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Deregulating Naloxone to Combat Opioid-Related Overdoses in British Columbia: The Potential Moral Hazard of a Progressive Harm Reduction Policy

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Abstract

British Columbia fully unscheduled the opioid overdose-reversing drug known as naloxone on 21 September 2016 in an attempt to reduce opioid overdose-related mortality. Having a large population of injectable drug users, the move represents just one harm reduction initiative out of many the province has executed over the years. The change was intended to remove any regulatory barriers to the drug, thereby granting users, their peers, and public health organizations greater access. Given the devastating impacts of the opioid crisis in North America, particularly the Western coast, the political climate favoured the quick and unopposed implementation of this reform. The move was supported by physicians and pharmacists alike, who recognized the importance of harm reduction strategies alongside the availability of proper training. While no evaluation has been completed, anecdotal evidence from paramedics has suggested that illicit, off-label uses of naloxone are on the rise, posing a potential moral hazard of increased availability.

La Colombie-Britannique a rendu la naloxone, un antagoniste d'opiacés, disponible en vente libre le 21 septembre 2016, dans l'objectif de réduire le taux de mortalité par surdose d'opiacés. Cette décision ne représente qu'une parcelle de l'initiative de réduction des méfaits déjà enclenchée par la province au cours des dernières années, compte tenu du vaste nombre d'utilisateurs de drogues injectables. Ce changement avait pour objectif premier de faciliter l'accès au médicament, tant pour les utilisateurs que pour leurs pairs ou encore les organisations de santé publique. Considérant les conséquences importantes de la crise des opiacés en Amérique du Nord, particulièrement sur la côte ouest, le climat politique était favorable à la mise en place rapide et sans ambages de cette réforme. Cette dernière a autant été appuyée par les médecins que par les pharmaciens, qui reconnaissent l'importance des stratégies de réduction des méfaits, ainsi que d'une formation adéquate des utilisateurs. Malgré l'absence d'évaluation formelle de cette réforme, une augmentation de l'utilisation illicite et non-indiquée de la naloxone a été rapportée par les premiers répondants, ce qui pourrait poser un risque moral quant à son accessibilité.

Key Messages

- In September of 2016, the opioid antagonist naloxone was removed from British Columbia's *Drug Schedules Regulation*, permitting the sale of naloxone outside of pharmacies without a prescription.
- Increasing access to naloxone is an easy-to-implement harm-reduction policy that can reduce the incidence of opioid-related hospitalizations and opioid overdose-related deaths.
- Unsheduling naloxone presents a possible moral hazard insofar as off-label misuses of the drug may lead to riskier behaviour and a lack of appropriate training may diminish the drug's efficacy.

Messages-clés

- *En septembre 2016, la naloxone, un antagoniste des opiacés, a été retirée du Règlement sur les listes de médicaments de la Colombie-Britannique, permettant ainsi la vente de naloxone en dehors des pharmacies sans ordonnance.*
- *L'amélioration de l'accès au naloxone est une politique de réduction des méfaits facile à mettre en œuvre qui peut réduire l'incidence des hospitalisations liées aux opiacés et des décès liés à une surdose d'opiacés.*
- *Rendre la naloxone disponible en vente libre présente un risque moral possible dans la mesure où une mauvaise utilisation non conforme du médicament peut entraîner un comportement plus risqué et qu'un manque de formation appropriée peut réduire l'efficacité du médicament.*

1 BRIEF DESCRIPTION OF THE HEALTH POLICY REFORM

Illicit and prescription drug-related deaths and hospitalizations in BC have risen drastically since 2010, affecting persons of all ages (BCMPSSG 2018; BCMPSSG 2019; CIHI 2016). Fentanyl, an extremely potent synthetic opioid, accounts for the drastic increase in illicit drug overdose deaths, suggesting not only an increase in the availability of opioids but also an increase in lethality. In response, BC became the first province to pilot deregulation of the powerful opioid antagonist, naloxone: first by rescheduling the drug as Schedule II on 23 March 2016, and by 21 September 2016, then by removing naloxone from its drug schedule entirely (Drug Schedules Regulation 2016). In 2016 alone, over 20,000 naloxone kits were dispensed at over 400 sites by the BC Centre for Disease Control’s (BCCDC) Take Home Naloxone (THN) program (Irvine *et. al.* 2018). Naloxone temporarily reverses the effects of an opioid overdose on the central nervous and respiratory systems within one to five minutes of administration. Doses may be injected or sprayed into the nose. The typical THN kit contains three 1 mL ampoules of 0.4 mg/mL injectable naloxone along with syringes, latex gloves, alcohol swabs, a breathing mask, and an instruction sheet.

2 HISTORY AND CONTEXT

- 2012:** Illicit drug overdose deaths related to fentanyl begin to rise rapidly (BCMPSSG 2018).
- 2012:** On 31 August, the first THN pilot program is launched by the BCCDC.
- 2013:** By December, all BC Health Authorities have THN sites.
- 2014:** By April, the College of Physicians and Surgeons of British Columbia (CPSBC) endorses THN programs (CPSBC 2014).
- 2014:** An evaluation of the THN program is published in the *Canadian Medical Association Journal* suggesting that communities across Canada consider its implementation (Banjo *et al.* 2014).
- 2015:** The illicit opioid overdose death rate, driven by illegal fentanyl, reaches a record high of 11.2 per 100,000 population in BC (BCMPSSG 2019).
- 2016:** On 22 March, Health Canada removes naloxone from its *Prescription Drug List*.
- 2016:** Non-prescription, emergency-use naloxone is made available under the *Pharmacy Operations and Drug Scheduling Act* as Schedule II (behind-the-counter) in BC on 23 March (Drug Schedules Regulation 2016).
- 2016** On 14 April, BC declares the opioid crisis a public health emergency (GOBC 2016a).
- 2016:** The College of Pharmacists of BC (CPBC) amend the *Drug Schedules Regulation* by unscheduling emergency-use naloxone on 20 September, making it available for sale outside of pharmacies (CPBC 2016).

3 GOALS OF THE REFORM

3.1 Stated

The primary goal was to reduce both prescribed and illicit opioid overdose mortality. By deregulating naloxone, the province intended to make naloxone more widely available to users and community organizations, thus keeping BC communities safe (CPBC 2016; GOBC 2016b). The reform empowered users and peers of overdose victims by enabling them to administer naloxone and reverse overdoses without emergency medical personnel; it also gives first responders, provincial corrections, businesses, and community organizations more freedom to disperse the drug (CPBC 2016).

3.2 Implicit

Implicitly, the policy helps users and their peers overcome the perceived separation they have from the health system (Faulkner-Gurstein 2017). By utilizing users' expertise, the government decreases the burden on emergency health services (EMS) by reducing the number of emergency department (ED) visits and hospitalizations. Additionally, it raises awareness about the dangers of opioid overdoses and integrates an educational component into harm reduction programs (Toward the Heart 2019).

4 FACTORS THAT INFLUENCED HOW AND WHY

4.1 The issue came onto the government's agenda

Several factors contributed to the decision to unschedule naloxone. Many stakeholders began to call for greater implementation of harm reduction policies (in contrast to historically-dominant prohibitionist policies), as the surge in opioid-related mortality and increase in lethality of overdose due to the introduction of fentanyl created a sense of urgency within communities. In March of 2012, Health Canada decided to remove emergency naloxone used outside hospital settings for opioid overdoses from its Prescription Drug List (CPBC 2016). In the same year, the first THN program was launched by BCCDC and would be scaled up to all BC Health Authorities before the end of 2013, thanks in part to BC's policy legacy of harm reduction. Indeed, harm reduction practices have been supported and experimented with for several years in BC. The province launched its first needle exchange program in 1989, opened the first legal supervised drug injection site in North America in 2003, and centralized its harm reduction supply distribution in 2008 (BCCDC 2012).

4.2 The final decision was made or not made

Given the high degree of public support for harm reduction policies in BC, the removal of emergency-use naloxone from the drug schedule did not meet with significant resistance.

The groundwork by the federal government in descheduling naloxone and the previous rescheduling of naloxone from a Schedule I drug to Schedule II made the act of unscheduling naloxone logistically feasible. The rapid series of actions and nearly full consensus is a testament to the province’s commitment to mobilize against the opioid crisis. The political weight of the BCCDC, two provincial health professional colleges (CPSBC and CPBC), patient advocacy groups, and national actors such as Health Canada and the Canadian Drug Policy Coalition (CDPC) generated the political climate that supported deregulating naloxone.

Pharmacist organizations strongly supported the change, recognizing the life-saving properties that increased access to naloxone afforded (CDPC 2015; CPSBC 2016). After rescheduling emergency-use naloxone to Schedule II, the BC Pharmacy Association (BCPhA) noted that remaining barriers to access still existed and advocated for the complete coverage of naloxone through pharmacare (BCPhA 2016). In a public statement, the CPBC hoped to improve access, noting that “the benefit of greater accessibility clearly outweighs any real or perceived risks associated with having naloxone available outside of pharmacies” (CPBC 2016). However, some pharmacists expressed a reticence to such initiatives, feeling their implementation to be rushed (Edwards *et al.* 2017). Other early concerns came from police officers, who considered the possibility that increased access to the kits may embolden users to not seek medical attention (Banjo *et al.* 2014).

5 HOW THE REFORM WAS ACHIEVED

5.1 Policy instruments

Unscheduling emergency-use naloxone was executed through changes to legislation after approval by the CPBC and consultation with the BCCDC and patient advocacy groups. On 20 September, the specification scheduling naloxone and its salts “when used for opioid overdose emergencies outside hospital settings” as Schedule II was removed entirely, making emergency-use naloxone available without a prescription and outside of pharmacies (Drug Schedules Regulation 2016). While naloxone is available to anyone for purchase, only those “most likely to witness and respond to an opioid overdose” and have completed the THN training program have access to the publicly-funded THN naloxone kits, free of charge (CPhA 2017). Locations that are suited for reaching people at high risk of overdoses, such as clinics, churches, and health centres, can apply for THN supplies through the BCCDC. Otherwise, the drugs may be purchased at a pharmacy for \$5-\$20 for the injectable form (and around \$125 for the nasal spray).

5.2 Communication plan

No explicit communication plan was in place for the regulatory changes in access to naloxone. However, in September 2016, the Ministry of Health released a public awareness cam-

campaign alongside the unscheduling of naloxone which included public service announcements and a social media campaign (GOBC 2016b). Training for the administration of naloxone was offered by the BCCDC and patient advocacy groups. The Ministry of Health, the BCCDC, and the CPBC also continue to maintain websites updated with educational resources for professionals and patients seeking more information. The government also regularly releases progress updates on its action plan.

6 EVALUATION

No official evaluation has been planned. However, researchers have published early impact assessments of the THN program in BC, finding that the program reduced the number of illicit drug overdose deaths due to fentanyl (Irvine *et al.* 2018), and decreased hospitalizations (Rees *et al.* 2017). Furthermore, evidence suggests an array of secondary positive outcomes, including users entering drug treatment programs, a decrease in overall drug use, and a willingness to be tested for HIV and hepatitis C virus (HCV) (McDonald and Strang 2016). Studies have also found that within a 3-month follow-up period of a THN training program, almost 30% of the participants had trained a family member or peer (McDonald and Strang 2016). As of yet, however, the crisis shows no signs of abating: the BC Coroner's Service released data indicating that in 2017, 872 BC residents died of suspected illicit drug overdoses in which fentanyl was detected 79% of the time (BCMPSSG 2019).

The success of BC's strategy requires the mobilization of drug users and their peers who are without established remuneration nor any defined consequences should they fail (Faulker-Gurstein 2017). As such, consideration should be given to the direct and indirect costs of increasing access to naloxone. As the price of naloxone has steadily increased over the past several years due to increased demand, efforts to ensure affordability are needed lest the program become unsustainable (Gupta, Shah, Ross 2017). Moreover, while some evidence has suggested that users of illicit opioids demonstrate a decrease in use after overdose education (Jones *et al.* 2017), others have noted that as access to naloxone is expanded, the perceived risks of overdosing are reduced (Doleac and Mukherjee 2018). This might lead users to use opioids more frequently than before and in more dangerous manners, therefore increasing opioid-related ED visits without reducing overdose mortality.

These concerns were echoed by the Ambulance Paramedics of BC (APBC). The group worried about the off-label misuse of naloxone among illicit drug users, who believe that their overdose will be prevented by mixing naloxone with their drugs (Correia 2017). As far as risk of overdose death is concerned, naloxone survivors are already the most vulnerable group: although adverse events are typically rare, users who are dependent on opioids may experience acute withdrawal symptoms upon using naloxone which may lead to further use (McDonald and Strang 2016). Thus, proactive policies that do not target the root causes of opioid addiction mean that these abuses of naloxone are likely to continue, impacting the efficacy that paramedics can achieve. The call was reiterated by the Centre for Addictions

Research of BC at the University of Victoria, who maintained that a comprehensive suite of harm reduction services is critical to effectively respond to the crisis (UVIC 2016).

Resolving issues of user access to the health care system is another important facet. As pointed out in the BC Coroner’s Report, many decedents were regular users of illicit drugs who had already had previous contact with the health system (BCMPSSG 2018). The availability of naloxone may mean that users do not interact with the health system at all and continue to use opioids in ever more dangerous manners. Karamouzian *et al.* (2019) found that emergency medical help was sought in only 56% of overdose events where naloxone was administered, suggesting that users and bystanders may not feel the need to call EMS, which may lead to unintended consequences if the overdose victim is not linked to care. Naloxone use might also end up entrenching stigmatization against users, thereby preventing them from seeking EMS even in the presence of Good Samaritan laws promising legal protection to those suffering from an overdose (Buchman *et al.* 2018).

Lastly, knowledge regarding appropriate use of naloxone varies widely among users (Heavey *et al.* 2018). Indeed, a lack of education is a major barrier to the reform’s success: even the CPBC stressed the importance of continuing training without pharmacist participation (Bains 2017; CPBC 2016). This includes recognizing the signs of an overdose, how many doses should be given depending on the opioid consumed, knowing how long a dosage lasts before a possible second overdose (which in turn depends on the amount of opioids in the user’s system), and whether or not the naloxone has expired or has been stored properly. This knowledge is crucial considering the dosage contained within a THN kit is equivalent to those carried by paramedics (BCEHS 2018). Strict guidelines exist concerning the administration of naloxone (e.g., for children and those in cardiac arrest) between different licenses of EMS personnel, the misuse of THN kits by untrained hands could pose a serious risk.

7 STRENGTHS, WEAKNESSES, OPPORTUNITIES AND THREATS

Table 1: Strengths, weaknesses, opportunities, and threats of expanding the availability of emergency-use naloxone by removing the drug from the *Drug Schedules Regulation* in BC

STRENGTHS	WEAKNESSES
<ul style="list-style-type: none"> ● Innovative and progressive harm reduction policy that empowers users and their peers. ● Turns control over to users and their peers. ● Supported by public and health care professionals. ● Easy to implement. ● Minimizes the risks of overdose. 	<ul style="list-style-type: none"> ● Requires knowledge of the symptoms of an overdose and proper administration of the drug. ● Ambiguity over responsibility and risk of usage. ● Follow-up with emergency health services is not guaranteed. ● Reactive in nature—addresses only one facet of the complicated opioid crisis. ● Costs associated with obtaining emergency-use naloxone are prohibitive. ● BC’s THN kits do not include nasal spray which is easier to administer.
OPPORTUNITIES	THREATS
<ul style="list-style-type: none"> ● Possible reduction in overdose mortality. ● Possible reduction in associated health care costs from overdose deaths. ● Unanticipated benefits vis-à-vis willingness to seek further treatment, test for HIV and HCV, and use fewer drugs. ● Trainees of THN programs may be inclined to encourage peers and family to participate as well. 	<ul style="list-style-type: none"> ● Potential off-label misuse of naloxone. ● As perceived risks of overdose appear less potent, possible consequences for users’ risky behaviour. ● Diminution in the effective responses by paramedics given riskier behaviour (yo-yoing). ● Without an appropriate communication strategy, THN programs may reinforce stigmatization that users face.

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