MEDICAL CANNABIS AND IMPAIRED DRIVING: PRELIMINARY RESEARCH REVIEW

JUNE 27, 2017

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Executive Summary

As Canada moves towards the legalization of cannabis, the Government of Canada has introduced legislation around driving under the influence of cannabis to create “a new, modern, simplified and more coherent system to better deter drug and alcohol-impaired driving” (Health Canada 2017). While cannabis remains the most widely used illicit substance in Canada, approximately 170,000 Canadians are legally authorized to use cannabis for medical purposes (Hajizadeh, 2016; Health Canada, 2016b). As policy continues to develop in this area, the literature around cannabis and driving risk is rapidly expanding as well (Capler et al., 2017; Beirness and Porath-Waller, 2015; Hajizadeh, 2016). However, much of this work does not thoroughly consider the risk relative to individuals who use cannabis for medical purposes, which has been federally legal since 2001 in Canada. The medical use of cannabis poses distinct concerns when it comes to the accuracy of possible enforcement measures used to identify those driving while impaired.

Situated amid the recent introduction of Bill C-46 (42-1), which deals with cannabis and driving, the current report looks at the issue of impaired driving in the context of medical cannabis use. Key differences between recreational and medical cannabis use include administration, dosing, intent, tolerance, and how effects are experienced. Many medically authorized Canadians use cannabis daily or near daily to manage symptoms associated with their illness and are expected to follow advice from health care providers including safe-use guidelines, such as waiting 4+ hours after consumption, to help eliminate risk of impairment.

Although the proposed driving legislation draws on a tough approach to driving under the influence of cannabis, there is still an ongoing debate within the scientific literature on the most effective and accurate ways to establish a level of impairment, similar to blood alcohol content (BAC). As it currently stands, cannabis detection devices or tests are only able to determine previous use of cannabis through presence of THC, which has not yet proven to be a reliable test of impairment itself. This issue in detection is further complicated when assessing individuals using cannabis for medical purposes, as they may have high levels of THC in their system for long periods after consumption.

When combined, these factors make impairment caused by responsible medical cannabis use unique from recreational consumption. Failing to consider medical users as a distinct group in developing policy may lead to the unfair criminalization of this population or prejudicial restrictions on driving. It is essential to understand potential policy considerations for medical cannabis would not give patients a license to drive impaired, but rather, could recognize the distinct nature of responsible medical cannabis use from non-medical use.
Acknowledgements

A version of this paper was first submitted by Jonathan Zaid as an undergraduate thesis for University of Waterloo’s Knowledge Integration program. Special thanks to thesis project supervisor Jenna Valleriani (University of Toronto), course supervisor Dr. Kathryn Plaisance (University of Waterloo), University of Waterloo’s Department of Knowledge Integration, and The Arthritis Society.

About the Organization

Founded in 2014, Canadians for Fair Access to Medical Marijuana (CFAMM) is a national non-profit, patient-run organization dedicated to protecting and improving the rights of medical cannabis patients. CFAMM’s goal is to enable patients to obtain fair and safe access to medical cannabis with a special focus on affordability, including private and public insurance coverage. For more information, visit CFAMM.ca.

Methodology

The following review represents a comprehensive scoping review/survey of both grey and published literature in regard to medical cannabis use and driving impairment. Searches for peer-reviewed journal articles and dissertations were conducted using the University of Waterloo and University of Toronto online library databases using a combination of key terms, including: "medical marijuana", “medical cannabis”, “impairment”, “THC”, “CBD”, “per se limits”, “driving”, “oral fluid testing”, “medication”, “policy”, and “laws”. The Google Scholar search engine was used to conduct general searches and to identify related organizational reports or other grey literature. Of these reports and articles, abstracts and summaries were assessed for relevance to the topic of cannabis and driving, as well as relevance to medical cannabis use. Once abstracts had been identified as relevant to the topic and deemed to fit within the scope of the report, the full article was accessed. Articles were considered even if they did not explicitly refer to medical uses of cannabis and driving, and focused on cannabis use more generally. The material was reviewed and included based on relevancy to the topic. All searches were limited to those published in English and were not limited by date. Experts and organizations in the field were consulted, including a review of the paper.

Note: The bilingual, complete version of this paper will be released in Summer-Fall 2017
# Table of Contents

**EXECUTIVE SUMMARY** ........................................................................................................... 2  
**ACKNOWLEDGEMENTS** ........................................................................................................... 3  
**ABOUT THE ORGANIZATION** .................................................................................................. 3  
**METHODOLOGY** .................................................................................................................... 3  
**PART 1: BACKGROUND** .......................................................................................................... 5  
  **INTRODUCTION** .................................................................................................................. 5  
  **MEDICAL CANNABIS USE IN CANADA** ................................................................................... 6  
  **PROPOSED LEGISLATION** ..................................................................................................... 6  
  **STEERING THE DISCOURSE** .................................................................................................. 8  
**PART 2: RESEARCH AND CONTEXTUALIZING MEDICAL CANNABIS USE** ....................... 9  
  **PREVALENCE OF IMPAIRED DRIVING** .................................................................................... 9  
  **DRIVING RISKS RELATED TO THC** ....................................................................................... 9  
  **REVIEW OF SCREENING TESTS FOR THC IMPAIRMENT** ................................................. 11  
    **Standardized Field Sobriety Tests** ....................................................................................... 11  
    **Drug Recognition Experts (DRE)** ....................................................................................... 11  
    **Establishing THC Per Se Limits: Blood/Serum Testing** ...................................................... 12  
    **Establishing THC Per Se Limits: Oral Fluid (OF) Testing** ................................................... 15  
  **SPECIAL CONSIDERATIONS FOR MEDICAL USE** .............................................................. 16  
    **Risk of Driving with Chronic Illness** .................................................................................... 16  
    **Administration of Medical Cannabis** ............................................................................... 17  
    **Tolerance** .......................................................................................................................... 17  
    **Mitigation of Risk** .............................................................................................................. 18  
**PART 3: POLICY REVIEW** ....................................................................................................... 19  
  **CURRENT CANADIAN DRUG-IMPAIRMENT LAWS: “EFFECT-BASED”** ........................... 19  
  **INTERNATIONAL MODELS** .................................................................................................. 20  
    **United States** .................................................................................................................... 20  
    **Europe** ............................................................................................................................. 21  
    **Australia and New Zealand** ............................................................................................. 21  
  **CANADA’S APPROACH: THE ROAD AHEAD** ...................................................................... 22  
  **CONCLUSION** ...................................................................................................................... 22  
**REFERENCES** ......................................................................................................................... 23
Part 1: Background

Introduction

Cannabis-impaired driving is a crucial, divisive area of policy that has seen much attention since the Liberal’s call to legalize cannabis in the 2015 federal election (Liberal Party of Canada, 2015). In this report, cannabis-impaired driving refers to the operation of a motor vehicle while one's ability is adversely affected by cannabis use (Beirness and Porath-Waller, 2015). Since impaired driving is an issue that affects all Canadians, it is vital that considerations around enforcement of cannabis-impaired driving prioritize a fair but swift approach to public health and safety. In existing work around cannabis-impaired driving research and policy, the parallel use of cannabis for medical purposes is often overlooked. Medical cannabis use refers to the use of herbal cannabis to treat or manage symptoms of an illness with a specific health-related objective in mind (i.e. pain reduction, muscle relaxation, better sleep, etc.). The medical use poses unique challenges and concerns when it comes to the current impairment evidence base, including the feasibility and accuracy of possible enforcement measures (i.e. oral fluids (OF) or blood testing, standard field sobriety tests (SFST), and Drug Recognition Expert (DRE) tests). Importantly, medical cannabis is used to manage a variety of health-related symptoms to improve an individual’s quality of life, which may be reflected in the way it is administered or dosed and its effect on a person may be different from those who use cannabis for non-medical purposes.

Although impaired driving under the influence of any drug is already against the law under the Criminal Code of Canada and in many provinces, the shift towards legalization has brought the issue to the forefront of both developing research and the media (Criminal Code, 1985). A recent public poll found 84% of the general population citing driving under the influence of cannabis as their main concern around legalization (Navigator Ltd., 2017). In response, the government introduced Bill C-46 in April 2017, which among others things, would expand police powers, authorize new THC detection tools (i.e. roadside oral fluid tests and blood tests) and establish charges related to per se limits of THC in blood (Government of Canada, 2017b).

Despite the government’s tough approach to driving under the influence of cannabis, there is still much debate within the scientific and medical communities on the most effective and accurate way to determine actual level of impairment. Current technology in this realm is limited, allowing the detection of the previous use cannabis (via presence of THC), which is different from the ability to test for actual impairment. The issue around medical users and restricting their ability to drive is complex as many use cannabis daily or near daily, and in these cases, may always have a certain level of THC present in the blood, despite not being impaired. Existing in a complex political landscape, this conversation is infused with various beliefs, misunderstandings and a lack of evidence around impairment in the medical use realm. Thus, in addition to reviewing current research on cannabis and driving, as well as drawing on models being currently used in other jurisdictions, this report also advocates for the importance of precise terminology and responsible public discourse which avoids vague language and misrepresentation of the issue at hand.
Medical Cannabis Use in Canada

Since 2001, the Canadian government has allowed patients to legally possess cannabis for medical purposes on the basis of a health care provider’s authorization (Government of Canada, 2014). The current medical access regime, known as the Access to Cannabis for Medical Purposes Regulations (ACMPR), supplies approximately 170,000 patients through over 45 licensed producers/‘LPs’ (Health Canada, 2016b). The ACMPR has no restrictions on specific conditions or symptoms to qualify for authorization, and the average amount authorized per patient is 2.5/grams per day (Health Canada, 2016b). The medical cannabis system is expected to continue in parallel to the proposed non-medical cannabis market post-legalization, and the concurrent medical regulations are set to be reviewed in 5 years (Government of Canada, 2017a). While Canadians can legally access cannabis for medical purposes under the ACMPR, cannabis users still face stigma and accessing legally often comes with many barriers (Bottorff et al., 2013), including finding a health care provider willing to authorize the use of cannabis, and as such, some may turn to illegal sources to purchase their medicine.

While therapeutic benefits or harms associated with cannabis are outside the scope of this report (see Hill, 2015; National Academies of Sciences, 2017), it is worth noting that a 2013 survey found that 72% (n=439) of Canadian medical cannabis users self-report cannabis as “always helpful” in treating their symptoms, and an additional 24% (n=147) described it as “often helpful” (Walsh et al., 2013). One of the most thorough analysis to date, conducted by the U.S. National Academies of Sciences, Engineering, and Medicine, reviewed over 10,000 articles and concluded strong evidence exists for medical cannabis/cannabinoid use in adult chronic pain, MS related-spasms, and chemotherapy-induced nausea and vomiting (National Academies of Sciences, 2017). As the medical cannabis program in Canada continues to grow at a rapid rate, so does the need to have unique impaired driving policy that considers the distinct, safe use of medical cannabis.

Proposed Legislation

The proposed impaired driving legislation (Bill C-46) would create “new and stronger laws to punish more severely those who drive while under the influence of drugs, including cannabis” (Health Canada, 2017) and would enact new criminal offenses for driving with THC blood concentrations over a specified limit (Government of Canada, 2017b, p. ii). It would also allow police to more easily submit drivers to drug recognition expert examination and/or drug screening tests. If passed as originally proposed, Bill C-46 and its forthcoming regulations would legislate the following changes (see next page):
**Figure 1 – Proposed Offenses (Bill C-46)**

**Roadside oral fluid drug screening devices**

- Following a legal roadside stop, an officer could administer a roadside oral fluid drug test if they have reasonable suspicion that a driver has drugs in their body.
- Once the officer establishes reasonable grounds that an offence has been committed (i.e. failed drug screen test), the officer could then demand the driver submit to a drug recognition expert evaluation or a blood sample.

**Establish *per se* offenses for THC**

- **2 nanograms (ng) but less than 5 ng/ml of THC:** Between 2-5 ng of THC per millilitre (ml) in blood (within two hours of driving) would result in a summary conviction criminal offence, punishable by a maximum fine of $1000.
  - “This lower level offence is a precautionary approach that takes into account the best available scientific evidence related to cannabis” (Health Canada, 2017)
- **5 ng or more of THC:** 5 ng/ml or more of THC (within two hours) of driving would result in a “hybrid” offence.
  - Depending on the severity of the offence, the charge may be prosecuted either by indictment or by summary conviction.
- **Combined THC and Alcohol:** A hybrid offense would also be established for drivers with a combined blood alcohol concentration of 50 mg/100ml of blood and a THC level above 2.5ng/ml blood (within two hours of driving).

**Penalties**

- Both hybrid offences would be punishable by mandatory penalties of $1,000 for a first offence and escalating penalties for repeat offenders (e.g., 30 days imprisonment on a second offence and 120 days on a third or subsequent offence).
- The maximum penalties would mirror the existing maximum penalties for impaired driving. These would be increased in Part 2 to two years less a day on summary conviction (up from 18 months), and to 10 years on indictment (up from 5 years). The latter would make a dangerous offender application possible in appropriate circumstances.

*Chart adapted from: (Government of Canada, 2017b; Health Canada, 2017)*
Steering the Discourse

Current nomenclature related to cannabis-impaired driving is problematic, imprecise, and often does not accurately represent the issues at hand. Often coloured by a misunderstanding of the complexities of the cannabis plant itself, shifting the dialogue to include more precise language is important to improving the clarity of these issues around driving as well as policy development.

The *Cannabis sativa* plant contains over 100 active ingredients, known as cannabinoids, which vary in potency from strain to strain (Russo, 2011). ‘Cannabis impairment’ generally refers to the impairment caused by THC, the cannabinoid responsible for the stereotypical ‘high’ or ‘psychoactivity,’ rather than cannabis as a whole. Explored further below, patients using cannabis for medical purposes may use different types of cannabis (i.e. CBD strains) that are non-impairing or administer cannabis differently than a recreation user (Russo & Guy, 2006).

The term “impairment” is widely used but is not always clearly defined. For example, in the government backgrounder and preamble for Bill C-46, the government’s aim is targeted at drug ‘impaired’ driving, yet the proposed legislation refers exclusively to testing for *presence* of THC in saliva and blood - not impairment per se (emphasis added; Health Canada, 2017). Correlating specific levels of THC present in bodily fluids to levels of impairment has not been studied within the context of long-term medical use, and is still debated related to recreational use (Capler et al., 2017). When speaking of impairment, crucial to this dialogue is speaking to the *actual* impairment of cognitive, psychomotor, and other functions necessary to safely drive – not simply a measure of previous use. A measure of previous use does not actually indicate impairment or risk to driving and is further complicated by daily or regular use.

Closely related, the phrase “driving under the influence” is overly broad, may include users who are not impaired but have detectable levels of a drug (i.e. THC) within their system, and is commonly confused with impairment (Royal Canadian Mounted Police, 2013). Although there is little doubt that driving under the influence of THC can impair driving in certain instances and doses – there is also evidence that demonstrates simply having a detectable level of THC from previous cannabis consumption is not necessarily indicative of driving impairment or accident risk (Capler et al., 2017; Compton and Berning, 2015; Crean, Crane, and Mason, 2011; Freidel et al., 2015; Kelly, Darke, and Ross, 2004; Logan, Kacinko, and Beirness, 2016). Given the complexity of this issue, a fair question asks: if a patient who previously consumed medical cannabis had small amounts of cannabis/THC remaining in their blood or oral fluid but didn't show any signs of impairment (i.e. slow reaction times), are they still “under the influence” of cannabis?

There are no straight forward answers available in the scientific literature, yet it is crucial to identify at what point patients are *impaired* by their cannabis use - not simply if they have previously consumed cannabis or have presence of THC in their body. Moreover, with the absence of reliable and enforceable tests that can accurately determine impairment (Owusu-Bempah, 2014), it is likely that medical cannabis users, in particular, will be unfairly criminalized, further catalyzed by existing evidence excluding the distinct use of cannabis as medicine.
Part 2: Research and Contextualizing Medical Cannabis Use

Prevalence of Impaired Driving

Cannabis-impaired driving in Canada is a widespread concern, but its prevalence is hard to estimate and especially so when referring to medical use related impairment. The Canadian Alcohol and Drug Use Monitoring Survey (CADUMS) demonstrates 2.6% of Canadian drivers reported driving within two hours of using cannabis in the previous year (Health Canada, 2013 as cited in Beirness & Porath-Waller, 2015). Further, random roadside sampling (n=2500) found that 5.8% of drivers tested positive for THC (over 2ng/ml THC in OF) with a mean concentration of 23.9 ng/ml THC in OF (Beirness and Beasley, 2011, p. 12). Similarly, a survey of experienced cannabis users in Toronto (n=104) found that roughly two-thirds had ever driven under the influence of cannabis, 20% reported using in their cars within the past three months, and up to 40% reported using cannabis in someone else’s vehicle (Hathaway, 2004). This may be attributed to a lack of perceived risk among experienced recreational users (Hathaway, 2004). In the most current review of cannabis and driving, Capler et al. (2017) speak to some of the implications of new laws in Canada for medical users, citing the potential for the unfair criminalization for a prescribed medication and the consideration that using cannabis to treat particular symptoms may allow medical users to drive more safely. No studies were found to have measures specific to medical use of herbal cannabis and impaired driving prevalence.

Driving Risks Related to THC

While the precise risk of cannabis-impaired driving remains a highly-debated issue (Armentano, 2011; Hartman and Huestis, 2014; Sewell et al., 2009), there is a consensus among scholars that acute consumption of THC likely causes an increased motor vehicle accident risk. A meta-analysis by Li et al. (2012) reviewed 9 studies and concluded an odds-ratio (OR) of 2.66 (2.6x or 266% increased risk), however these studies were mainly based on previous consumption of THC by testing urine for THC metabolites (THCCOOH and 11-OH-THC), which are detectable much longer than THC (possibly weeks) and accordingly, their presence do not demonstrate consumption of THC caused the accident (Armentano, 2011). A similar meta-analysis done by Asbridge et al. (2012) found an increased risk of motor vehicle collisions compared with unimpaired driving with an OR of 1.92. A comprehensive meta-analysis by Rogeberg and Elvik (2016) included two major reviews of the evidence: Study 1 re-analyzed results from the 2012 meta-analyses by Li et al. and Asbridge et al.; and Study 2, which reviewed 21 various published studies. The authors found that "acute cannabis intoxication is associated with a statistically significant risk increase of low-to-moderate magnitude" (p. 1348) and concluded that the odds-ratio (OR) for cannabis-impaired driving crash risk was 1.18 for studies that had controlled for alcohol and 1.22 out of all studies analyzed (Rogeberg and Elvik, 2016). Interestingly, the authors also noted that:

> While our estimates suggest that the impact on crash rates would be low to moderate, even if this argument were correct we would stress that such simple extrapolations are unlikely to be robust to larger policy changes: driving under the influence of legal cannabis would probably be made a direct target for policy, leading to efforts with documented effects from the alcohol field. (p. 1357)
The heterogeneity among these studies can be attributed to a few factors. The first major factor is most studies test for THC metabolites, which can last in the body for weeks after use and are not indicative of impairment (Asbridge et al., 2014). Secondly, there is no differentiation between medical or recreational use and many studies do not include adequate control groups (i.e. drivers in general population compared to MVA subjects or healthy drivers compared to ones with an illness). Further, some of these past studies may not have adequately controlled for the combined presence of alcohol use, which is thought to have a much higher combined risk than alcohol or cannabis use alone (Asbridge et al., 2014; Fischer et al., 2011).

On the contrary, the U.S. National Highway Traffic Safety Administration conducted the first large-scale case-control study of MVA risk from presence of THC demonstrated the importance of proper controls; after adjusting for alcohol consumption and demographic factors including age, gender and ethnicity, they concluded THC has an odds-ratio of one (meaning there was no increased risk from presence of THC after controlling for other factors) (Compton and Berning, 2015).

There is some literature that has assessed the impact of pharmaceutical cannabinoids on driving outcomes. A 2012 study explored the effects of Dronabinol, a synthetic pharmaceutical version of THC, and found that both occasional and heavy users of the drug had greater measures of weaving compared to alcohol-impaired drivers with a BAC of 0.5 mg/ml and a smaller magnitude of overall impairment was found in heavy users (Bosker et al., 2012). However, this study included small sample size (n=24) and drew on participants that were not using cannabis for a medical reason.

In a pilot observational study by Freidel et al. (2015), researchers followed 33 multiple sclerosis (MS) patients and tracked various driving performance measures over a four to six-week course of nabiximols, a pharmaceutical phytocannabinoid-based medicine with a 50:50 THC and CBD ratio. The authors concluded nabiximols treatment possibly improved moderate to severe treatment-resistant MS spasticity, demonstrated drivers taking the drug remained fit to drive, and found improved driving performance in stress tolerance tests (a measure of reaction time and attention) (Freidel et al., 2015). This was the only study exploring how the impairment of medical cannabis affects people with illness – and beyond demonstrating no impairment, it showed possible signs of improved driving.

Although there is concern legalization will cause increased cannabis-impaired driving, it is worth considering US jurisdictions which have legalized medical cannabis have recorded an 8-11% drop in traffic fatalities one year following medical cannabis legislation (Anderson, Hansen, & Rees, 2013). Anderson et al. (2013) attribute the drop in traffic fatalities to people using cannabis as a substitute for alcohol. Other studies have also demonstrated that patients report reducing the consumption of other impairing drugs, notably alcohol, opioids, and benzodiazepines with their use of cannabis (Bradford and Bradford, 2016; Lucas and Walsh, 2017). The impact of substitution has not been explored within the context of driving safety.
Again, most of the studies on driving safety and cannabis use were not specific to medical use. The majority of studies calculate odds-ratios and risk based on comparisons to healthy drivers with no drugs present in their system. Further research specific to medical cannabis use is needed.

Review of Screening Tests for THC impairment

Standardized Field Sobriety Tests

The Standardized Field Sobriety Tests (SFST) were originally designed to detect alcohol-related impairment and consists of three different tests: Horizontal Gaze Nystagmus (HGN) test, Walk and Turn Test and the One-Leg Stand Test. In the previously mentioned Bosker et al. (2012) dronabinol study, impairment was detected in all treatment categories but when the SFST was administered, it did not detect presence of THC or impairment in any group. The authors came to the conclusion that the SFST is not effective in detecting THC-related impairment (Bosker, Kuypers, et al., 2012).

Another study with regular cannabis users found the SFST was mildly sensitive to determining THC presence on certain measures, namely the one-leg stand test (Bosker, et al., 2012). Bosker et al. 2012 found similar results to other studies: cannabis only adversely affected performance on the OLS test but neither the WAT or HGN tests (Porath-Waller and Beirness, 2014). It appears that SFST are not fully suited to cannabis-related impairment and additionally have not yet been evaluated for medical cannabis patients.

Drug Recognition Experts (DRE)

The International Association of Chiefs of Police Drug Evaluation and Classification (DEC) Program certifies police officers to become Drug Recognition Experts (DREs) that “are trained to conduct a systematic and standardized 12-step evaluation consisting of physical, mental and medical components” ("7 Drug Categories" - IACP DEC Program, n.d.). DREs are trained to detect presence of drug and classify the use into seven categories of drugs, including cannabis and alcohol. The 12 steps DRE’s use to determine presence and class of drug are ("12 Step Process"- IACP DEC Program, n.d.) :

1. Breath Alcohol Test
2. Interview of the Arresting Officer
3. Preliminary Examination and First Pulse
4. Eye Examination
5. Divided Attention Psychophysical Tests
6. Vital Signs and Second Pulse
7. Dark Room Examinations
8. Examination for Muscle Tone
9. Check for Injection Sites and Third Pulse
10. Subject’s Statements and Other Observations
11. Analysis and Opinions of the Evaluator
12. Toxicological Examination
As the DRE evaluation is meant to detect various classes of drugs in the system, not all tests conducted by DREs apply equally to cannabis impairment. One of the largest evaluations of cannabis-only DRE cases to date found that the most reliable impairment indicators included, “elevated pulse, dilated pupils, LOC, rebound dilation, and documented impairment in 2 of 4 psychophysical tasks” (Hartman, Richman, Hayes, & Huestis, 2016, p. 227). Similarly, an exhaustive evidence review conducted by Capler et al. concluded that,

...while [SFST and DRE] observational tests may indeed identify impairment, they fail to meet minimal standards for sensitivity or specificity for identifying impairment related to cannabis use. As such, these tests do not satisfy fundamental criteria of test validity, especially given that these tests have serious implications for individuals designated as impaired and are meant to be used as tools to improve road safety” (2017, pp. 32).

A report by the American Automobile Association supported the above conclusion by Capler et al. (2017), finding low levels of specificity and sensitivity for DREs related to impairment and levels of THC in blood (Logan et al., 2016). While DRE’s may be able to identify previous use of cannabis, the high possibility of false positives and subjectivity remain problematic. Accordingly, DRE evaluations resulting in criminal charges should still be viewed with caution in instances with little corroborating evidence.

Once again, this area of research has not yet been aimed specifically at medical use (see review by Neavyn et al. 2014) and potential bias towards patients prescribed cannabis would not be surprising based on stigma and misunderstanding. If DREs are to become more prevalent, it is necessary to conduct further research to ensure their examinations are accurate for medical cannabis patients that have developed tolerance and other considerations.

Establishing THC Per Se Limits: Blood/Serum Testing

Per se limits refer to a specific concentration of a substance (i.e. THC in blood or blood alcohol concentration/’BAC’) that trigger a criminal charge when the set limit/cut-off is exceeded (i.e. 0.05 Blood Alcohol Concentration or BAC). Per se limits, however, do not factor in impairment and may result in criminal charges for any user who exceeds the limit, even if no signs of impairment are demonstrated. Contrarily, if a user demonstrates impairment but remains below the cut-off, they will not be criminally charged under per se laws.

For police to be able to conduct a legal blood or oral fluid test as proposed in Bill C-46, officers must have reasonable grounds to suspect that a person “has alcohol or drugs in their body” to submit drivers to tests (Government of Canada, 2017b). A key consideration which addresses the intersection between enforcement and citizen rights includes transparency in how police officers will establish “reasonable grounds” to initiate an assessment of impairment. Although the necessity to establish reasonable grounds can act as a potential safeguard against random testing, these grounds, such as smell of cannabis, are not always indicative of impairment at the time of driving. There are important concerns that what is considered ‘reasonable’ is up to the
police officers discretion, which can lead to unequal targeting and application of these new laws, particularly for medical users.

The most problematic policy concern when it comes to medical cannabis-impaired driving is determining what specific per se limit could be set that would also factor in distinct medical use and high inter-individual variability. As one example, a study by Johnston et al. (2012) demonstrated that “permit holders” for medical cannabis use in California were significantly more likely than non-permit holders to test positive for THC – even among heavy or regular non-permit users, concluding that, “police officers may need to modify their enforcement effort to apprehend cannabis-impaired drivers based on medical cannabis legislation” (Johnson et al., 2012, pp. 109).

An in-depth report by the American Automobile Association (Logan, Kacinko and Beirness, 2016) compared roadside testing and impairment to blood levels of THC and found that blood concentrations of THC did not accurately correlate to impairment or roadside evaluation measures (i.e. SFST and DRE). The AAA report concluded per se limits of 5 ng/ml THC are not scientifically supported and would (a) criminalize drivers who exceed the limit but are not impaired and (b) would miss catching drivers who are impaired but are under the per se limit (Logan et al., 2016). Contrarily, other research has concluded per se limits between 2-10 ng/ml may be appropriate. In an epidemiological study that also reflects the government’s proposal in Bill C-46, Ramaekers et al. (2006) found significant impairment correlated to THC blood concentrations between 2-5 ng/ml after acute use, recommending this as a lower and upper range of THC for impairment per se limits. A meta-analysis of experiential studies by Grotenhermen et al. (2007) found that a higher level of THC in blood (7-10 ng/ml) correlated to impairment similar to a BAC of 0.05%, and concluded this range might represent a suitable per se limit. Although a very limited amount of evidence exists related to driving impairment functions related in medical cannabis users, the authors concluded that a range of 7-10 ng/ml reduces the chances of medical users from being unfairly subject to per se limits (Grotenhermen et al., 2007).

While a lower per se limit has the potential to over-criminalize medical users, raising the limit higher than 2-5 ng/ml may not catch novice or infrequent cannabis users who are impaired (Johannes G. Ramaekers et al., 2006). An epidemiological study over ten years found that setting a per se limit at 5 ng/ml would result in a majority of recent cannabis users going undetected and recommended a zero-tolerance approach to per se limits (Jones, Holmgren, and Kugelberg, 2008). However, the authors also noted a zero-tolerance approach might essentially ban regular users (i.e. patients) from driving regardless of impairment.

Conversely, the reason why per se limits (0.05-0.08 BAC) for alcohol make sense is that they have well-established links to significantly increased MVA risk (OR 2.07-3.93 respectively) and impairment through extensive research (Compton and Berning, 2015, Logan et al., 2016) and, “alcohol levels, which have linear pharmacokinetics, are easier to back-calculate to the time of the accident, and are consistently linked with increased culpability in crashes” (Sewell, Poling and Sofuoglu, 2009: p. 6).
It has been well established that regular cannabis users have different metabolism and distribution of THC than that in occasional users, leading to prolonged excretion of THC from lipid cells (Health Canada Government of Canada, 2012, Huestis, 2007). The current evidence base is cause for concern as the impaired driving literature has almost solely studied acute use, yet there are notable differences between acute and regular consumption. This has been illustrated in a few studies to date, such as Toennes et al. (2008) who followed 12 heavy users and found that the THC concentrations in abstinence/sober phases matched that of occasional users after acute use. This demonstrates that even though regular users may have THC in their blood that matches that of acute use, the impairment caused by their level of THC does not correlate to the same level of THC in acute users. Schwilke et al. (2009) followed participants over seven days and exposed them to sustained doses of oral cannabis and found that 22.5 hours after the last dose administration, the mean blood concentration was 3.8 ng/ml THC. These results suggest that even after 22.5 hours of consumption abstinence, many patients consuming oral cannabis would exceed a 2 ng/ml per se limit and some would exceed a 5 ng/ml limit. Finally, a similar study by Karschner et al. (2009) followed 18 participants over 7 days of monitored abstinence and found about 22% of participants would have exceeded the 2 ng/ml per se limit, and at least one would have exceeded the 5 ng/ml per se limit 7 days after consuming oral THC (Karschner et al., 2009 - see Figure 2 below).

Similar results were found by Skopp et al. (2002), which demonstrated a portion of regular cannabis users would exceed the limit 1-2 days following inhaled cannabis use. Based on these studies, regardless of actual impairment, long-term medical cannabis patients would have to wait at least a week after last orally consuming THC to ensure a per se limits would not be exceeded, and no criminal charges would result.

Patients regularly using medical cannabis may have different tolerance, strains, and methods of administration than recreational users – a key area yet to be well explored. Raising the limit to the point that would allow non-impaired, daily medical cannabis users to drive would also likely result in riskier, occasional users being able to drive without being caught. Put simply, there is no scientific basis for any per se limit that would accurately relate to impairment in all populations,
leaving per se limits as primarily arbitrary decisions that likely will leave a portion of the population unfairly disadvantaged – most likely patients. The proposed THC limits of 2 ng/ml and 5ng/ml would essentially bar daily users of medical cannabis from driving without prolonged periods of abstinence (1+ week for oral use, 3+ days for inhaled). Even a responsible patient who never drives while impaired and follows safe-use guidelines to mitigate risk would be left with the decision to either (a) continue driving and risk exceeding the per se limit, (b) never drive, (c) or stop using cannabis. Although driving is a privilege and not a right, people with medical conditions that include mobility challenges, such as severe arthritis, have a genuine need for vehicles to go about their daily activities. Discontinuing cannabis altogether may result in patients switching back to other medications such as benzodiazepines or opioids – neither of which are currently subject to per se limits even though they may cause impairment.

The Canadian Association of Chiefs of Police (CACP 2017a,b) has been advocating for changes to the Canadian impaired-driving landscape. Especially considering the government’s proposal to establish per se limits for THC, it is significant to note that the Chiefs of Police did not endorse the use of per se limits, stating:

Evidence-based permissible limits are not defined and supported by science. There is no evidence that “per se” limits adequately quantify impairment and therefore we are concerned with regards to potential challenges within our judicial system. We know with cannabis that people react differently to its effects. Per se limits must be research-based and the science must catch-up to strengthen their credibility (Canadian Association of Chiefs of Police, 2017a, p. 4)

The Association also cited concerns around too few Drug Recognition Experts due to the high training costs ($17,000 per officer) and requested increased government funding to train officers in the context of cannabis legalization (Canadian Association of Chiefs of Police, 2017a).

Establishing THC Per Se Limits: Oral Fluid (OF) Testing

In addition to establishing per se limits and charges, Bill C-46 would also enable police to use roadside oral fluid (OF) testing devices when an officer reasonably suspects someone to have drugs in their body (Government of Canada, 2017b). The OF test would help police establish recent use and a positive THC test would assist officers in establishing reasonable grounds that an offence has been committed (Health Canada, 2017).

At time of publication, the government has yet to announce what specific cut-off level of THC in OF would yield a pass/fail on the roadside test. One difficulty in setting an OF cut-off is how to extrapolate THC presence in OF to blood, and although some calculations do exist, there is significant inter-individual variability (Desrosiers et al., 2012; Gjerde et al., 2014). A randomized cross-over, double-blind placebo-controlled study of occasional cannabis users also found that smoked cannabis had a high degree of inter-individual variability between the relationship of THC detected in blood and THC detected in OF, meaning different people had wide-ranging levels of THC in their system from similar doses of cannabis (Marsot et al., 2016). Additionally, currently available OF testing devices have a false positive rate of 3-7%, so charges should not be directly applied due to their potential for error (Beirness and Smith, 2017).
Special Considerations for Medical Use

Risk of Driving with Chronic Illness

The impaired driving risk among medical cannabis patients and recreational users is also influenced by the fact that medical cannabis patients are concurrently dealing with health-related symptoms and, often, the use of other medications. Medical conditions themselves have been demonstrated to increase the risk of motor vehicle accidents (Charlton et al., 2010). Impairing conditions carrying an estimated increased crash risk of at least double (OR 2.0+) include dementia, epilepsy, multiple sclerosis, psychiatric disorders (considered as a group), schizophrenia, sleep apnea, and cataracts (Charlton et al., 2010). A population study of older drivers found that other conditions carried risk too, including those suffering from heart disease (OR 1.5), stroke (OR 1.9), or arthritis in females (OR 1.8) (McGwin et al., 2000). It is worth considering that many of these estimated odds-ratios are higher than those of acute cannabis impairment (Asbridge et al., 2012; Rogeberg and Elvik, 2016). Further, the most common symptoms being treated with medical cannabis may be impairing in and of themselves, including sleep onset insomnia (OR = 1.87), tiredness (OR = 1.36), anxiety (OR = 3.15), and depression (OR = 2.43) (Sagberg, 2006; Walsh et al., 2013). This demonstrates that driving impairment for medical cannabis users is a multi-faceted issue which cannot be extrapolated from recreational use and driving risk.

Additionally, tightly coupled to these circumstances includes a discussion of how policy deals with other prescribe medications in the driving context, some of which cause increased driving risk. Health Canada's data shows that 22% of Canadians used psychoactive pharmaceuticals in 2013, a rate that remains unchanged from the previous year (Health Canada, 2015). Even drugs generally thought of as non-impairing, such as anti-inflammatory drugs (OR = 1.7), angiotensin converting enzyme inhibitors (OR = 1.6), and anticoagulants (OR = 2.6), have been demonstrated to increase risk of MVA (McGwin et al., 2000).

Surprisingly, although one may suspect opioids to result in increased driving risk, long-term or “managed” usage of opioids in patients with chronic pain has been demonstrated to carry little or no increased risk compared to healthy controls (Byas-Smith et al., 2005; Compton & Berning, 2015; Fishbain et al., 2003). This may be attributed to the fact that opioid users develop tolerance to side effects and the treatment of a chronic condition could potentially lower impairment from such condition (Schumacher et al., 2017).

Benzodiazepines, which are generally used for anxiety and sleep, were found to carry increased risk in a meta-analysis (with an OR of 1.6) (Rapoport et al., 2009). Further, the co-use of particular substances also deserves consideration, where this study additionally found that the co-administration of alcohol and benzodiazepines is extremely dangerous, with an OR of 7.69 (Dassanayake et al., 2011).

As previously mentioned, multiple studies demonstrate patients are using cannabis in place of many of these drugs including alcohol, opioids, and benzodiazepines (Bradford and Bradford, 2016; Lucas and Walsh, 2017; Mikuriya, 2004; Reiman, 2009). This raises the possibility that by using cannabis as a substitute for extremely impairing drugs, such as benzodiazepines and alcohol, patients may reduce an individual’s risk for MVA.
The complexities of driving and drug impairment are furthered when it comes to illness and medication. In the near future, the legal dual-use of cannabis for both medical and non-medical purposes will create a paradigm not seen elsewhere. Given the ability for symptoms to cause impairment, people suffering from illnesses must be given separate consideration. Even though THC carries the risk of impairment, the net benefit from reducing symptom-related impairment in medical cannabis patients may demonstrate results similar to opioid impairment studies where long-term managed doses do not demonstrate increased MVA risk.

Administration of Medical Cannabis

The most prevalent and researched cannabinoids are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). While THC has therapeutic benefits including analgesia, muscle relaxation, and anti-inflammation, it also is responsible for inducing the stereotypical "high" and impairment associated with cannabis (Crean et al., 2011, E. B. Russo, 2011). As a non-impairing cannabinoid, CBD has gained much attention recently and is thought to have analgesic, anti-oxidant, and anti-consultant effects and has, “modulatory effect on THC-associated adverse events such as anxiety, tachycardia, hunger, and sedation in rats and humans” (Russo, 2011, p. 1348; Dalton et al., 1976).

Although there are no specific studies measuring CBD-related to driving, it is unlikely that the drug by itself would carry much, if any, MVA risk due to its non-impairing proprieties. Patients may also consume CBD alongside THC, which could reduce impairment, as demonstrated in the nabiximols study previously discussed (Freidel et al., 2015).

Vaporization has become the most prevalent form of medical cannabis administration, with 53% of Canadian medical cannabis patients using vaporizers as their primary method of administration (Shiplo et al. 2016). Vaporization heats up dried cannabis to a temperature just below the point of combustion, thus being a preferred and safer alternative to smoking. The effects of inhalation can be felt within minutes, allowing easy dose titration and management of sudden symptoms, such as seizures or breakout pain (Abrams et al., 2007, Health Canada, 2012, Shiplo et al., 2016). Oral use, such as the consumption of a cannabis infused food product, is less popular than inhaled, with about 30% of patients self-reporting oral cannabis consumption (Shiplo, 2015). The peak effects from oral use can be felt within 30-180 minutes, with effects lasting up to 6 hours with high variability between individuals (Health Canada Government of Canada, 2012, Walsh, Nelson, & Mahmoud, 2003).

Tolerance

While patients frequently report development of ‘tolerance’ to THC and its side effects from regular use of medical cannabis, this area has yet to be adequately explored in most impaired driving literature. As Ramaekers et al. (2004) states,

The experimental approach has been mostly limited to studies assessing the acute effects of THC on performance, i.e. the effects of THC on performance after a single dose. Experimental data on performance effects after repeated doses of THC is generally lacking [i.e. as in a medical user]. As a consequence, it is currently not known whether THC users adapt to acute effects of this drug as a result of tolerance. Neither have the effects of THC been systematically
Further, and perhaps most importantly, a 2006 study demonstrated the importance of considering tolerance and found drivers who claimed to be regular users of cannabis were less often judged as impaired, but there was no difference in THC concentration between regular users and non-regular users (Khiabani, 2006). These results demonstrate the possible effects of tolerance as both regular and inexperienced users had equal THC concentrations, but the regular user group demonstrated decreased frequency and levels of impairment. Again, this is important because regular users of medical cannabis may have THC concentrations that do not correlate to impairment caused by occasional or acute use, which ultimately leads to problems when setting a specific level of THC-related to *per se* charges.

Another study, although outdated, found that tolerance to side-effects was developed after sustained dosing (4+ days) of THC. Further, they concluded that CBD produced no side-effects and was virtually the same as placebo (Jones, Benowitz and Herning, 1981). Future research related to sustained administration and tolerance to whole plant THC, CBD, and a combination of both should be strongly considered.

Contrary to these reports, other research has found that history of use and tolerance made no significant difference on impairment (Ramaekers et al., 2016). However, the study had several limitations including a population of combined cocaine and cannabis users, no medical focus, and the administration of inhaled cannabis only one hour prior to performance testing, whereas patients are instructed to follow safe-use guidelines including waiting 4+ hours after inhaling cannabis/THC to drive (College of Family Physicians of Canada, 2014; Ramaekers et al., 2016). The lack of sub-group differentiation, particularly regarding experienced medical cannabis patients with tolerance to THC, has become a fatal error in much of the cannabis-impaired driving research. It is necessary for research and policy to consider tolerance in relation to medical use as a major factor when considering levels of impairment.

**Mitigation of Risk**

The mantra of medical cannabis dosing is “start low, go slow” to obtain maximum clinical benefit with the smallest dose possible. Health Canada’s (2016a) dosage fact sheet states that, “doses of THC as low as 2.5–3 mg of THC (and even lower) are associated with a therapeutic benefit and minimal psychoactivity” and that “acute effects generally peak between 3 and 4 hours after dosing and can last up to 8 hours or longer (e.g. 12–24 hours).” For most patients, the goal of medical cannabis use is not to experience its psychoactive effects, but rather to treat or manage symptoms of an illness using the smallest effective dose.

When it comes to driving, The College of Family Physicians of Canada’s evidence-based recommendations/safe-use guidelines on cannabis prescribing (2014) advises that patients wait, “four hours after inhalation, six hours after oral ingestion, and eight hours after inhalation or oral ingestion if the patient experiences euphoria” (p. 13) before driving. These recommendations are somewhat general as both dose and cannabinoid content are relevant, with some patients using very small/micro doses or non-impairing CBD rich strains. It is also important for physicians and patients to know these recommendations are based on impairment, not recent use, and will not
ensure patients remain below future per se charges as proposed in Bill C-46, which could apply regardless of impairment. With that said, safe-use guidelines are essential to ensuring patients can balance their medical cannabis consumption and the ability to safely drive when not impaired.

Part 3: Policy Review

Cannabis impaired driving is a significant and highly charged policy issue. Coupled with surveys demonstrating the number one concern among Canadian citizens is cannabis-impaired driving, there is mounting political pressure to ensure legalization results in minimal harms to public health and safety (Navigator Ltd., 2017, Pace, 2016). This section will explore the current policy landscape in Canada and internationally, and consider implications related to Bill C-46.

Current Canadian Drug-Impairment Laws: “Effect-based”

Since 2008, the criminal code has enabled law enforcement to screen drivers for impairment using Standardized Field Sobriety Tests (SFST), evaluation by a Drug Recognition Expert (DRE), or to provide a sample of blood, urine or oral fluid to test for presence of drugs (including cannabis) (Beirness and Smith, 2017). If a police officer has reasonable grounds to suspect impairment by drugs or alcohol and conducts a legal traffic stop, they can conduct an SFST at the roadside (Criminal Code, 1985, 254(2)). Although the results of the SFST are not used to charge drivers directly, they allow officers to collect evidence that can then be used to force drivers to submit to a DRE evaluation which includes blood tests (Solomon and Chamberlain, 2014). The DRE can be used to confirm initial findings of the SFST, and if drug impairment is detected, a blood test is ordered to confirm presence of the drug in order to press charges (Solomon and Chamberlain, 2014).

Canada has only been collecting data on drug-impaired driving since 2009. In 2015, just under 3000 drug-impaired incidents were reported, equivalent to 4% of all impaired driving incidents (Statistics Canada, 2016). In addition to federal laws, each province has varying legislation, including fines for high BAC, zero tolerance for novice or young drivers, and educational programs (Statistics Canada, 2016).

The Task Force on Cannabis Legalization and Regulation (2016) examined the current laws and available research, coming to the conclusion more research is needed, especially around linking specific THC blood levels to impairment. Among other things, the Task Force recommended the creation of a comprehensive public education program, increased funding for SFST and DRE training and staffing, and broadening data collection (Task Force on Cannabis Legalization and Regulation, 2016).

A Saskatchewan court case, R. v. Perillat (2012), illustrated the difficulty of using results of SFST and DREs to press charges when no other signs of impairment exist. The accused in the case was pulled over as part of a police initiative targeting drug-impaired drivers. When the police officer smelled cannabis on the accused, she admitted to using cannabis 2.5 hours prior, and an SFST and later, a DRE, was administered accordingly. In the end, the accused was acquitted of the charges, with the judge concluding that "...at its best, Constable Schaefer's [the DRE's] evidence convinces me that the accused had used marijuana at some point prior to her being stopped at
the police check stop that evening and that she still had some of it in her system at the time he did his Drug Recognition Evaluation on her at the police station. What his evidence does not convince me of is that at the time she was driving, her ability to operate a motor vehicle was impaired by marijuana” (R. v. Perillat, 2012). This case illustrates a potential concern for medical cannabis patients, where the lingering smell of cannabis or the admission of having a medical authorization may lead to biases in field sobriety tests, particularly towards detecting previous use rather than actual impairment while driving.

International Models

United States

Although the federal illegality of both medical and recreational cannabis in the United States makes it a difficult comparison to Canada, it is still worthwhile to explore examples of how individual states have approached impaired driving. Overall, approximately one-third of US states have laws related to THC-impaired driving with policy ranging state-to-state. Sixteen states have zero-tolerance approaches, meaning any detectable level of THC presence results in a charge, and six others have per se laws (see figure 3) (National Conference of State Legislatures, 2017; NORML, n.d.).

States with per se limits, such as Washington and Colorado, have been using blood tests to determine THC levels as a measure of impairment (Drug Policy Alliance, 2016). Both states use a legal threshold of five ng/ml THC of a driver’s blood. However, in Colorado, five ng/ml only triggers a "presumption" of impairment and drivers can challenge this presumption at trial. In other states without per se limits, such as Oregon, Alaska and Washington, D.C., trained observations by police are used to determine impairment (Drug Policy Alliances, 2016). However, medical uses of cannabis have not been reviewed in these contexts.

Although the stated goal of per se limits was to reduce “drugged driving” by 10%, a recent review demonstrated the per se limits had had no effect on drug-impaired fatalities in the United States (Anderson & Rees, 2015). The per se and zero-tolerance approaches have also been challenged in court, including a few notable cases regarding medical cannabis use. In Arizona, where there is zero tolerance to presence of THC, patients can make an "affirmative defense" that allows them to demonstrate that they were not impaired and were legally authorized cannabis by a physician (Novak and P.L.L.C., 2015). The Supreme Court of Arizona ruled on the matter and stated that the affirmative defense “[does] not immunize a medical marijuana cardholder from prosecution under [impaired driving laws], but instead affords an affirmative defense if the cardholder shows that the marijuana or its metabolite was in a concentration insufficient to cause impairment” (Novak and P.L.L.C., 2015). Rhode Island has a similar exemption that requires impairment to be established beyond proof of metabolites for “qualifying” medical cannabis patients (“RI Gen L § 21-28.6-7,” 2013). Michigan’s Supreme Court also heard this argument and in a unanimous

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<tr>
<th>State</th>
<th>Per Se Cut-off</th>
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<td>Colorado</td>
<td>5 ng/ml THC</td>
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<tr>
<td>Illinois</td>
<td>5 ng/ml THC</td>
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<tr>
<td>Pennsylvania</td>
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<tr>
<td>Montana</td>
<td>5 ng/ml THC</td>
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<tr>
<td>Nevada</td>
<td>10 ng/ml THC or 15 ng/ml metabolite</td>
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<td>Washington</td>
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decision, ruled that driving under the impairment of THC laws cannot lead to criminal charges based on detection of THC alone without signs of impairment (People v Koon 2013).

Europe
Many European countries have progressed their drug-impaired driving laws, with many implementing zero-tolerance approaches or low per se limits (under 3 ng/ml) (Wolff & Johnston, 2014). The United Kingdom has taken a unique approach to per se limits and created laws that allow for a ‘medical defense’ if people are taking drugs, including cannabis, for medical reasons and are not impaired (Government of the United Kingdom, 2014). According to the medical defense, drivers are not guilty of per se offenses if they are not impaired and the following conditions are met:

- “the medicine was prescribed, supplied, or sold to treat a medical or dental problem, and
- it was taken according to the instructions given by the prescriber or the information provided with the medicine” (Government of the United Kingdom, 2014; Wolff & Johnston, 2014).

A medical defense for per se limits ensures that other evidence of impaired driving, rather than indicators of previous use, must be established to ensure patients are not criminalized for simply exceeding a per se limit. Despite Canada being one of the first countries with a legal medical cannabis access program, it has not considered medical defenses in its recent driving legislation (Bill C-46). As impaired driving is currently the number one offence heard by Canadian criminal courts, in addition to the serious problem with court delays, an arbitrary per se limit applied to patients that is not based in science could further clog courts with cases that never posed risk to public safety (Standing Senate Committee on Legal and Constitutional Affairs, 2016; Statistics Canada, 2016).

Australia and New Zealand
In Australia, drugged driving laws vary state-by-state with many taking zero-tolerance approaches, using saliva testing for enforcement (Blackwell, 2016; Watson & Mann, 2016). States offer various public education to drivers, with some recommending waiting at least 12 hours before driving after THC consumption (Blackwell, 2016). New Zealand’s government and laws recognize the low level of evidence for drug screening technology and focus solely on tests of impairment (New Zealand Ministry of Transport, 2016). Accordingly, drivers must first fail a field sobriety test and the results of which are then supported by a saliva screening test (New Zealand Ministry of Transport, 2016).
Canada’s Approach: The Road Ahead

Canada’s approach to impaired driving policy must simultaneously tackle being the first G7 country to legalize non-medical cannabis in addition to having a parallel medical cannabis system. It is necessary to ensure policy captures a fair and swift approach to impaired driving, even if a lack of robust evidence exists concerning cannabis-impaired driving.

In their final report, the Task Force stated that, “Despite uncertainty with the current scientific evidence around a per se limit, establishing one would nevertheless be an important tool for deterring cannabis-impaired driving. As the scientific knowledge base continues to grow, a per se limit should be revisited and adjusted as necessary” (Task Force on Cannabis Legalization and Regulation, 2016: 43). Health Canada’s decision framework for managing risks further demonstrates this type of precautionary approach:

> A key feature of managing health risks is that decisions are often made in the presence of considerable scientific uncertainty. A precautionary approach to decision making emphasizes the need to take timely and appropriately preventative action, even in the absence of a full scientific demonstration of cause and effect ... a lack of full scientific certainty should not be used as a reason not to take preventive measures when reasonable evidence indicates that a situation could cause some significant adverse health effect (Government of Canada, 2000).

While a precautionary approach to cannabis-impaired driving may very well be appropriate, the government’s shift to abolish the prohibition and criminalization of cannabis must also ensure driving laws are not be used to re-criminalize the use of medical cannabis. Although driving is not a right, but a privilege, patients who use cannabis responsibly and are not impaired should still be able to drive without risk or fear of being charged.

Conclusion

In this paper, we have reviewed research and policy related to impaired driving within the context of cannabis used for medical purposes, a significantly understudied area. Impaired driving research continues to focus on acute recreational cannabis impairment, which is likely not applicable to medical use due to the variables discussed in this report (such as tolerance or context of use). Patients following safe-use guidelines, which ensure chance of impairment is eliminated, may still be targeted under the proposed per se limits. Given the paucity of research, policy must consider the limitations of tests in measuring cannabis impairment, particularly when it comes to medical cannabis use.

It is necessary for government to incentivize further research and include considerations for patients using cannabis. Although a precautionary approach may be appropriate in light of limited evidence, policymakers have a responsibility to both safeguard road safety and balance the rights of medical cannabis patients to ensure they are not unfairly criminalized by drugged driving laws that do not target impairment.
References:


MEDICAL CANNABIS AND IMPAIRED DRIVING


