From:	
To:	Select Committee into Cannabis and Hemp
Subject:	Medicinal cannabis and driving
Date:	Wednesday, 17 November 2021 11:45:55 AM
Attachments:	image001.png Effects of chronic marijuana use on driving performance Touro paper 2018.pdf Medicinal cannabis and driving the intersection of health and road safety.pdf

17 November 2021

Select Committee into Cannabis and Hemp
Parliament House
4 Harvest Tce
West Perth WA 6005

RE: Medicinal cannabis and driving: Please review the evidence attached regarding this very important matter regarding driving Safety on Australian roads and highway.

It does appear that the Australian Medical Cannabis industry, Universities, and some States Department of Health here in Australia in the paper called **Medicinal cannabis and Driving: the intersection of health and road safety'** made the following comments.
https://www.sciencedirect.com/science/article/pii/S0955395921002127

'Conclusion: We conclude that in medical-only access models there is little evidence to justify the differential treatment of medicinal cannabis patients, compared with those taking other prescription medications with potentially impairing effects. More broadly, our analysis suggests that in jurisdictions utilising doctor-supervised, medical-only access models, where medicinal cannabis is captured in broader medicines safety frameworks, patient exemptions from road safety THC 'zero tolerance' presence (but not impairment) offences, as well as those based on per se limits, should be considered.'

As you can glean from the above conclusion, a single study produced in Australia suggests 1. THC in Medical Marijuana will only cause a small risk to Road Safety to the Australian community and have assumed that CBD (Cannabidiol) along with other cannabinoids has not psychotropic impact at all on the user. The complexity of this now heavily engineered plant, and the idiosyncratic nature of substances on individuals, does not negate, but rather enhances unpredictability of intoxication or other psycho-disruptive elements.

To ostensibly 'legalize' medical marijuana for driving as this paper suggests it will create a two-tier system and make it very difficult for the Police and Transport Department to meet road safety standards here in Australia.

Although the authors of the paper are at pains to delineate the so called 'pharmaceutical' grade THC containing medicines 'permitted' not authorized by the TGA, they fail to outline how the Drug Detection Officer, will determine the source of that THC, regardless of level of intoxication present.

This very real potential obfuscation is either overlooked or ignored by the authors, and subsequently will present an avenue for the recreational cannabis user and the faux medical user to not simply drive with impunity, but add significantly to the public safety risks and public health decline in other areas.

The illicit cannabis trade will have yet another permission portal to exploit which will, in turn, add to this largely now un-policed trade – except in the Road Safety arena.

Confirmation bias should not be part of any legitimate peer reviewed research when tabling results, though authoritative commentary and opinion are both normal and regarded as legitimate under such genre.

However, serious reflection must be made on not so much the veracity, but strength of data when authors have strong affiliations/associations with the industry they are writing for or from.

As the clear 'Declarations of Interest' disclose and the following affirm, it is important to, again, reflect and little more robustly on both the evidence and conclusions presented in the paper.

1. **Bias in research based on linkage to funding is a well-known phenomena** Industry sponsorship and research outcome.

   Lundh A, Lexchin J, Mintzes B, Schroll JB, Bero L.

   Sponsorship of drug and device studies by the manufacturing company leads to more favorable efficacy results and conclusions than sponsorship by other sources. Our analyses suggest the

existence of an industry bias that cannot be explained by standard 'Risk of bias' assessments.

2. **Clinical trial transparency update: an assessment of the disclosure of results of company-sponsored trials associated with new medicines approved in Europe in 2013**.

https://pubmed.ncbi.nlm.nih.gov/27869482/ Deane BR, Sivarajah J. Curr Med Res Opin. 2017

The disclosure rate within 12 months of 90% suggests that industry is continuing to achieve disclosure in a timely manner. The overall disclosure rate at study end of 93% indicates that the improvement in transparency amongst company-sponsored trials has been maintained in the trials associated with new medicines approved in 2013.

3. **Industry sponsorship and research outcome** Lundh A, Sismondo S, Lexchin J, Busuioc OA, Bero L. https://pubmed.ncbi.nlm.nih.gov/23235689/ Sponsorship ofdrug and device studies by the manufacturing company leads to more favorableresults and conclusions than sponsorship by other sources. Our analyses suggest the existence of an industry bias that cannot be explained by standard 'Risk of bias' assessments.

4. **Interactions between physicians and the pharmaceutical industry: what does the literature say?** Lexchin J. CMAJ. 1993 Nov 15;149(10):1401-7. Review. https://pubmed.ncbi.nlm.nih.gov/8221424/

Physicians are affected by their interactions with the pharmaceutical industry. Further research needs to be done in most cases to determine whether such interactions lead to more or less appropriate prescribing practices. The CMA's guidelines on this topic should be evaluated to see whether they are effective in controlling physician-industry interactions. Further measures may be necessary if the guidelines fail to prevent negative effects on prescribing practices.

5. **Evaluation of conflict of interest in economic analyses of new drugs used in oncology** Friedberg M, Saffran B, Stinson TJ, Nelson W, Bennett CL. https://pubmed.ncbi.nlm.nih.gov/10535436/ Although we did not identify bias in individual studies, these findings indicate that pharmaceutical company sponsorship of economic analyses is associated with reduced likelihood of reporting unfavorable results.

There is also some **evidence that tolerance to the acute effects of cannabis develops over time in regular users**, resulting in less pronounced cognitive impairment in several domains related to driving, such as divided attention and time perception (Colizzi & Bhattacharyya, 2018; McCartney et al., 2021)

What about reaction time, vision? The following studies show prolonged impairment in regular users…

However, in relation to psychomotor abilities, evidence suggests the development of tolerance to impairment relating to psychomotor coordination, but not other psychomotor processes such as response speed, sustained attention, visual spatial skills and set shifting (Colizzi & Bhattacharyya, 2018; Desrosiers, Ramaekers, Chauchard, Gorelick, & Huestis, 2015; J. G. Ramaekers, Kauert, Theunissen, Toennes, & Moeller, 2009; J. G. Ramaekers et al., 2016). As such, the development of tolerance to impairing effects in patients could be expected to partially, but not fully, diminish potential effects on driving skills compared with an occasional recreational cannabis consumer taking a similar dose.

- Memory impacted (12 hr abstinence), increased years use did worse, increased task complexity and demand had worse results – Solowij, *JAMA* 2002
- Tests of concept formation, planning or sequencing impaired - Crean, *J Addic Med* 2011
- Decision making and risk-taking still seen after 25 days abstinence – Whitlow, *Drug Alc Depen* 2004
- Significant attention and concentration deficits in 4 week to 2 years abstinence - Solowij, *Life Sci* 1995; Bolla, *Neurol* 2002
- Slower information processing – Kelleher, *Addict Behav* 2004
- PET scan show decreased CB1 receptor binding in basal ganglia, midbrain, cerebellum (motor impairment) – Hirvonen, *Clin Pharm Ther* 2015
- Chronic grey matter volume reduction in areas of brain responsible for emotional and affective processing – Nattistella, *Neuropsych* 2014
- Studies with "no chronic impairment" - too short of study period (lasting hours), using ineffective measurement tools (Stroop test).

As patients are typically taking the medication daily, a level of tolerance to these impairing effects would be expected (notice the non-science stance "would be expected" does NOT say that it has been proven). Available evidence suggests tolerance development is primarily pharmacodynamic (NOT true - see above prolonged physiologic and psychomotor changes with VERY LOW THC doses back in the early 2000's studies, the high (15% - 99%) THC content and other toxins found in today's products were absent in the early 2000's) , resulting from neuroadaptive changes in the brain rather than from users adjusting their behaviour to compensate for any impairing effects (J. G. Ramaekers, Mason, & Theunissen, 2020). (See many studies listed above, also these studies showing problems with chronic users IN simulated driving studies - see attached, the Diciano conclusion: *"The present study suggests that, even with repeated daily use, cannabis consumption among therapeutic users may alter driving behavior. This has implications for road safety and use of cannabis for therapeutic purposes" - the total number of people in the study was VERY low: 14 with 3 withdrawing; the Doroudger study conclusion for chronic users: "Chronic marijuana users had slower reaction times, deviated less in speed, and had difficulty matching a lead vehicle's speed compared to nonusers. The effects on SDS and modulus were present at cutoffs of 2 and 5 ng/mL.")*

It is a scientific fact that THC is fat soluble and collects in fatty tissue. The brain is one of the largest collections of fatty tissue - in the human body. It is pure FANTASY to think that chronic users of marijuana do not have very HIGH residual stores of THC in their BRAINS - impacting motor and mental skills. The marijuana proponents even admit that THC lasts a long time in (the water-soluble) blood. This occurs because of THC slowly leeching out of the fat stores (i.e. brain tissue) over several days after cessation of marijuana consumption. This admission is proof that THC is still having an IMPACT on the person's brain due to its presence in those fatty tissues. This is why it takes several weeks for chronic marijuana users to show signs/symptoms of marijuana withdrawal - due to this slow release from fat stores over time. This is unlike the other water-soluble drugs - alcohol, opiates, benzodiazepines - that quickly leave the blood/body and illicit withdrawal symptoms within hours.

North American Cannabis Summit in 2019 Marijuana-Impaired Driving: What the Data Shows - Bing video

Effects of chronic marijuana use on driving performance (attached) Moves to recommend that because marijuana use is becoming more widespread, for both medical and nonmedical purposes, it *would be worthwhile to further study this population*. Chronic marijuana use is a common public health concern with regards to driving. Future studies comparing acute to chronic marijuana users' driving impairments will allow for better understanding this population's driving patterns. Additionally, better detection tools that are more relevant and feasible on the road are needed to assess drivers under the influence of marijuana.

And last, by not least, the chronic users of alcohol could argue for their 'adaptive' capacity over time, and thus be exempt from probation standards. The salient point being that drink drivers could also claim that every metabolism is different and that some of them can drive perfectly well with 0.10 readings instead of 0.05. However, the law simply cannot work this way, cannabis being more complex than alcohol regarding its various modes of delivery (i.e. smoked or ingested) and difficult to resolve whether waiting 6 or 10 hours is applicable.

Since safe driving will require abstinence from cannabis consumption for hours, any "on site" cannabis consumption (lounges, restaurants, bars, etc.) will ***require*** *the user to use alternative methods of transportation following use to protect society from impaired driving.* Like tobacco second hand marijuana exposure for non-users may also impair their ability to drive safely.

The only way to keep the Australian community safe on the roads and highways here in Australia now is to have **ZERO** tolerance for THC while driving.

Kind Regards

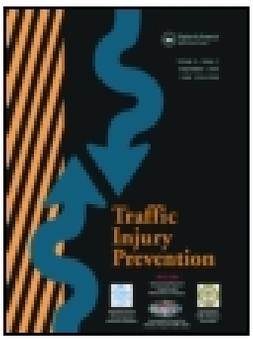
Herschel Baker

International Liaison Director,

Queensland Director

Drug Free Australia

Prevent. Don't Promote Drug Use.



Traffic Injury Prevention

ISSN: 1538-9588 (Print) 1538-957X (Online) Journal homepage: http://www.tandfonline.com/loi/gcpi20

Effects of chronic marijuana use on driving performance

Shadi Doroudgar, Hannah Mae Chuang, Kimberly Bohnert, Joanne Canedo, Sahai Burrowes & Paul J. Perry

To cite this article: Shadi Doroudgar, Hannah Mae Chuang, Kimberly Bohnert, Joanne Canedo, Sahai Burrowes & Paul J. Perry (2018): Effects of chronic marijuana use on driving performance, Traffic Injury Prevention, DOI: 10.1080/15389588.2018.1501800

To link to this article: https://doi.org/10.1080/15389588.2018.1501800

Published online: 09 Nov 2018.

TRAFFIC INJURY PREVENTION
https://doi.org/10.1080/15389588.2018.1501800

Effects of chronic marijuana use on driving performance

Shadi Doroudgar[a], Hannah Mae Chuang[a], Kimberly Bohnert[a], Joanne Canedo[a], Sahai Burrowes[b], and Paul J. Perry[a]

[a]College of Pharmacy, Touro University California, Mare Island, Vallejo, California; [b]Public Health Program, College of Education and Health Sciences, Touro University California, Mare Island, Vallejo, California

ABSTRACT

Objectives: The effects of marijuana on driving pose a significant public health concern. More studies on chronic marijuana use in driving are needed. The study objectives were to (1) assess differences in the Standardized Field Sobriety Test (SFST) and driving performance outcomes between chronic medical marijuana users and nonusers and (2) identify a cutoff tetrahydrocannabinol (THC) concentration above which chronic medical marijuana users demonstrate driving impairment.

Methods: This prospective cross-sectional study assessed 31 chronic marijuana users and 41 nonusers. Rapid Detect Saliva Drug Screen 10-panel was administered to all participants. Participants were given a simple visual reaction time test (SVRT) and SFST consisting of the horizontal gaze nystagmus (HGN), the one leg stand (OLS), and the walk and turn (WAT) tests. The STISIM Drive M100 driving simulator assessed driving performance. Driving parameters included standard deviation of speed (SDS), deviation of mean lane position, off-road accidents, collisions, pedestrians hit, and car-following modulus, delay, and coherence. Cannabinoid blood plasma was obtained from marijuana users.

Results: Marijuana users and nonusers did not differ in age (40.06 ± 13.92 vs. 41.53 ± 15.49, $P = .6782$). Marijuana users were more likely to fail the SFST ($P = .005$) and the WAT ($P = .012$) and HGN ($P = .001$) components. Marijuana users had slower SVRT ($P = .031$), less SDS ($P = .039$), and lower modulus ($P = .003$). Participants with THC >2 ng/mL ($P = .017$) and TCH >5 ng/mL ($P = .008$) had lower SDS. Participants with THC >2 ng/mL ($P = .021$) and THC >5 ng/mL ($P = .044$) had decreased modulus.

Conclusion: Chronic marijuana users had slower reaction times, deviated less in speed, and had difficulty matching a lead vehicle's speed compared to nonusers. The effects on SDS and modulus were present at cutoffs of 2 and 5 ng/mL.

ARTICLE HISTORY
Received 27 March 2018
Accepted 14 July 2018

KEYWORDS
Marijuana; driving performance; driving simulator; standard field sobriety test; driving impairment

Introduction

Marijuana is the most commonly used illicit drug in the United States, with approximately 22.2 million past-month users according to the 2014 National Survey on Drug Use and Health. In the United States, marijuana has now been legalized for medical use in 29 states and the District of Columbia (ProCon.org 2018). A number of states have expanded marijuana legalization to include recreational use. Currently, marijuana is legalized for recreational use in 9 states plus the District of Columbia (ProCon.org 2018).

Though marijuana decriminalization and legalization has increased over the past decade, driving under the influence laws still apply in all of the U.S. states (Wong et al. 2014). Additionally, marijuana is still illegal at the federal level, retaining Drug Enforcement Administration categorization as a schedule I controlled substance (Neavyn et al. 2014; Passaro et al. 2000). Schedule I drugs, substances, or chemicals are defined as drugs with "no currently accepted medical use and a high potential for abuse" (US Drug Enforcement Administration n.d.).

Despite recent changes, the public health impact of marijuana remains a controversial topic (Greydanus et al. 2013; Hartman et al. 2015). Advocates of marijuana legalization predict that recent policy changes will allow for more opportunities to study its positive health effects (Monte et al. 2015) and more appropriate allocation of law enforcement resources (Barry et al. 2014; Ogrodnik et al. 2015) and will not increase adolescent marijuana use (Choo et al. 2014). Those opposing marijuana legalization fear that it will lead to increased use and driving under the influence. Since medical marijuana legalization in Colorado, driving under the influence of cannabis cases have increased (Urfer et al. 2014).

Given the rapidly changing landscape with regards to marijuana legalization for medical and recreational uses, the effects of marijuana on driving performance are an increasing public health concern (Ramaekers 2018; Richer and

CONTACT Shadi Doroudgar Shadi.doroudgar@tu.edu Clinical Sciences Department, Touro University California, College of Pharmacy, 1310 Club Dr., Mare Island, Vallejo, CA 94592.
Associate Editor Kathy Stewart oversaw the review of this article.

Bergeron 2009). With the exception of alcohol, marijuana is currently the most prevalent illicit drug in impaired driving, including fatal accidents (Brady and Li 2014). The past-year prevalence of marijuana use was 4.1% in 2001–2002 and more than doubled to 9.5% in 2012–2013 (Hasin et al. 2015). Some experts believe that acute and long-term exposure to marijuana may impair driving (Volkow et al. 2014). However, establishing a causal relationship between marijuana use and on-the-road driving accidents is difficult given multiple confounders such as tolerance to marijuana and varying modes of administration (Sewell et al. 2009; Wilkinson et al. 2016). A population-based case–control study using motor vehicle crash data from Auckland, New Zealand, found that after adjusting for confounders such as age, gender, ethnicity, education level, passenger carriage, driving exposure, time of day, as well as other risky behaviors at the time of crash (blood alcohol concentration, seat belt use, traveling speed, and sleepiness score), the impact of acute marijuana use on driving was not significant (odds ratio [OR] = 0.8; 95% confidence interval [CI], 0.2–3.3). However, a statistically significant association (OR =9.5; 95% CI, 2.8–32.3) was found between habitual use and car crash injury after adjustment for all confounders as well as acute use before driving (Blows et al. 2005). In this study, acute marijuana use was considered marijuana use in the 3 h prior to the crash/survey, whereas habitual marijuana use was defined as an average of at least once per week over the past 12 months (Blows et al. 2005). Results of epidemiological studies do not indicate a clear relationship between acute marijuana use and motor vehicle accidents (Kelly et al. 2004). However, other studies indicate that acute use of marijuana can impact cognitive and motor skills, such as attention, reaction time, motor coordination, information processing skills, and time and distance estimation, required for driving (Block and Ghoneim 1993; Broyd et al. 2016; De Aquino et al. 2018).

A number of studies have used controlled scenarios of driving simulation, which are good predictors for real-world driving, to investigate the relationship between marijuana concentrations in the blood and driving performance (Lenné et al. 2010). Driving simulator studies indicate a dose-dependent relationship effect of marijuana use on driving performance outcomes, with more impairment at higher doses (Klonoff 1974; Lamers and Ramaekers 2001; Sewell et al. 2009). Notably, blood tetrahydrocannabinol (THC) concentrations of 2 to 5 ng/mL are associated with considerable driving impairment (Hartman and Huestis 2013). However, heavy marijuana users, daily users smoking 7.7–23.1 joints/day, who have developed tolerance to marijuana over time show minimal impairments in certain driving tasks (Bosker, Kuypers, et al. 2012). In sum, evidence on the impact of marijuana use on driving performance either in real-world settings or in driving simulations is mixed and provides poor guidance for policymakers. Furthermore little is known about how chronic marijuana users perform on the commonly used Standard Field Sobriety Test (SFST).

The SFST is used universally by U.S. law enforcement officials to establish psychomotor and cognitive impairment of drivers. The SFST includes 3 tests used to determine whether a detained driver is under the influence of drugs or alcohol (Stuster and Burns 1998). The test is a validated method that is used to determine whether a person has a blood alcohol concentration of 0.04% (legal limit for class A drivers) or 0.08% (legal limit for class C drivers in the United States) per the Department of Motor Vehicles' Vehicle Code: VC Section 23152 and 23153 (California Law n.d.). Given the assumption that acute marijuana use impairs performance on the SFST, chronic marijuana users may also demonstrate higher SFST failure rates than sober controls (Downey et al. 2013). It is important to note that though the SFST has been validated to detect impairment due to alcohol (Stuster 2006; Stuster and Burns 1998), it is not validated for other drugs and its sensitivity to other drug impairments is not known (Bosker, Theunissen, et al. 2012).

More research is needed to assess driving impairments in regular medical marijuana users under chronic THC exposure conditions (i.e., habitual use; Hartman and Huestis 2013). Complex tasks that require multiple neurocognitive skills have been shown to be sensitive to the impairing effects of THC and have demonstrated less tolerance (Hartman and Huestis 2013). Some parameters such as divided attention tasks and tracking tasks have shown impairment in chronic marijuana smokers, whereas other parameters have not (Ramaekers et al. 2009, 2011). The aim of this study is to assess the effects of medical marijuana on driving performance and the SFST in chronic medical marijuana users. Three hypotheses involved with chronic cannabis users were tested throughout the study: (1) SFST failure rates will be different between the chronic marijuana users and the control group. (2) There is a THC concentration threshold above which regular medical marijuana users experience driving impairment. (3) There are differences in driving simulator performance parameters between individuals who do not use marijuana and chronic users without acute exposure.

Methods

Study design

This was a prospective cross-sectional study with convenience sampling comparing chronic medical marijuana users to nonusers. Healthy adult participants, including males, females, and minorities, were recruited to take part in this study. Participants began by signing an informed consent form followed by an oral drug test. All participants then performed a simple visual reaction time test (SVRT). Next, an SFST was performed by all participants prior to driving the driving simulator. A 10-min simulator adaptation scenario allowed the participants to familiarize themselves with the simulator. Following the baseline scenario, participants entered the main scenario for approximately 40 min. Cannabinoid blood plasma and oral samples were obtained from the chronic marijuana users after the driving simulator scenarios. The study adhered to the ethical standards of the Helsinki Declaration and were approved by the Touro University California institutional review board (IRB #P-1313).

Participants and recruitment

Participants in the medical marijuana group were recruited through paper advertisements at medical marijuana clubs in Vallejo and Oakland, California; by email announcements to other medical marijuana groups; and through Nextdoor, a private social network for neighborhood communities. Participants of the control group were recruited through paper advertisements posted throughout the campus of Touro University California and an email announcement sent throughout the campus to students, faculty, and staff.

Inclusion criteria were that the participants held a valid California driver's license (or equivalent from another jurisdiction) for at least 12 months and were not currently taking any prescription or over-the-counter medications that are known to cause psychomotor changes or have psychoactive properties. Exclusion criteria were history of brain tumor, recent inner ear infection or vestibular/balance abnormalities within the past 12 month, diagnosis of severe psychiatric conditions, pregnancy, unwilling to comply with restrictions and instructions disclosed in the consent form, consumed alcohol or alcohol-containing beverages 24 h prior to the study, consumed caffeine or other stimulant-containing beverages 24 h prior to the study, blind, color blind, and/or deaf, resulting in an inability to perform the required tests for this study. Control participants were excluded if they tested positive for any drug on the saliva drug screen. Marijuana users with a positive saliva drug screen for drugs other than marijuana were excluded. Participants who met the above criteria were included in the chronic marijuana use group if they used cannabis at least 4 days per week and were included in the control group if they had not used cannabis in the past 12 months.

Saliva drug screen

The Rapid Detect Saliva Drug Screen 10-panel (Rapid Detect Inc., Poteau, OK) was used to screen for drugs of abuse, including amphetamine, cocaine, marijuana, methamphetamine, opiates, phencyclidine, benzodiazepines, oxycodone, barbiturates, and alcohol. Study participants were excluded if they tested positive for any drugs of abuse, with the exception of the active arm participants testing positive for marijuana.

Simple visual reaction time

Subjects performed an SVRT available on the Internet at http://cognitivefun.net/test/1. The test consists of a small red dot on the screen that morphs into a large green dot. The participant was instructed to hit the computer space bar as soon as the green dot appeared on the monitor. The test was repeated 5 times for each participant, without any practice. The average reaction time from the 5 attempts was recorded in milliseconds. SVRT was one of the outcome variables tested.

Standardized Field Sobriety Test

Law enforcement officials use the SFST as a tool to assess intoxication or driving under the influence. The SFST consists of 3 independent tests: (1) Horizontal gaze nystagmus (HGN), (2) the one leg stand (OLS), and (3) walk and turn (WAT; Papafotiou et al. 2005b). Researchers found that the specificity and sensitivity of the SFST were highest if all 3 test results were combined. Failure of any of the 3 was defined as a failed SFST. HGN is an involuntary jerking movement of the eye that may occur as the eyes move laterally. Subjects are required to follow a pen with their eyes only. Clues for impairment include lack of smooth pursuit, distinct nystagmus at maximum deviation, and onset of nystagmus before 45° for each eye. OLS is performed by having the participant raise either leg approximately 6 in. off the ground and count out loud until told to stop. This procedure usually lasts for 30 s. Clues for impairment include putting the raised foot down more than one time, hopping, and using arms to balance. WAT is performed by having the participant walk on a straight line while taking 9 heel-to-toe steps forward, turn around in a series of small steps with the front foot on the line, and walk in the same manner in the opposite direction. Clues counted for impairment include the incorrect number of steps in both directions, stopping while walking, stepping off the line, raising arms for balance, unable to touch heel to toe, and having trouble turning. HGN test failure requires 4 or more impairment clues, and a WAT or OLS test failure requires 2 or more impairment clues. Failure in any of the 3 components leads to a failure of the entire SFST.

The SFST was administered by 2 independent evaluators, each trained by a physician prior to the driving simulator scenarios. The scores on each individual test were summed and averaged between the 2 raters for statistical analysis. Performance on the SFST was one of the outcome variables of the study.

Driving scenario

The study used the STISIM M100 Drive driving simulator software (System Technology, Inc. Hawthorne, CA) to assess driving performance. The software was written to simulate a range of psychomotor, divided attention, and cognitive tasks involved while driving. The driver was able to control steering and speed while visual and auditory feedback was provided. The software was programmed to meet specific test requirements for this study (Doroudgar et al. 2017). The initial driving simulator encounter was a practice session. It consisted of driving on a straight rural road with very few curves at a speed of 55 mph for 10 min.

The main driving session, used for study data collection and assessment, was approximately 33 miles long and consisted of 4 segments (Ronen et al. 2008, 2010). The first segment of 10 miles consisted of a 2-way primarily straight road, with desert scenery, a few trees and curves, and low traffic density at a speed limit of 55 mph. The second segment was an 8-mile 2-way winding mountainous road with steep curves and a posted speed limit of 40–45 mph with reduced speed to 40 mph when approaching a curve. The third segment was a 7-mile 2-lane road where the participants were asked to drive behind a lead car and match its speed at a speed limit of 55 mph. The fourth segment was

an 8- mile 2-lane road in an urban setting with 4 unexpected events: Pedestrians crossing, cars stopped in the middle of the road, jaywalking, and traffic lights with a posted speed limit of 55 mph. The 4 segments transitioned into each other continuously for an approximate total drive time of 40 min. The output parameters from the simulator were mean lane position in feet, standard deviation of mean lane position measured in feet, mean speed in miles per hour, standard deviation of mean speed in miles per hour, car-following delay in seconds, car-following modulus, car-following coherence, off-road accidents, collisions, pedestrians hit, and traffic light tickets. Car-following delay is the time taken for a driver to respond to lead vehicle's speed. A value of 0 indicates that the driver was able to respond appropriately when there were changes in the speed of the lead car. Higher values indicate a longer time to recognize and react to the lead vehicle's speed variations. The car-following modulus measures how well the driver matches the lead vehicle's speed; a value of 1 indicates a perfect match. Values less than 1 indicate that the driver tended to drive slower than the lead vehicle, and values greater than 1 indicate that the driver drove faster and had to slow down when he caught up to the lead car, indicating tailgating driving behavior. Car-following coherence indicates how well the driver's data follow the pace car; a value of 1 indicates a perfect match and values less than 1 indicate less reliable data. Collisions were defined as the total number of times the driver contacted another vehicle or object other than a pedestrian. Pedestrians hit were the total number of times the vehicle touched a pedestrian model. Traffic light tickets assessed the total number of times the driver crossed the limit line at a red light. These driving parameters were outcome variables assessed in the 2 groups. The primary driving parameters were mean speed, standard deviation of speed, deviation of lane position, modulus, delay, and coherence. The secondary driving parameters were off-road accidents, collisions, and pedestrians hit.

Laboratory results

NMS Labs (Willow Grove, PA) assessed the plasma THC levels. Analytical testing was performed in accordance to all NMS Labs standard operating procedures and final results were reviewed by laboratory certifying scientists. Delta-9 THC (ng/mL) plasma concentrations were determined through quantitative analysis performed by 2D chromatography–tandem mass spectrometry using deuterated internal standards. A lower limit of detection of 0.13 ng/mL for delta-9 THC and lower limit of quantification of 0.52 ng/mL was achieved. Standard curves for delta-9 THC were linear with correlation coefficients (r) of 0.989. The assay calibration curve was precise with $r > 0.99$. The within-run precision for the lower limit of quantification was 6.8%; for the lower limit spiked control, 3.2%; and for the upper limit spiked control sample, 5.8%. The between-day precision for the lower limit of quantification was 5.7%; for the lower limit spiked control, 2.3%; and for the upper limit spiked control sample, 3.8%. The accuracy bias estimate was −6.1%; for the lower limit spiked control, 5.3%; and for upper limit spiked control sample, −2.3%.

Table 1. Demographic comparison of THC and control groups.

	THC (N 31)	Controls (N 41)	P value
Age (years)	40.06 ± 13.92	41.53 ± 15.49	.6782
Age range (years)	19 65	23 71	
Gender, male (%)	22 (71.0)	26 (63.4)	.501
Ethnicity, N (%)	17 (54.8)	9 (22.0)	<.001
Caucasian/white	6 (19.4)	3 (7.3)	
African American/black	0 (0)	20 (48.8)	
Asian	5 (16.1)	2 (4.9)	
Hispanic	3 (9.7)	7 (17.0)	
Other			
Height (in.)	69.0 ± 3.9	66.2 ± 3.1	.001
Weight (lb.)	188.7 ± 36.9	158.6 ± 36.1	<.001

Table 2. Comparison of SFST between chronic marijuana users and controls.

	THC (N 31)	Controls (N 41)	P value
WAT, >2 clues (fail), n (%)	19 (61.3)	13 (31.7)	.012
OLS, >2 clues (fail), n (%)	10 (32.3)	10 (24.4)	.460
HGN, >4 clues (fail), n (%)	21 (67.7)	11 (26.8)	.001
Combined, >1 test (fail), n (%)	27 (87.1)	23 (56.1)	.005

Statistics

All statistical analyses were performed using STATA version 14.0 (College station, TX). Continuous data were reported as mean ± standard deviation and categorical data were reported as numbers and percentages. t Tests were used for continuous data. Chi-square and Fisher's exact tests were used for categorical data. Statistical significance was established as $P < .05$. Multivariate linear regressions were conducted to identify THC cutoff concentrations that correlated with differences in driving parameters.

Results

Forty-two chronic marijuana users and 41 controls initially met the inclusion criteria for the study. However, 10 participants in the chronic marijuana user group were excluded after laboratory results indicated nondetectable plasma concentrations for cannabinoids. Results from a total of 41 non-marijuana users and 31 marijuana users are included.

Table 1 summarizes the demographics of the study participants. The majority of participants in the THC group ($N = 22$; 71.0%) and control group ($N = 26$; 63.4%) were male. There were no statistically significant differences in age or gender between the THC and control groups. THC users ranged from 19 to 65 years of age, and the control group ranged from 23 to 71 years of age. However, the groups differed based on ethnicity ($P < .001$). More than half of the participants in the THC group were white ($N = 17$; 54.8%), whereas the most predominant ethnicity in the control group was Asian ($N = 20$; 48.8%). The results of the SFST are summarized in Table 2. With regards to the specific components of the SFST, more participants in the THC group failed the WAT ($P = .012$) and the HGN ($P = .001$) test compared to the controls. Considering the combined results, 27 participants in the THC group (87.1%) and 23 participants in the control group (56.1%) failed the SFST; this result was statistically significant ($P = .005$). However, there were no statistically significant differences in the OLS between the THC and control group ($P = .460$).

Table 3. Comparison of driving parameters and SVRT between chronic marijuana users and controls (mean ± SD).

	THC (N 31)	Controls (N 41)	P value
SVRT (ms)[d]	649.0 ± 453.2	471.4 ± 219.2	.031
Mean speed (mph)[d]	51.1 ± 9.6	52.6 ± 12.2	.572
TD of speed (mph)[d]	14.5 ± 5.7	17.4 ± 5.8	.039
Deviation of lane position (ft.)[d]	4.1 ± 1.2	4.4 ± 1.4	.326
Modulus[a,d] (0 to 1 correlation)	0.56 ± 0.28	0.75 ± 0.27	.003
Delay[b,d] (s)	1.27 ± 2.4	0.94 ± 2.4	.641
Coherence[c,d] (0 to 1 correlation)	0.44 ± 0.26	0.54 ± 0.27	.121
Off road accidents[d]	0.48 ± 1.15	1 ± 2.1	.223
Collisions[d]	0.26 ± 0.77	0.12 ± 0.33	.315
Pedestrians hit[d]	0.13 ± 0.34	0.26 ± 0.50	.188

[a]Modulus how well the driver matches lead vehicle speed where a value of 1 is perfect;
[b]Delay time taken for a driver to respond to the lead vehicle's speed; higher values indicate longer times to recognize speed changes.
[c]Coherence how well the driver's simulator data follow the lead car, where a value of 1 is perfect.
[d]mean ± SD.

Table 4. THC cutoff values as predictors of impairment.[a]

Delta 9 THC	Number of participants with THC above a given threshold	Coefficient	95% CI	*P* value
SVRT				
>2 ng/mL	28	132.77	(24.39, 289.93)	.096
>5 ng/mL	21	57.27	(115.21, 229.76)	.510
>10 ng/mL	11	44.30	(262.87, 174.26)	.678
SDS				
>2 ng/mL	28	2.11	(3.84, 0.39)	.017
>5 ng/mL	21	2.49	(4.33, 0.66)	.008
>10 ng/mL	11	1.81	(4.22, 0.60)	.138
Modulus				
>2 ng/mL	28	0.0002	(0.30, 0.03)	.021
>5 ng/mL	21	0.15	(0.30, 0.004)	.044
>10 ng/mL	11	0.12	(0.31, 0.07)	.205

[a]Multivariate linear regression was used to predict a THC cutoff for SVRT, SDS, and modulus. Age was an added variable for SVRT prediction. Mean speed was an added variable for SDS prediction. Mean speed was an added variable for modulus prediction.

Table 3 summarizes the results of the various driving simulator parameters and SVRT. Participants in the THC group had a slower SVRT than those in the control group (649.0 ± 453.2 vs. 471.4 ± 219.2; $P = .031$), deviated less in their speed (14.5 ± 5.7 vs. 17.4 ± 5.8; $P = .039$), and had a lower modulus (0.56 ± 0.28 vs. 0.75 ± 0.27; $P = .003$). There were no other statistically significant differences in the driving parameters between the THC and control groups.

Various THC cutoff points were considered with regards to predicting impairment in the parameters that were statistically significantly different between the THC and the control group. Evidence suggests that THC concentrations of 2–5 ng/mL are associated with substantial driving impairment, especially in occasional users (Hartman and Huestis 2013). Additionally, Nevada and Ohio have 2 ng/mL of THC for their THC *per se* limit, and Washington and Colorado have 5 ng/mL of THC as the *per se* limit. However, limited studies indicate that serum concentrations of THC below 10 ng/mL are not associated with an elevated accident risk (Grotenhermen et al. 2007). Because cutoff concentrations of 2, 5, and 10 ng/mL are recognized but controversial, they were selected for the regression. Marijuana users in this study had an average plasma delta-9 THC concentration of 11.7 ng/mL, with a standard deviation of 12.5 ng/mL and a range of 0.5–63 ng/mL. Multivariate linear regression to predict a cutoff THC level for the SVRT taking into consideration age yielded no significant results. Age was considered a variable in this regression because older drivers tend to have slower reaction times than younger drivers (Doroudgar et al. 2017). Mean speed was an added variable in the standard deviation of speed (SDS) prediction and modulus prediction models. Multivariate linear regression to predict a cutoff THC level that correlated with SDS demonstrated that those participants with a THC >2 ng/mL (95% CI, −3.84, −0.39; $P = .017$) and THC >5 ng/mL (95% CI, −4.33, −0.66; $P = .008$) had lower SDS compared to those below those cutoff values. Additionally, multivariate linear regression to predict a cutoff THC level that correlated with the modulus showed that participants with a THC >2 ng/mL (95% CI, −0.3, −0.03; $P = .021$) and THC >5 ng/mL (95% CI, −0.3, −0.004; $P = .044$) had decreased modulus compared to those below those cutoff values. Though a THC cutoff value of >10 ng/mL was considered, no statistically significant findings were found with regards to the SVRT or driving parameters when comparing participants above and below the 10 ng/mL cutoff.

Discussion

This prospective cross-sectional study compared chronic marijuana users to nonusers on driving simulator performance, visual reaction times, and performance on the SFST. The results indicate that there are associations between chronic marijuana use and SFST failure as well as driving performance. Additionally, THC cutoff levels are associated with these outcomes.

The results of the SFST revealed that there was a statistically significant difference between chronic THC users and control participants with regards to the percentage failing the WAT, HGN, and combined SFST. SFST failure rates were higher for chronic marijuana users, suggesting that they may be more likely to be arrested for driving under the influence. However, it is also notable that even among the control group, a large percentage of the participants (26.8–56.1%) were likely to fail the WAT, HGN, and combined SFST. This is in line with studies that show high false-positive rates for SFST failure (Yoshizuka et al. 2014).

Previous groups have studied the effects of cannabis on the SFST. Porath-Waller and Beirness (2014) assessed the validity of the 3 components of the SFST in identifying impairment in suspected drug-impaired drivers using central nervous system stimulants, central nervous system depressants, narcotic analgesics, cannabis, or no drugs. Analysis of data recorded during drug evaluation and classification evaluations revealed that all drug categories were significantly associated with impaired performance on the SFST (Porath-Waller and Beirness 2014). The overall finding of impairment on the SFST is consistent with the results of this study. Porath-Waller and Beirness (2014) further found that marijuana impairs the OLS test but not WAT and HGN, a finding that is consistent with a study by Bosker and colleagues (Bosker, Theunissen, et al. 2012) but contrasts the findings of this study, with detected impairments in WAT,

HGN, and overall, as well as Papafotiou et al. (2005a), who attributed cannabis use to impairment on all 3 tests of the SFST. Though these studies contribute to our growing knowledge of the effects of cannabis, they vary with regards to study design and frequency of marijuana use. Additional confirmatory studies are needed to elucidate these findings.

The SVRT and driving parameters indicated that marijuana users performed differently given a reaction time test and driving performance. Marijuana users reacted significantly slower than nonusers, consistent with findings from other studies that marijuana impairs psychomotor and cognitive functions (Busardo et al. 2017; Hartman and Huestis 2013; Ramaekers et al. 2004; Riedel and Davies 2005). Slowed reaction time is concerning because it can pose a danger during many different driving scenarios. For example, a slowed reaction time may not allow for timely detection of changes in the driving scenario. Another finding was that the marijuana users deviated less in their speeds than nonusers, suggesting that they were less likely to speed up and slow down during the drive. One possible explanation could be that marijuana users had insight into their reaction time impairment and in turn deviated less in speed to compensate for their driving. Another possible reason for this is that the increased reaction time also accounted for less likelihood of changing speeds in the face of changing driving environments. Additionally, the driving modulus of the chronic marijuana users was significantly decreased compared to that of non-marijuana users. Because modulus is how well a driver matches the lead vehicle's speed, the lower modulus among the marijuana users may be related to the increased reaction time. Inability to match a car's speed while on the road can be dangerous. These results are similar to the findings of another study of chronic marijuana users that found that chronic marijuana use increased time to speed adaptation, the primary reaction time measure in the car-following test (Bosker, Kuypers, et al. 2012).

Per se THC legal limits (5 ng/mL) in Colorado and Washington are based on studies of acute exposure causing increased lane variability. In our study, the driving performance of chronic marijuana users was assessed. A significant finding was that at THC cutoff values of 2 and 5 ng/mL, differences in the SDS and modulus were detected in the marijuana users compared to nonusers. Overall, 28 participants were marijuana users with THC above 2 ng/mL. Twenty-one of the participants had a THC value greater than 5 ng/mL. Only 11 participants had THC levels greater than 10 ng/mL. A limited number had THC levels greater than 10 ng/mL, posing a possible explanation for not observing significant differences at that cutoff. Overall, the results indicate that even at low THC plasma concentrations, difference in driving can be observed.

This study is not without limitations. A limitation of this study was that deviation of lane position was the outcome variable generated by the STISIM drive software after each participant's drive. The raw data were not edited to calculate the standard deviation of lateral position (SDLP) reported in some studies. The SDLP is a continuous outcome measuring the weaving of the car. The SDLP is a measure of vehicle control and has been used in other standardized driving studies as a primary measured parameter because it is sensitive to dose-dependent effects of a number of psychoactive drugs such as hypnotics, antidepressants, and antihistamines (Penning et al. 2010; Ramaekers 2003; Verster and Mets 2009; Verster et al. 2004, 2006; Verster and Volkerts 2004). In other studies, the raw data from a driving test must be edited before SDLP can be calculated because certain driving maneuvers, such as passing other cars and traffic jams, affect the maintenance of a steady lane position and constant speed (Verster and Roth 2011). The deviation of lane position used within this study cannot be directly compared to other studies that report SDLP findings.

Another limitation was the use of the Internet-based SVRT test. SVRT only assessed simple reaction time. The online test used for the SVRT required a minimum of 5 attempts to provide a reaction time estimate. The participants were not allowed to practice to maintain consistency. Although attempts were made to keep the testing method consistent between the participants, no data on the validity and reliability of this particular SVRT test are available through the website used.

Additionally, the participants were recruited using convenience sampling, leading to groups that were not balanced with regards to ethnicity. Participants in the THC group tended to be mostly Caucasian, whereas many of the participants in the control group were Asian. Due to our limited sample size, we were not able to control for ethnicity in our tests of association or regression models. As such, the results may not be generalizable to all population demographics. Additionally, this was a small study, including only 72 participants in the California Bay Area.

Larger studies are needed to confirm the findings of this study. Because marijuana use is becoming more widespread, for both medical and nonmedical purposes, it would be worthwhile to further study this population. Chronic marijuana use is a common public health concern with regards to driving. Future studies comparing acute to chronic marijuana users' driving impairments will allow for better understanding this population's driving patterns. Additionally, better detection tools that are more relevant and feasible on the road are needed to assess drivers under the influence of marijuana.

ORCID

Shadi Doroudgar https://orcid.org/0000 0001 8879 7795
Sahai Burrowes http://orcid.org/0000 0002 4944 402X

References

Barry RA, Hiilamo H, Glantz SA. Waiting for the opportune moment: the tobacco industry and marijuana legalization. *Milbank Q.* 2014;92(2):207 242.

Block RI, Ghoneim MM. Effects of chronic marijuana use on human cognition. *Psychopharmacology (Berl).* 1993;110(1 2):219 228.

Blows S, Ivers RQ, Connor J, Ameratunga S, Woodward M, Norton R. Marijuana use and car crash injury. *Addiction.* 2005;100:605 611.

Bosker WM, Kuypers KP, Theunissen EL, et al. Medicinal Δ(9) tetrahydro cannabinol (dronabinol) impairs on the road driving performance of occasional and heavy cannabis users but is not detected in Standard Field Sobriety Tests. *Addiction.* 2012;107:1837 1844.

Bosker WM, Theunissen EL, Conen S, et al. A placebo controlled study to assess Standardized Field Sobriety Tests performance during alco hol and cannabis intoxication in heavy cannabis users and accuracy of point of collection testing devices for detecting THC in oral fluid. *Psychopharmacology (Berl)*. 2012;223:439 446.

Brady JE, Li G. Trends in alcohol and other drugs detected in fatally injured drivers in the United States, 1999 2010. *Am J Epidemiol*. 2014;179:692 699.

Broyd SJ, van Hell HH, Beale C, Yucel M, Solowij N. Acute and chronic effects of cannabinoids on human cognition a systematic review. *Biol Psychiatry*. 2016;79:557 567.

Busardo FP, Pellegrini M, Klein J, di Luca NM. Neurocognitive corre lates in driving under the influence of cannabis. *CNS Neurol Disord Drug Targets*. 2017;16:534 540.

California Law. *Vehicle code. Article 2. Offenses Involving Alcohol and Drugs [23152 23229.1]*. n.d. Available at: https://leginfo.legislature.ca.gov/faces/codes displaySection.xhtml?lawCode=VEH&sectionNum=23152. Accessed February 1, 2018.

Choo EK, Benz M, Zaller N, Warren O, Rising KL, McConnell KJ. The impact of state medical marijuana legislation on adolescent mari juana use. *J Adolesc Health*. 2014;55(2):160 166.

De Aquino JP, Sherif M, Radhakrishnan R, Cahill JD, Ranganathan M, D'Souza DC. The psychiatric consequences of cannabinoids. *Clin Ther*. 2018. [Epub ahead of print]

Doroudgar S, Chuang HM, Perry PJ, Thomas K, Bohnert K, Canedo J. Driving performance comparing older versus younger drivers. *Traffic Inj Prev*. 2017;18:41 46.

Downey LA, King R, Papafotiou K, et al. The effects of cannabis and alcohol on simulated driving: Influences of dose and experience. *Accid Anal Prev*. 2013;50:879 886.

Greydanus DE, Hawver EK, Greydanus MM, Merrick J. Marijuana: current concepts. *Front Public Health*. 2013;1:1 17.

Grotenhermen F, Leson G, Berghaus G, et al. Developing limits for driving under cannabis. *Addiction*. 2007;102:1910 1917.

Hartman RL, Brown TL, Milavetz G, et al. Cannabis effects on driving lateral control with and without alcohol. *Drug Alcohol Depend*. 2015;154:25 37.

Hartman RL, Huestis MA. Cannabis effects on driving skills. *Clin Chem*. 2013;59:478 492.

Hasin DS, Saha TD, Kerridge BT, et al. Prevalence of marijuana use disorders in the United States between 2001 2002 and 2012 2013. *JAMA Psychiatry*. 2015;72:1235 1242.

Kelly E, Darke S, Ross J. A review of drug use and driving: epidemi ology, impairment, risk factors and risk perceptions. *Drug Alcohol Rev*. 2004;23:319 344.

Klonoff H. Marijuana and driving in real life situations. *Science*. 1974;186:317 324.

Lamers CT, Ramaekers JG. Visual search and urban driving under the influence of marijuana and alcohol. *Hum Psychopharmacol*. 2001;16(5):393 401.

Lenné MG, Dietze PM, Triggs TJ, Walmsley S, Murphy B, Redman JR. The effects of cannabis and alcohol on simulated arterial driving: influences of driving experience and task demand. *Accid Anal Prev*. 2010;42:859 866.

Monte AA, Zane RD, Heard KJ. The implications of marijuana legal ization in Colorado. *JAMA*. 2015;313(3):241 242.

Neavyn MJ, Blohm E, Babu KM, Bird SB. Medical marijuana and driv ing: a review. *J Med Toxicol*. 2014;10(3):269 279.

Ogrodnik M, Kopp P, Bongaerts X, Tecco JM. An economic analysis of different cannabis decriminalization scenarios. *Psychiatr Danub*. 2015;27(Suppl 1):S309 S314.

Papafotiou K, Carter JD, Stough C. An evaluation of the sensitivity of the Standardised Field Sobriety Tests (SFSTs) to detect impairment due to marijuana intoxication. *Psychopharmacology (Berl)*. 2005a;180:107 114.

Papafotiou K, Carter JD, Stough C. The relationship between perform ance on the standardised field sobriety tests, driving performance and the level of Δ9 tetrahydrocannabinol (THC) in blood. *Forensic Sci Int*. 2005b;155(2 3):172 178.

Passaro A, Volpato S, Romagnoni F, Manzoli N, Zuliani G, Fellin R. Benzodiazepines with different half life and falling in a hospitalized population: the GIFA study. *J Clin Epidemiol*. 2000;53:1222 1229.

Penning R, Veldstra JL, Daamen AP, Olivier B, Verster JC. Drugs of abuse, driving and traffic safety. *Curr Drug Abuse Rev*. 2010;3:23 32.

Porath Waller AJ, Beirness DJ. An examination of the validity of the standardized field sobriety test in detecting drug impairment using data from the Drug Evaluation and Classification program. *Traffic Inj Prev*. 2014;15(2):125 131.

ProCon.org. *Legal recreational marijuana states and DC*. 2018. Available at: https://marijuana.procon.org/view.resource.php?resourceID 006868. Accessed June 20, 2018.

Ramaekers JG. Antidepressants and driver impairment: empirical evidence from a standard on the road test. *J Clin Psychiatry*. 2003;64:20 29.

Ramaekers JG. Driving under the influence of cannabis: an increasing public health concern. *JAMA*. 2018;319:1433 1434.

Ramaekers JG, Berghaus G, van Laar M, Drummer OH. Dose related risk of motor vehicle crashes after cannabis use. *Drug Alcohol Depend*. 2004;73(2):109 119.

Ramaekers JG, Kauert G, Theunissen EL, Toennes SW, Moeller MR. Neurocognitive performance during acute THC intoxication in heavy and occasional cannabis users. *J Psychopharmacol*. 2009;23(3):266 277.

Ramaekers JG, Theunissen EL, de Brouwer M, Toennes SW, Moeller MR, Kauert G. Tolerance and cross tolerance to neurocognitive effects of THC and alcohol in heavy cannabis users. *Psychopharmacology (Berl)*. 2011;214:391 401.

Richer I, Bergeron J. Driving under the influence of cannabis: links with dangerous driving, psychological predictors, and accident involvement. *Accid Anal Prev*. 2009;41:299 307.

Riedel G, Davies SN. Cannabinoid function in learning, memory and plasticity. In: *Handbook of Experimental Pharmacology*. 2005;445 477.

Ronen A, Chassidim HS, Gershon P, et al. The effect of alcohol, THC and their combination on perceived effects, willingness to drive and performance of driving and non driving tasks. *Accid Anal Prev*. 2010;42:1855 1865.

Ronen A, Gershon P, Drobiner H, et al. Effects of THC on driving per formance, physiological state and subjective feelings relative to alco hol. *Accid Anal Prev*. 2008;40:926 934.

Sewell RA, Poling J, Sofuoglu M. The effect of cannabis compared with alcohol on driving. *Am J Addict*. 2009;18(3):185 193.

Stuster J. Validation of the standardized field sobriety test battery at 0.08% blood alcohol concentration. *Hum Factors*. 2006;48:608 614.

Stuster J, Burns M. *Validation of the Standardized Field Sobriety Test Battery at BACs Below 0.10 Percent*. 1998.

Urfer S, Morton J, Beall V, Feldmann J, Gunesch J. Analysis of Δ9 tetrahydrocannabinol driving under the influence of drugs cases in Colorado from January 2011 to February 2014. *J Anal Toxicol*. 2014;38:575 581.

US Drug Enforcement Administration. *Drug Scheduling*. n.d. Available at: https://www.dea.gov/drug scheduling. Accessed January 1, 2016.

Verster JC, Mets MA. Psychoactive medication and traffic safety. *Int J Environ Res Public Health*. 2009;6:1041 1054.

Verster JC, Roth T. Standard operation procedures for conducting the on the road driving test, and measurement of the standard deviation of lateral position (SDLP). *Int J Gen Med*. 2011;4:359 371.

Verster JC, Veldhuijzen DS, Patat A, Olivier B, Volkerts ER. Hypnotics and driving safety: meta analyses of randomized controlled trials applying the on the road driving test. *Curr Drug Saf*. 2006;1:63 71.

Verster JC, Veldhuijzen DS, Volkerts ER. Residual effects of sleep medication on driving ability. *Sleep Med Rev*. 2004;8(4):309 325.

Verster JC, Volkerts ER. Antihistamines and driving ability: evidence from on the road driving studies during normal traffic. *Ann Allergy Asthma Immunol*. 2004;92(3):294 303.

Volkow ND, Baler RD, Compton WM, Weiss SR. Adverse health effects of marijuana use. *N Engl J Med*. 2014;370:2219 2227.

Wilkinson ST, Yarnell S, Radhakrishnan R, Ball SA, D'Souza DC. Marijuana legalization: impact on physicians and public health. *Annu Rev Med*. 2016;67:453 466.

Wong K, Brady JE, Li G. Establishing legal limits for driving under the influence of marijuana. *Inj Epidemiol*. 2014;1:1 10.

Yoshizuka K, Perry PJ, Upton G, Lopes I, Ip EJ. Standardized Field Sobriety Test: false positive test rate among sober subjects. *J Forensic Toxicol Pharmacol*. 2014;3(2):1 3.

International Journal of Drug Policy 97 (2021) 103307

Contents lists available at ScienceDirect

International Journal of Drug Policy

journal homepage: www.elsevier.com/locate/drugpo

Policy analysis

Medicinal cannabis and driving: the intersection of health and road safety policy

Daniel Perkins[a,b,*], Hugh Brophy[a], Iain S. McGregor[c], Paula O'Brien[d], Julia Quilter[e], Luke McNamara[f], Jerome Sarris[g,h], Mark Stevenson[i], Penny Gleeson[j], Justin Sinclair[g], Paul Dietze[k]

[a] Office of Medicinal Cannabis, Department of Health, Melbourne, VIC 3000, Australia
[b] School of Social and Political Science, University of Melbourne, Parkville, VIC 3010, Australia
[c] The Lambert Initiative for Cannabinoid Therapeutics, Brain and Mind Centre, The University of Sydney, Sydney, NSW 2050, Australia. Faculty of Science, School of Psychology, The University of Sydney, Sydney, NSW 2006, Australia
[d] Melbourne Law School, University of Melbourne, Parkville, VIC 3010, Australia
[e] School of Law, University of Wollongong, Northfields Ave, Wollongong, NSW 2522, Australia
[f] Centre for Crime, Law and Justice, Faculty of Law and Justice, University of New South Wales, Sydney, NSW 2052, Australia
[g] NICM Health Research institute, Western Sydney University, Westmead, NSW 2145, Australia
[h] Professorial Unit, The Melbourne Clinic, Department of Psychiatry, University of Melbourne, Melbourne, 130 Church St, Richmond, VIC 3121, Australia
[i] Urban Transport and Public Health, University of Melbourne, Parkville, VIC 3000, Australia
[j] Deakin Law School, Deakin University, Burwood, VIC 3125, Australia
[k] Behaviours and Health Risks Program, Burnet Institute, Melbourne, VIC 3004, Australia. National Drug Research Institute, Curtin University, Melbourne, VIC 3004, Australia

ARTICLE INFO

Keywords:
Medicinal cannabis
Cannabis
Road safety
Access to treatment
Government regulation
Drug driving

ABSTRACT

Background: Recent shifting attitudes towards the medical use of cannabis has seen legal access pathways established in many jurisdictions in North America, Europe and Australasia. However, the positioning of cannabis as a legitimate medical product produces some tensions with other regulatory frameworks. A notable example of this is the so-called 'zero tolerance' drug driving legal frameworks, which criminalise the presence of THC (tetrahydrocannabinol) in a driver's bodily fluids irrespective of impairment. Here we undertake an analysis of this policy issue based on a case study of the introduction of medicinal cannabis in Australia.

Methods: We examine the regulatory approaches used for managing road safety risks associated with potentially impairing prescription medicines and illicit drugs in Australian jurisdictions, as well as providing an overview of evidence relating to cannabis and road safety risk, unintended impacts of the 'zero-tolerance' approach on patients, and the regulation of medicinal cannabis and driving in comparable jurisdictions.

Results: Road safety risks associated with medicinal cannabis appear similar or lower than numerous other potentially impairing prescription medications. The application of presence-based offences to medicinal cannabis patients appears to derive from the historical status of cannabis as a prohibited drug with no legitimate medical application. This approach is resulting in patient harms including criminal sanctions when not impaired and using the drug as directed by their doctor, or the forfeiting of car use and related mobility. Others who need to drive are excluded from accessing a needed medication and associated therapeutic benefit. 'Medical exemptions' for medicinal cannabis in comparable jurisdictions and other drugs included in presence offences in Australia (e.g. methadone) demonstrate a feasible alternative approach.

Conclusion: We conclude that in medical-only access models there is little evidence to justify the differential treatment of medicinal cannabis patients, compared with those taking other prescription medications with potentially impairing effects.

Introduction

The last decade has seen a dramatic shift in global attitudes relating to the therapeutic use of cannabis based medicines, with over 50 countries now having established legal access pathways allowing patients to utilise medicinal cannabis products across a wide range of medical

* Corresponding author.
E-mail address: daniel.perkins@health.vic.gov.au (D. Perkins).

https://doi.org/10.1016/j.drugpo.2021.103307

conditions (Schlag, 2020; United Nations, 2020). Reflecting this shift, the United Nations General Assembly voted in December 2020 to remove cannabis from Schedule IV of the *Single Convention on Narcotic Drugs* (1961), the most restrictive of the schedules (UNCND, 2020). However, this recasting of cannabis as a potentially legitimate medicine has created some tensions with other regulatory frameworks in which cannabis remains positioned as a dangerous drug with no legitimate therapeutic application. A notable example of this is the so called 'zero tolerance' drug driving legal frameworks that have been adopted in many countries, which criminalise the presence of a drug (almost always illicit) in a driver's blood or oral fluid irrespective of impairment (Morgland, 2020).

Here we undertake an analysis of this issue, with a focus on medical only access frameworks (involving no legalisation or decriminalisation of recreational use), based on a case study of the introduction of legal medicinal cannabis access pathways in Australia. The paper explores this policy issue by outlining the Australian medicinal cannabis access framework and considers the current regulatory approaches to reduce road safety risks associated with other potentially impairing prescription medicines and illicit drugs. It then reviews the evidence relating to cannabis and road safety risk, and unintended impacts of the 'zero tolerance' approach on patients taking or wanting to take medicinal cannabis. At the core of this issue is the need to optimise the regulatory framework to minimise potential harms relating to road safety risk, impediments to accessing a needed medication, and exclusion of a vulnerable patient group from motor vehicle access, while ensuring that medicinal cannabis patients are not discriminated against due to the historical status of the drug.

Medicinal cannabis access in Australia

The introduction of legal medicinal cannabis access in Australia was initiated in November 2016, via regulatory amendments implemented by the Commonwealth Government that enabled Australian patients to legally access medicinal cannabis when prescribed by their doctor with relevant Commonwealth and State/Territory Government approvals. In doing so, it brought an end to the blanket prohibition on cannabis, which had been classified as a Schedule 9 (Prohibited) substance in the Australian Poisons Standard and was considered to have no recognised medical value.

Unlike some other countries, the regulatory framework for medicinal cannabis in Australia is based on the provision of pharmaceutical grade medicines available only via prescription from a doctor after any required Commonwealth and State/Territory Government approvals have been obtained. These medicines are prescribed at precise doses and dispensed from a pharmacy. All other use of cannabis (i.e. recreational or using illicit cannabis for self attributed medicinal purposes) remains illegal. There are now an estimated 190 medicinal cannabis products available in Australia, which vary in composition of the two primary cannabinoids, delta 9 tetrahydrocannabinol (THC; which produces an intoxicating effect), and cannabidiol (CBD; non intoxicating). Most contain at least some level of THC and many are described as 'full spectrum', containing a wide range of other chemical constituents present in the cannabis plant . Unlike illicit cannabis (or herbal products available for medicinal use in some other jurisdictions e.g. Israel and some US states), all legal medicinal products available in Australia are standardised pharmaceutical grade medicines (TGA, 2021b). A wide range of product formulations are available, however recent analysis by the Commonwealth Department of Health found that the vast majority of approvals (>89%) are for oral solutions (oils or sprays), while around 10% involve preparations including wafers, transdermal gels and dried plant intended for vaporisation (smoking is not permitted) (Department of Health, 2020, p.17).

As of 31 March 2021, over 100,000 approvals for medicinal cannabis products had been granted by the Australian Therapeutic Goods Administration ('TGA') (TGA, 2021a). However, the interaction of legal medicinal cannabis and driving continues to be contentious, with most road safety agencies around Australia remaining committed to a drug driving regulatory framework that treats patients taking legally prescribed medicinal cannabis containing THC in the same manner as users of some illicit drugs, by criminalising the presence of the drug regardless of impairment. Some advocacy groups and politicians have asserted the need for change due to perceived inequitable treatment of medicinal cannabis patients (Patten, 2020). A 2015 report by the Victorian Law Reform Commission noted the right of patients 'not to be discriminated against because of their treatment' when managing risks such as driving. (VLRC, 2015, p.140)

In one of the first legal tests in January 2020, a South Australian magistrate found a medicinal cannabis patient guilty of driving with a prescribed drug in his system but then exercised her legal discretion to dismiss the charge on the basis of a lack of evidence of impairment. The magistrate did note that a conviction would be upheld if the patient was charged again (Bartle, 2020).

Prescription drugs and driving

It is well known that a range of prescription medications cause impairment that may pose a risk to the safe operation of a motor vehicle. This issue is managed in Australia via a regulatory framework including the Commonwealth *Poisons Standard* and corresponding state based legislation. The Poisons Standard uses a scheduling system reflecting the differing levels of potential harms and therapeutic benefit of various substances. Drugs with a recognised medicinal value are identified as Schedule 2, 3, 4 or 8 depending on the level of regulatory control restricting their availability, while those with no recognised medicinal value and the potential for harm, abuse/misuse are listed as Schedule 9 prohibited substances.

Recognised medicinal drugs (Schedules 2,3,4 and 8) may still have risks associated with their use, including causing impairment that can affect the ability of patients to drive. A significant number of medicines prescribed in Australia are known to have such effects, including anticonvulsants, opiates, antihistamines, antipsychotics, benzodiazepines, muscle relaxants, hypnotics, and antidepressants (O. Drummer, 2008a).

Experimental studies have found these medicines to have negative effects on psychomotor, cognitive, and driving skills, with an increased crash risk reported in epidemiological studies (e.g. case control and culpability studies). Table 1 provides a summary of such effects reported in systematic and meta analytic reviews.

However, it is important to note that there are methodological difficulties in achieving accurate estimates of impairment and crash risk, particularly in patients. Experimental studies are almost always undertaken on healthy controls, for whom it is impossible to incorporate potential health benefits of the medication that may lead to a net reduction in impairment and improved driving ability. For epidemiological studies, which are typically observational, it is very difficult to adequately control for all potential confounding variables such as simultaneous use of other drugs (including alcohol), polypharmacy, time delays between crashes and drug testing, plus un observed confounding factors. In addition, risks associated with some medications appear to diminish after a tolerance to the impairing effects has developed (Rudisill, Zhu, Kelley, Pilkerton, & Rudisill, 2016).

Reducing risks associated with prescription drugs

Impairing medications such as those described above are prescribed in very high volumes in Australia for the treatment of various medical conditions. In 2016 17, for example, there were 15.4 million prescriptions dispensed for opioids and in 2014 15 4.9 million benzodiazepine prescriptions were dispensed (AIHW, 2020a). To reduce road safety risks associated with the use of such medications, their use is regulated via mandatory labels and warnings, road safety legislation outlawing driving when impaired, and fitness to drive assessments.

Table 1
Impairing prescription drugs: effects on driving performance and crash-risk.

Class of drug	Reported impairing effects (experimental studies)	Crash risk ratio (systematic or meta-analytic reviews)
Anti-depressants	Drowsiness, hypotension, dizziness, decreased seizure threshold. (Johannes G. Ramaekers, 2003).	↑ 1.40 (Hill et al., 2017).
		↑ 1.39 (Elvik, 2013)
	Impaired in psychomotor functions (Brunnauer, Laux, Geiger, Soyka, & Möller, 2006)	↑ NQ[1] (Gjerde et al., 2015)
Antihistamines	Primarily sedation that can cause impairment comparable to >0.05 BAC (J. C. Verster & Volkerts, 2004).	↑ 1.20 (Gibson et al., 2009)
		↑ 1.12 (Elvik, 2013)
	Impaired reaction time and psychomotor performance (variation by type) (Popescu, 2008)	↑ NQ (Rudisill et al., 2016)
Benzodiazepines	Sedation, drowsiness, learning impairment, psychomotor slowing (Longo & Johnson, 2000 2016).	↑ 1.65-2.30 (Elvik, 2013)
		↑ 1.6-1.8 (Dassanayake, Michie, Carter, & Jones, 2011)
	Almost every aspect of driver behaviour shown to be affected (Rudisill et al., 2016)	↑ (Rudisill et al., 2016)
		↑ NQ (Gjerde et al., 2015)
Z-class hypnotics[2]	Sedation, increase attention lapses, increased tracking errors, reduced alertness, reduced body stability (Leufkens, Lund, & Vermeeren, 2009; Joris C. Verster, Bervoets, de Klerk, & Roth, 2014)	↑ 1.4 (Elvik, 2013)
		↑ NQ (Rudisill et al., 2016)
		↑ NQ (Gjerde et al., 2015)
Opiates	Sedation; diminished reaction times, reflexes and coordination; reduced peripheral vision due to the persistent miotic effects and impaired concentration (O. Drummer, 2008b; Stout & Farrell, 2003; M. C. Strand, Fjeld, Arnestad, & Mørland, 2013; Wilhelmi & Cohen, 2012).	↑ 2.29 (Chihuri & Li, 2017)
		↑ 1.94 (Elvik, 2013)
		↑ NQ (Rudisill et al., 2016)
		↑ NQ (Gjerde et al., 2015)

[1] NQ – statistically significant increase reported but not quantified. [2] GABA α^1 agonists e.g. zolpidem, zopiclone.

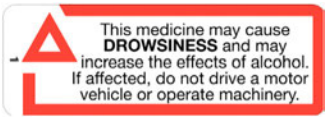


Fig. 1. Sedating medicines warning label.

Warnings and labelling requirements

To reduce risks associated with the use of prescription drugs such as those in the table above, a product labelling and warning system has been established via several legislative instruments, including the Poisons Standard, Therapeutic Goods Orders 91 and 69 (Standard and General requirements for labels of prescription and related medicines), the Medicines Advisory Statements Specification, and the Required Advisory Statements for Medicine Labels (No.5). This system includes warnings about possible sedating effects/drowsiness, recommendations not to drive or operate machinery if experiencing such effects, and to avoid alcohol or be aware that the medication may increase its effects. The label required on sedating medications, including medicinal cannabis products that contain THC, is shown in Fig. 1. Prescribing doctors and dispensing pharmacists are also required to provide patients using these medications with warnings to monitor drug effects and refrain from driving if impaired.

Driving under the influence/Driving while impaired

In addition to the labelling and warning system, most Australian jurisdictions also have offences relating to driving under the influence (DUI) of alcohol or other drugs (licit or illicit). These offences usually require a level of impairment in driving capacity caused by alcohol or other drug use, with this assessed based on evidence of a driver's behaviour witnessed by police or others. The common formula is driving under the influence of a drug so 'as to be incapable of having proper control of the motor vehicle' (Victoria, Tasmania, Western Australia, Australian Capital Territory and Northern Territory). In South Australia, the test is 'so as to be incapable of exercising effective control of the vehicle' (Road Traffic Act 1961 (**SA**) s 47(1a)). The DUI offences in New South Wales and Queensland do not define what 'under the influence' means in impairment terms. Western Australia and Victoria also have driving while impaired (DWI) offences, which resemble the DUI laws but relate only to drugs (licit or illicit) other than alcohol.

Measuring Impairment. DUI/DWI offences applicable to prescription medicines (and other substances) require noticeable signs of impaired driving for a charge to be laid by police, although as mentioned above, definitions of 'under the influence' and 'impairment' are not consistent across state drug driving legislation. Typically, the method used to determine whether a driver is 'impaired' is a roadside sobriety or impairment test, which involves a trained police officer observing and recording suspected drivers performing a battery of tasks examining reaction speed, physical appearance (e.g. shaking, pupil dilation), speech, mode of walking, etc. (Commonwealth of Australia, 2018). A sample of blood or urine may also be obtained, but additional supportive evidence is generally required to prove the charge (National Transport Commission, 2018). Penalties for DUI and DWI offences include fines, licence cancellation periods and possible imprisonment for repeat offences.

Fitness to drive

Individuals with certain health conditions (e.g. epilepsy) may also be referred for fitness to drive assessments (these can be mandatory in South Australia and Northern Territory), which are undertaken according to guidelines established by the National Transport Commission (2017). In relation to prescription drugs, these guidelines state that health professionals should consider "the balance between potential impairment due to the drug and (effect of) the patient's improvement in health on safe driving ability" in addition to factors such as individual response, drug interactions, and a history of substance abuse (National Transport Commission, 2017, p.12).

Illicit drugs and driving

The regulation of road safety risks associated with the use of illicit drugs is the subject of drug driving legislation in each Australian State and Territory, which, in turn, is informed by the National Road Safety Strategy (ATC, 2011). In all States and Territories, road safety legislation specifies a group of substances for which it is an offence to drive with any amount in a person's bodily fluids, regardless of impairment. These offences are loosely referred to as 'presence offences'. Because any detectable amount in the driver's system constitutes an offence, Australian jurisdictions have been described as having a 'zero tolerance' approach to drug driving (Quilter & McNamara, 2017). Although just the presence of these drugs is an offence, in practice, minimum detection thresholds have been adopted to control for accidental exposure, often reflecting the detection and quantification limits of the roadside drug testing devices and analytical instruments employed by the police and forensic services. These thresholds vary across jurisdictions. Drivers can alternatively be charged with the DUI and DWI offences referred to in the

Table 2
Presence offences in Australian states and territories (oral fluid, blood or urine).

JurisdictionLegislation	Drugs covered in addition to THC, methamphetamine, and MDMA	Potential medical exemptions	Penalties[1]
Victoria Road Safety Act 1986	None	No	F, LS, DE
New South Wales Road Transport Act 2013	Cocaine, morphine	Morphine	F, LS
Queensland Transport Operations (Road Use Management) Act 1995	None	No	F, LS[2], IM
South Australia Road Traffic Act 1961	None	No	F, LS, DP
Western Australia Road Traffic Act 1974	None	No	F, LS[2], DP
Tasmania Road Safety (Alcohol and Drugs) Act 1970	MDA, MDEA, amphetamine, cocaine, heroin, GBH, ketamine, LSD, Quaalude, morphine, DET, DMT, PMA, PCP, psilocybin	Yes – all	F, LS, IM
Northern Territory Traffic Act 1987	MDA, heroin, cocaine, morphine, methadone, amphetamine	Morphine, methadone and amphetamine	F, LS[2], IM
Australian Capital Territory Road Transport (Alcohol and Drugs) Act 1977	None	No	F, LS, IM[2]

[1] F=Fine; LS=licence suspension; DE=driver education; IM=imprisonment; DP=demerit points[2] Repeat offences

section above if a police officer reasonably suspects that a person's driving ability has been impaired by an illicit drug. Although jurisdictional approaches vary, in practice, a person would not be charged with both a presence and a DUI/DWI offence in relation to the same incident. In NSW for example, there is a specific double jeopardy defence which prevents a person from being charged and convicted for a both a DUI and a presence offence simultaneously (Road Transport Act 2013, Schedule 3, Clause 40). DUI/DWI offences involve more severe penalties, but due to greater complexity in prosecution would rarely be used if a person can be charged with the presence offence.

Enforcement of presence offences for illicit substances is most commonly conducted via roadside oral fluid drug testing regimes (noting that Tasmania uses blood sampling)(Quilter & McNamara, 2017). Presence offences are also enforced through mandatory blood tests, which are administered to any driver admitted to a hospital following a road accident in which a person is injured (regardless of fault). Typically, only three illicit drugs are tested for in oral fluid: THC; MDMA; and methamphetamine. New South Wales added cocaine to this list of drugs tested for in oral fluid in 2018. While presence offences apply overwhelmingly to illicit drugs, Tasmania and the Northern Territory include a much larger number of drugs most illicit, but some of which could be medically prescribed (see Table 2 below). New South Wales also has a separate offence of driving with the presence of morphine in the driver's blood or urine. No Australian jurisdiction currently tests for the presence of prescription drugs (other than medicinal cannabis) in preliminary oral fluid tests conducted at the roadside, with the examples above being tested for in secondary testing.

Notably, in some Australian jurisdictions there exists a medical defence for having the presence of certain drugs with potential therapeutic application in blood or oral fluid, if they have been prescribed by a doctor and taken in accordance with a prescription. In New South Wales, this medical defence covers morphine (Road Transport Act 2013 s 111(5)) and, in the Northern Territory, morphine, methadone and amphetamine (Traffic Act 1987 ss 29(1) and (2); Traffic Regulations 1999 reg 55A, Schedule 1A Part B). In Tasmania, the medical defence covers any drug referenced in the legislation if it was obtained and administered in accordance with the Poisons Act 1971 (Tas), including medicinal cannabis (Road Safety (Alcohol and Drugs) Act 1970 s 6A(2); Road Safety (Alcohol and Drugs) Regulations 2018 s 15). To be clear, these medical defences provide an exemption to presence offences, but not the DUI or DWI offences that exist in Australian States and Territories. Other than Tasmania, there is no medical defence for patients prescribed medicinal cannabis (containing THC) taking it as directed and who are not impaired.

Policy status

The application of presence based drug driving offences, originally designed to combat road safety risks associated with the use of illicit drugs, to patients receiving legal medicinal cannabis treatment has started to gain some policy attention in Australia. A recent Australian Senate Inquiry considering barriers to patient access to medicinal cannabis recommended a review of current 'presence based' drug driving offences (Commonwealth of Australia, 2020). However, in states other than Tasmania (a review was also recently undertaken in Victoria[1]), road safety agencies remain opposed to any change in the treatment of medicinal cannabis, due to concerns about the potentially impairing effects of THC. When a bill to change this situation in South Australia was introduced to its parliament in 2017, the Police Minister labelled it 'crazy' and 'inconsistent' with road safety objectives (ABC, 2017). The bill was not passed. The National Drug Driving Working Group recommended no change to current legislative arrangements in 2018, with reference to the 0.00 BAC alcohol requirement for some groups of drivers (Commonwealth of Australia, 2018). The key areas of concern for road safety agencies include possible impairment and elevated crash risk associated with legal medicinal cannabis products, and the potential for misuse and supplementation by patients. We discuss these issues in turn below as well as the patient impacts of the current regulatory framework.

Areas of concern

Cannabis and road safety

As with many other active ingredients found in a diverse range of prescription medications discussed above (Table 1), experimental studies have found that THC can have negative impacts on driving via impeded coordination, visual function and attention, which can persist for several hours after consumption (Arkell et al., 2020; McCartney, Arkell, Irwin, & McGregor, 2021; Ogourtsova, Kalaba, Gelinas, Korner Bitensky, & Ware, 2018; M. Strand, Gjerde, & Mørland, 2016). However, on road and driving simulation studies have also identified evidence of changes in driver behaviours that mitigate potential crash risk associated with these impairing effects (M. Strand et al., 2016). These changes include an increased likelihood of overestimating impairment, leading to more cautious driving through the use of compensatory behaviours such as driving more slowly, maintaining an increased 'following distance' to

[1] Authors DP and PD are members of the Victorian review group.

the cars ahead, and having fewer attempts to overtake (Hartman et al., 2016; Lenné et al., 2010; Smiley, 1999). This contrasts with driving under the influence of alcohol, where drivers tend to underestimate their level of impairment and display more risky driving behaviours (Sewell, Poling, & Sofuoglu, 2009).

Findings of epidemiological studies have been less consistent than experimental studies in identifying an increased road safety risk associ ated with cannabis use (US Congress, 2019; Wood & Dupont, 2020). A recent review of meta analyses by Rogeberg and Elvik (2016) found that cannabis impaired driving was associated with a 'low to moderate in crease in crash risk' with an odds ratio of 1.22 1.36, and below 1.2 when alcohol was controlled for. Similar estimates of increased crash risk and culpability risk odds of between 1.1 and 1.4 are confirmed by a number of other recent meta analyses (Elvik, 2013; Gjerde, Strand, & Mørland, 2015; Ole Rogeberg, 2019). Some older meta analyses have identified higher and lower odds ratios, but these typically failed to control for con founders such as age, gender, alcohol intoxication, and polydrug use (O. Rogeberg & Elvik, 2016). The impairing effects of cannabis are known to increase when combined with alcohol (J. G. Ramaekers et al., 2011), contributing to a higher estimated crash risk for individuals using both substances concurrently (O. H. Drummer et al., 2004).

Road safety risks associated with prescribed medicinal cannabis

The studies discussed above are only of partial relevance to medic inal cannabis as none have differentiated between medical and recre ational use. There are several characteristics of medicinal use that may lead to a lower road safety risk among patients than among recreational users. In Australia, patients accessing legal medicinal cannabis are do ing so under the supervision of a doctor and the goal of this treatment is to achieve a clinical benefit using dosing strategies that can avoid unwanted psychoactive side effects, such as a low commencing dose and slow upward titration (MacCallum & Russo, 2018). This contrasts to most recreational use, which specifically relates to obtaining a psy choactive effect. Driving under the influence of cannabis is also asso ciated with being a young, male adult, a subpopulation holding 'high risk' attitudes towards driving and an elevated crash risk irrespective of cannabis use (J Bergeron, Langlois, & Cheang, 2014; Jacques Bergeron & Paquette, 2014; Richer & Bergeron, 2009; O. Rogeberg & Elvik, 2016). The demographic profile of the average Australian medicinal cannabis patient is notably different, with available data provided by the TGA indicating the majority of patients are female and over 50 years of age (TGA, 2019). Older drivers with physical ailments are also known to re duce their driving exposure, generally only driving during the day and in locales they know well, leading to a lower crash risk than younger age groups (Alvarez & Fierro, 2008; Stutts, 1998).

A further potential risk reduction factor relates to the harm benefit assumptions that underlie the usual prescribing of potentially impair ing medications, and potential offsetting of increased road safety risks (National Transport Commission, 2017). In medicinal cannabis patients, substitution away from drugs with known impairing effects, including benzodiazepines and opioids, has been documented, with one study re porting that 45% of medicinal cannabis patients taking benzodiazepines at baseline had ceased use of these drugs at six months, while an other found large reductions in opioid use among chronic pain pa tients (Boehnke, Litinas, & Clauw, 2016; Purcell, Davis, Moolman, & Taylor, 2019). Similarly, improvements in clinical symptoms follow ing treatment with THC may offset any detrimental cognitive effects, either directly or indirectly. Such outcomes have been reported for Sativex, the one medicinal cannabis medicine containing THC listed on the Australian Register of Therapeutic Goods. Both driving simula tion and large patient registry studies of Sativex have identified no evi dence of increased accident risk (Celius & Vila, 2018; Etges et al., 2016; Freidel et al., 2015). A recent review investigating the acute effects of THC on driving related cognitive skills, primarily for recreational use, also identified a small number of studies in clinical populations, which reported mostly non significant subtle positive or negative effects on driver impairment. The authors suggest this evidence of minimal im pairment associated with medical use may reflect lower doses typically administered in a medical context and the likely amelioration of clinical symptoms that had been causing impairment (McCartney et al. 2021).

While experimental studies investigating the effect of medicinal cannabis on driving ability remain limited, a number of US epidemi ological studies have examined road safety risks specifically associated with legal medicinal cannabis, by analysing changes in road accident data after the introduction of such access schemes. Using fatal crash data from 2010 2017 in US states, Cook et al. (2020) found that in states with 'medical cannabis only' frameworks (i.e. where cannabis had not also been decriminalised or legalised for recreational use) the move away from prohibition was associated with fewer total fatal crashes for both males and females. A similar finding was reported by Santaella Tenorio et al. (2017), however some variation among states was noted. Other studies have examined change in the prevalence of fatally injured drivers testing positive to THC (not total number of fatalities), however this measure is problematic as detecting presence after an accident relies on the use of blood samples (which can detect THC for up to a week af ter consumption). Hence, an increase in the proportion of fatally injured THC positive drivers may simply reflect a greater proportion of the pop ulation having used cannabis at some time in the last week (as would be expected due to new legal medical access pathways), without signalling impairment, causality, or recent use. Nevertheless, studies looking at this metric have also in general found no significant increase in the pro portion of fatally injured drivers testing positive for THC in states mov ing to 'medical cannabis only' access models, although exceptions for some states or supply types have been noted (Lee, Abdel Aty, & Park, 2018; Masten & Guenzburger, 2014; Sevigny, 2018).

Other research has also reported a reduced presence of opioids among fatally injured drivers aged 21 to 40 in states introducing medical cannabis legalisation (without decriminalisation/legalisation), suggest ing a potential substitution effect (Kim et al., 2016). It is worth noting that the findings above have been reported in US states with much more permissive medicinal cannabis schemes than Australia's prescription only access model, with less regulation and quality controls governing access to these products.

There is also some evidence that tolerance to the acute effects of cannabis develops over time in regular users, resulting in less pro nounced cognitive impairment in several domains related to driv ing, such as divided attention and time perception (Colizzi & Bhat tacharyya, 2018; McCartney et al., 2021). As patients are typically tak ing the medication daily, a level of tolerance to these impairing effects would be expected. Available evidence suggests tolerance development is primarily pharmacodynamic, resulting from neuroadaptive changes in the brain rather than from users adjusting their behaviour to com pensate for any impairing effects (J. G. Ramaekers, Mason, & Theunis sen, 2020). However, in relation to psychomotor abilities, evidence sug gests the development of tolerance to impairment relating to psychomo tor coordination, but not other psychomotor processes such as response speed, sustained attention, visual spatial skills and set shifting (Colizzi & Bhattacharyya, 2018; Desrosiers, Ramaekers, Chauchard, Gorelick, & Huestis, 2015; J. G. Ramaekers, Kauert, Theunissen, Toennes, & Moeller, 2009; J. G. Ramaekers et al., 2016). As such, the development of toler ance to impairing effects in patients could be expected to partially, but not fully, diminish potential effects on driving skills compared with an occasional recreational cannabis consumer taking a similar dose.

Misuse and supplementation

Concerns about the potential misuse of prescribed medicinal cannabis are relevant to consider given the serious safety issues that currently exist around other prescription medications such as opioids and benzodiazepines (AIHW, 2020a). In addition to misuse, supplemen tation with a chemically indistinguishable illicit version of the substance (i.e. prescribed cannabis being supplemented with illicit cannabis), or

black market prescription cannabis products, would also be possible. The widespread availability of illicit/recreational cannabis creates a somewhat different risk profile compared with other prescription med ications such as opioids or benzodiazepines, where risk is more likely to be associated with misuse or overuse of prescription products. While both misuse and supplementation of medicinal cannabis are possible, there are some factors that may mitigate these risks.

In contrast to other medicines with a risk of misuse, no medici nal cannabis products are currently subsidised via the Pharmaceutical Benefits Scheme (the Australian government's drug subsidisation pro gram), meaning that patients need to pay the full cost of the prod uct themselves, which is higher than the street price of illicit cannabis (Freshleaf Analytics, 2020). As a result, there is little financial incen tive for the diversion or overuse of prescribed medicinal cannabis prod ucts. Conversely though, the high cost of medicinal cannabis products may provide an incentive for patients to either supplement their pre scription with illicit cannabis or substitute their prescribed medication with an illicit cannabis product. In 2019, the National Drug Strategy Household Survey found that of people who had used cannabis in the previous 12 months 6.8% always used it for (self attributed) medical purposes and 16.3% used it for both medical and non medical reasons. Only 1.8% of respondents who had recently used cannabis for medical purposes had obtained this via a prescription, but no analysis of con current recreational use among this group was possible due to the low numbers (AIHW, 2020b). It is therefore difficult to draw firm conclu sions about supplementation risk among patients prescribed medicinal cannabis, and this would be difficult to accurately ascertain in future research as patients are unlikely to admit illegally supplementing their prescribed medicinal cannabis.

In relation to misuse, it is noteworthy that almost all Australian pre scribing of medicinal cannabis products containing THC (with one ex ception, Sativex) is via the TGA's Special Access Scheme Category B pathway, under which approval for access involves an assessment of clinical appropriateness on a case by case basis by the TGA. A further safeguard relating to potential misuse is that state/territory level ap proval, in the form of a Schedule 8 treatment permit, is also required for any products containing THC in most jurisdictions if the patient is a known drug dependent person. More generally, patients accessing pre scribed medicinal cannabis have explicitly chosen to use a legal, phar maceutical grade medicine and do not fit the demographic profile of peo ple who use cannabis recreationally, who are typically younger males (AIHW, 2020a). Supplementing or substituting with an illicit medicinal cannabis product of unknown composition, strength, and with poten tial contamination would likely be at odds with the effort and expense of obtaining a quality assured and standardised legal pharmaceutical grade product for legitimate medical patients. However, as with other psychotropic prescription medications, the potential for misuse cannot be entirely excluded.

Access and patient impacts

A particular difficulty for regulating driving for patients prescribed medicinal cannabis relates to the nature of THC, which is a highly lipophilic substance that accumulates in body fat and soft tissue of people who regularly use the drug, from where it is slowly re leased, enabling detection in blood over a prolonged period (Wood & Dupont, 2020). A recent systematic review found that among people who frequently use cannabis, detectable blood levels of THC could re main elevated at above 2ng/ml (or even 5ng/ml in some individuals) for 6 days (Peng, Desapriya, Chan, & J, 2020). This group have been found to have a higher baseline THC blood level, and display no direct correlation between driving impairment and blood THC level (Wood & Dupont, 2020). Oral fluid THC readings have been reported for a shorter but also extended period of up to 78 hours after last consumption, with concentrations not correlated to either degree of impairment or blood THC level (Busardo et al., 2018; Jin, Williams, Chihuri, Li, & Chen, 2018; Odell, Frei, Gerostamoulos, Chu, & Lubman, 2015). This is important to note, given that an estimated 89% of medicinal cannabis approvals in Australia are for orally administered products (oil or spray), meaning the THC is metabolised at a significantly slower rate (Department of Health, 2020; Freshleaf Analytics, 2020; Vandrey et al., 2017). A re cent US Congress research report on cannabis and road safety reported a 'lack of correlation between both marijuana consumption and the level of THC in a person's system, and THC levels and driver impairment', con cluding that simple driver guidelines such as that provided with alcohol, are not possible (US Congress, 2019). As such, it is near impossible for medical practitioners or law enforcement agencies to provide accurate information about THC clearance to medicinal cannabis patients, with current advice that patients should not drive at all if they wish to avoid the risk of being charged with a presence offence (VicRoads, 2021).

The scope of presence offences in most Australian jurisdictions cre ates a major impediment to accessing medicinal cannabis for those who wish or need to continue driving lawfully, and a severe limitation on personal mobility for those who do access medicinal cannabis and then refrain from driving (Commonwealth of Australia, 2020). A typical ex ample of such an impact is provided by this 62 year old female patient who has had ovarian cancer for 10 years:

'After exhausting all conventional treatments, I received medicinal cannabis as part of a clinical trial and found the results to be favourable. I wanted to continue via a prescription from my GP, however, the police informed me that even though it was medically prescribed, I would be fined and have to go to court should I ever take a roadside drug test. I decided not to continue as I didn't want to give up driving, which is crucial for me to be able to live an independent life. Because of this I am continuing to use MS Contin [opioid] and Lyrica [pregabalin], which I don't like, and would much rather be taking medicinal cannabis to deal with the discomfort.'

Patients accessing medicinal cannabis in Australia are typically fac ing serious health conditions, most commonly chronic pain and cancer, for which this treatment provides a final therapeutic option. This group would be classified as 'vulnerable/impaired' based on a framework of transport disadvantage developed by Currie et al. (2010). They are par ticularly reliant on car travel and face high travel difficulties related to getting on and off buses, trains or trams, being able to get around alone, feeling safe when travelling, and experience an overall heightened risk of social exclusion due to transport disadvantage (Currie et al., 2010). Documented effects of lack of car transport include exclusion from ac cessing basic goods and services, social/recreational opportunities, and employment and education, with greater impacts identified in rural and remote areas (Kamruzzaman & Hine, 2011; Rose, Witten, & McCreanor, 2009). Lack of car access has also been identified as an important barrier to healthcare access, contributing to poorer chronic illness management and health outcomes. Identified effects include an increase in missed ap pointments, delayed care, and poorer medication adherence, with one study quantifying an 88% increase in odds of ED presentation among individuals citing 'lack of transport' as a barrier to primary care use (Rose et al., 2009; Rust et al., 2008; Syed, Gerber, & Sharp, 2013).

For medicinal cannabis patients who do drive, when not impaired, they face the possibility of conviction under the presence offences and associated serious penalties including fines, licence suspensions or even imprisonment, a situation noted as problematic in a recent Australian Senate inquiry (Commonwealth of Australia, 2020). However, they may also incur further substantial financial penalties if claiming compensa tion following a traffic related accident and THC is detected in their blood or oral fluids. For example, in Victoria, patients who have THC detected in blood or oral fluids within 3 hours of driving following an accident, even if not at fault, can have their income compensation re duced by a third (Transport Accident Commission, 2020).

Driving restrictions have also been reported to be the major imped iment to recruiting patients to medicinal cannabis clinical trials in Aus tralia (ACRE, 2020; NICM, 2020). Prohibiting driving for the length of a clinical trial, which can run for several weeks or months, is an oner

Table 3
International drug-driving (THC) enforcement approaches.

Country	THC presence offence?	THC detection method	Situation for medicinal cannabis patients	Additional information
United Kingdom	Yes	Oral fluid taken at roadside. Blood at police station or hospital and sent to laboratory.	Medical defence - if not impaired, and using a prescribed product as directed	Prescription medicines also tested for, but 'Zero tolerance' towards the presence of illicit substances. (Norwegian Ministry of Transport and Communications, 2020)
Norway	Yes	Oral fluid taken at roadside. Blood at police station or hospital and sent to laboratory.	Medical defence - if not impaired and using a prescribed, registered product as directed	20 drugs both licit and illicit are tested for against per se limits correlating with impairment. Gjerde et al., 2015)
Germany	Yes	Oral fluid taken at roadside. Blood at police station or hospital and sent to laboratory.	Medical defence - if not impaired, and using a prescribed product as directed	'Zero tolerance' towards the presence of illicit substances, some licit substances also tested for (Bundesregierung, 2020).
Ireland	Yes	Oral fluid taken at roadside. Blood at police station or hospital and sent to laboratory.	Statutory medical exemption certificate – does not apply if the person is found to be impaired (Road Safety Authority, 2020).	'Zero tolerance' towards the presence of illicit substances. (Irish Government, 2017)
New Zealand**	No	Field impairment assessment at roadside. Blood at police station or hospital and sent to laboratory.	Medical defence - if using a prescribed product as directed.	Presence of a licit or illicit drug (in blood) alone is not an offence, there must be additional evidence of impairment. (Ministry of Transport, 2019)

*A bill was introduced into the NZ Parliament in July 2020 which, if passed, will introduce a presence offence for THC detected in oral fluid. A medical defence will be available to patients prescribed medicinal cannabis (Ministry of Transport, 2020). Note, a recent report of the New Zealand Attorney General has concluded that provisions of the proposed Bill are inconsistent with the New Zealand Bill of Rights and recommends changing the focus from general deterrence to impaired driving (Attorney General, 2020).

ous requirement that deters participants and results in reduced access to novel medicinal cannabis treatments.

International approaches

As international jurisdictions continue to move toward legalising and regulating access to cannabis, the issue of driving impairment and how to manage or deter such behaviour has gained greater attention. While some research has attempted to evaluate international approaches to deter driving under the influence of cannabis (Watson & Mann, 2016; Wolff, 2016), there has been little attention given to how different juris dictions have managed the legalisation of medicinal cannabis in relation to drug driving legislation.

Although many jurisdictions have introduced medicinal cannabis ac cess schemes over the last decade, some of these, such as Canada and most states within the United States, are far more permissive than Aus tralia's medical access model (Abuhasira, Schleider, Mechoulam, & No vack, 2018). Several of these overseas jurisdictions have also decrim inalised or legalised the recreational use of cannabis and are there fore not comparable to Australia when considering road safety risks (Lancione et al., 2020).

An examination of regulatory and policy documents sourced primar ily from governmental websites, identified several international juris dictions which have introduced similar medical only access models to Australia, with pharmaceutical grade products available only via pre scription from a doctor. These jurisdictions include Norway, Ireland, the United Kingdom, Germany, and New Zealand. These countries, other than New Zealand, have drug driving presence offences relating to THC, similar to those that exist in Australia. However, in all cases they have adopted some form of medical defence enabling patients to drive when using a prescribed product as directed and not impaired (see Table 3). In all countries listed, other than New Zealand, it remains an offence to drive if impaired.

In many of these countries (UK, Norway, New Zealand) the medical defence applies to various prescription medicines that can be tested for and that have *per se* limits (blood or oral fluid limits deemed to reflect impairment) attached (Ministry of Transport NZ, 2019; Norwegian Min istry of Transport and Communications, 2020; UK Department of Trans port, 2013). However, in Ireland, where only illicit substances are tested for, a medical defence specific to medicinal cannabis was introduced and utilises a statutory medical exemption certificate (Irish Government, 2017). In Norway the medical exemption applies to registered medicines (at the time of writing only Sativex, a 50:50 THC CBD product) and health guidance recommends the patient not drive for 2 weeks after starting treatment (Norwegian Directorate of Health, 2021).

Other than medicinal cannabis, the only international example of a medical drug being included in zero tolerance offences is benzodi azepines in Sweden, but patients there are not guilty of this offence if using the drug as directed by a doctor (Morgland, 2020).

Discussion

As the number of patients accessing medicinal cannabis in Australia continues to increase, achieving the appropriate balance between road safety and patient access objectives is likely to gain further attention. Extensive experimental and epidemiological research indicates that the recreational use of cannabis is associated with a low to moderate in crease in crash risk, which is of a similar or lower magnitude than sev eral other potentially impairing prescription medications available and widely prescribed in Australia. However, the crash risk for prescribed medicinal cannabis is likely to be substantially lower due to a range of factors, with this outcome supported by available international epi demiological data that suggests a null road safety impact in jurisdictions introducing 'medical only' access models.

Given this risk profile, the appropriateness of the current regulatory approach criminalising the presence of THC for medicinal cannabis pa tients irrespective of impairment is questionable. Only in Tasmania does a medical defence cover medicinal cannabis patients. In all other juris dictions, patients risk criminal conviction for the presence of THC, even when not impaired and using the medicine as directed by their doctor. This approach has serious negative impacts on patient access, health, and mobility. It also fails to adhere to established principles that mo bility should not be limited on the basis of a specific treatment, and that the potentially impairing effects of a medication should be bal

anced against a patient's improvement in health and safe driving ability (Austroads, 2003; Commonwealth of Australia, 2017). These principles are incorporated into the risk minimisation framework used for other impairing prescription medications, coordinated via the TGA and state health and transport agencies.

The discrepancy in the treatment of medicinal cannabis patients compared with patients using other impairing medications is particu larly marked when considering that medical defences are currently in place for all other potentially impairing prescription medications that are included in drug driving presence offences in Australian jurisdictions (morphine, methadone and amphetamine). This creates a strange situa tion where medicinal cannabis patients are more vulnerable to prosecu tion than users of some illicit drugs (such as heroin, LSD or psilocybin, in Victoria, New South Wales and Queensland) who are able to drive while the drug is detectable in their bodily fluids if not impaired. Sim ilarly, even recreational users of alcohol with a BAC 0.01 to 0.05, who have crash risk odds of 1.2 1.8, face no restrictions on driving in nor mal circumstances (Bernhoft, Hels, Lyckegaard, Houwing, & Verstraete, 2012; Chihuri, Li, & Chen, 2017; Taylor et al., 2010).

The question then arises whether there may be other specific issues relating to medicinal cannabis that necessitate a harsher approach for these patients. Some potential concerns include possible misuse or sup plementation of medicinal cannabis with black market products, and the difficulty in communicating why medicinal cannabis patients can drive (if not impaired), but not recreational users. Both issues are com mon to, and currently managed for, other potentially impairing prescrip tion medications, with the public now well accustomed to different legal frameworks being in place for medical and illicit cannabis. The need for further research on road safety risk prior to any change has also been suggested. But the value or justification for such an apparent higher ev idence bar for medicinal cannabis is unclear, given the large number of observational and epidemiological studies that have already been under taken in relation to THC, as well as agreement of recent meta analyses of a relatively low risk profile even among recreational users (Elvik, 2013; Gjerde et al., 2015; Ole Rogeberg, 2019; O. Rogeberg & Elvik, 2016). These studies provide an evidence base far exceeding numerous other known impairing medications.

It is also noteworthy that other countries with medicinal cannabis schemes similar to Australia's tightly controlled, medical only access model, have implemented some form of exemption from usual drug driv ing offences for patients. In the UK, Norway, Germany, New Zealand and Ireland, patients with a valid prescription for medicinal cannabis who have taken the drug in accordance with instructions from a health practitioner are permitted to drive, as long as they are not impaired.

While it is beyond the scope of this paper to examine the issue of how to define 'impairment' and the most effective means of establish ing it at the roadside, standardised sobriety tests remain the most widely used method of screening for impairment internationally. They are also currently accepted by legal authorities in Australia as a valid screening tool for impairment caused by other potentially impairing prescription drugs, which are being prescribed at vastly higher rates than medicinal cannabis (e.g. benzodiazepines and opioids) . Although research assess ing sensitivity and specificity to drugs aside from alcohol is limited and interactions with medical condition symptoms may complicate such as sessments, sobriety tests have been found to be a moderate predictor of cannabis impairment (Ginsburg, 2019; Papafotiou, Carter, & Stough, 2005; Porath Waller & Beirness, 2014). As such, we see little justifica tion for not applying this method of detecting impairment to patients prescribed medicinal cannabis in Australia.

There are also further policy options that may be considered along side a medical defence or exemption for THC presence offences, in cluding: requiring a zero blood alcohol limit for medicinal cannabis pa tients (due to alcohol THC cross impairment increasing road safety risk (Downey et al., 2013)); prohibition from driving during the first weeks of treatment (as in Norway) to allow for dose finding and tolerance de velopment; specifying a maximum daily prescribed THC limit, above which the medical exemption would not apply; and simply improving patient education and advice. Due to the nature of THC metabolism and elimination, lack of correlation between oral fluid or blood levels and impairment in high frequency users, and the inability to provide accu rate advice to patients regarding THC clearance, the use of oral fluid or blood threshold levels is near unworkable. Even in Norway, for exam ple, where an upper blood threshold of 9ng/ml has been adopted for the general population, an exemption from this limit (and maximum per se limits applying to other psychotropic medicines for which limits have been set) is in place when medicinal cannabis has been prescribed by a doctor and is being used as directed (Norwegian Ministry of Transport and Communications, 2020). Ongoing improvement in roadside impair ment detection, including the potential application of new technologies such as apps and artificial intelligence, is also important for improv ing enforcement of DUI/DWI offences and relevant for all potentially impairing medications, including medicinal cannabis.

The current regulatory approach to medicinal cannabis and driving in most Australian jurisdictions, which criminalises the presence of THC in bodily fluids while driving irrespective of impairment, appears to de rive from the historical status of cannabis as a Schedule 9 substance with no recognised medical value. There is little evidence to justify this dif ferential treatment of medicinal cannabis patients, compared with those taking other potentially impairing medications. The relatively low risk profile of medicinal cannabis, harms associated with the current regu latory approach, and successful implementation of alternative policies in comparable countries suggest that a review of the regulatory frame work for prescribed medicinal cannabis and driving in Australia is war ranted. More broadly, our analysis suggests that in jurisdictions util ising doctor supervised, medical only access models, where medicinal cannabis is captured in broader medicines safety frameworks, patient exemptions from road safety THC 'zero tolerance' presence (but not im pairment) offences, as well as those based on *per se* limits, should be considered.

Ethics

As a policy analysis no primary research was undertaken, hence ethics approval was not required.

Funding

None.

Declarations of Interest

IM has acted as a consultant to Kinoxis Therapeutics, has sat on the Medical Advisory Board of BOD Australia, and has received honoraria from Janssen. He is an inventor on several patents relating to novel cannabinoid therapeutics. J Sarris has received consultancy payment from Australian Natural Therapeutics Group (as an independent scien tific advisor to a manufacturer of cannabis products). Other authors re port no competing interests. J Sinclair has pro bono appointments on the scientific advisory boards of United in Compassion and the Australian Medicinal Cannabis Association.

References

ABC. (2017). Medicinal cannabis plan crazy, SA Minister says. Retrieved from https://www.abc.net.au/news/2017-07-07/medicinal-cannabis-driving-plan-crazy,-sa-police-minister-says/8686688.

Abuhasira, R., Schleider, L. B.-L., Mechoulam, R., & Novack, V. (2018). Epidemiological characteristics, safety and efficacy of medical cannabis in the elderly. *European Journal of Internal Medicine, 49*, 44–50. 10.1016/j.ejim.2018.01.019.

ACRE, A. C. f. C. C. a. R. E. (2020). Current barriers to patient access to medicinal cannabis in Australia: Submission to the Senate Standing Committees on Community Affairs.

AIHW. (2020a). Alcohol, tobacco & other drugs in Australia, Cat. no: PHE 221. Retrieved from Canberra: https://www.aihw.gov.au/reports/phe/221/alcohol-tobacco-other-drugs-australia/contents/harm-minimisation/demand-reduction.

AIHW. (2020b). Alcohol, tobacco & other drugs in Australia. Cat. no. PHE 221.

Alvarez, F. J., & Fierro, I. (2008). Older drivers, medical condition, medical impairment and crash risk. *Accident Analysis & Prevention, 40*(1), 55–60. 10.1016/j.aap.2007.04.001.

Arkell, T. R., Vinckenbosch, F., Kevin, R. C., Theunissen, E. L., McGregor, I. S., & Ramaekers, J. G. (2020). Effect of Cannabidiol and Δ9-Tetrahydrocannabinol on Driving Performance: A Randomized Clinical Trial. *JAMA, 324*(21), 2177–2186. 10.1001/jama.2020.21218.

ATC. (2011). National Road Safety Strategy 2011–2020. Retrieved from Canberra.

Attorney General. (2020). Report of the Attorney General under the New Zealand Bill of Rights Act 1990 on the Land Transport (Drug Driving) Amendment Bill: Presented to the House of Representatives pursuant to Section 7 of the New Zealand Bill of Rights Act 1990 and Standing Order 265 of the Standing Orders of the House of Representatives. Retrieved from Wellington.

Austroads. (2003). Assessing Fitness to Drive for Commercial and Private Vehicle Drivers: Medical Standards for Licensing and Clinical Management Guidelines: Guidelines and Standards for Health Professionals in Australia (0855885076).

Bartle, J. (2020). Australia: Magistrate dismisses drug driving charge for medicinal cannabis user. Retrieved from https://www.mondaq.com/australia/crime/887728/magistrate-dismisses-drug-driving-charge-for-medicinal-cannabis.

Bergeron, J., Langlois, J., & Cheang, H. (2014). An examination of the relationships between cannabis use, driving under the influence of cannabis and risk-taking on the road. *European Review of Applied Psychology, 64*(3), 101–109.

Bergeron, J., & Paquette, M. (2014). Relationships between frequency of driving under the influence of cannabis, self-reported reckless driving and risk-taking behavior observed in a driving simulator. *Journal of Safety Research, 49*(19), e11–e24.

Bernhoft, I. M., Hels, T., Lyckegaard, A., Houwing, S., & Verstraete, A. G. (2012). Prevalence and Risk of Injury in Europe by Driving with Alcohol, Illicit Drugs and Medicines. *Procedia - Social and Behavioral Sciences, 48*, 2907–2916. 10.1016/j.sbspro.2012.06.1259.

Boehnke, K. F., Litinas, E., & Clauw, D. J. (2016). Medical Cannabis Use Is Associated With Decreased Opiate Medication Use in a Retrospective Cross-Sectional Survey of Patients With Chronic Pain. *Journal of Pain, 17*(6), 739–744. 10.1016/j.jpain.2016.03.002.

Brunnauer, A., Laux, G., Geiger, E., Soyka, M., & Möller, H. J. (2006). Antidepressants and driving ability: results from a clinical study. *Journal of Clinical Psychiatry, 67*(11), 1776–1781. 10.4088/jcp.v67n1116.

Bundesregierung, D. (2020). Fahren unter Drogen. Retrieved from https://www.polizei-beratung.de/themen-und-tipps/drogen/drogen-im-strassenverkehr/

Busardo, F. P., Pichini, S., Pellegrini, M., Montana, A., Lo Faro, A. F., Zaami, S., & Graziano, S. (2018). Correlation between Blood and Oral Fluid Psychoactive Drug Concentrations and Cognitive Impairment in Driving under the Influence of Drugs. *Current Neuropharmacology, 16*(1), 84–96 doi:10.2174/1570159X15666170828162057.

Celius, E. G., & Vila, C. (2018). The influence of THC:CBD oromucosal spray on driving ability in patients with multiple sclerosis-related spasticity. *Brain and Behavior, 8*(5), e00962. 10.1002/brb3.962.

Chihuri, S., & Li, G. (2017). Use of prescription opioids and motor vehicle crashes: A meta analysis. *Accident Analysis & Prevention, 109*, 123–131. 10.1016/j.aap.2017.10.004.

Chihuri, S., Li, G., & Chen, Q. (2017). Interaction of marijuana and alcohol on fatal motor vehicle crash risk: a case-control study. *Injury Epidemiology, 4*(1), 8. 10.1186/s40621-017-0105-z.

Colizzi, M., & Bhattacharyya, S. (2018). Chapter 7- Neurocognitive effects of cannabis: Lessons learned from human experimental studies. In T. Calvey (Ed.), *Progress in Brain Research (Vol. 242, pp. 179-216)*. Elsevier.

Commonwealth of Australia. (2017). Assessing fitnesss to drive 2016 - medical standards for licencing and clinical management guidelines (As amended up to August 2017). Retrieved from Canberra: https://austroads.com.au/ data/assets/pdf file/0022/104197/AP-G56-17 Assessing fitness to drive 2016 amended Aug2017.pdf.

Commonwealth of Australia. (2018). Australia's second generational approach to roadside drug testing: A report from the National Drug Driving Working Group October 2018. Retrieved from Canberra.

Commonwealth of Australia. (2020). Current barriers to patient access to medicinal cannabis in Australia: Senate, Community Affairs References Committee. Retrieved from Canberra.

Cook, A. C., Leung, G., & Smith, R. A. (2020). Marijuana Decriminalization, Medical Marijuana Laws, and Fatal Traffic Crashes in US Cities, 2010-2017. *American Journal of Public Health, 110*(3), 363–369. 10.2105/ajph.2019.305484.

Currie, G., Richardson, T., Smyth, P., Vella-Brodrick, D., Hine, J., Lucas, K., & Stanley, J. (2010). Investigating links between transport disadvantage, social exclusion and well-being in Melbourne – Updated results. *Research in Transportation Economics, 29*(1), 287–295. 10.1016/j.retrec.2010.07.036.

Dassanayake, T., Michie, P., Carter, G., & Jones, A. (2011). Effects of benzodiazepines, antidepressants and opioids on driving: a systematic review and meta-analysis of epidemiological and experimental evidence. *Drug Safety, 34*(2), 125–156. 10.2165/11539050-000000000-00000.

Department of Health. (2020). Submission to the Senate Community Affairs References Committee: Senate inquiry into the current barriers to patient access to medicinal cannabis in Australia.

Desrosiers, N. A., Ramaekers, J. G., Chauchard, E., Gorelick, D. A., & Huestis, M. A. (2015). Smoked Cannabis' Psychomotor and Neurocognitive Effects in Occasional and Frequent Smokers. *Journal of Analytical Toxicology, 39*(4), 251–261. 10.1093/jat/bkv012.

Downey, L. A., King, R., Papafotiou, K., Swann, P., Ogden, E., Boorman, M., & Stough, C. (2013). The effects of cannabis and alcohol on simulated driving: Influences of dose and experience. *Accident Analysis & Prevention, 50*, 879–886. 10.1016/j.aap.2012.07.016.

Drummer, O. (2008a). The role of drugs in road safety. *Australian Prescriber, 31*(33-5).

Drummer, O. (2008b). The role of drugs in road safety (Vol. 31).

Drummer, O. H., Gerostamoulos, J., Batziris, H., Chu, M., Caplehorn, J., Robertson, M. D., & Swann, P. (2004). The involvement of drugs in drivers of motor vehicles killed in Australian road traffic crashes. *Accident Analysis & Prevention, 36*(2), 239–248.

Elvik, R. (2013). Risk of road accident associated with the use of drugs: A systematic review and meta-analysis of evidence from epidemiological studies. *Accident Analysis & Prevention, 60*, 254–267. 10.1016/j.aap.2012.06.017.

Etges, T., Karolia, K., Grint, T., Taylor, A., Lauder, H., Daka, B., & Wright, S. (2016). An observational postmarketing safety registry of patients in the UK, Germany, and Switzerland who have been prescribed Sativex(®) (THC:CBD, nabiximols) oromucosal spray. *Therapeutics and Clinical Risk Management, 12*, 1667–1675. 10.2147/TCRM.S115014.

Freidel, M., Tiel-Wilck, K., Schreiber, H., Prechtl, A., Essner, U., & Lang, M. (2015). Drug-resistant MS spasticity treatment with Sativex((R)) add-on and driving ability. *Acta Neurologica Scandinavica, 131*(1), 9–16. 10.1111/ane.12287.

Freshleaf Analytics. (2020). Australian Medicinal Cannabis Market - Patient, Product and Pricing Analysis Q1 2020

Gibson, J. E., Hubbard, R. B., Smith, C. J., Tata, L. J., Britton, J. R., & Fogarty, A. W. (2009). Use of self-controlled analytical techniques to assess the association between use of prescription medications and the risk of motor vehicle crashes. *American Journal of Epidemiology, 169*(6), 761–768.

Ginsburg, B. C. (2019). Strengths and limitations of two cannabis-impaired driving detection methods: a review of the literature. *American Journal of Drug and Alcohol Abuse, 45*(6), 610–622. 10.1080/00952990.2019.1655568.

Gjerde, H., Strand, M. C., & Mørland, J. (2015). Driving under the influence of non-alcohol drugs - an update. Part I: epidemiological studies. *Forensic Science Review*, 27(2), 89-113. Retrieved from

Hartman, R. L., Brown, T. L., Milavetz, G., Spurgin, A., Pierce, R. S., Gorelick, D. A., & Huestis, M. A. (2016). Cannabis effects on driving longitudinal control with and without alcohol. *Journal of Applied Toxicology, 36*(11), 1418–1429.

Hill, L. L., Lauzon, V. L., Winbrock, E. L., Li, G., Chihuri, S., & Lee, K. C. (2017). Depression, antidepressants and driving safety. *Injury Epidemiology, 4*(1) 10-10. 10.1186/s40621-017-0107-x.

Irish Government, R. S. A. (2017). Anti Drug Driving - Campaign tackles drug driving and promotes awareness of new Preliminary Drug Testing. Retrieved from https://www.rsa.ie/RSA/Road-Safety/Campaigns/Current-road-safety-campaigns/Anti-Drug-Driving/.

Jin, H., Williams, S. Z., Chihuri, S. T., Li, G., & Chen, Q. (2018). Validity of oral fluid test for Delta-9-tetrahydrocannabinol in drivers using the 2013 National Roadside Survey Data. *Injury Epidemiology, 5*(1), 3. 10.1186/s40621-018-0134-2.

Kamruzzaman, M., & Hine, J. (2011). Participation index: a measure to identify rural transport disadvantage? *Journal of Transport Geography, 19*(4), 882–899. 10.1016/j.jtrangeo.2010.11.004.

Kim, J. H., Santaella-Tenorio, J., Mauro, C., Wrobel, J., Cerda, M., Keyes, K. M., & Li, G. H. (2016). State Medical Marijuana Laws and the Prevalence of Opioids Detected Among Fatally Injured Drivers. *American Journal of Public Health, 106*(11), 2032–2037. 10.2105/ajph.2016.303426.

Lancione, S., Wade, K., Windle, S. B., Filion, K. B., Thombs, B. D., & Eisenberg, M. J. (2020). Non-medical cannabis in North America: an overview of regulatory approaches. *Public Health, 178*, 7–14. 10.1016/j.puhe.2019.08.018.

Lee, J., Abdel-Aty, A., & Park, J. (2018). Investigation of associations between marijuana law changes and marijuana-involved fatal traffic crashes: A state-level analysis. *Journal of Transport & Health, 10*, 194–202. 10.1016/j.jth.2018.05.017.

Lenné, M. G., Dietze, P. M., Triggs, T. J., Walmsley, S., Murphy, B., & Redman, J. R. (2010). The effects of cannabis and alcohol on simulated arterial driving: Influences of driving experience and task demand. *Accident Analysis & Prevention, 42*(3), 859–866. 10.1016/j.aap.2009.04.021.

Leufkens, T. R. M., Lund, J. S., & Vermeeren, A (2009). Highway driving performance and cognitive functioning the morning after bedtime and middle-of-the-night use of gaboxadol, zopiclone and zolpidem. *Journal of Sleep Research, 18*(4), 387–396. 10.1111/j.1365-2869.2009.00746.x.

Longo, L. P., & Johnson, B. (2000). Addiction: Part I. Benzodiazepines–side effects, abuse risk and alternatives. *American Family Physician, 61*(7), 2121–2128.

MacCallum, C. A., & Russo, E. B. (2018). Practical considerations in medical cannabis administration and dosing. *European Journal of Internal Medicine, 49*, 12–19. 10.1016/j.ejim.2018.01.004.

Masten, S. V., & Guenzburger, G. V. (2014). Changes in driver cannabinoid prevalence in 12 U.S. states after implementing medical marijuana laws. *Journal of Safety Research, 50*, 35–52. 10.1016/j.jsr.2014.03.009.

McCartney, D., Arkell, T. R., Irwin, C., & McGregor, I. S. (2021). Determining the magnitude and duration of acute Δ 9 -tetrahydrocannabinol (Δ 9 -THC)-induced driving and cognitive impairment: A systematic and meta-analytic review. *Neuroscience & Biobehavioral Reviews, 126*, 175–193.

Ministry of Transport. (2019, 23/05/2019). Questions and answers on law to combat drug impaired driving. Retrieved from https://www.transport.govt.nz/legislation/acts/QAsdrugimpaireddrivinglaw/.

Ministry of Transport. (2020). Road to Zero: A New Road Safety Strategy for NZ, Drug Driving, Questions and Answers. Retrieved from https://www.transport.govt.nz/multi-modal/keystrategiesandplans/road-safety-strategy/drug-driving/questions-and-answers/.

Ministry of Transport NZ. (2019). Discussion Document: Enhanced Drug Impaired Driver Testing. Retrieved from Wellington.

Morgland, J. G. (2020). Driving under the influence of non-alcohol drugs: review of earlier studies. In A. Jones, J. G. Morland, & R. H. Liu (Eds.), *Alcohol, Drugs, and Impaired Driving Forensic Science and Law Enforcement Issues* (pp. 381–420). Boca Raton: CRC Press.

National Transport Commission. (2017). Assessing Fitness to Drive for Commercial and Private Vehicle Drivers: Medical standards for licensing and clinical management guidelines. Retrieved from Sydney.
National Transport Commission. (2018). Towards a national approach to drug driving: Information paper. Retrieved from Melbourne.
NICM. (2020). Submission: Current barriers to patient access to medicinal cannabis in Australia: Senate, Community Affairs References Committee. Retrieved from Westmead.
Norwegian Directorate of Health. (2021). Drivers licence guide regulations (Førerkortveileder). Retrieved from https://www.helsedirektoratet.no/veiledere/forerkortveileder.
Norwegian Ministry of Transport and Communications. (2020). Driving under the influence of non-alcohol drugs – legal limits implemented in Norway. Retrieved from Oslo: https://www.regjeringen.no/contentassets/61d8bf75d02e4b64ab0bfbea244b78d9/sd ruspavirket kjoring net.pdf.
Odell, M. S., Frei, M. Y., Gerostamoulos, D., Chu, M., & Lubman, D. I. (2015). Residual cannabis levels in blood, urine and oral fluid following heavy cannabis use. *Forensic Science International, 249*, 173–180. 10.1016/j.forsciint.2015.01.026.
Ogourtsova, T., Kalaba, M., Gelinas, I., Korner-Bitensky, N., & Ware, M. A. (2018). Cannabis use and driving-related performance in young recreational users: a within-subject randomized clinical trial. *CMAJ open, 6*(4), E453–E462. 10.9778/cmajo.20180164.
Papafotiou, K., Carter, J. D., & Stough, C. (2005). The relationship between performance on the standardised field sobriety tests, driving performance and the level of Delta9-tetrahydrocannabinol (THC) in blood. *Forensic Science International, 155*(2-3), 172–178. 10.1016/j.forsciint.2004.11.009.
Patten, F. (2020). Medicinal Cannabis Driving Laws Must Change Now: Fiona Patten MP. Retrieved from https://fionapatten.com.au/news/medicinal-cannabis-driving-laws-must-change-now-fiona-patten-mp/.
Peng, Y. W., Desapriya, E., Chan, H., & J, R. B (2020). Residual blood THC levels in frequent cannabis users after over four hours of abstinence: A systematic review. *Drug and Alcohol Dependence, 216*, Article 108177. 10.1016/j.drugalcdep.2020.108177.
Popescu, F. D. (2008). H1 antihistamines and driving. *Journal of medicine and life, 1*(3), 262–268. Retrieved from https://pubmed.ncbi.nlm.nih.gov/20108503 .
Porath-Waller, A. J., & Beirness, D. J. (2014). An examination of the validity of the standardized field sobriety test in detecting drug impairment using data from the Drug Evaluation and Classification program. *Traffic Injury Prevention, 15*(2), 125–131. 10.1080/15389588.2013.800638.
Purcell, C., Davis, A., Moolman, N., & Taylor, S. M. (2019). Reduction of Benzodiazepine Use in Patients Prescribed Medical Cannabis. *Cannabis and Cannabinoid Research, 4*(3), 214–218. 10.1089/can.2018.0020.
Quilter, J. A., & McNamara, L. (2017). 'Zero Tolerance' Drug Driving Laws in Australia: A Gap Between Rationale and Form? *International Journal for Crime, Justice and Social Democracy, 6*(3), 47–71. 10.5204/ijcjsd.v6i3.416.
Ramaekers, J. G. (2003). Antidepressants and driver impairment: empirical evidence from a standard on-the-road test. *Journal of Clinical Psychiatry, 64*(1), 20–29 Retrieved from. http://europepmc.org/abstract/MED/12590619.
Ramaekers, J. G., Kauert, G., Theunissen, E. L., Toennes, S. W., & Moeller, M. R. (2009). Neurocognitive performance during acute THC intoxication in heavy and occasional cannabis users. *Journal of Psychopharmacology, 23*(3), 266–277. 10.1177/0269881108092393.
Ramaekers, J. G., Mason, N. L., & Theunissen, E. L. (2020). Blunted highs: Pharmacodynamic and behavioral models of cannabis tolerance. *European Neuropsychopharmacology*. 10.1016/j.euroneuro.2020.01.006.
Ramaekers, J. G., Theunissen, E. L., de Brouwer, M., Toennes, S. W., Moeller, M. R., & Kauert, G. (2011). Tolerance and cross-tolerance to neurocognitive effects of THC and alcohol in heavy cannabis users. *Psychopharmacology, 214*(2), 391–401. 10.1007/s00213-010-2042-1.
Ramaekers, J. G., van Wel, J. H., Spronk, D., Franke, B., Kenis, G., Toennes, S. W., & Verkes, R. J. (2016). Cannabis and cocaine decrease cognitive impulse control and functional corticostriatal connectivity in drug users with low activity DBH genotypes. *Brain Imaging and Behavior, 10*(4), 1254–1263. 10.1007/s11682-015-9488-z.
Richer, I., & Bergeron, J. (2009). Driving under the influence of cannabis: Links with dangerous driving, psychological predictors, and accident involvement. *Accident Analysis & Prevention, 41*(2), 299–307.
Road Safety Authority. (2020). Anti Drug Driving. Retrieved from https://www.rsa.ie/RSA/Road-Safety/Campaigns/Current-road-safety-campaigns/Anti-Drug-Driving/.
Rogeberg, O. (2019). A meta-analysis of the crash risk of cannabis-positive drivers in culpability studies—Avoiding interpretational bias. *Accident Analysis & Prevention, 123*, 69–78. 10.1016/j.aap.2018.11.011.
Rogeberg, O., & Elvik, R. (2016). The effects of cannabis intoxication on motor vehicle collision revisited and revised. *Addiction, 111*(8), 1348–1359. 10.1111/add.13347.
Rose, E., Witten, K., & McCreanor, T. (2009). Transport related social exclusion in New Zealand: Evidence and challenges. *Kōtuitui: New Zealand Journal of Social Sciences Online, 4*(3), 191–203. 10.1080/1177083X.2009.9522454.
Rudisill, T. M., Zhu, M., Kelley, G. A., Pilkerton, C., & Rudisill, B. R. (2016). Medication use and the risk of motor vehicle collisions among licensed drivers: A systematic review. *Accident Analysis & Prevention, 96*, 255–270. 10.1016/j.aap.2016.08.001.
Rust, G., Ye, J., Baltrus, P., Daniels, E., Adesunloye, B., & Fryer, G. E. (2008). Practical Barriers to Timely Primary Care Access: Impact on Adult Use of Emergency Department Services. *Archives of Internal Medicine, 168*(15), 1705–1710. 10.1001/archinte.168.15.1705.
Santaella-Tenorio, J., Mauro, C. M., Wall, M. M., Kim, J. H., Cerdá, M., Keyes, K. M., & Martins, S. S. (2017). US Traffic Fatalities, 1985-2014, and Their Relationship to Medical Marijuana Laws. *American Journal of Public Health, 107*(2), 336–342. 10.2105/AJPH.2016.303577.
Schlag, A. K. (2020). An Evaluation of Regulatory Regimes of Medical Cannabis: What Lessons Can Be Learned for the UK? *Medical Cannabis and Cannabinoids, 3*(1), 76–83. 10.1159/000505028.
Sevigny, E. L. (2018). The effects of medical marijuana laws on cannabis-involved driving. *Accident Analysis & Prevention, 118*, 57–65. 10.1016/j.aap.2018.05.023.
Sewell, R. A., Poling, J., & Sofuoglu, M. (2009). The effect of cannabis compared with alcohol on driving. *The American journal on addictions /American Academy of Psychiatrists in Alcoholism and Addictions, 18*(3), 185–193. 10.1080/10550490902786934.
Smiley, A. (1999). Marijuana: on road and driving simulator studies. *The Health Effects of Cannabis*, 173–191.
Stout, P. R., & Farrell, L. J. (2003). Opioids-Effects on human performance and behavior. *Forensic Science Review, 15*(1), 29–58.
Strand, M., Gjerde, H., & Mørland, J. (2016). Driving under the influence of non-alcohol drugs - an update. Part II: experimental studies. *Forensic science review, 28*(2), 79–101 Retrieved from.
Strand, M. C., Fjeld, B., Arnestad, M., & Mørland, J. (2013). Can Patients Receiving Opioid Maintenance Therapy Safely Drive? A Systematic Review of Epidemiological and Experimental Studies on Driving Ability With a Focus on Concomitant Methadone or Buprenorphine Administration. *Traffic Injury Prevention, 14*(1), 26–38. 10.1080/15389588.2012.689451.
Stutts, J. C. (1998). Do Older Drivers with Visual and Cognitive Impairments Drive Less? *Journal of the American Geriatrics Society, 46*(7), 854–861. 10.1111/j.1532-5415.1998.tb02719.x.
Syed, S. T., Gerber, B. S., & Sharp, L. K. (2013). Traveling towards disease: transportation barriers to health care access. *Journal of Community Health, 38*(5), 976–993. 10.1007/s10900-013-9681-1.
Taylor, B., Irving, H. M., Kanteres, F., Room, R., Borges, G., Cherpitel, C., & Rehm, J. (2010). The more you drink, the harder you fall: A systematic review and meta-analysis of how acute alcohol consumption and injury or collision risk increase together. *Drug and Alcohol Dependence, 110*(1), 108–116. 10.1016/j.drugalcdep.2010.02.011.
TGA. (2019). *SAS B approvals for medicinal cannabis products between 03/2017 and 03/2019. In F. 1081-1819-01 (Ed.)*. TGA. https://www.tga.gov.au/sites/default/files/foi-1081-1819-01.pdf.
TGA. (2021a). Access to medicinal cannabis products: SAS Category B approval statistics. Retrieved from https://www.tga.gov.au/access-medicinal-cannabis-products-1.
TGA. (2021b). Medicinal cannabis: Information for sponsors and manufacturers. Retrieved from https://www.tga.gov.au/medicinal-cannabis-information-sponsors-and-manufacturers.
Transport Accident Commission (2020) "Who is not eligible to receive loss of earnings benefits." Retrieved 26 August 2020, from https://www.tac.vic.gov.au/clients/how-we-can-help/treatments-and-services/policies/other/loss-of-earnings-benefits/who-is-not-eligible-to-receive-loss-of-earnings-benefits.
UK Department of Transport. (2013, 27 August 2017). Changes to drug driving law. Retrieved from https://www.gov.uk/government/collections/drug-driving#table-of-drugs-and-limits.
UNCND. (2020). Commission on Narcotic Drugs Reconvened sixty-third session: Draft report. Retrieved from Geneva.
United Nations. (2020). *UN commission reclassifies cannabis, yet still considered harmful*. UN News (December). Retrieved from. https://news.un.org/en/story/2020/12/1079132.
US Congress. (2019). Marijuana Use and Highway Safety. Retrieved from Washington
Vandrey, R., Herrmann, E. S., Mitchell, J. M., Bigelow, G. E., Flegel, R., LoDico, C., & Cone, E. J. (2017). Pharmacokinetic Profile of Oral Cannabis in Humans: Blood and Oral Fluid Disposition and Relation to Pharmacodynamic Outcomes. *Journal of Analytical Toxicology, 41*(2), 83–99. 10.1093/jat/bkx012.
Verster, J. C., Bervoets, A. C., de Klerk, S., & Roth, T. (2014). Lapses of attention as outcome measure of the on-the-road driving test. *Psychopharmacology, 231*(1), 283–292. 10.1007/s00213-013-3236-0.
Verster, J. C., & Volkerts, E. R. (2004). Antihistamines and driving ability: evidence from on-the-road driving studies during normal traffic. *Annals of Allergy, Asthma & Immunology, 92*(3), 294–303 quiz 303-295, 355. 10.1016/s1081-1206(10)61566-9.
VicRoads. (2021). Medicinal Cannabis and Driving. Retrieved from https://www.vicroads.vic.gov.au/safety-and-road-rules/driver-safety/drugs-and-alcohol/medicinal-cannabis-and-driving
VLRC. (2015). Medicinal Cannabis issues paper March 2015. Retrieved from Melbourne:
Watson, T. M., & Mann, R. E. (2016). International approaches to driving under the influence of cannabis: A review of evidence on impact. *Drug and Alcohol Dependence, 169*, 148–155. 10.1016/j.drugalcdep.2016.10.023.
Wilhelmi, B. G., & Cohen, S. P. (2012). A framework for "driving under the influence of drugs" policy for the opioid using driver. *Pain physician, 15*(3 Suppl) ES215-230. Retrieved from.
Wolff, K. (2016). Different approaches to Setting Limits for Drugs and Alcohol Use when Driving. In K. Wolff, J. White, & S. Karch (Eds.), *The SAGE Handbook of Drug and Alcohol Studies: Biological Approaches* (pp. 434–445). London, UK: Sage Publications.
Wood, E. C., & Dupont, R. L. (2020). Cannabis-Impaired Driving: Evidence and the Role of Toxicology Testing. In K. Finn (Ed.), *Cannabis in Medicine: An Evidence-Based Approach* (pp. 493–513). Cham: Springer International Publishing.