There are two ways of obtaining hydromorphone: either through advanced compounding and preparation of doses in a pharmacy compliant with jurisdictional professional requirements, or via delivery of single-use vials by a local pharmacy. Doses prepared using advanced compounding allow for a beyond-use date of up to nine days if the syringes are refrigerated, and up to thirty hours if at room temperature. Hydromorphone 50mg/ml is available in single use vials. Best practices and established standards for preparing and handling injections must be followed. For information about preparing injections and prescribing injectable hydromorphone, please see:

> British Columbia Centre on Substance Use. (2017). *Guidance for Injectable Opioid Agonist Treatment for Opioid Use Disorder.* Retrieved from: http://www.bccsu.ca/wp-content/uploads/2017/10/BC-iOAT-Guidelines-10.2017.pdf
>
> Canadian Research Initiative in Substance Misuse (CRISM). (Not yet published). *National Injectable Opioid Agonist Treatment for Opioid Use Disorder Clinical Guideline*.

[1] Silent Knight pill crusher: http://shop.gohcl.com/Customer/hecalo/specpages/7423-01_Instructions.pdf
[2] Noël L., Dubé P.-A., Tremblay, P.-Y., et Groupe de travail sur la révision du matériel d'injection destiné aux personnes UDI. (2015). *Matériel d'injection: réduire les risques chez les injecteurs de médicaments opioides*. Québec, Institut national de santé publique du Québec.

Table 3-3 – Obtaining opioids: navigating the regulatory landscape

Question	Diacetylmorphine (DAM)	Hydromorphone (HDM Injectable)	Hydromorphone tablets (HDM)	Legislation/ Regulation and Oversight
Is it legal for use in Canada and indicated for Opioid Use Disorder (OUD)?	Yes. It is currently on *List of Drugs for an Urgent Public Health Need* for OUD in all jurisdictions across Canada.	Yes. Injectable hydromorphone at low and high potency are indicated for OUD.	No. Hydromorphone tablets are not indicated for OUD. They are used off-label.	• Controlled Drugs and Substances Act (CDSA) and Narcotic Control Regulations (NCR). • *Food and Drugs Act* (FDA) and *Food and Drug Regulations* (FDR).
Is it produced in Canada?	No	Yes	Yes	• CDSA-NCR • FDA and FDR
Is it covered under most provincial formularies?	No. Individuals can apply for coverage under provincial cost coverage programs.	No. High potency hydromorphone is not covered by most provincial formularies. Individuals can apply to provincial cost coverage programs. Yes. Lower potency (e.g., 10mg/ml) is covered.	Yes. There may be caps or limits on quantities covered. Not indicated for injection, or for OUD.	• Provincial legislation.
Who can prescribe it?	Doctors and nurse practitioners trained in prescribing for OUD.		Doctors and nurse practitioners. (Requirements for training in prescribing for OUD may vary by jurisdiction).	• CDSA-NCR, • Professional regulatory Colleges.
Prescription requirements	Requires a written order or prescription that is signed and dated by a practitioner and the signature of the practitioner, if not known to the pharmacist, has been verified by the pharmacist.			• CDSA – NCR.
Transport and storage	• Depending on the jurisdiction, a nurse practitioner/nurse may transport controlled substances • Storage requirements for Licensed Dealers are the same for all narcotics as laid out in *Security Requirements for Licensed Dealers for the Storage of Controlled Substances* (includes: bolted safe, inventory management, etc.) • See: https://www.canada.ca/en/health-canada/services/health-concerns/reports-publications/controlled-substances-precursor-chemicals/directive-physical-security-requirements-controlled-substances-licensed-dealers-security-requirements-storage.html • Health Canada has developed guidance[1] for community pharmacists to minimize the potential diversion of controlled substances from their establishments, including: security measures, destruction procedures, inventory and reconciliation, and record-keeping.			• Professional regulatory Colleges, • CDSA-NCR, NCPR.

Table 3-3 – Obtaining opioids: navigating the regulatory landscape

Question	Diacetylmorphine (DAM)	Hydromorphone (HDM Injectable)	Hydromorphone tablets (HDM)	Legislation/ Regulation and Oversight
Compounding requirements	Yes. Requires a compounding pharmacy that is compliant with jurisdictional professional requirements.	Yes. For advance compounding, the pharmacy must be compliant with jurisdictional professional requirements for compounding. Check with jurisdictional college to see if nurses can compound on site.	N/A	• Professional regulatory Colleges (nursing, pharmacy). Note: The National Association of Pharmacy Regulatory Associations (NAPRA) provides model standards for compounding, but requirements are established and enforced by provincial Colleges. Requirements may be based on NAPRA's model standards.
Who can prepare doses?	Trained pharmacists working in pharmacies that are compliant with jurisdictional professional requirements for compounding. Nurses can prepare doses from single use ampules according to jurisdictional College regulations.		It's complicated. Current standards of practice do not support the prescription of tablets for injection. Research protocols may provide a way for nurses to prepare pills for injection by crushing them and providing Sterifilt® and cotton filters.	• Professional regulatory Colleges
Who can administer doses?	Health practitioners. Varies by jurisdiction May only permit intramuscular or subcutaneous injection, or not at all.	Health practitioners May vary by jurisdiction. May only permit nurses to inject intramuscular or subcutaneous, or not at all.	*See above*. Use of pills for injection is not currently supported by professional Colleges.	• Professional regulatory Colleges

Table 3-3 – Obtaining opioids: navigating the regulatory landscape

Question	Diacetylmorphine (DAM)	Hydromorphone (HDM Injectable)	Hydromorphone tablets (HDM)	Legislation/ Regulation and Oversight
Stakeholder Perspectives	**Service providers:** Very interested because it has been found to be superior to methadone[2] but too many regulatory and supply concerns. **PWUD:** Very interested.	**Service providers:** Hydromorphone is seen to be non-inferior to diacetylmorphine[3]. Higher confidence than tablets; concern about volume needed when only 10mg/ml is listed on formularies. **PWUD**: Very interested.	**Service Providers:** Colleges have regulatory concerns (crushing tablets for injection); concern with number of tablets required to match doses needed; diversion concerns. **PWUD:** Report a preference for name brand Dilaudid® because they say that generic does not cook the same way and it provides a different high.	

[1] Health Canada (2019). Recommended guidance in the areas of security, inventory reconciliation and recordkeeping for community pharmacists. Retrieved from: https://napra.ca/sites/default/files/2019-04/CS-GD-022%20Recommended%20guidance%20for%20community%20pharmacists_EN.pdf

[2] See *Section2: Review of the evidence*

[3] Oviedo-Joekes E, Guh D, Brissette S, Marchand K, Macdonald S, Lock K, et al. (2016). Hydromorphone Compared With Diacetylmorphine for Long-term Opioid Dependence. *JAMA Psychiatry*, *73*(5), 447–9.

3.2.2 Regulated pharmaceutical stimulants used in safer supply programs

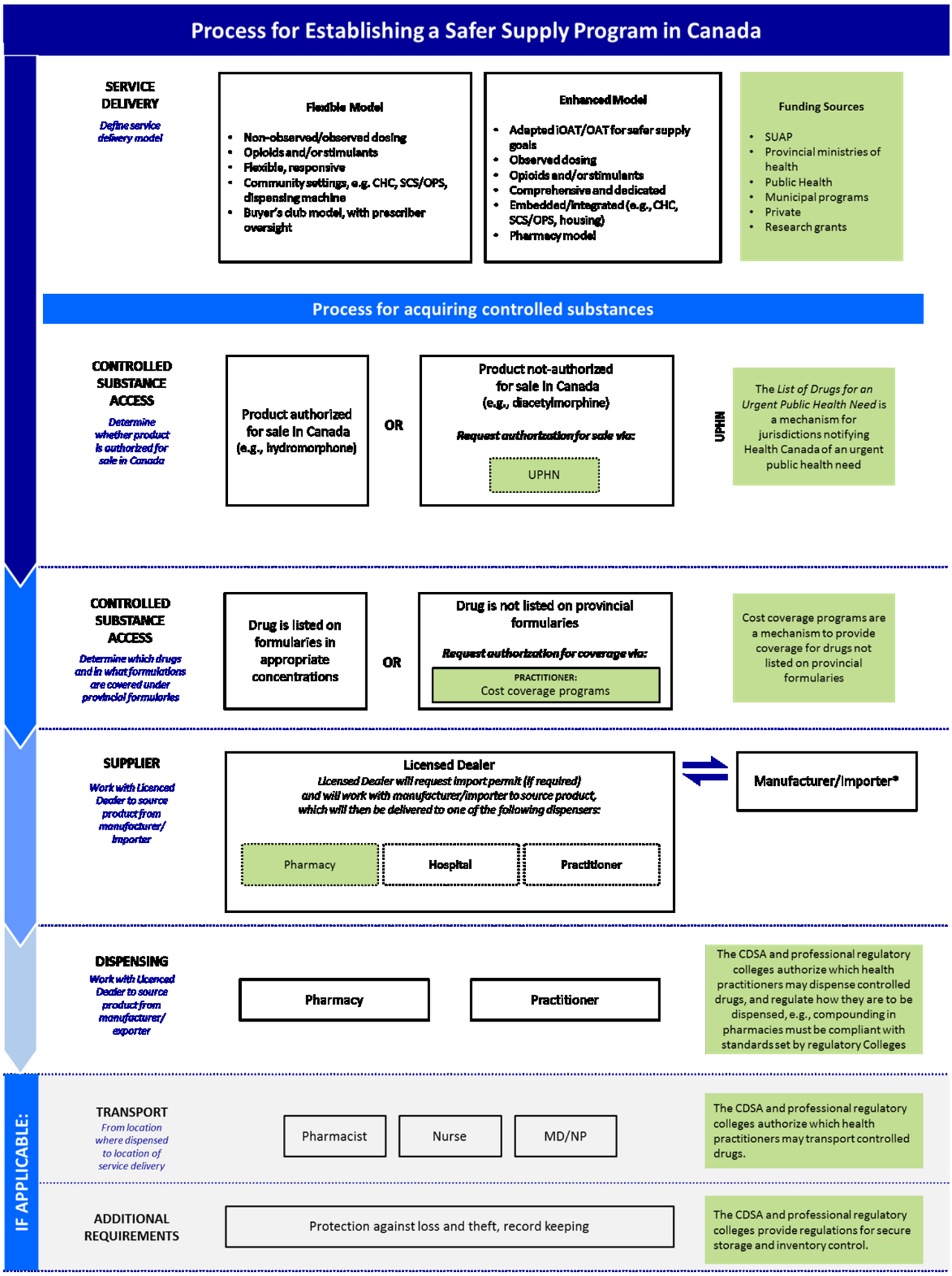
The Safer Supply Implementation Task Team also discussed the need for regulated alternatives for people who use stimulants such as cocaine, crack cocaine, and crystal methamphetamine. While the research on safer supply stimulant programs is not as robust as the research on oral or injectable opioid agonist treatments, there is increasing interest in the use of pharmaceutical stimulants as substitution therapy.

People may use stimulants on their own, or together with opioids. The culture of stimulant use, in which stimulants are smoked or injected, and in which use is often concentrated into intensive binges, is not as easily replicable in safer stimulant programs.

Polysubstance use is also common: opioids can help someone who has been using stimulants come down more gently, and stimulants can help those using opioids stay awake and aware to enjoy their high. These patterns of use, and the dependence on the illegal drug supply, should be considered when designing safer supply programs. Consulting with people who use drugs will help to identify which drugs are being used and how, and this can inform decisions about prescribing stimulants, including formulations.

Examples of pharmaceutical drugs that are currently being prescribed off-label as stimulant substitution treatment include Vyvanse (lisdexamfetamine dimesylate), Adderall, Dexedrine, methylphenidate, and modafinil. These are covered under most formularies.

3.2.3 *Map of the regulatory landscape for acquiring controlled substances*



** Some manufacturers may place restrictions on use of controlled substances for specific purposes.*
*** For more information for security requirements, please see: https://www.canada.ca/en/health-canada/services/health-concerns/reports-publications/controlled-substances-precursor-chemicals/directive-physical-security-requirements-controlled-substances-licensed-dealers-security-requirements-storage.html*

Other Considerations

- *Provincial and professional health and safety regulations must be followed.*
- *Engaging and employing people with lived/living experience to design, deliver, and evaluate programs is critical to providing effective services.*

3.3 Considerations for Operational and Clinical Protocols and Policies

There are several guiding documents now available that can be used as templates for protocols and policies, including both operational considerations and clinical guidance. The following iOAT guidelines can be adapted for safer supply programs:

> British Columbia Centre on Substance Use (2017**) Guidance for Injectable Opioid Agonist Treatment for Opioid Use Disorder**. Available at: http://www.bccsu.ca/wp-content/uploads/2017/10/BC-iOAT-Guidelines-10.2017.pdf
>
> Canadian Research Initiative in Substance Misuse (CRISM). National Injectable Opioid Agonist Treatment for Opioid Use Disorder Operational Guidance. [not yet published]. Available at: https://crism.ca/projects/ioat-guideline/

3.3.1 Operational policies

The following list is meant to identify different facets of safer supply program operations that require policy and protocol development.

A. Eligibility

a. Eligibility criteria
b. Eligibility assessment

Programs should define the target population and eligibility criteria, including factors such as level of risk, stability, age, substance use, and connection to programs and services. In addition to defining eligibility criteria, policies should be developed regarding how criteria will be assessed.

B. Medical assessments

a. Prescriber (i.e., nurse practitioner or physician) assessment
b. Nursing assessment

In addition to assessing program eligibility, potential clients should be medically assessed using clinical assessment tools.

C. Rights and Responsibilities of Clients and Service Agreements

Clients' rights and responsibilities and general rules for accessing services must be clearly defined. Service agreements may contain standard rights and responsibilities that apply to all clients at all times, including expectations of privacy according to provincial health privacy laws, confidentiality, and the right to be treated with respect and dignity. Service agreements may also be individualized plans of care, including agreements negotiated between service providers and clients for specific situations, such as "carries" privileges.

D. General responsibilities and rules for all staff

Policies and procedures, expectations and responsibilities must be clearly defined for all staff, including a defined schedule for regular review and revision of policies.

a. Protocols for data collection and documentation
b. Maintaining clean and safe space protocols
c. Access and Security policies
d. Protocols for assessing intoxicated individuals
e. Policies about conditions for refusing service
f. Policies for providing referrals to additional services
g. Crisis and conflict intervention policies
h. Security protocols and procedures
i. Occupational health and safety protocols

E. Models with on-site dispensing and consumption must include policies to address regulatory requirements, such as:

a. Medication storage protocols
b. Medication preparation and administration protocols
c. Monitoring Injections/witnessed doses policy and procedure
d. Policies for designated assistance with injection, including consent forms to be signed by both client and the designated assistant
e. Injection equipment disposal
f. Infection control policies
g. Opioid intoxication assessment and procedure
h. Protocols for overdoses and medical emergencies
i. Policies to reduce risk of diversion:
    - Medication and injection counts, narcotic control policies (receiving, returning, preparing, dispensing, waste)
    - Witnessed dosing (in person or by camera)
    - For tablets to be injected, moisten crushed/powdered tablets by adding 8-10 drops of sterile water to crushed/powdered tablets
    - For tablets to be ingested, add crushed/powdered tablets to apple sauce or pudding
    - For providing slow-release oral morphine (Kadian®), open capsules and put beads in pudding/water
    - No personal belongings in the consumption space
    - General monitoring of all clients

F. General security

Protocols, policies, and procedures are needed for:

a. Property security
b. Client and staff health and safety
c. Managing challenging behaviours
d. Responding to emergencies

3.3.2 Clinical protocols

Clinical protocols are required and must be developed according to regulatory guidelines and requirements, professional standards of care, best practices, research protocols approved by ethics boards, and emerging evidence-informed practice.

There are two guiding documents for clinical protocols for supervised injection opioid agonist treatment (iOAT). These are:

> *British Columbia Centre on Substance Use (2017) Guidance for Injectable Opioid Agonist Treatment for Opioid Use Disorder.* Retrieved from: http://www.bccsu.ca/wp-content/uploads/2017/10/BC-iOAT-Guidelines-10.2017.pdf
>
> Canadian Research Initiative in Substance Misuse (CRISM). (Not yet published) *National Injectable Opioid Agonist Treatment for Opioid Use Disorder Clinical Guideline.* Retrieved from: https://crism.ca/projects/ioat-guideline/

Clinical protocols commonly include, but are not limited to, the following:

1. Obtaining, storing, and disposing of medications
2. Medical eligibility assessment
3. Health assessments and nursing care
4. Selection of dose
5. Initiation and re-initiation protocols, including titration protocols and dosing schedules.
6. Co-prescription of oral OAT
7. Dosage equivalents with oral methadone and slow-release oral morphine (SROM – Kadian®)
8. Clinical protocols for people who are pregnant or could become pregnant
9. Urine drug testing protocols (if needed)
10. Protocols for “carries”, absences, and missed doses
11. Overdose medical directives
12. Non-overdose medical directives
13. Management of seizures
14. Management of chest pain
15. Management of anaphylaxis
16. Protocol for soft tissue care
17. Providing additional health services
18. De-intensification, transition to oral OAT, and discontinuation protocols.

19. Transitions: hospitalization, other.
20. Letter to hospital explaining clients' engagement in a safer supply program
21. Continuity of care

In addition to the above, models with on-site dispensing and consumption require the additional clinical protocols:

1. Purchasing and transporting hydromorphone or diacetylmorphine – including delivery and reconciliation policies[1];
2. Preparing hydromorphone or diacetylmorphine (must be in accordance with college requirements);
3. Pre-injection assessment and post-injection assessments
    - The (modified) Pasero Opioid-induced Sedation Scale (POSS) is a clinical intoxication assessment tool
4. Health care provider administration of injection (must be in accordance with College requirements);
5. Supervision of injections; and
6. Research protocols need to build in flexibility or a trial protocol to allow for adjustments in dosages to determine the optimal dosages.

Providence Health Care Crosstown Clinic provides the following order sets:

1. Medication orders
2. Titration orders for high dose hydromorphone
3. Accelerated titration orders for high dose hydromorphone
4. Missed days protocol for post-initiation dose of high dose hydromorphone
5. Titration orders for diacetylmorphine
6. Missed days orders for post-initiation dose of diacetylmorphine

[1] Community pharmacists may wish to consult the following document for guidance on security measures, destruction procedures, inventory and reconciliation, and record-keeping: Health Canada (2019). Recommended guidance in the areas of security, inventory reconciliation and recordkeeping for community pharmacists. Retrieved from: https://napra.ca/sites/default/files/2019-04/CS-GD-022%20Recommended%20guidance%20for%20community%20pharmacists_EN.pdf

3.4 Site requirements and staffing considerations

All models require:

- An assessment and treatment room to be used by physicians, nurse practitioners, and nurses for assessment and enrollment, and program staff for interviews and support;
- A comfortable, welcoming waiting area for clients;
- Space to store a wide range of sterile supplies, equipment, and kits;
- Education, information, resource materials;
- Secure sharps disposal containers;
- Overdose assessment and management equipment: naloxone and related supplies; breathalyzer, pulse oximeter, blood pressure monitor, oxygen, and bag valve mask; and
- Infrastructure for medical records and client files (electronic or other).

Models that provide dispensing and observed dosing require the additional considerations:

- Controlled entry to supervised consumption room (including staff accompaniment);
- Space for clients to store their belongings outside of the consumption area;
- A consumption/witnessing room: comfortable, clean, safe; for supervised consumption; equipped with stainless steel table, chair, secure sharps container, hand sanitizer, antiseptic cleaning wipes, paper towel dispenser, sterile injection equipment; and
- A post-consumption "chill-out" room for monitoring clients.

In compliance with CDSA standards and their jurisdictions' regulatory bodies, appropriate storage (i.e., a bolted safe [TRTL15 or TRTL30]), supplies, documentation, and inventory management for the storage, preparation, and disposal of drugs. For more information on storage security, please see: Directive on Physical Security Requirements for Controlled Substances (Security Requirements for Licensed Dealers for the Storage of Controlled Substances), available at:

https://www.canada.ca/en/health-canada/services/health-concerns/reports-publications/controlled-substances-precursor-chemicals/directive-physical-security-requirements-controlled-substances-licensed-dealers-security-requirements-storage.html

Staffing Considerations

Staffing models, including the roles and number of staff required during program operating hours will depend on the model of safer supply program, and the number of clients enrolled. However, there are several key activities and responsibilities that must be considered and planned for, and tasked to appropriately trained and qualified staff. These may include:

- Client intake, orientation, and education;
- Ongoing support and service navigation (including providing or referring to additional health care and social services); and
- Medical assessments and nursing care.

In addition to the professionally trained health professionals, people who use drugs should also be involved and employed in the delivery of services, whenever possible (please see **Section 4.5**).

All staff must be properly trained as appropriate to their role and responsibility, including organizational and program policies, protocols, and procedures; training in anti-oppression practices, trauma informed practice, harm reduction, non-violent conflict resolution and strategies for creating a welcoming, non-judgmental environment.

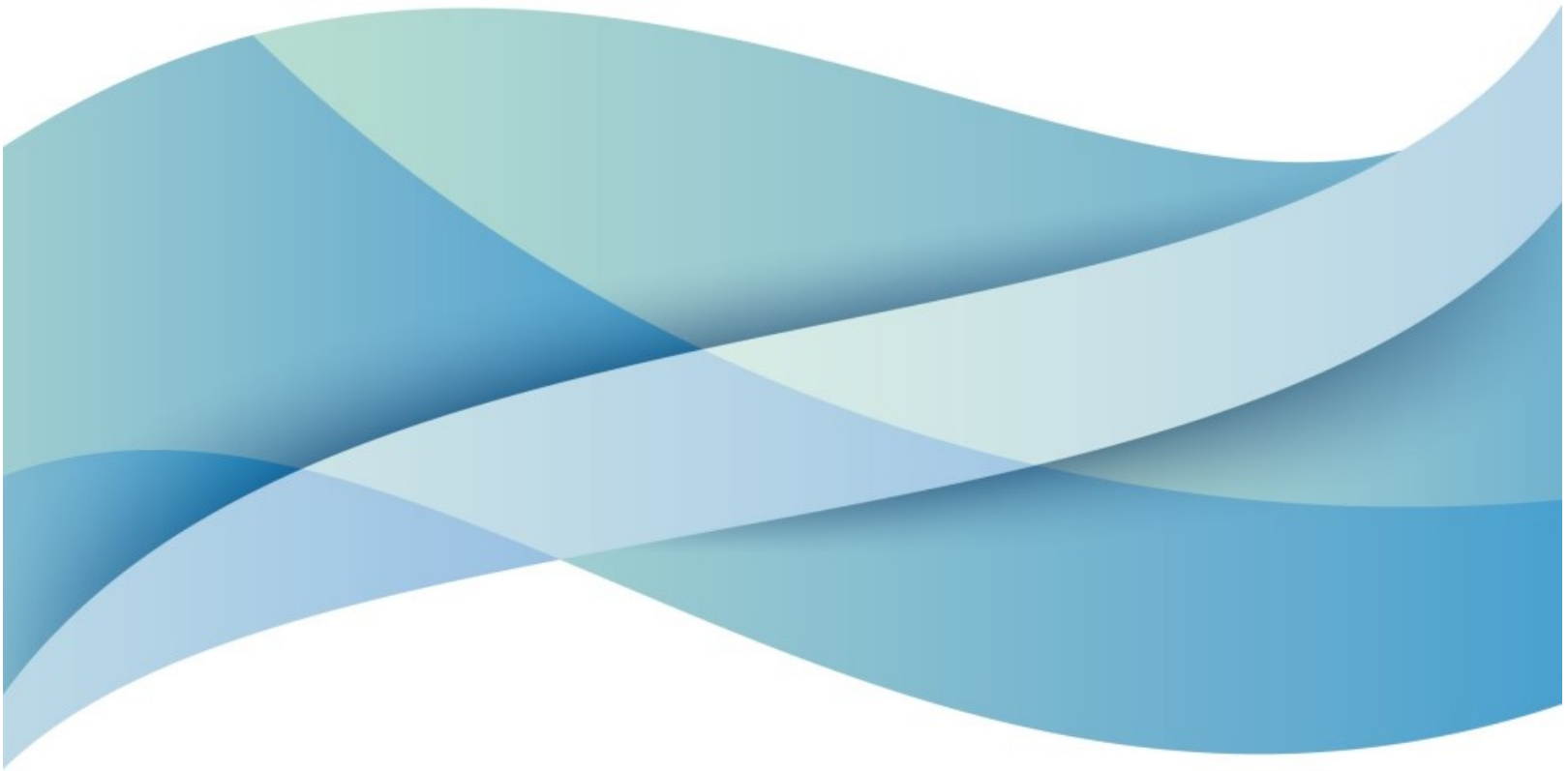
Table 3-4 – Operational requirements (adapted from BC iOAT Guidelines 2017)

Flexible models (unobserved dosing)	Comprehensive and dedicated iOAT model	Integrated iOAT Model (CHC, SCS, Housing)	Pharmacy based model	Requirements
				Injection area
N/A	X	X	X	Private room with space for supervised injection
	X	X	X	Table/bench space with cleanable surface (i.e. not wood)
	X	X	X	Seating that is easily moved and cleaned
	X	X		Storage area for clients' belongings to prevent diversion
				Storage and preparation
X	X	X	X	Storage area for tourniquets, Steri-wipes; and needles of various gauges
	X	X	X	Secure area for storage and preparation of the medication that is not accessible to patients or outsiders
	X	X	X	Drug log tracking vials in and out, batch numbers, dose used, and disposal of any unused medication
				Safety
Syringe disposal containers	X	X	X	Syringe disposal that enables syringes to be examined and counted prior to being placed in destruction container
	X	X	X	Access to electronic recordkeeping method to record each prescription, dose, time and variances
	X	X	X	Monitoring system to ensure minimum of 3 hours between doses
X	X	X	X	Resuscitation equipment
X	X	X	X	Take home naloxone
				Compounding pharmacy requirements
X	X	X	X	To compound hydromorphone, pharmacies must comply with standards of practice set by the regulatory college. These are often modelled after NAPRA's *Model Standards for Compounding of Non-Hazardous Sterile Preparations*
				Staffing model
	X	X	X	Qualified health professionals or supervised trained staff for pre- and post-assessment, administration of correct dose, and supervision of self-administered injections
			X	All pharmacy staff must be trained to follow the policies and procedures in place, including clinical procedures if pharmacy is acting as a clinic

Table 3-4 – Operational requirements (adapted from BC iOAT Guidelines 2017)

Flexible models (unobserved dosing)	Comprehensive and dedicated iOAT model	Integrated iOAT Model (CHC, SCS, Housing)	Pharmacy based model	Requirements
			X	A minimum of two pharmacy staff must be available at all times to ensure an adequate response in the event of an overdose
	X	X	X	Access to qualified health professionals and trained staff 7 days per week, 365 days per year
X	X	X	X	Access to continuity of care through prescriber coverage when primary prescriber is away/unavailable
	X	X	X	Hours of operation must allow a minimum of 3 hours between dosing (i.e., up to a 12-hour shift)
X	X	X		Peer workers and or allied health worker for support and connection to community agencies and services
				Security considerations
	X	X	X	Supervision of self-administered injections to observe for diversion
	X	X	X	Narcotic security tailored to setting and capacity (e.g., safe for storage in community, locked narcotic cupboard)
			X	Bolted down time-lock safes
			X	Maintenance of Daily Perpetual Inventory accounting for every milligram produced, wasted, lost in production, dispensed, pre-wasted, unused, waiting for destruction, and destroyed
			X	Monthly reports accounting for daily count of above to ensure proper reconciliation
	X	X	X	Controlled entry into injection room (including simple accompaniment from staff member)
	X	X	X	Syringes must be accounted for post-injection and prior to client leaving facility
	X	X	X	Syringe labeling requirements of relevant regulatory bodies should be followed

Section 4
Addressing the Social Determinants of Health



4. Addressing the Social Determinants of Health

There are numerous complex factors that influence the initiation and continuation of substance use, including individual, social, cultural, economic, political and socio-structural contexts. These factors are often referred to as the *social determinants of health*, and they account for the ways in which some people who use substances experience extreme marginalization, both due of their substance use and to its intersection with multiple other factors including poverty, criminalization, housing instability or homelessness, food insecurity, gender, race, and experiences of colonialism[1].

Programs for people who use drugs need to consider ways of addressing broader social determinants of health, such as food, income, social inclusion, housing, and social supports. In this section, we suggest ways safer supply programs can address social determinants of health, such as:

[1] Galea S., Nandi A., Vlahov D. (2004). The Social epidemiology of substance use. *Epidemiologic Reviews, 26*(1):36-52. doi.org/10.1093/epirev/mxh007

4.1 Designing low-threshold safer supply programs

Offering low-threshold services is a key feature of harm reduction programming and an important characteristic for safer supply programs. Islam et al.[1] suggest that there are three criteria for services to be considered low-threshold: that people who use drugs are the key target population, that abstinence is not required, and that barriers to service access must be reduced as much as possible. Barriers arise when services are not tailored to meet the needs of the population being served. Some specific ways that barriers arise include:

- Employing service limitations or restrictions and other punitive measures to respond to problematic behaviours;
- Providing services only through set scheduled appointments;
- Offering service in narrow windows of time and operating with restrictive hours; and
- Costs associated with services, e.g., costs of prescription medications.

Ways to make services low-threshold

- Consult with clients and co-write program rules, responsibilities, and expectations, including program hours of operation. This can increase buy-in, and establish expectations that are understandable and acceptable to clients, while also ensuring that the organization is providing services that are meeting the needs of clients.

- Ensure that policies, including responsibilities, expectations, and rules, are well communicated and understood. Consider collaboratively writing with individual clients their own 'service agreements' (also referred to as 'behaviour agreements', 'care plans') to reinforce expectations and ensure their understanding of expectations.

- Provide regulated drugs free of charge.

- Offer as many drop-in programs and drop-in group appointments as possible.

- Focus on engagement between clients and staff. Prioritize the building of relationships and the nurturing of a safe, non-judgmental, welcoming space.

- Encourage people to keep coming back, and make sure to find ways of keeping the door open to them.

- Look at ways of designing spaces and working with people that feel less clinical.

- Assist clients with applications for any income benefits for which they may be eligible, e.g., drug benefits, travel allowance for attending medical appointments and/or programs.

- Use skills such as motivational interviewing, flexibility, and adaptability, and engage with clients without expectations or requirements for them to change. The focus is always on meeting the client where they are at.

- Respond to conflict and problematic behaviours using non-violent crisis intervention and restorative justice approaches.

- For models that have on-site consumption spaces (SCS, OPS, CTS) and witnessing rooms, consider permitting clients to use more than one substance. Many people who use drugs use more than one drug at a time, such as using both a stimulant and an opioid. When appropriate and necessary, engage in conversation with the client about the potential risks of polysubstance use, offer test strips so that they can test an illegal drug, and support them to use as safely as possible.

- Staff should receive appropriate training, supervision, and support to prevent burn-out that can result in reactive responses.

[1] Islam, M. M., Topp, L., Conigrave, K. M., White, A., Haber, P. S., & Day, C. A. (2013). Are primary health care centres that target injecting drug users attracting and serving the clients they are designed for? A case study from Sydney, Australia. *International Journal of Drug Policy*, 24(4), 326-332. doi:10.1016/j.drugpo.2012.06.002

4.2 Trauma informed practice

Past, continuous, and current experiences of trauma are frequent amongst those who struggle with substance use issues. Studies suggest that people with substance use disorders have higher rates of past trauma and comorbid post-traumatic stress disorder compared to the general population[1]. Trauma-informed practice recognizes the impact of trauma in the lives of clients, and seeks to avoid re-traumatizing individuals, and support safety, choice, and control to promote healing[2]. Trauma-informed practice is centred on six core principles[3]:

- Safety
- Trustworthiness and transparency
- Collaboration
- Empowerment
- Choice
- Intersectionality

Organizational and program policies and procedures can be designed with these principles in mind. The following resources, recommended in the CRISM National iOAT Guidelines (2019), provide guidance in how to work from a trauma-informed approach:

Nathoo, T., Poole, N. and Schmidt, R. (2018). *Trauma-Informed Practice and the Opioid Crisis: A Discussion Guide for Health Care and Social Service Providers.* Vancouver, BC: Centre of Excellence for Women's Health. Retrieved from: http://bccewh.bc.ca/wp-content/uploads/2018/06/Opioid-TIP-Guide_May-2018.pdf

Canadian Centre on Substance Use. (2012). *Essentials of Trauma-informed Care.* Retrieved from: http://bccewh.bc.ca/wp-content/uploads/2014/05/PT-Trauma-informed-Care-2012-01-en.pdf

Klinic Community Health Centre. (2013). *Trauma-Informed: the Trauma Toolkit, Second Edition*. Retrieved from: https://trauma-informed.ca/wp-content/uploads/2013/10/Trauma-informed_Toolkit.pdf

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4.3 Continuity of Care and Wrap-around Care

4.3.1 Continuity of care

The needs and goals of clients of safer supply programs may change over time, and programs and services must be able to respond accordingly. Changes may involve intensifying care (e.g., moving to observed dosing) or de-intensifying care (e.g., move to unobserved dosing), or re-initiating care as needed, based on clinical judgment and in collaborative discussion with individual clients.

Policies should be in place to ensure that clients' access to prescribed regulated alternatives is not interrupted or discontinued without their consent. This includes policies for transitioning clients to other prescribers, and policies to address periods of travel, hospitalization or incarceration.

When and where possible, explore ways of flagging people as clients of safer supply programs. In some areas, this may be done through healthcare databases that would automatically notify hospitals and incarceration facilities that clients are receiving ongoing care from specific organizations that includes the provision of regulated substances as alternatives to the illegal market. Some programs issue clients photo identification cards that indicate that they are clients of safer supply programs. These can be shown to police, emergency room personnel, or others to ensure ongoing access to their prescribed pharmaceutical alternatives and any other medications (including oral opioid agonist treatment).

In addition to the above, organizations offering safer supply programs should engage in outreach to community members, such as police, jails, and hospitals, to inform them of the program, what it entails, how to support clients of the program, and how to get in touch with the safer supply program staff to discuss continuity of care. Organizations providing safer supply services should keep police informed about the program, including any changes to services.

4.3.2 Wrap-around care, pathways to care, and accessing additional services

Wrap-around care refers to intensive case management used to provide coordinated and comprehensive care. The literature on the provision of case management to people who use drugs, particularly people who use drugs and/or have mental health challenges and are experiencing homelessness, generally shows some positive effects on quality of life, and access to specific health services[1]. A more recent systematic review also provides support for case management improving health outcomes for a variety of different groups of people, including people who use drugs and people with mental health challenges[2]. Studies of case management within supportive housing, including of Housing First models where housing is provided with

case management support, have also found it generally effective for people who use drugs[3] [4]. All of this supports the provision of comprehensive case management, regardless of the exact nature of the population or the setting in which it is delivered.

A particularly good model for providing wrap-around care has been developing in Toronto[5]. In this model, targeted towards working with people with hepatitis C, teams of primary health care providers, specialists in hepatitis C treatment, case managers and workers with lived experience provide holistic, wrap-around care for a population of people who often continue to use drugs. The program is demonstrating positive outcomes for hepatitis C treatment adherence and completion, as well as increasing engagement, social inclusion, and addressing other social determinants of health[6]. This model is particularly appealing as it provides comprehensive services directly within the agencies that are already providing harm reduction programs, allowing for trust to be built rapidly with people who use drugs. Safer supply programs could adopt this model to expand service delivery to people who use drugs and have complex care needs.

Pathways to care refer to the collaborative provision of comprehensive services established through partnerships with a range of community organizations. Safer supply programs should invest in developing pathways to care with community organizations, in order to stream line referral processes to ancillary services in the community, such as mental health care, housing support, primary care, and substance use treatment. This is particular important for those programs that are not embedded in organizations with more comprehensive ancillary services. Additional services for clients of safer supply programs may include access to:

- Comprehensive case management/wrap-around care
- Primary care services
- Chronic pain management
- HIV/Hepatitis C care and support
- Mental health services
- Podiatry
- Housing support
- Home care support (assistance with activities of daily living)
- Income support
- Drop-in programs
- Employment and vocational training
- Substance use treatment and recovery services
- Dental care
- Nutrition care
- Social recreational programs
- Group appointments

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4.4 Considerations for Working with Specific Populations

Marginalization and the social determinants of health

The social determinants of health account for the ways in which some people who use substances experience extreme marginalization, both due of their substance use and to its intersection with multiple other factors including poverty, housing instability or homelessness, food insecurity, gender, race, experiences of colonialism and criminalization[1]. These factors can have a strong influence on health, and the intersection of these factors can greatly affect the availability of resources and access to health and social services for people who use drugs, thereby creating a major health equity issue[2].

Attention must be paid to the social determinants of health, as well as power-imbalances that exist between service providers and service users. Many people who have experienced marginalization have faced discrimination, violence, and barriers to accessing services. As such, establishing safety is an essential element to working with people who have experienced marginalization. Safer supply programs must be welcoming, non-judgemental spaces, in which physical, emotional, and cultural safety is nurtured. There are many ways of working towards providing such a space, including appropriate training for all staff (including support staff), tailoring the program to particular populations where possible, and ensuring that all referrals are to appropriate services. Below are some considerations for working with specific populations, including women, youth, First Nations and Indigenous peoples, and LGBT2Q+ individuals.

Women

Women, particularly those who are street-involved, are at high risk of overdose and are particularly affected by the intersection of forms of marginalization, thereby exacerbating risks of harm and increasing vulnerability. Studies show that in comparison to men, women starting iOAT have higher rates of HIV and hepatitis C infections, cocaine use, experiences of physical and sexual abuse, suicide attempts, involvement with sex work, and lower rates of employment[3] [4]. A recent study[5] of an overdose prevention site in Vancouver BC found that services designated as 'gender-neutral' were often experienced as 'masculine' by women, and a site where they were confronted with harassment from men. Given these reasons, women-only services, spaces, or hours should be offered, whenever possible, and referrals to ancillary services would be ideally to services specialized for women.

Youth

It is well established that youth and young adults are amongst those at risk of overdose and other harms related to using toxic illegal drugs, and that youth face significant barriers to accessing addiction treatment services. Safer supply programs must consider if, when, and how they will engage with youth who are at high risk. Youth are more likely to engage in services that are tailored specifically for youth. Safer supply programs that work with youth should refer to youth-focused ancillary services. Provincial benefit plans may require a Collaborative Practice Agreement and an exemption in order to provide coverage for hydromorphone for youth.

There are concerns that youth may be misled by the term 'safer supply'. Studies have suggested that youth perceive pharmaceutical drugs to be safe, and may underestimate the potential for harm inherent in opioid use[6] [7]. As such, safer supply education targeted at youth is important component to safer supply interventions.

First Nations and Indigenous communities

In the work of our task team, we spoke to people who work with First Nations and Indigenous communities. We heard that harm reduction approaches to substance use are not always well understood or well received in First Nations and Indigenous communities. With the support of elders and chiefs, it is possible to set up safer supply programs based on the success of community-based OAT programs. First Nations communities need appropriate resources and capacity. In many areas, there are very few addiction treatment or harm reduction services. As such, it is important to provide information and education about harm reduction and safer supply, and to approach providing safer supply projects in a culturally aware manner. Indigenous harm reduction principles and practices integrate cultural knowledge and values into the strategies and services of harm reduction. Models for First Nations and Indigenous communities need to address issues such as intergenerational trauma, poverty, and resource scarcity. Models need to take into consideration that many people may already be caught up in systems that impose abstinence and heavily surveil them (e.g., child welfare, probation). Protocols for safer supply should also include spiritual protocols, created by elders.

Safer supply interventions should be designed, delivered, and evaluated by or in partnership with members of the First Nations or Indigenous community being served. Non-Indigenous prescribers, health practitioners, or program staff must receive training in cultural safety and cultural humility. There are several learning opportunities available that are listed below.

Resources:

- **Honouring our Strengths: A Renewed Framework to Address Substance Use Issues Among First Nations People in Canada.** Thunderbird Partnership Foundation. Available at: https://thunderbirdpf.org/honouring-our-strengths-full-version/

- **The Native Wellness Assessment (NWA**) instrument measures wellness from a cultural and strength-based approach. It demonstrates the effectiveness of First Nations culture as an intervention for addressing substance use and mental health issues. Available at: https://thunderbirdpf.org/about-tpf/scope-of-work/native-wellness-assessment/#bookshelf

- **Indigenous Harm Reduction Principles and Practices: Fact Sheet**. First Nations Health Authority. Available at: http://www.fnha.ca/wellnessContent/Wellness/FNHA-Indigenous-Harm-Reduction-Principles-and-Practices-Fact-Sheet.pdf

Cultural safety learning opportunities (recommendations provided by CRISM 2019):

- National Indigenous Cultural Safety Learning Series: http://www.icscollaborative.com/

- Ontario Indigenous Cultural Safety Program (Southwest Ontario Aboriginal Health Access Centre) http://soahac.on.ca/ics-training/

- Nunavut Program's Cultural Competency Modules: https://www.cheo.on.ca/en/Nunavut-Program-Modules

- Saskatoon Health Region Cultural Competency and Cultural Safety Tool Kit: https://www.saskatoonhealthregion.ca/locations_services/Services/fnmh/Pages/Cultural-Competency-Safety-Resource-Centre.aspx

- Manitoba Indigenous Cultural Safety Training: http://www.wrha.mb.ca/aboriginalhealth/education/MICST.php

- College and Association of Registered Nurses of Alberta's Cultural Safety Webinar: https://www.nurses.ab.ca/practice-and-learning/learning-opportunities/webinars/webinar/cultural-safety

- San'yas Indigenous Cultural Safety Training (BC Provincial Health Services Authority Aboriginal Health Program): http://www.sanyas.ca/

- Cultural Safety and Cultural Humility Webinar Series (First Nations Health Authority and BC Patient Safety and Quality Council): http://www.fnha.ca/wellness/cultural-humility/webinars

For information about service delivery models that may be adapted for First Nations and Indigenous communities in remote or rural areas, please see **Section 3.1.3**.

LGBT2Q+

The term LGBT2Q+ refers to lesbian, gay, bisexual, trans, Two-Spirited, queer and other gender and sexually diverse individuals. LGBT2Q+ individuals frequently face barriers to accessing services, including stigma, discrimination, and harassment. Safer supply programs need to be safe, non-judgmental spaces that welcome LGBT2Q+ individuals and that demonstrate sensitivity and awareness. Strategies[8] include:

- The use of inclusive language by all staff and in all documentation and materials;
- Providing trans and gender-non-conforming brochures and materials;
- Asking about gender identity on intake forms;
- Providing gender-neutral bathrooms;
- Ensuring all staff are appropriately trained; and
- Ensuring that referrals to community services are inclusive and appropriate.

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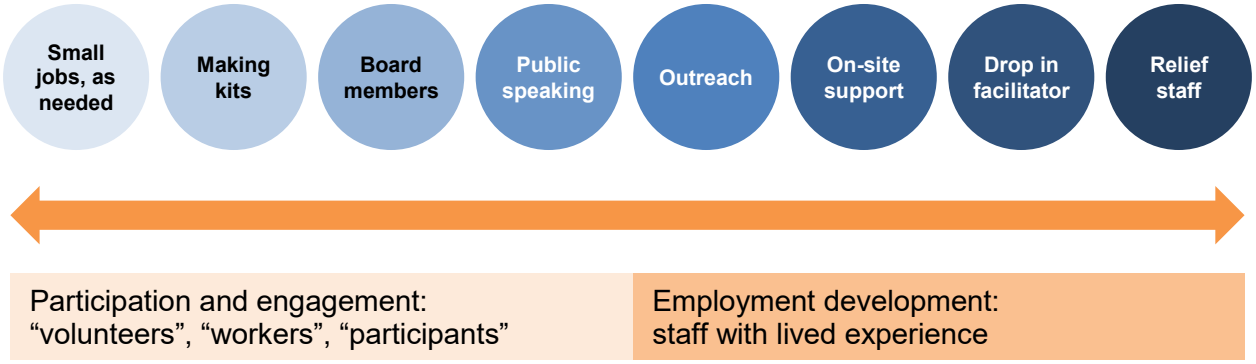
4.5 Engaging and employing people who use drugs

Engaging people with lived experience of drug use in the design, delivery, and evaluation of programs and services is a core principle of harm reduction and a best practice for harm reduction programs[1]. Studies show the effectiveness of services delivered by people who use drugs to reach a wide range of people, and to promote safer drug use behaviour[26 2 3]. For those engaged in program design, delivery, and evaluation, studies demonstrate positive outcomes such as improved health, stabilized substance use, and reduced social isolation[26 27 4]. Providing engagement and employment opportunities to people who use drugs is one way that organizations providing services to this community can directly address their social determinants of health (e.g., social inclusion, income, employment).

There are multiple ways to include people who use drugs across all stages of the design, implementation, and evaluation of safer supply programs, ranging from very low-threshold 'odd jobs', to consultation, to formal casual or permanent employment. This is depicted on a continuum of peer work, shown in Figure 4.5[32]:

Figure 4-1 – A continuum of engaging and employing people who use drugs



On this continuum, the *participation and engagement model* is one that is designed with empowerment ideals, has inclusive goals (i.e., open to anyone regardless of their level of stability, skills, or experience), a focus on relationship-building, and a commitment to work with people who use drugs in a low-threshold, non-coercive manner. Only basic training is required to complete supervised instrumental tasks such as assembling safer injection kits, or welcoming people to the program. Opportunities to participate in these ways are believed to help participants increase control over their health by providing a supportive environment, health education, and harm reduction supplies, and building community capacity to share information within their social networks. Participants should be provided compensation for their work, such as through honoraria.

The *participation and engagement model* provides a critical entry point to employment by providing opportunities for people who use drugs to develop skills and self-confidence and, perhaps, to spark their interest and ability to embark on more advanced employment training and work opportunities, including formal employment in casual, part-time, or full-time positions. Employment development models provide a balance between low-threshold and more structured employment, providing a supportive environment that recognizes the challenges to maintaining employment that are faced by people who use drugs, including those arising from criminalization, homelessness or precarious housing, and mental and physical health challenges.

There are an increasing number of examples of programs across Canada that are formally employing people who use drugs as staff members, many of whom worked their way up from volunteer positions. Many funders are now requiring that people who use drugs are involved in services geared for them. However, it is important that engaging and employing people who use drugs is well thought out by agencies, and that they do the organizational work to ensure that employees with lived experience are engaged meaningfully and equitably. This includes funders and/or organizations clearly defining terms such as 'engagement', 'involvement', 'representation', and 'consultation' (amongst others), using criteria to make sure that these terms are used to provide meaningful and equitable opportunities for people who use drugs.

There are a number of resources available to assist with supporting the engagement and employment of people who use drugs. These are listed at the end of this section. Here, some considerations are offered to support the safety, equity, equality, and meaningful engagement and employment of people who use drugs in the design, delivery, and evaluation of safer supply projects.

Consultation and program design

Consulting with people who use drugs will help identify ways of making programs accessible, welcoming, and effective, and in ensuring that the vision and mission of the project reflects the needs and wants of people who use drugs in the community. Efforts to be made to consult with people in a variety of ways, including multiple consultation meetings, interviews, and surveys. Time spent providing consultation should be recognized as labour, and compensated with an honorarium sufficient to also cover expenses incurred (e.g., travel costs).

In addition to consultations, people who use drugs should have a presence on a program advisory committee, alongside other stakeholders, such as physicians, nurses, social workers, and harm reduction workers. Again, this participation should be recognized as labour, and compensated accordingly. Advisory committees should have a terms of reference that ensures that all members are to be treated with respect, dignity, and as equals.

Please see **Section 6**: *Community of Practice* for more information on how organizations of people who use drugs may be engaged to support safer supply program development.

Program delivery

People who use drugs have a valuable role in the delivery of programs. Employing people who use drugs to deliver services provides benefits to the clients, and the employed people. Clients report feeling more comfortable and having more confidence in services where people who use drugs are employed. And people who use drugs often face considerable barriers to employment and income. Low threshold employment provides opportunities to gain some skills and earn some extra income, while also enhancing self-esteem, a sense of inclusion and purpose. For some, this leads to increased stability in other areas of their lives (housing, substance use).

There are different titles for staff roles held by people who use drugs: some that identify them as people with lived experience, e.g., 'peer workers', and other roles are named according to the task or program but are reserved for people with lived experience, e.g., outreach worker, harm reduction worker, intake worker. Safer supply programs require a number of professional staff, including nurses and a prescriber, but there are many roles that people without such training but with lived experience could hold. For example, welcoming clients, providing orientation to the program and services, delivering harm reduction and overdose prevention education, maintaining stocks of drug use equipment and supplies, appointment accompaniment, providing referrals, facilitating support groups, and more.

Organizations who employ people who use drugs, especially in low threshold work opportunities, must ensure that organizational policies do not create conflicts or barriers, and do promote equity and equality in the workplace. Workplaces must ensure that people are fairly compensated, and that they are included in organizational opportunities and functions (e.g., training, meetings, support). People who use drugs and are in low threshold employment should be well trained and provided with regular supervisory support. For more information on providing positive low threshold employment opportunities for people with lived experience, please see the resources below.

Evaluation

People who use drugs should be involved in the design, data collection, analysis, and dissemination of evaluation findings. The involvement of people who use drugs and have lived/living experience should be recognized as labour and be fairly compensated. Community-based research and participatory action research are two approaches that prioritize the involvement of community members, in this case, people who use drugs. These approaches should inform evaluations and other research on safer supply programs.

Resources for engaging and employing people who use drugs:

Balian, R. and White,C. (2010). *Harm Reduction at Work: A guide for organizations employing people who use drugs.* Open Society Foundations. Retrieved from: https://www.opensocietyfoundations.org/sites/default/files/work-harmreduction-20110314.pdf

Becu, A. and Allan, L. (2017). *Peer Payment Standards for Short-Term Engagement.* Vancouver, BC: BC Centre for Disease Control. Retrieved from: http://www.bccdc.ca/resource-gallery/Documents/Educational%20Materials/Epid/Other/peer_payment-guide_2018.pdf

Canadian HIV/AIDS Legal Network. (2005). *"Nothing About Us Without Us"—Greater, Meaningful Involvement of People Who Use Illegal Drugs: A Public Health, Ethical, and Human Rights Imperative*. Toronto, ON. Retrieved from: http://www.aidslaw.ca/site/wpcontent/uploads/2013/04/Greater+Involvement+-+Bklt+-+Drug+Policy+-+ENG.pdf.

Greer, A.M., Amlani, A.A., Buxton, J.A. & the PEEP team. (2017**).** *Peer Engagement Best Practices: A Guide for Health Authorities and other providers*. Vancouver, BC: BC Centre for Disease Control. Retrieved from: http://www.bccdc.ca/resource-gallery/Documents/PEEP%20Best%20Practice%20Guideli

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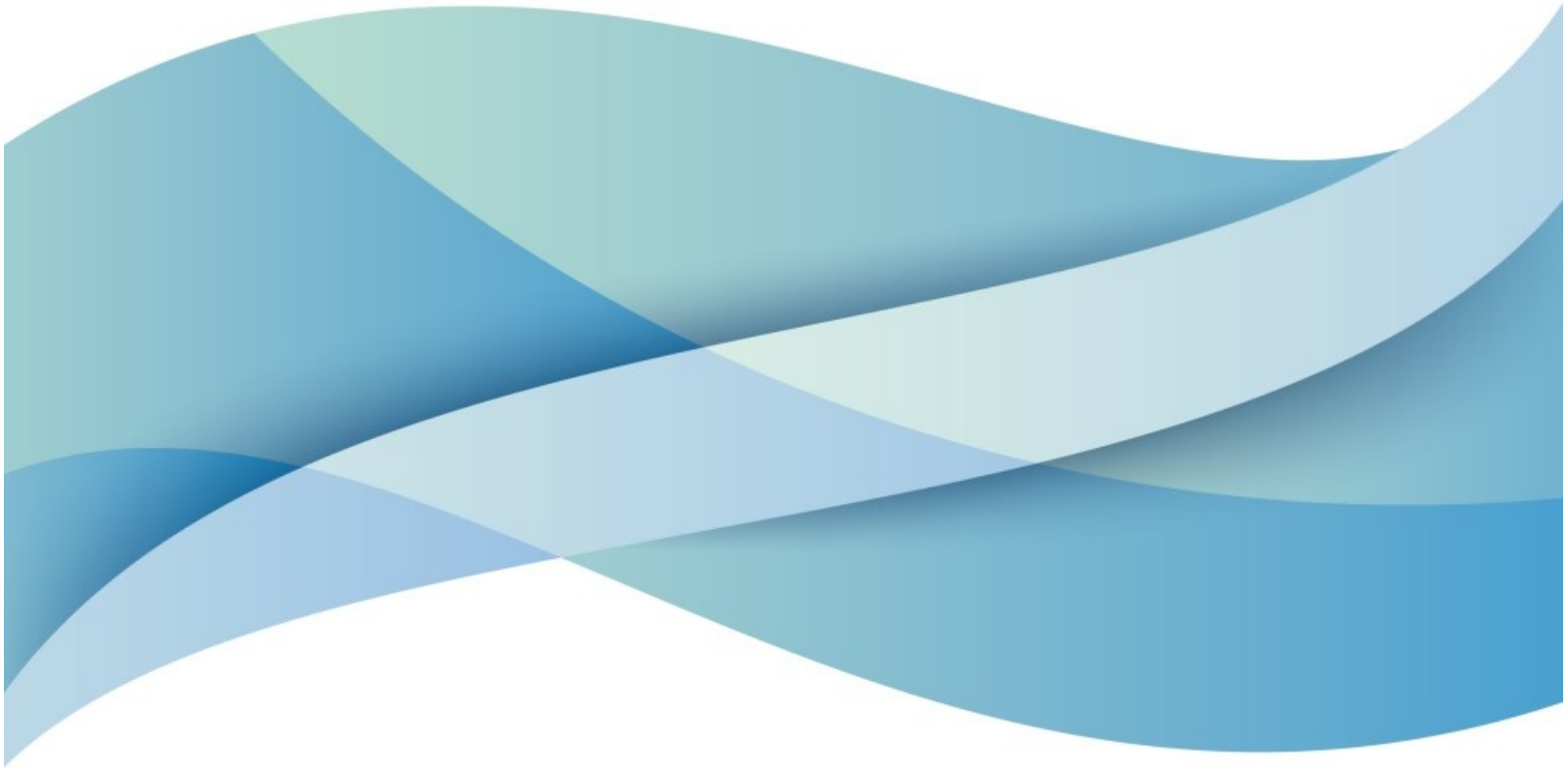
Section 5
Approaches to Evaluation



5. Approaches to Evaluation

Evaluation is a critical component of piloting safer supply projects. There are a number of approaches that may be used for evaluation. Here, considerations are offered for looking at evaluating safer supply evaluations in multiple sites, as well as individual sites.

Key considerations:

- Research activities for safer supply programs should be looked at as **implementation science**, instead of as clinical trials. Clinical and evaluation studies can be separated, thereby streamlining the review processes. There is a sufficient body of evidence supporting the use of iOAT for opioid use disorder; however, evaluations of the effectiveness of safer supply programming in reducing illegal drug use and harms are still in the early stages, due to the recent emergence of these services.

- The establishment of an **expert peer-review committee** to review research protocols would streamline review processes for both funding and research ethics reviews. This committee could be a branch of a safer supply community of practice.

- **Ethical evaluation tools** are available to assist organizations working through the considerations involved with establishing safer supply research pilot projects and evaluations. These include:

  British Columbia Ministry of Health. (2017). *Responding to British Columbia's Overdose Public Health Emergency – An Ethics Framework*
  Retrieved from: https://www2.gov.bc.ca/assets/gov/health/about-bc-s-health-care-system/office-of-the-provincial-health-officer/overdose-public-health-emergency-ethics-framework-march-2017.pdf

  Public Health Agency of Canada. (2017). *Framework for Ethical Deliberation and Decision-Making in Public Health: a Tool for Public Health Practitioners, Policy-Makers, and Decision-Makers.*
  Retrieved from:
  http://publications.gc.ca/collections/collection_2017/aspc-phac/HP5-119-2017-eng.pdf

- **Research and evaluation of new models** of safer supply programs, i.e., flexible models, are needed to determine the effectiveness of these approaches to safer supply, as well as to understand any potential risks or harms. There currently exists a growing evidence base on iOAT; additionally, there are already current and upcoming funded research pilot projects of lower-threshold iOAT and TiOAT community programs (e.g., PHS Moslon OPS, Ottawa Inner City Health MOP, BCCDC Oral Hydromorphone feasibility study).

- There are arguments that support a **coordinated Canada-wide, multi-site evaluation** of safer supply projects that uses a single protocol and with data collected by local researchers (including peer researchers). This would provide a wealth of data using a higher sample, permitting greater confidence in results. However, such a study would be costly and take considerable time to get off the ground. It may also be difficult to tease out the safer supply interventions, if they are embedded in treatment interventions.

- Others argue that evaluations should be **smaller scale and locally-driven,** reflecting the needs and goals of the local community, and conducted by members of the community (e.g., local researchers, selected by the organization, using participatory and community-based research approaches, including employing people with lived experience).

- Where possible, **operations and evaluation should be kept separate**. This may be difficult in the context of resource restraints.

- **Innovative approaches** to program evaluations may be developed to combine both small-scale process evaluations, with larger scale multi-site studies. Approaches may include:

    - All SUAP-funded projects being required to collect specific types of data, using standardized definitions of outcomes of interest and ways of measuring;
    - Using a low-cost open data model to allow researchers to access data to use, with the consent of the communities involved (see below);
    - Having a national evaluation committee with local representatives from safer supply projects oversee the development of a standardized protocol that includes outcomes of interest, data collection tools, and a data dictionary to ensure common understanding and interpretation

- Both a multisite study and local research and evaluations need to draw on **participatory and community-based research approaches**, in which community members (people who use drugs and safer supply services) are involved in the design of the evaluation, data collection, analysis, and dissemination.

- Research and evaluation of safer supply pilot projects in rural and remote areas and/or involving First Nations and Indigenous people should employ community-based research and evaluation methods that include **community capacity building**. For example, if relying on researchers from outside of the community, community research and evaluation capacity should be developed, and analysis should be undertaken in partnership with community members.

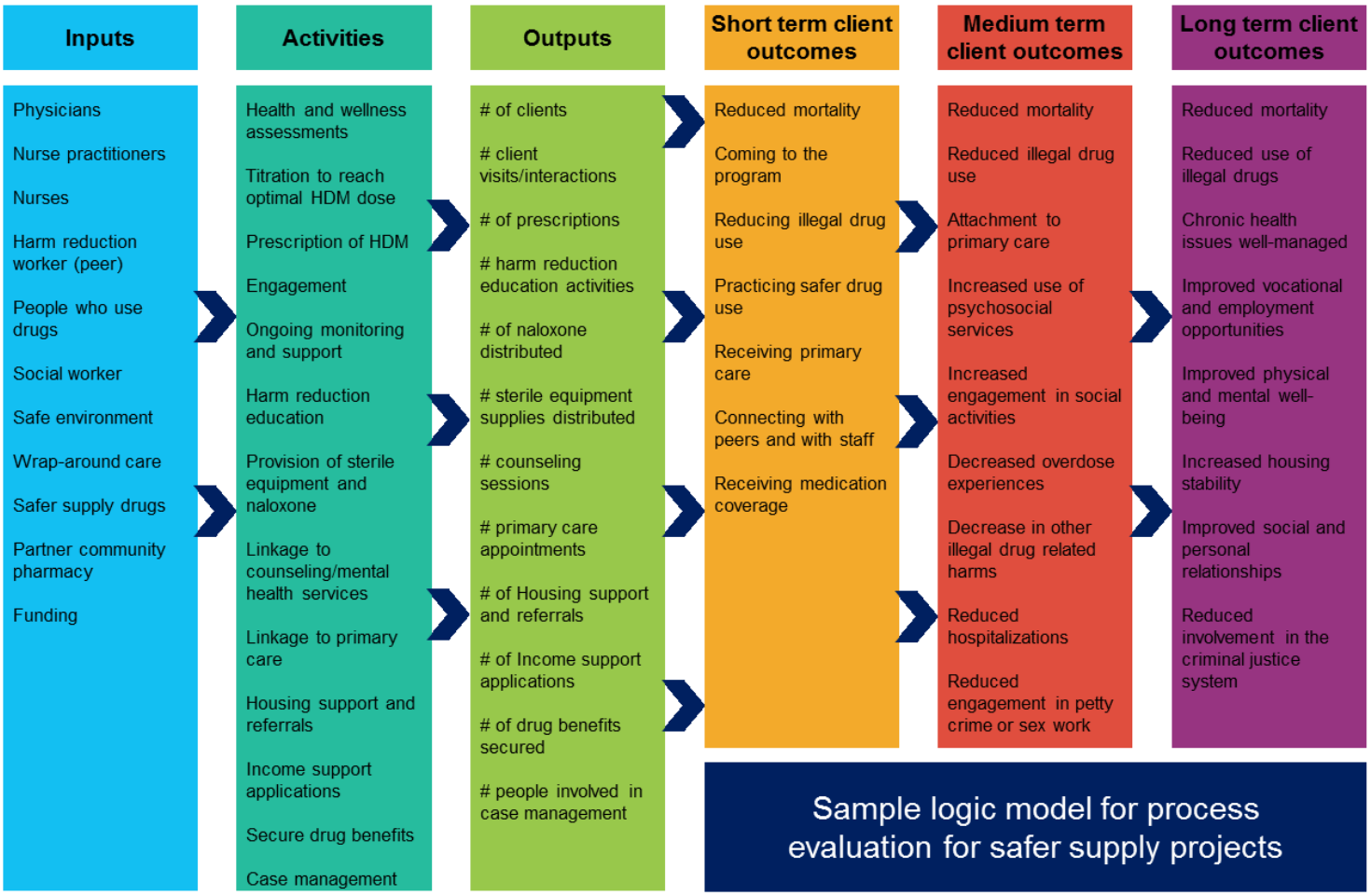
- **Primary outcomes of interest:** The primary outcomes of interest must be connected to the goals of safer supply: ***to reduce illegal drug use and to reduce adverse events related to illegal drug use*** (including death, overdoses, and other health harms, as well as criminalization, involvement in petty crime, and sex work). Other outcomes of interest

may include: *attachment to primary care, connecting with additional health and social services, engagement in programming, reduced hospitalizations, reduced interactions with the criminal justice system*.

- **Process evaluations** (also known and formative or implementation evaluations) are useful for assessing project operations and determining if the project is operating as intended. This is critical for safer supply projects, where evidence is needed to help ensure that the benefits outweigh the risks of harm or actual harms. This is particularly the case for prescribing practices that extrapolate from the evidence and are not well supported with clinical guidelines. Process evaluations can identify where and how project components may need to be adjusted to improve service delivery.

- Process evaluation **findings can be shared through communities of practice**, and contribute to the development of best practices and a framework for safer supply interventions.

The following logic model provides an example of how a process evaluation may work:



Open data models

Open data models refers to mechanisms that make data that is collected for monitoring or evaluation as accessible as possible to people who want to do evaluations. For example, programs are often required to report their data routinely to their funders as a condition of funding. For safer supply programs embedded in supervised consumption sites, supportive housing, or community health centres, this data reporting is already in place. Such organizations that receive funding from the Substance Use and Addictions Program (SUAP) may have reporting requirements for outcomes of interest. By establishing an open data model, researchers could have access to that data, without having to file a data request or even a freedom of information request to access those data. One step beyond this would be to have de-identified individual-level data available, such as through a registry in which everyone who enrols in a Health Canada (ideally) or provincial-funded program to access safer supply would be entered into an registry that tracks a core set of data.

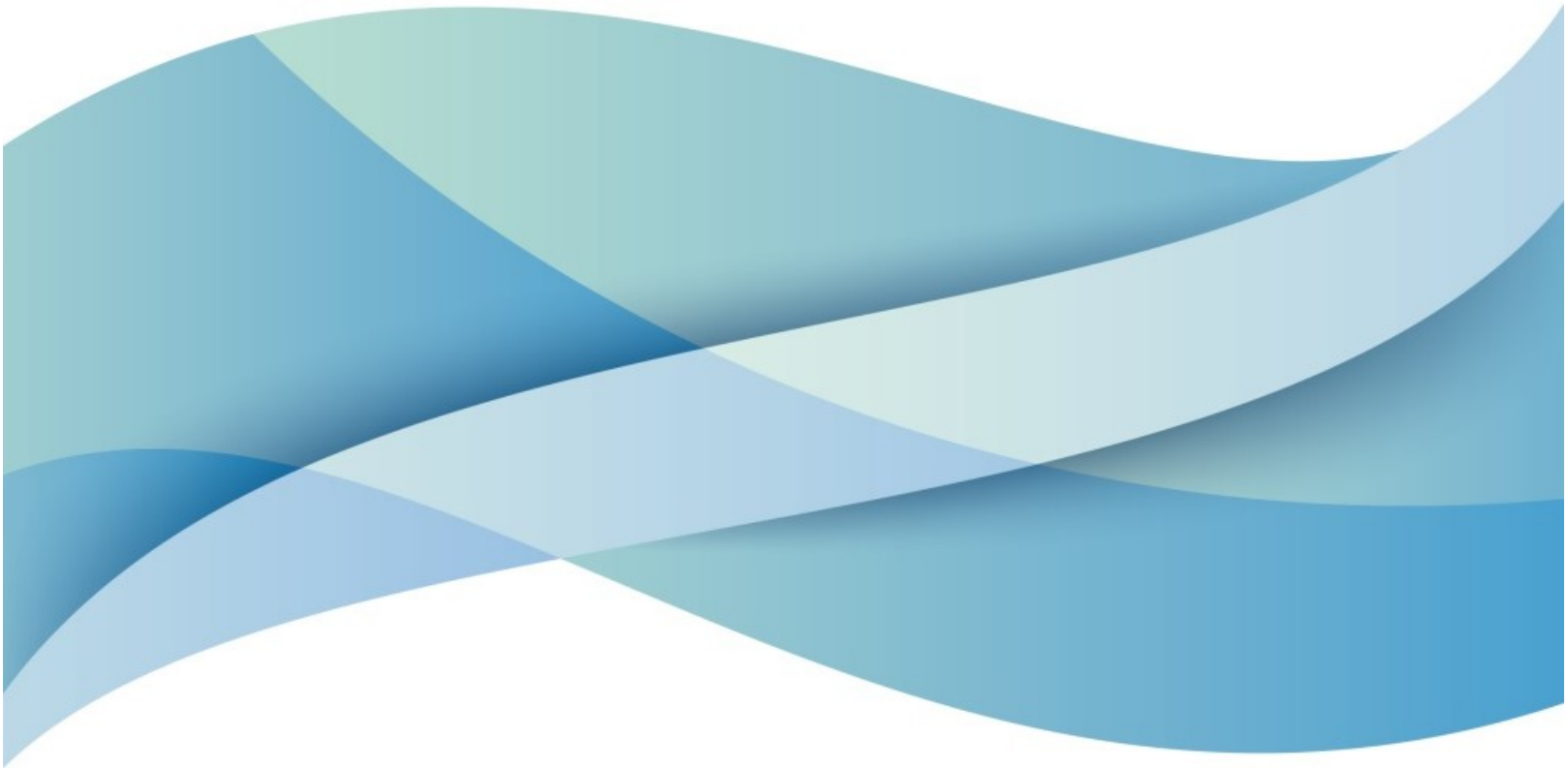
Open data models are an increasingly common practice in the United States, and are beginning to be employed in Canada. For examples of open data sharing, see:

- National Institute on Drug Abuse funded studies: https://datashare.nida.nih.gov
- National Survey on Drug Use and Health data: https://www.samhsa.gov/data/ and https://pdas.samhsa.gov

Data dictionaries

It's important to note that open data sharing might not be accepted in some communities, including Indigenous and First Nations communities. Communities may be averse to open data models, and prefer to have control over where their data goes and how it is used. It is important to **explore alternative approaches to promoting comparability** without the sharing of specific data, for example using data dictionaries to define outcomes.

Section 6
Engaging with a community of practice



6. Engaging with a Community of Practice

Responding to the current overdose crisis requires multiple bold, innovative approaches to reduce illicit drug use as well as strengthening existing harm reduction and treatment services. One way of encouraging innovation and enhancing the capacity of health care and social care providers is to create a community of practice. Across Canada, many health care and social care providers, drug policy organizations, and organizations of people who use drugs are engaged in conversations about safer supply more broadly, and safer supply programs specifically. Some of these are informal email groups, while others are more formalized regional groups. The conversations are diverse, and reflect the complexity of the issue, and the different ways that safer supply is conceptualized and operationalized.

A community of practice is particularly important for health care professionals who are extrapolating from the evidence and trying new approaches, and practicing without the safety net of established professional guidelines and bodies of evidence. Consulting with peers (including clinical, social, PWLE) provides a way of working through ethical issues and professional standards of care, as well as gaining insights into practices, successes, and failures.

A Safer Supply community of practice should include participants from multiple disciplines, including health practitioners, harm reduction and addictions workers, and community members (i.e., people who use safer supply programs, people with lived/living experience).

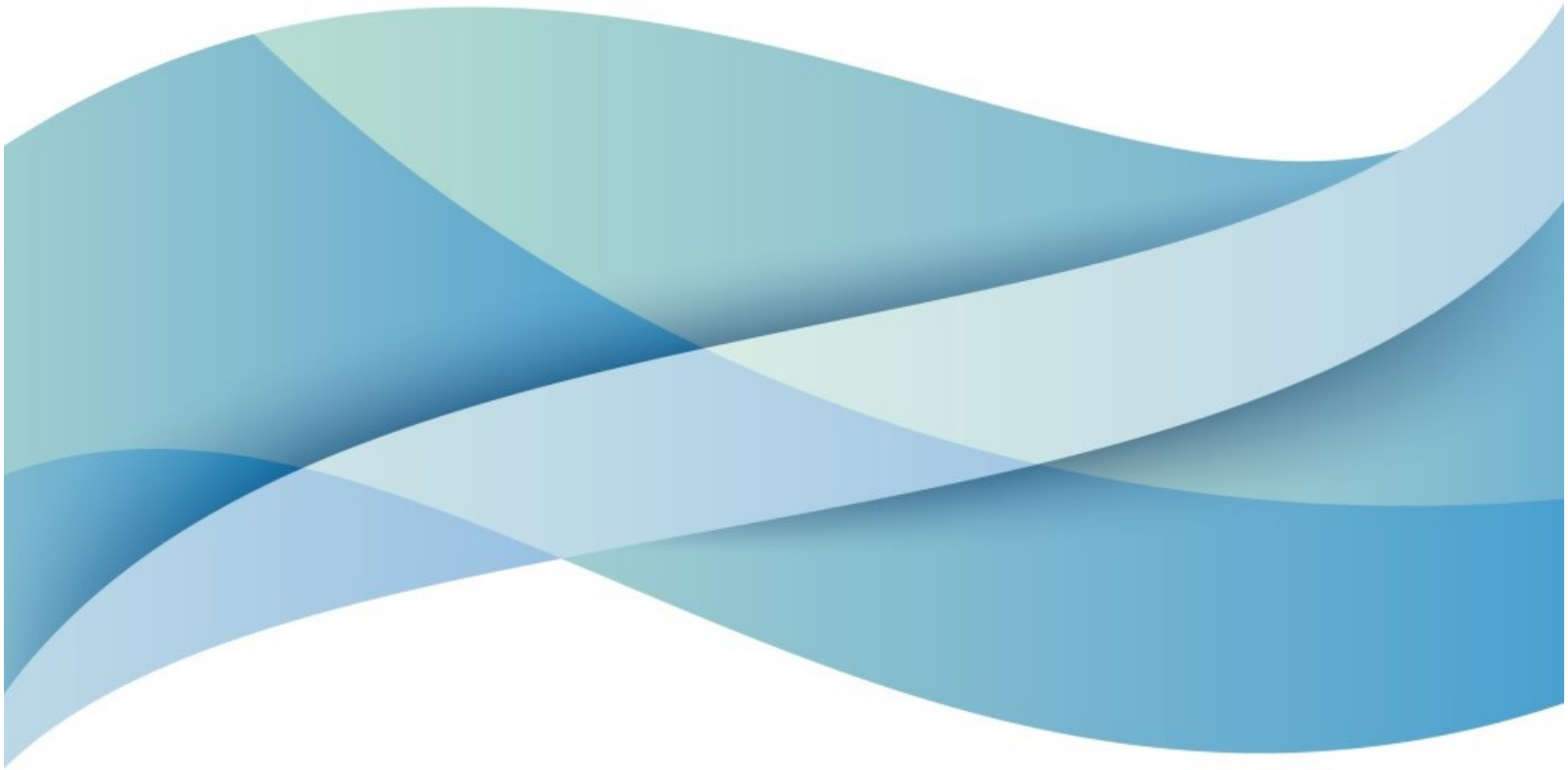
Sub-groups could be established from a community of practice, such as:

- An expert peer-review committee to review research protocols and funding applications
- An evaluation committee to develop evaluation protocols (including data dictionaries) and to disseminate findings
- A emerging practices committee to collectively develop safer supply practice guidelines

Building capacity of organizations of people who use drugs and harm reduction networks

If sufficiently resourced, new and existing organizations of people who use drugs and harm reduction networks may be deployed to provide education and support about safer supply. Additionally, these organizations and networks could assist organizations to develop capacity to meaningfully and effectively engage and employ people with lived experience. This may include a cross-organizational network of PWLE who work with agencies to develop equitable workplace policies. The establishment of a *Safer Supply Access Council*, led by people who use drugs, service providers, and practitioners, could provide support to local safer supply efforts, as well as provide education and information to service providers and regulatory bodies.

Section 7
Additional Resources



7. Additional Resources

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