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Research paper

The regulation project: Tools for engaging the public in the legal regulation of drugs

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ABSTRACT

Lack of legal regulation and oversight of scheduled drugs in Canada has led to an unsafe drug supply responsible for the deaths of tens of thousands. In addition to contributing to the worst unregulated drug poisoning crisis in Canada's history, the policy framework prohibiting non-medical access to certain drugs has exacerbated numerous public health and safety concerns. An alternative approach to prohibition is for government to retake control of the currently illegal drug market through legal regulatory mechanisms. This paper presents the work of an ongoing international collaboration of organizations advocating legal regulation and some of the knowledge translation tools used to educate and engage the public on legal regulation within Canada. In order to encourage thinking and decision-making among stakeholders in a productive way, models of legal regulation for various substances were created as discussion tools to emerge values and considerations supporting different approaches. The models focus on five questions: 1) who has access to drugs; 2) how access is obtained; 3) where drugs can be accessed; 4) how much people can obtain; and 5) where drugs can be consumed. The models were presented to stakeholders in the context of an international meeting on legal regulation, and then adapted to a more "user-friendly" form: a collaborative negotiation-based Regulation Game, which was presented at a workshop in Montréal, Canada. Engaging different stakeholder groups on policy choices of legal regulation revealed initial barriers that we feel more confident can be overcome through creative and innovative tools such as the Regulation Game. Use of the game as a foundation for more traditional focus groups could be effective in reducing barriers to fulsome policy discussions on legal regulation.

Introduction

Canada is in the midst of a crisis. Each day eleven people die from drug overdose, totaling over 16,364 lives lost in the past three years (2020c). These deaths are the product of unsafe conditions imposed by a lack of regulation and oversight in the illegal drug market, a fact exacerbated by years of overprescribing of opioids to consumers who now turn to alternate sources. As a result of punitive drug policies that leave non-medical substance use unregulated, there is a thriving illegal drug market where the quality, content and potency of products are largely unknown to consumers. Although figures vary across provinces, approximately 82% of opioid-apparent deaths over the past three years included the potent opioid fentanyl or its analogues (2020c). In addition to preventable overdose deaths, current drug law enforcement and supply reduction-focused policies — often referred to as "prohibition" — contribute to the proliferation of organized crime, money laundering, violence, infectious disease, stigma, and other well-documented social and individual harms (Boyd, Carter, & MacPherson, 2016). It is widely acknowledged that these policies perpetuate legacies of racism and classism that emerged over a century ago (Boyd, MacPherson, & Vancouver Area Network of Drug Users, 2018). Further, in the climate of prohibition, benefits of currently illegal drugs – including the historical and current use of psychedelics such as ayahuasca, psilocybin, and LSD for spiritual, religious and medical uses – has been greatly downplayed (Carhart-Harris & Goodwin, 2017).

An alternative approach is the legal regulation of drugs. In the widely recognized 1972 report of the Le Dain Commission, Marie-Andree Bertrand, writing for a minority view, recommended cannabis be regulated similarly to alcohol (1974). Unfortunately this report did not find traction within government in its day, and policy change for cannabis remained out of reach until Canada implemented legal regulation of adult recreational cannabis production, distribution and

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possession in October 2018 (Cannabis Act, 2018). Due to the current overdose crisis, the idea of creating a legally regulated and controlled source of substances for people who consume illegal drugs – often termed "safe supply" - is gaining attention, and is being implemented selectively in Canada as a response to COVID-19 (Uguen-Csenge, 2020). Support for safe supply includes calls by public health authorities in Toronto, Vancouver and Montreal (MacPherson & Bernstein, 2019) and most recently, the Canadian Association of Chiefs of Police (Canadian Association of Chiefs of Police, 2020). Despite increasing risks to people who use drugs during the "dual public health crises," efforts to implement interventions such as injectable Opioid Agonist Treatment (iOAT), observed hydromorphone tablet distribution and injection, hydromorphone dispensing machines, or stimulant distribution, however, have thus far been limited to a handful of innovative, small-scale pilot projects (Government of Canada, 2020a). Broader consideration of legal regulation of all or most illegal drugs remains largely on the sidelines.

Legal regulation of risky behaviour is not a radical policy shift. The state regulates many activities and products harbouring potential risk, including alcohol, tobacco, food, mining, forestry, gambling, financial investing, health services and transportation(e.g. (Government of Canada 2020b; Mayer, 2011; Government of Canada, 2018b). Pharmaceutical drugs — including ones with substantial risks if misused — are subject to comprehensive systems of regulation governing all aspects of their production, distribution and use in Canada (2018a). Considering the many risky activities that are encompassed by regulatory regimes aimed at managing individual and societal risks, and that over half of Canadians report having used an illegal drug, today's prohibitionist policies seem out of place with Canada's general approach to public health and safety (Statista, 2018) and are the radical approach (Rolles & McClure, 2009).

Despite the ever-increasing harms of current drug policies, discourse around drug regulation has been limited by generalized concerns that regulation would introduce new public health challenges. Unsubstantiated expectations that substances such as heroin or cocaine would be sold to anyone at a local corner store, or that drugs lead to violence, have precluded legitimate consideration of legal models for heroin and other opioids that would support public health objectives better than current policies. Legal regulation of drugs was even used as a "scare tactic" in the most recent federal election in Canada (Walsh, 2019).

This paper aims to introduce one piece of an ongoing, long-term collaboration among drug policy organizations called the "Regulation Project," as a strategy to move the discourse beyond *whether* drugs should be legalized and towards *how* a government might structure legalization in a post-prohibition world. The Regulation Project was formed in April 2017 as a collaborative effort among six Canadian-based drug policy organizations to develop strategies to advance policy around the legal regulation of drugs in Canada but has grown to be an international collaborative of 15 organizations from four countries. The primary work of the Regulation Project is based in the belief that engagement with the specifics of legal regulation will dispel myths, address concerns of stakeholder groups, determine whether there is agreement about characteristics of a regulated system, and ultimately foster meaningful discussion about alternative approaches to drug policies. Early on, the Regulation Project partners identified multiple prioritized activities, including the development of a "Canadian blueprint" of the best ways to implement legal regulation in Canada, and the creation of a national campaign to shape public opinion favourable towards regulation and to mobilize people to action. From these initial strategies of articulating models and engaging the public evolved a novel set of tools in the field of drug policy advocacy for education and engagement.

In order to present the intellectual and emotional landscape that the Regulation Project seeks to traverse, this paper will outline some basic principles regarding the legal regulation of drugs, present a set of stakeholder engagement tools designed to educate and further discussion about models of legal regulation, and discuss the effectiveness to date and potential of using these models as a way to increase depth and breadth of policy alternatives.

Envisioning legal regulation

There has been extensive research on the harms of prohibition globally and in Canada. For example, rising levels of violence have been described as the inevitable consequence of drug prohibition, and disrupting drug markets through law enforcement interventions may increase drug-related harms (Werb et al., 2011); cannabis prohibition has been linked to harms to Canadian youth while failing to reduce the rate of use (Elrod, 2017); and since its inception, drug prohibition has been used to demonize non-white and poor consumers of illegal drugs (Boyd, MacPherson, & Vancouver Area Network of Drug Users, 2018). These harms are not limited to drug prohibition in Canada. The Global Commission on Drug Policy has noted how unregulated drug markets empower organized crime and increase the harms of drugs internationally (Global Commission on Drug Policy, 2018).

The majority of debate around drug regulation, with exception (e.g. Rolles & McClure, 2009; Rolles & Murkin, 2013; Haden, 2008; Haden, Emerson, & Tupper, 2016), has focused on whether policy reform is justified, rather than how reforms might be implemented. The vast majority of the public and many academics and other stakeholders remain uninformed about what legal regulation could entail. Recent scholarship is attempting to shift the discourse towards a "management" approach, based on recognition of basic implications of legal regulation, including: (1) accepting non-medical use of psychoactive drugs; (2) erasing the false dichotomy between "legal" and "illegal" drugs; and (3) blurring distinctions between medical and non-medical uses (Emerson, 2019). Proposed frameworks now include general models (prescription, pharmacy sales, licensed sales, licensed premises, and unlicensed sales) for regulating supplies of all classes of drugs (Rolles & McClure, 2009); detailed models for regulating a particular class of drugs or individual drugs within a public health framework (Haden, 2008; Haden et al., 2016; Moore, Wells, & Fielding, 2019); and innovative models designed to address specific harms of the unregulated market (British Columbia Centre on Substance Use, 2019). Additional scholarship has focused on "unpacking" various tools, including identifying 120 regulatory "levers" available to regulators to minimize harms in a legal market, addressing production, distribution, consumption, enforcement, health information, and more (Haden, 2015) and identifying design considerations for legal regulation (Kilmer, 2019). Largely missing from this discourse is scholarship focusing on public knowledge and perceptions of legal regulation and the relationship of consumer "buy-in" to particular models in order for them to be successful.

To that end, we sought to transform concepts of legal regulation into a format that would best promote discussion among the public. Importantly, we wanted to present not only the rationale for legal regulation, but the principles upon which such a system should be created, overall objectives, and a selection of models along a spectrum of options which support public health outcomes. We aimed to distill complex systems into simpler models than those that would emerge in practice, but with sufficient nuance to elicit fulsome discussion about the merits and shortcomings of each.

Principles for the legal regulation of drugs

Under prohibition, control over drug markets rests in the hands of profit-seeking groups who often engage in unethical and violent practices (Global Commission on Drug Policy, 2018). Additionally, prohibition has proven an impractical means of reducing availability and demand of drugs and improving public health, evidenced by the continued use of drugs in the unregulated market and increased risks

associated with that use (Degenhardt et al., 2008). Legal regulation offers the opportunity to create an ethical, practical, and readily adaptable system aimed at remedying the harms of existing policies. To that end, any approach to legal regulation of drugs should be grounded in public health, meaning a scheme designed to further not only physical health, but social justice, human rights and equity outcomes as well.

A public health approach to drug control employs strategies aimed at maximizing health and well-being (Health Officers Council of British Columbia, 2005). As these outcomes are unlikely if the legal system fails to attract consumers, it is imperative that regulation account for consumer preferences. Discourse among people with lived experience, for example as described in the Canadian Association of People who Use Drugs (CAPUD) concept paper on safe supply, suggests that models appealing to health professionals might be viewed as too restrictive by consumers, who often don't view their drug use in a medical frame (Canadian Association of People who Use Drugs, 2019). Lower than predicted uptake of legal cannabis a year after legalization is sometimes attributed to excessive prices and irregular access. Both are issues of consumer preference that have not been addressed to date in the new system (Edward, 2019). However, neither consumer preference, nor profit motives or corporate interests should be allowed to dominate regulatory models, as these elements have worked against public health in the cases of alcohol and tobacco (Ireland et al., 2019). Public health goals can only be achieved by striking a balance between these competing interests. As one of the key decisions to make will be who has control of the legal market, considering novel options such as non-profit management of many aspects of the new system may better support public health and human rights outcomes than a for-profit managed system.

Importantly, a public health approach requires abandoning abstinence-centered policies and acknowledging that among adults who choose to consume drugs, the majority do not develop problematic use (United Nations Office of Drugs and Crime, 2019). It is also important to separate the harms associated with drug use related to prohibition from the intrinsic risks of drugs themselves, which are often exaggerated (Moore et al., 2019). Chief among the outcomes of prohibition has been systemic production of dangerous, unregulated supplies and an environment actively discouraging open engagement around information and harm reduction practices. A regulated system can offer safer alternatives to street drugs by meaningfully integrating evidence-based information for consumers about the risks of substances, techniques to reduce those risks, and low-barrier access to services aimed at reducing or eliminating problematic consumption when it occurs. Strategies aimed at discouraging youth drug use, for example, should be balanced with the reality that youth excluded from the legal market may seek drugs in an illegal one and appropriate harm reduction services offered to those consumers regardless of the legal status of their use. Because criminalization of drugs inhibits use generally and consequent addiction (Morse, 2012), it is logical to conclude that legal regulation may lead to temporary or long-term increases in demand and, to a degree, increased rates of dependence. The individual and public health harms of increased use and dependence, however, need to be weighed against the harms of an unregulated system, including preventable overdose deaths and the fact that increased drug use may not necessarily lead to increased harms (MacCoun & Reuter, 2001).

In order to meet public health goals, Canada's framework for drug regulation should prioritize five principles underpinning all evidence-informed drug policy and practice, adopted from Moore et al. (2019): (1) promoting public health and reducing harms; (2) protecting vulnerable populations, including youth; (3) supporting human rights; (4) promoting social justice; and (5) supporting participatory democracy. More specifically, legal regulation that promotes social justice should seek to achieve justice across multiple disciplines (economic, health, race, gender, environment, trade, etc.) (see International Drug Policy, 2020).

Finally, the regulatory system needs to be adaptive to emergent risks and feedback from those involved in the system. Adjusting factors such as price, availability, and selection based on real-time feedback is important to ensure public health outcomes are maximized.

Barriers to moving to a system of legal regulation

As with climate change, it is often challenging to meaningfully engage the general public on drug policy issues. It is a topic that is historically loaded with morality (Gopalan, 2017) leading to strongly held personal beliefs about the “right” thing to do. It is also a topic that is largely argued in abstractions, such as morality and health vs. liberty and public safety, as opposed to debating desired policy outcomes (measures of health and wellbeing, criminal justice, public safety, etc.) or alternative systems of regulation (Kleiman & Ziskind, 2019). Perspectives on the value of legal regulation are more often grounded in unfounded fears, such as the ease of access to drugs in a legal market or the paternalistic role of government as “big brother” in overseeing drug consumption habits.

The complexity and entrenchment of drug policy systems present additional barriers to developing practical solutions with demonstrable outcomes. Over a century of prohibition has not only supported an unregulated market composed of many producers, distributors and consumers, but also global, national and sub-national law enforcement and control systems designed to address the illegal economy. Many parts of this system operate clandestinely, making it impossible to accurately gauge the scale or details of supply chains. Like climate change, the overall complexity of the system makes many discussions about policy change seem insignificant or without a clear starting point; if minds *are* open to consider solutions, it's difficult to know where to begin. Unlike climate change, however, drug policy conversations carry the stigma of criminalized drug use, creating an additional barrier to discussion. And yet, without meaningful education and discussion of alternative drugs policies, such as legal regulation, it is difficult to amass political will for change or determine the kind of system that would be supported by a wide variety of stakeholders.

We approached these challenges from the perspective that knowledge translation - the synthesis, exchange and ethically-sound application of knowledge (Canadian Institutes of Health Research, 2016) was required to move discussion forward. Our perspective was informed by the unrealized value of participatory democracy in creating drug policies, which has only recently included expertise and opinions of drug consumers alongside the recommendations of health and government professionals (Greer & Ritter, 2020; Lancaster, Ritter, & Diprose, 2018; Ritter, Lancaster, & Diprose, 2018). Our objective was to move beyond simply gaining public opinion on issues, onto creating environments that were an “inclusive, democratic, deliberative and thoughtful process of political decision-making on drug policy…”(Ritter et al., 2018).

Creating regulatory models

In order to facilitate discussion and input from a diverse group of stakeholders, we created regulatory discussion models for select drugs within four classes (opioids, stimulants, sedatives, and psychedelics). This required us to craft parameters for the conversations we wished to have with stakeholders by focusing our models on limited areas of regulation.

Among the many available regulatory levers discussed in the literature, we categorized each as applicable to all regulated drugs, some as class-specific, and some as applicable to individual drugs or conditions (Haden, 2015). We then isolated five drug-specific regulatory choices that directly influenced (either mitigated or exacerbated) the risks of taking drugs, and – based on a review of the literature – would shape the “front end” or consumer experience of a legally regulated market: (1) who has access to the drug; (2) what must a person do to access the drug; (3) where can a person obtain the drug; (4) what

quantity of the drug could someone get; and (5) where can the drug be consumed.

Within each class of drug, we selected a limited number of substances to represent common consumer choices and less risky alternatives (either because of potency, transmission route, or another factor). For each substance, we reviewed the literature to better understand the risks, benefits and methods of use. We integrated additional health, safety, or social measures into our models as needed given the nature of the substance (for example, providing naloxone to opioid consumers).

Next, three models were designed for each substance along a spectrum from less restrictive to more restrictive, incorporating the five regulatory choices above. For example, access to anyone of legal age was presented as less restrictive than a model requiring a medical diagnosis. One hypothesis we wish to test was that, while certain groups would favour less restrictive models and others more restrictive models, there may be a "middle-ground" choice where the needs of most stakeholders could be met, and that a majority of stakeholders would support. We hoped a spectrum of choices would provide ample space for discussion among those with differing opinions. For those levers applicable to legal regulation generally, we created some overarching recommendations applicable to any legal system in support of public health outcomes (Table 1).

The spectrum of choices for regulatory models

Who has access to the drug?

The spectrum on this issue includes open access on one end and medicalized access on the other. Open access means anyone of legal age can obtain a substance, while medicalized access requires a diagnosed medical condition or a history of drug use to obtain access. Open access helps move the largest segment of people into the legal market and mirrors regulations for alcohol, tobacco and non-medical cannabis, but may increase demand. For medicalized access, barriers limit substances to those most at risk from ongoing use and necessitate interactions with health professionals who provide links to health and social services, but may exclude a large portion of those consuming drugs, many of whom may turn to the unregulated market.

Table 1
Basic controls in a regulated market to support public health outcomes.

- **Minimum Age Requirement:** Like alcohol and tobacco, access could be limited to people over the provincial age of majority (18 or 19). A regulated system must minimize risks to young people who do choose to use drugs, while discouraging use through evidence-based education.
- **Production, Labelling, and Packaging:** High quality standards for production, product content, and maximum dosage should be set and enforced. Packaging should convey relevant health information, and restrictions on advertising should be enforced.
- **Pricing**: Prices must remain affordable for consumers, but high enough to discourage over-consumption. Preferably, demand should be curtailed through education rather than price controls.
- **Diversion**: A well-designed system should minimize diverted supplies. However, the potential for some supplies to be diverted is not reason to reject an otherwise productive scheme. Diversion of regulated products can reduce harm in the unregulated market by providing a safer supply, but it may also cause consumers to forego the legal market.
- **New Consumers:** Regulation should create access for those likely to consume regardless of legality without encouraging new consumers motivated by easy access to a safer supply.
- **Safer Equipment:** Providing safer consumption equipment such as clean needles, sterile water, tin foil, safer smoking kits, and alcohol swabs at the point of distribution is essential. Overdose reversal tools, such as naloxone, should be available to anyone likely to witness an overdose.
- **Decriminalizing Unregulated Market Consumption:** Criminalization creates negative outcomes including stigma and discrimination hindering consumers from seeking harm reduction or other health services. Consumers continuing to access the unregulated market is an indication that the regulatory system needs adjusting, and those consumers should not be criminalized.
- **Privacy:** Because of the historical stigmatization of drug use, consumers are likely to be concerned about personal data being stored and shared. Necessary information should be secured and anonymized where possible.
- **Public Consumption:** Regulations must recognize some individuals do not have access to private spaces to consume substances.
- **Invite Safer Choices:** Different substances within a class of drugs often carry greater or lesser risks. A regulated system should provide scaled controls for access which make it easier for consumers to consume safer substances and encourage safer use practices.

What must a person do to access the drug?

On the most lenient end, there may be no requirements other than proof of legal age. Beyond that, a regulated system may require registration in a program; training and licensing in safer use, alternatives, available mental health and dependence resources, and/or risks of use; or other strategies aimed at educating and monitoring substance use. These could be operated through a non-governmental, non-commercial oversight body. Training programs could train "facilitators" who supervise drug consumption and intervene if necessary. Programs may require periodic refresher training. Perceived privacy issues about registering individuals might be mitigated by including consumers in the design and operation of a training and licensing system.

Where can a person obtain the drug?

Substances with minimal risks may be distributed in restaurants or cafés, in corner stores, or on pharmacy shelves. Riskier substances might be obtained through pharmacists, supervised consumption sites, or secure dispensing machines requiring ID (biometric or otherwise) following registration in a program or with a physician's oversight. Models such as compassion clubs, where consumers cooperatively manage distribution of supply, should also be considered.

Dispensing machines with 24/7 access could reduce reversion to the unregulated market after business hours, increase autonomy around drug use, minimize stigmatizing interactions with health professionals, and allow consumers to take substances in a comfortable environment.

On the other hand, mandating contact with health professionals at points of distribution could facilitate conversations about safer use and be more adaptive to the immediate needs of consumers. Controlling access through pharmacies or consumption sites would reduce diversion to those not authorized to access the legal system.

What quantity of the drug could someone get?

Public health strategies suggest reasonable limits should be placed on how much of a riskier substance can be obtained in order to prevent diversion to unauthorized users and reduce the potential for excessive use (Rolles & McClure, 2009). Although ceilings could be set on how many days' supply an individual could obtain to manage various risks, limits should be negotiated and agreed upon with consumers within such limits in order to ensure their participation in the program. Because the regulated system is intended to attract and retain consumers who would otherwise patronize the unregulated market, and it is reasonable to expect any unmet need will be addressed through the unregulated market, increasing risks to consumers. The mechanisms in place governing access will determine who sets limits and how they are enforced.

Where can the drug be consumed?

On the most lenient end, the answer is anywhere that is allowed by law and local ordinances. Given a choice, people choose to consume drugs in a variety of environments. With alcohol, tobacco and cannabis, there are restrictions prohibiting public consumption which might, but not necessarily, apply to other substances in a regulated system.

To increase control and safety of consumption, the regulated system

may require a licensed facilitator be present, consumption be witnessed at a pharmacy or distribution centre, or that drugs be consumed at a designated consumption venue, which could include medically-supervised sites or merely a licensed venue (as a bar is for alcohol). As with other controls, increased monitoring correlates with increased barriers that could dissuade consumers from participating in the legal system.

Field testing and evolving models

Once developed, our models were initially "field-tested" with stakeholders to receive feedback and suggestions for improvement. The test occurred during a four-day invitation-only research roundtable on legal regulation of substances at the Peter Wall Institute for Advanced Studies in Vancouver, British Columbia, from May 14th to May 17th, 2019. The 39 participants to this meeting included an international group of academics and advocates from six countries (Canada, Australia, UK, Thailand, US, and Mexico) with a primary focus on Canadians, who made up 75% of participants. Participants included five people with lived experience of criminalized drug use. Nearly all participants had an above-average understanding of drug policy and legal regulation of substances, and twenty would be considered experts in the field.

Participants were introduced to the objectives and methodology of the exercise via PowerPoint and were then divided into groups of approximately five. For each of two rounds, each table was assigned one of the four substances under consideration (diacetylmorphine/hydromorphone for injection; oral hydromorphone; poppy tea; and methamphetamine). Each participant was given a colour-coded table presenting: (1) three models for that drug; and (2) some pros and cons of each option. Additionally, each participant was given a questionnaire about their preferred choices, to be filled out at the end of each round. Each table was also given a handout of factual information about the relevant drug. Tables were given 50 minutes to discuss the options and see if they could reach consensus on any aspects of the models. Round two repeated the exercise with a different drug. Following the two rounds, participants regrouped to discuss their choices and comment on the exercise generally. Feedback from this session was compiled and analyzed to identify key trends.

Largely based on this feedback — from both participant comments and our own observation of discussions — we decided to rethink the design of the models in order to further simplify engagement. Coincidentally, after presenting this project at the International Harm Reduction Conference in Porto, Portugal in May 2019, we were invited to conduct a workshop associated with the annual Québec public health conference - *Journées annuelles de santé publique* - in Montréal in November 2019. This necessitated a redesign as the workshop was designed in a "world café" format, limiting us to approximately 20 minutes for each of the three rounds of the exercise, including time to debrief. We were to lead three out of six tables at the café — one each addressing opioids, stimulants and psychedelics. Participation in this workshop was largely comprised of healthcare professionals, with additional participation by people with lived experience of substance use, for a total of approximately 60 people. Tables were comprised of approximately 8 to 10 participants and a facilitator, and at the conclusion of the 20 minutes, participants moved to a different table and topic. As the initial field test allowed 50 minutes to canvass options for each drug, the reduction in discussion time by 60% presented new challenges.

In order to foster a fulsome discussion in the short timeframe, we experimented with designing a role-based, collaborative, negotiation-based board game we've named "The Regulation Game." We hypothesized that a game format would be successful in "jumpstarting" discussions and creating a novel, engaging and interesting way to focus conversations in a limited timeframe. In our view, a game format would also have the potential to diffuse various barriers to considering policy options, including participants' existing value framework and the inherent complexity of legal regulation generally.

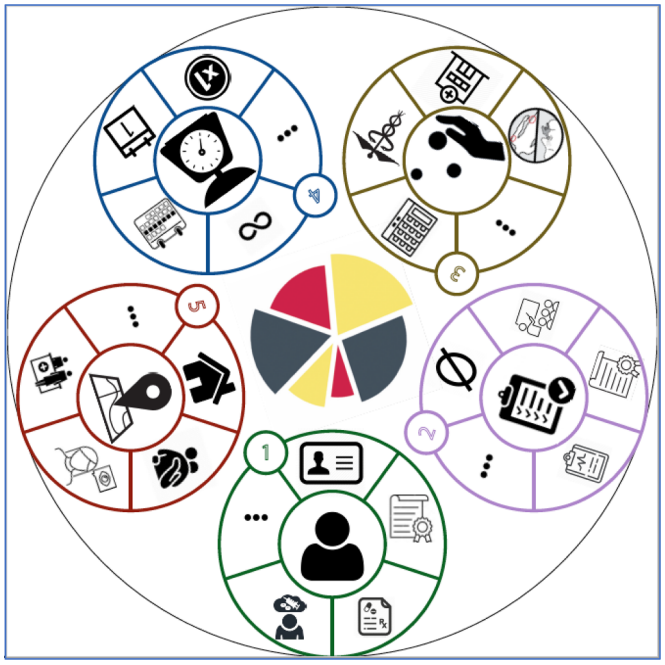

Fig. 1. Regulation Game board.

We adopted the five questions that guided our previous work on the regulation models, which are represented on the game board as five smaller numbered circles. For each question, icons representing four policy options (from more lenient to strict) are within the smaller circle, with an option for a player to introduce their own model if they wish (Fig. 1). We also designed a set of ten characters, which are presented with some personal background, values and starting opinions about some of the regulatory choices (Fig. 2).

Play mechanics of the game are as follows: players choose a character to play, collectively decide which question(s) they want to negotiate and drug they want to focus on and begin staking out their positions by placing pawns on the board. Positions are informed by an "option card" that describes each policy choice, notes some pros and cons, and tracks how well the choice meets (or doesn't) the objectives of legal regulation (Fig. 3). Aided by a facilitator, players introduce themselves as their character and motivations for their particular choices. Once all characters are introduced, each player attempts to persuade others to their position or considers being persuaded themselves using the information presented on the option card and an additional information sheet about the specific drug they are considering. The objective of the game is to attempt to reach consensus on a regulatory model at the table, within the values of one's character (Figs. 4 and 5).

Player negotiation towards a common position around the five questions of legal regulation forms an integral part of the game. The game is designed to be collaborative, highlighting the importance of reaching solutions that most stakeholders can live with rather than what might be their first or optimal choice. If agreement is reached on a particular model, all players collectively win. As there are a limited number of options presented for each question, players are encouraged to be creative in coming up with their own models, whether novel or adaptations of presented models. Additionally, players are instructed to reflect on and share the most important aspects of models they prefer in order to see if those aspects can be ported to another model to reach compromise with other players. We ask players to document any of these necessary conditions they need in place to be in agreement with others.

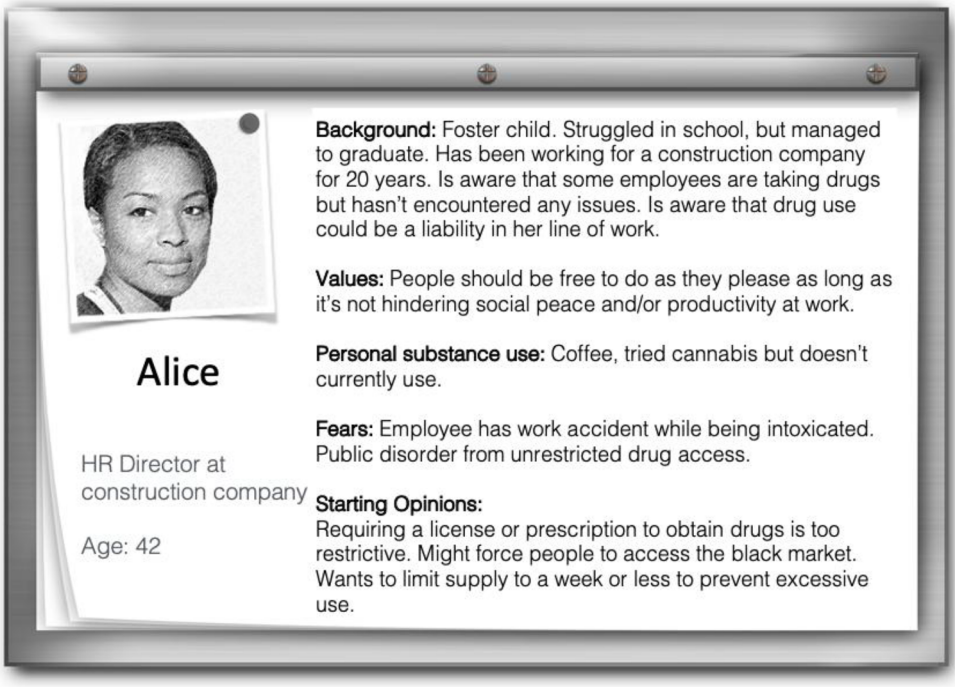

Fig. 2. Sample character bio for the Regulation Game.

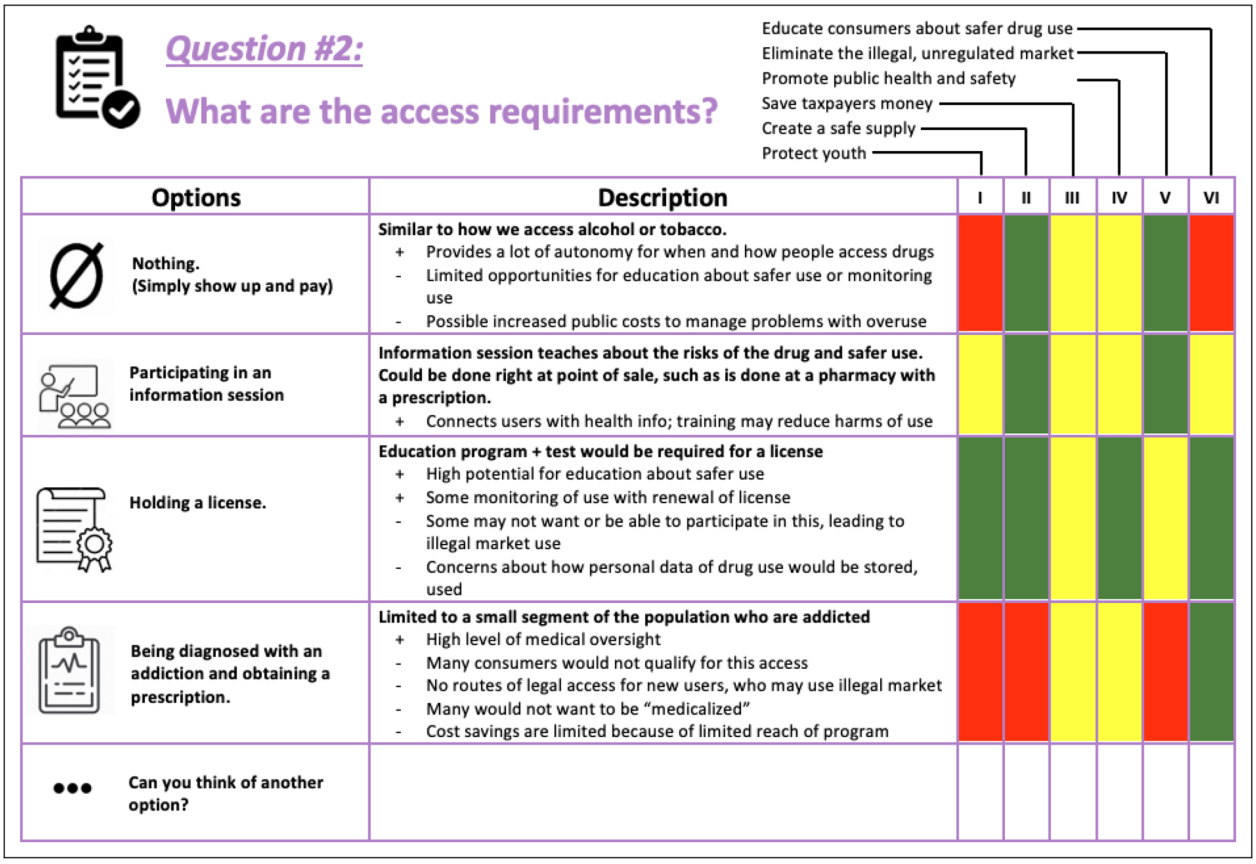

Fig. 3. Option card for question 2 in the Regulation Game.

Fig. 4. Playing the Regulation Game.

Fig. 5. Playing the Regulation Game.

For the Montréal workshop, materials were translated into French where necessary. Each facilitator spurred discussion, recorded outcomes and observations of the session at their table. Following the game play, facilitators reported to the larger group on the choices to which participants gravitated and organized a "debate" between each side of the room on policy alternatives.

Results of stakeholder engagement sessions

The feedback from the May 2019 Vancouver consultation provided important learnings that helped improve our tools for discussion. First, the majority called for removing mandatory interactions with medical professionals in the models as much as possible, because of the potential for stigmatizing interactions. Second, there was a general call to place control and profits in the hands of not-for-profit and non-governmental organizations, rather than allowing the government to run production and distribution. There was also a general sense that multiple means of access should be available for any given drug to allow consumers to choose the option that best suits them. These suggestions caused us to widen the scope of options available and to be less prescriptive in offering model choices moving on. Additionally, stakeholders generally preferred the least restrictive option available, regardless of the drug, which we attributed to the experience base of that select set of participants.

Several participants noted that it would be pragmatic to utilize existing infrastructure as much as possible in order to lower costs. Participants also indicated that it was challenging to evaluate individual drugs in isolation, and recommended including different populations of drug consumers in future engagements, as populations of consumers are not homogenous. Several participants also highlighted the importance of simplicity in conveying information, leading in part to the rationale for exploring other formats such as a game.

Objectives for the November 2019 stakeholder workshop in Montréal were to not only provide an engaging and educational experience for participants, but to playtest the game's functionality. Specifically, we were interested in the level of discussion occurring during and after play, whether the distinction between different regulatory choices was clear, and the extent to which participants creatively collaborated towards a common goal. Contrary to initial concerns raised by the organizers of the event, the majority of participants enjoyed the role-playing aspect of the game and engaged in honest negotiation within the confines of their character's values. Although not precisely tracked as an outcome for this session, consensus was reached at a number of tables on regulatory options despite beginning negotiations from polarized positions. Largely, using the board game as a tool for engagement around our models of regulation was successful in generating thoughtful discussion and consideration of models for legal regulation and presented no obvious hurdles to using this tool for future engagement.

Discussion

Engaging different stakeholder groups on policy choices of legal regulation revealed initial barriers that we feel more confident can be overcome through interesting and innovative tools such as the Regulation Game. The game falls into a category of tools called "civic games," which are designed to engage citizen players with facts, values, and strategies that help to educate them about civic policy issues towards broader collective impact. As noted by Raphael et al. (2010), "games foster civic learning when they help players to develop knowledge, skills, and dispositions that players then apply to public matters in the world outside the game." There are three primary mechanisms at work in the Regulation Game to that end.

First, the adoption of roles not only allows players to see (and argue) things from another's perspective, but also diffuses the social risks of taking a position on a contentious issue. Because it's "just a game," players are given wide latitude to argue positions with which they might be uncomfortable to publicly state in the real world, but are likely to be held by some members of the public.

Second, the game works to circumvent abstraction barriers. Instead of focusing on abstract topics such as the health, moral, or justice value of a drug policy writ large, the game centres discussion around pragmatic choices, such as whether or not making heroin available in the corner store meets or defeats desired health and safety outcomes. Moving away from abstractions appears to lessen barriers based on deeply held beliefs, address fears based on misinformation and myth, and engage people's inherent problem-solving skills.

Finally, limiting the questions and choices at hand lowers the barrier related to engagement with complex problems. Negotiating around five key questions allows players to focus their opinions toward real solutions without becoming overwhelmed by the complexity of the larger problem.

Since its inception, the Regulation Game has been tested with various stakeholders, including informal sessions with youth, municipal government officials, and attendees at a drug policy conference in the United States, and we anticipate using this tool in the future as part of research and education into legal regulation policy options, incorporating appropriate tools for recording opinions and issues raised. Introduction of the game in different environments to date has generated a great deal of enthusiasm and has garnered welcomed feedback on its utility as a tool for a range of policy discussions from racial justice to climate change. Outside the game format, other advocates have

adapted the structure of discussion models for legal regulation that we pioneered to engage different audiences, such as in a meeting of legal regulation experts held via Zoom in fall 2020.

Recently, we developed versions of the game focusing on models of decriminalization and "safe supply." Our intention is to use all three of these games on their own, but also in conjunction with more formal focus group research where participants would play the game for a period and then regroup in a traditional focus group to discuss their own opinions and values (as opposed to their character's). One objective of our efforts at engagement is to collect sufficient input from a wide range of stakeholders that supports specific choices of models. Such data could prove useful for further advocacy efforts with government, media and the public. We are currently engaged in an ongoing research project evaluating participants attitudes and decision-making around safe supply, and the game may prove useful in that research. COVID-19 has, naturally, limited our ability to engage stakeholders in person, but we are currently developing online versions of the games to explore virtual engagement and exploring new opportunities to do so. Updates on the project and access to the game can be found on the Regulation Project website (regulationproject.org).

Conclusion

Legal regulation of drugs in Canada is not a radical concept. Canada currently regulates numerous legal, but risky products and activities. Indeed, legal regulation seems the next logical step for Canada's evolving drug policy to address the ongoing and growing harms of an unregulated market for drugs — many of which come from a risky supply and distribution network. Arguably, it is long overdue to move beyond the question of *whether* we should legalize drugs, towards *how* we should legalize them. Unless we are able to decide on regulatory safeguards for production, distribution and consumption of currently illegal drugs, we will continue to face challenges to public health, human rights, and safety that are inherent in an unregulated market. This includes the unnecessary death of tens of thousands of people. As it is now widely recognized that our current drug control system is broken, it is necessary to devise pragmatic and thoughtful solutions based on fundamental principles and which incorporate extensive feedback and adjustment mechanisms.

Turning the tide on drug policy requires engagement with the public in a non-threatening and purposeful way: introducing people to other perspectives, unpacking the values and beliefs behind opinions, and asking them to compromise on solutions that they can tolerate. Discussion models and the Regulation Game promises to be exciting and important tools for building such engagement from a wide variety of stakeholders, including consumers of drugs.

Ethics

The enclosed work did not require research ethics approval, as it falls into the category of stakeholder engagement and education at this stage of the project.

Declarations of Interests

The authors have no conflicts of interest to declare.

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