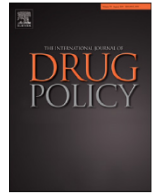




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Policy analysis

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



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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

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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 vapourisation (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 medic-

inal 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). Impaired in psychomotor functions (Brunnauer, Laux, Geiger, Soyka, & Möller, 2006)	↑ 1.40 (Hill et al., 2017). ↑ 1.39 (Elvik, 2013) ↑ NQ ¹ (Gjerde et al., 2015)
Antihistamines	Primarily sedation that can cause impairment comparable to >0.05 BAC (J. C. Verster & Volkerts, 2004). Impaired reaction time and psychomotor performance (variation by type) (Popescu, 2008)	↑ 1.20 (Gibson et al., 2009) ↑ 1.12 (Elvik, 2013) ↑ NQ (Rudisill et al., 2016)
Benzodiazepines	Sedation, drowsiness, learning impairment, psychomotor slowing (Longo & Johnson, 2000 2016). Almost every aspect of driver behaviour shown to be affected (Rudisill et al., 2016)	↑ 1.65-2.30 (Elvik, 2013) ↑ 1.6-1.8 (Dassanayake, Michie, Carter, & Jones, 2011) ↑ (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.

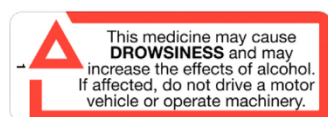


Fig. 1. Sedating medicines warning label.

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).

Jurisdiction/Legislation	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 points² 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 Victoria¹), 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 impaired coordination, visual function and attention, which can persist for several hours after consumption (Arkell et al., 2020; McCartney, Arkell, Irwin, & McGregor, 2021; Ogourtsova, Kalaba, Gelinis, 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 associated 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 increase 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 confounders 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 medicinal cannabis as none have differentiated between medical and recreational 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 doing 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 psychoactive effect. Driving under the influence of cannabis is also associated 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 reduce 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 impairing 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 reporting that 45% of medicinal cannabis patients taking benzodiazepines at baseline had ceased use of these drugs at six months, while another found large reductions in opioid use among chronic pain patients (Boehnke, Litinas, & Clauw, 2016; Purcell, Davis, Moolman, & Taylor, 2019). Similarly, improvements in clinical symptoms following 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 simulation and large patient registry studies of Sativex have identified no evidence 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 impairment 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 epidemiological 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 after consumption). Hence, an increase in the proportion of fatally injured THC positive drivers may simply reflect a greater proportion of the population 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 proportion of fatally injured drivers testing positive for THC in states moving 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), suggesting 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 pronounced cognitive impairment in several domains related to driving, such as divided attention and time perception (Colizzi & Bhattacharyya, 2018; McCartney et al., 2021). As patients are typically taking 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 compensate for any impairing effects (J. G. Ramaekers, Mason, & Theunissen, 2020). 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.

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, supplementation 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 medications 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 medicinal cannabis products are currently subsidised via the Pharmaceutical Benefits Scheme (the Australian government's drug subsidisation program), meaning that patients need to pay the full cost of the product themselves, which is higher than the street price of illicit cannabis (Freshleaf Analytics, 2020). As a result, there is little financial incentive for the diversion or overuse of prescribed medicinal cannabis products. Conversely though, the high cost of medicinal cannabis products may provide an incentive for patients to either supplement their prescription 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 concurrent recreational use among this group was possible due to the low numbers (AIHW, 2020b). It is therefore difficult to draw firm conclusions 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 prescribing of medicinal cannabis products containing THC (with one exception, 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 approval, 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 prescribed medicinal cannabis have explicitly chosen to use a legal, pharmaceutical grade medicine and do not fit the demographic profile of people 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 potential 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 released, 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 remain 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 recent 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', concluding 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 creates 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 example 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 facing 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 particularly 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 accessing 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 appointments, 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 compensation 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 reduced by a third (Transport Accident Commission, 2020).

Driving restrictions have also been reported to be the major impediment to recruiting patients to medicinal cannabis clinical trials in Australia (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 jurisdictions have managed the legalisation of medicinal cannabis in relation to drug driving legislation.

Although many jurisdictions have introduced medicinal cannabis access schemes over the last decade, some of these, such as Canada and most states within the United States, are far more permissive than Australia's medical access model (Abuhasira, Schleider, Mechoulam, & Novack, 2018). Several of these overseas jurisdictions have also decriminalised or legalised the recreational use of cannabis and are therefore not comparable to Australia when considering road safety risks (Lancione et al., 2020).

An examination of regulatory and policy documents sourced primarily from governmental websites, identified several international jurisdictions which have introduced similar medical-only access models to Australia, with pharmaceutical grade products available only via prescription 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 Transport, 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 benzodiazepines 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 increase in crash risk, which is of a similar or lower magnitude than several 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 epidemiological 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 patients irrespective of impairment is questionable. Only in Tasmania does a medical defence cover medicinal cannabis patients. In all other jurisdictions, 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 mobility 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 particularly 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 situation where medicinal cannabis patients are more vulnerable to prosecution 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. Similarly, 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 normal 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 supplementation 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 common to, and currently managed for, other potentially impairing prescription 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 evidence bar for medicinal cannabis is unclear, given the large number of observational and epidemiological studies that have already been undertaken 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 driving 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 establishing 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 assessing sensitivity and specificity to drugs aside from alcohol is limited and interactions with medical condition symptoms may complicate such assessments, 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 justification 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 alongside a medical defence or exemption for THC presence offences, including: requiring a zero blood alcohol limit for medicinal cannabis patients (due to alcohol-THC cross impairment increasing road safety risk (Downey et al., 2013)); prohibition on driving during the first weeks of treatment (as in Norway) to allow for dose finding and tolerance development; 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 accurate advice to patients regarding THC clearance, the use of oral fluid or blood threshold levels is near unworkable. Even in Norway, for example, 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 impairment detection, including the potential application of new technologies such as apps and artificial intelligence, is also important for improving 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 derive from the historical status of cannabis as a Schedule 9 substance with no recognised medical value. There is little evidence to justify this differential 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 regulatory approach, and successful implementation of alternative policies in comparable countries suggest that a review of the regulatory framework for prescribed medicinal cannabis and driving in Australia is warranted. 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.

Ethics

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

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None.

Declarations of Interest

IM has acted as a consultant to Kinosis 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 scientific advisor to a manufacturer of cannabis products). Other authors report no competing interests. J Sinclair has pro bono appointments on the scientific advisory boards of United in Compassion and the Australian Medicinal Cannabis Association.

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