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PAN Backgrounder: Heroin Assisted Treatment (HAT) - using diacetylmorphine (DAM) for Opioid Use Disorder

Background

Drug mortality rate is higher than ever at over 6 a day in BC (Coroner's Report). Over 10,000 dead in BC since the health emergency began 2016. Overall, the rate in BC is 42 deaths per 100,000 individuals in 2022, up from 20.4 in 2016.

Most of the overdose deaths involve fentanyl or other fentanyl analogues – which is why this is better termed a poisoned drug supply crisis. In BC, the presence of fentanyl in drug toxicity deaths has increased from 5% in 2012 to 87% in 2019. In the illicit market, it is cheaper and easier to transport than heroin and it is expected to expand further in the future. It has been shown that people will use drugs despite the dangers.

In 2022, 83% of illicit drug toxicity deaths occurred inside (55% in private residences and 28% in other inside residences including social and supportive housing, SROs, shelters, and hotels and other indoor locations) and 16% occurred outside in vehicles, sidewalks, streets, parks, etc. No deaths have been reported at supervised consumption or drug overdose prevention sites. There is no indication that prescribed safe supply is contributing to illicit drug deaths.

Naloxone and Drug Checking

Naloxone is our most effective tool at averting overdose deaths (see here), but it obviously cannot work when people use drugs alone, which is now the majority of deaths. Also, an early review concluded that the benefit of drug checking (FTIR machines) was mainly as a surveillance tool than as a harm reduction intervention, but the body of evidence has been growing since 2017 and we await the findings from current data. Benzos have been increasingly found in samples creating life-saving challenges for first responders, as Naloxone does not reverse a Benzo overdose.

Enforcement and the Drug War

Around the world, countries have tried to censure and criminalize people with lived and living experience (PWLLE) of drug use, but it has been shown that there is no 'obvious relationship between the toughness of a country's enforcement against drug possession, and levels of drug use in that country', and that, in this report, higher rates of drug imprisonment did not translate into lower rates of drug use, arrests, or overdose deaths.

OAT Treatment and Abstinence-based methods

Opioid Agonist Treatment (OAT) and Abstinence continue to be needed for those who are ready, but are limited in effectiveness for drug population overall. Over time the majority of PWLLE of drug use will relapse from treatment and again use illicit drugs. A cascade of care study in 2017 showed that 71% of those with Opioid Use Disorder had ever engaged in OAT, 33% were currently on it and only 16% had been retained in care for 1 year. OAT is more effective than abstinence-based treatment. Methadone has higher retention than suboxone, but with a higher risk of overdose. Other studies (1,2,3) have concluded that methadone maintenance retention is around 1/3 participants, with another showing an 85.8% relapse into heroin use within 5 years. There need to be other options for those who do not respond well to these treatments.

Oral Hydromorphone Treatment

In response to Covid-19 and to easing of regulations by Health Canada, British Columbia under the Ministry of Health launched a bold strategy to permit prescription of hydromorphone and/or morphine in oral tablet form (Dilaudid) to act as a substitute for opioids being sought in the illicit market (BCCSU Guidelines).

These work as a substitute for the street supply for some, but for more people it is complimentary because the tablets are not able to compete with the illicit supply in strength or experience of non-medical effects.

> *"If our goal is to get people away from the contaminated drug market, then we have to give them a choice of something that is going to compete with fentanyl," Guy Felicella (BCCSU)*

Research and recent surveys indicate that PWLLE of drug use (especially those who are older) still prefer heroin over fentanyl, and the recent political action(s) by the Drug User Liberation Front (DULF) involving purchasing heroin on the dark web as opposed to fentanyl backs this up.

Some PWLLE of drug use choose to inject crushed tablets to increase strength. In comparison to the risks of the illicit supply, the research on the risks of injecting tablets clearly do not compare. But there are injectable versions of the same drug that have been approved for use as opioid maintenance that do not carry the same risks.

It has also been recognized that there has been a lack of physicians willing to prescribe, leaving many people unable to benefit from the tablet program.

Injectable Opioid Agonist Treatment (iOAT)

iOAT using pharmaceutical-grade heroin, called diacetylmorphine (DAM), or hydromorphone has been proven to be effective at engaging and retaining clients who do not respond well to other forms of treatment. This is also known as Heroin-assisted Treatment (HAT).

There is a significant body of research demonstrating the clinical evidence and health economic evidence for DAM, including several BC studies. Released in 2009, the 3-year NAOMI study found that, for the small number of people who did not benefit from common oral medications such as methadone, injectable pharmaceutical-grade heroin (DAM) was safe and effective. The mean daily dose prescribed was 465 mg, co-prescribed with methadone. Participants, stabilized on a regulated opioid, were retained at a rate of 87.8% in treatment (as opposed to 54.1% on Methadone only), greatly reduced illicit drug use and criminal activity, improving their physical and mental health. Employment and economic situations also got better. At the time, compassionate access to continue treatment was not granted, and participants transitioned to other treatments.

The Study to Assess Long-Term Opioid Maintenance Effectiveness (SALOME), which ran from 2011 to 2015, found that liquid hydromorphone, a pain medication commonly used in acute and palliative care, produced a similar effect. This time compassionate access to continue was granted for the treatment.

Crosstown was a key location for both the NAOMI and SALOME projects. Crosstown is a pioneer in harm-reduction services and was the first full medical clinic in North America to provide DAM to clients experiencing severe opioid-use disorder, as well as hydromorphone as iOAT therapy as well. Of the total clients, 114 clients self-inject DAM, while another 12 receive hydromorphone. Thirty-four others are on other non-injectable OAT such as fentanyl patches. 10 people are now on the unsupervised 'carries' program. Fraser Health has copied the Crosstown model in one clinic, a tribute to its effectiveness, but at this scale (less than 200 in total on prescription DAM) it does not greatly impact the 1,000s at risk due to the poisoned drug supply.

iOAT / HAT has been used successfully in several European countries for over 25 years. Despite this evidence, injectable options with heroin or hydromorphone in BC is not reaching the vast majority of people who need it even though regulations have allowed for it since 2016.

Barriers to expanding iOAT in BC

Creating New Clinics:

One argument raised against wider adoption of DAM and injectable hydromorphone in BC, despite its proven cost-effectiveness as a treatment, has been the high cost of starting up clinics with the necessary facilities to utilize the currently available drugs.

However, even if true that the cost of duplication of success stories like Crosstown is too expensive, there are other viable solutions: dispensing fees can be reduced through the use of vending machines or compassion clubs, and OPS locations are ideally suited to be able to run these programs.

A non-profit government funded body tasked with providing health care decision-makers with objective evidence has shown that iOAT has more benefits than methadone treatment, and at lower cost for individuals who had previously used other treatment options.

Findings from the SALOME trial also approximated societal savings total approximately $140,000 per each person enrolled over their lifetime – mostly attributable to savings in property and violent crime.

Cost of DAM:

Another concern has been the cost of Diacetylmorphine (DAM), which has been imported from Switzerland at a cost of $50/g.

Recently, PharmaScience Inc. secured the license to manufacture injectable DAM for supervised injectable opioid agonist therapy (iOAT) for adult patients with severe opioid use disorder who use injectable opioids and have failed previous attempts at opioid agonist therapy. In order to be sold in Canada, it now has a Drug Identification Number (DIN) and/or Notice of Compliance (NOC) More Info.

Unfortunately, due to the inflated price of raw materials in North America, the cost is currently more expensive than the Swiss import, but without the import caps and wait times.

In the past, BC's Ministry of Mental Health and Addictions has said supply and import limitations have prevented the expansion of treatment with legal heroin, but that the province is working to expand access to injectable hydromorphone alongside other medications. With a domestic supply now available, the issue that remains is cost.

The current need for inhalable OAT

In March 2022, the coroner's Death Panel Review found the most common mode of consumption identified among decedents was smoking (44%), followed by injection (23%) and nasal insufflation (22%) (see Appendix 2, Table 13). In comparison to the previous review, smoking has increased, and injection drug use has decreased. Many overdose prevention sites (OPS) and supervised consumption sites (SCS) services do not offer inhalation services.

The BCCDC Harm Reduction client survey has 63% of PWLLE of drug use preferring to smoke their opioids/stimulants in 2019 , up 11% from a year earlier. In particular, 73% of heroin users reported smoking their drug vs 57% in 2018. People have moved toward a preference for inhalable drugs over injection.

If there is an evidenced lack of product (especially if there is no domestic manufacturer), therapeutic need, and ongoing client relationship, healthcare professionals, the combining or mixing of two or more ingredients (compounding) to create a final product in an appropriate form for dosing. The responsibility

for risk arising from compounding activities is assumed by licensed healthcare professionals in the treatment and servicing of their patients/clients.

Fair Price Pharma (FPP) has the goal of producing an affordable domestic supply of legal heroin for use in inhalable DAM treatment, as a medicalized solution. A prescriber is also needed, alongside a sponsor organization and the patient. Compounding of inhalable DAM does not require a Health Canada commercial license, a Drug Identification Number (DIN) or a Section 56 exemption. All it requires regular lighter for heating, and the cost is $5-14 per dose, considerably more cost effective than iOAT.

FPP is working towards a decision in March 2023 on this compounding option, but at present both the Ministry of Health and the Health Authorities would not cover the cost.

The Response from the federal and provincial governments re: Medicalized safe supply

While the Provinces had been dragging their feet in the earlier years of the crisis, in 2020, the federal government nudged expansion of the availability of heroin through a letter from the Minster of Health, the Substance Use and Addictions Program, and an exemption that allows greater latitude for administering drugs controlled under the CDSA due to the need for isolation during COVID-19.

In conjunction with BC's Risk Mitigation in the Context of Dual Public Health Emergencies (March 2020), they allowed prescribers and pharmacists to prescribe individualized take-home supplies of drugs, colloquially called "carries," and pharmacists to deliver medications and extend or refill prescriptions over the phone. Clients must have a history of ongoing active substance use, and be deemed at high risk of withdrawal or overdose. As mentioned before, the additional OAT option given to potential prescribers was oral hydromorphone.

In July 2021, the province released the Access to Prescribed Safer Supply in British Columbia: Policy Direction that supported the provision of pharmaceutical grade alternatives to illicit drugs to people who are at risk of drug toxicity events and death. In January 2022, the Guidance was updated, including an Opioid Use Practice Update.

Critiquing the provincial response

In March 2022, the Death Review Panel report was released to the coroner. It unequivocally stated that urgent action is needed – beyond what is currently in place.

> "The first priority must be to stop people from dying, and this will need to include a safer drug supply for people who use street drugs. Decriminalization of substance use is also required so that people using illicit drugs may access support and services without the stigma of drug use or having a substance use disorder."

Among its major findings, it highlighted that Indigenous people are disproportionately affected; that most decedents had recent contact with health professionals prior to their death; but that very few of the decedents engaged with substance use disorder treatment services.

The first recommendation was concerning safe supply:

- Create a provincial framework for safer supply distribution, in collaboration with the BC Centre for Disease Control and the BC Centre on Substance Use and people who use drugs, that includes both medical and non-medical models;
- Rapidly expand the safer drug supply throughout the province to ensure a safer supply is available in all communities, including rural/remote and Indigenous communities where people are at risk of dying due to toxic illicit drugs;
- Provide a range of medication options that reflect the needs and substance use patterns of those at risk;

It noted the recommendations from the 2018 report were still relevant, such as the need to expand access to evidence-based addiction care across the continuum including improved access to Opioid Agonist Therapies (OAT) and injectable Opioid Agonist Therapies (iOAT) access as well as full spectrum of recovery supports.

In November 2022, the Report from the Select Standing Committee on Health highlighted some the challenges with the current Safer Supply response, and made some recommendations for action.

> *"… the Committee heard about several challenges faced by those seeking a prescribed safer supply of substances. These include a lack of prescribers and barriers for users including the need for prescriptions, witnessed daily doses, and pharmaceutical alternatives that are not strong enough to prevent withdrawal symptoms or that are available in preferred modes of consumption, such as smoking. Noting the important role that the regulatory colleges and professional associations of physicians, nurse practitioners, nurses, and pharmacists play in BC's health care system, the Committee recommends urgent collaboration with these organizations to identify and resolve barriers to prescribing. It also recommends assessing the current policy and clinical guidelines for prescribing safer supply to limit barriers and to ensure a range of appropriate prescribed pharmaceutical alternatives are made available." (P.8)*

PAN and the Coalition of Substance Users of the North (CSUN) had presented to this committee on July 5th 2022. Our blog outlines our key messages around the need for sustainable, core funding for community based organizations and peer-led organizations to do the work on the front lines. We asked for the government to work on new funding approaches and procurement models. Our recommendations around expanding safer supply included expanding both medicalized and non-medicalized solutions, increasing numbers of prescribers and OPS sites, and exploring creative ways to meet people where they are at, including prescription delivery – lessons learned from CSUN's practice in the rural and remote parts of the province.