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Commentary

Medical marijuana. What can we learn from the experiences in Canada, Germany and Thailand?

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ABSTRACT

Cannabis policies are changing globally, and medical marijuana programs are part of these changes. Drawing from the examples of two high-income (Canada, an early adopter of medical marijuana, and Germany, a late adopter) and one middle-income (Thailand) countries, we illustrate two main pressures underlying these recent changes. First, in many high-income countries, cannabis has been used to self-medicate for different ailments and diseases, even though there is no evidence of effectiveness for many of these conditions. Second, the cannabis industry is pressuring governments and decision-makers to allow for medical marijuana use with lenient regulations—without specifying medical conditions (indications) and requiring only a prescription from a health professional to obtain it. As a result, demand is likely to increase, even in countries with low prevalence of use. Cannabis policy-makers need to consider a balance between the medical benefits of medical marijuana and the potential public health consequences and cost.

Medical marijuana as part of marijuana policy

Cannabis policies are changing globally (WHO Expert Committee on Drug Dependence Pre-Review, 2018a). More and more countries are considering alternatives to strict prohibition, either via legalization (e.g., Canada, Uruguay, some US states), decriminalization or tolerance (e.g., Portugal, The Netherlands, some places in India), or by allowing the use of cannabis solely for medical use. Accordingly, in 2018, the Expert Committee on Drug Dependence of the WHO recommended rescheduling cannabis given the evidence around its medical use (Mayor, 2019). To date, medical marijuana (MMJ) programs have been initiated in both high- and middle-income countries, including but not limited to Canada, Colombia, Chile, Germany, Israel, Italy, Jamaica, The Netherlands, Switzerland, Thailand, United Kingdom, Uruguay and more than 30 US states (Abuhasira, Shbiro & Landschaft, 2018). Some have considered MMJ programs to be a form of legalization or decriminalization "through the back door" (Hurley, 2018). However, a closer look reveals that MMJ programs do not denote a homogenous set of policies: these programs can involve anything from allowing unprocessed herbal cannabis (plants or resin) for the treatment of a limited number of conditions to an omnibus treatment option for any kind of ailment diagnosed by a medical professional. Accordingly, two kinds of reasoning are required: first, a medical reasoning to determine a limited set of medical indications, where enough evidence exists to allow MMJ as a treatment intervention (Abrams, 2018; National Academies of Sciences Engineering & Medicine, 2017) and second, a public health reasoning to determine whether the introduction of MMJ programs has effects on population health on a wider scale (Fischer, Murphy, Kurdyak, Goldner & Rehm, 2015).

When discussing MMJ, we are referring to unprocessed herbal

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cannabis and not to cannabinoid-based medicines, such as nabiximols (tradename: sativex; (WHO Expert Committee on Drug Dependence Pre-Review, 2018b). Such products are legal in many more countries without the controversies surrounding MMJ programs (Abuhasira et al., 2018).

While we will make general arguments that apply to all countries, we will mainly be describing the situation in Canada, Germany and Thailand and the different iterations of MMJ policies in them. They have been chosen to represent both high-income (Canada, Germany) and middle-income (Thailand) countries, as well as to show processes in one country which adopted MMJ early (Canada), and in two which adopted MMJ policies more recently (Germany, Thailand). We will attempt to demonstrate that there are some processes and considerations in regard to MMJ policy that are similar in all three countries, despite these differences.

The medical model: restricted use of marijuana only for limited indications

In 1999, Canada was the first country after the international prohibition of cannabis (United Nations: International Narcotics Control Board (INCB), 1972) to initiate a MMJ program in response to an Ontario court challenge (Lucas, 2008). The 1998 court case concerned a person living with HIV/AIDS who faced cannabis possession and cultivation charges for attempting to grow a personal supply of medical cannabis to treat the symptoms of his condition. The Ontario Superior Court recognized his legal right to access cannabis without legal consequences, and instructed Health Canada to create a process allowing for legal access to this medicine (Lucas, 2008). Health Canada first handled the case via an exemption of the Controlled Drugs and Substances Act (Government of Canada, 2018a), and in 2001 implemented the Marijuana Medical Access Regulations (MMAR), which replaced the exemption process (Lucas, 2008).

The MMAR was very bureaucratic and restrictive, and was focused on a limited number of conditions (end-of-life care, severe pain from a very limited number of conditions such as multiple sclerosis, spinal cord injury, cancer, HIV/AIDS infection, severe forms of arthritis; seizures from epilepsy). Only several hundred participants were enrolled in the program in the first decade of the 21st century, but many more used cannabis to self-medicate illegally. Cannabis was obtained via illegal but often tolerated community-based 'MMJ dispensaries' (Lucas, 2008).

This practice demonstrated one of the driving forces of MMJ in many high-income countries. A sizable portion of the general population in these countries (between 5% and 15%) were using cannabis (see the various World Drug Reports, most recently (United Nations Office on Drugs and Crime (UNODC), 2018)), and, among those, many used the substance for self-medicating purposes. While there is no estimate of the global proportion of cannabis users who self-medicate, a recent systematic review shows that for many medical conditions, the proportion of self-medication is high (WHO Expert Committee on Drug Dependence Pre-Review, 2018a). Many of the users experience relief of symptoms (WHO Expert Committee on Drug Dependence Pre-Review, 2018a), even though for most medical indications more controlled studies are lacking (National Academies of Sciences Engineering & Medicine, 2017), leading to a push for governments to create special regulations or laws to allow for MMJ use.

Even in middle-income countries, there is continuous pressure for implementation of MMJ laws. In Thailand, for example, the Thai National Legislative Assembly amended the original law, the Narcotic Act B.E. 2522 (1979), which had previously prohibited the use of marijuana for all reasons, to legally allow the use of marijuana for medical reasons if the patient obtained a prescription from his or her medical doctor, dentist or registered Thai-traditional medical personnel (Government Gazette (Thailand), 2019). This new MMJ law was enacted on February 18th, 2019. While household surveys indicate a very low 12-month prevalence of use level (0.2% among the general population) in this country (Angkurawaranon et al., 2018), further pressure was applied by those who used marijuana to self-medicate for pain such as end-stage cancer patients. A public campaign, 'Cannabis 268-km Walk for Patients, Thailand', by 11 civic groups in Thailand (Thai PBS NEWS, 2019) led by a group of patients and marijuana advocacy groups, began a 268-km walk on May 21st, 2019. This campaign advocated for an amendment to change the legal status of cannabis from an illegal substance to a controlled plant which would allow patients to grow their own cannabis plants for medical purposes (for more detail, see (Sornpaisarn, Manthey & Rehm, 2019)).

Thailand also illustrates other driving forces for implementing MMJ laws: industry and politics. In a recent meeting to discuss the details of their implementation, all major policy actors in Thailand reported having recently had discussions with industry representatives who pointed out the advantages of MMJ for Thailand. In general, in many countries pressure from users and from industry push decision-makers to initiate or loosen the requirements of MMJ programs without meeting the usual standard required for approval from the medical community.

Medical marijuana as a step towards tolerance or legalization

MMJ laws are often seen as the most convenient way for politicians to avoid making a decision regarding decriminalization or legalization—while still showing compassion and a willingness to listen to the public. For example, in 2013 and 2014, the Canadian government was facing an election in the following year, with the majority of Canadians stating a preference for the legalization of cannabis (59% in 2014; (Angus Reid Institute, 2016)). With the opposing parties either opting for decriminalization or legalization, and with cannabis policy being one of the major topics in the election, the ruling Conservative Party opted to support more lenient regulations for MMJ use.

By 2014, Canada's restrictive MMJ policies had already been widened to include more than 30,000 participants in the MMJ program, although the typical users at this time were severely ill and functionally disabled (Fischer et al., 2017). With the revised legislation under the Marijuana for Medical Purposes Regulations (Government of Canada, 2018b), the government's role was restricted to regulation, and the indication criteria were broadening to encompass almost any health benefits endorsed by a medical doctor.

Thailand may again serve as an example of how MMJ programs come under pressure to become a stepping stone for legalization. A Thai political party, Phumjaithai, home of the newly appointed health minister, announced one of its political campaigns, "Economic Marijuana Policy", for the national election held on March 24th, 2019 (MSN News, 2019). This political campaign aimed to change the legal status of cannabis from an illicit substance to a licit one, in order to allow citizens to grow 6 cannabis plants per household. According to the party estimates, households could earn $12,000 US per year by selling the plants to industry (the 2017 Gross Domestic Product *per capita* was about US$ 6500; (The World Bank, 2019)), without any evidence provided to support this claim. Both the campaign and the party were supported by cannabis industry (Chang International Circuit, 2019).

This one example illustrates that economic drivers can be important in MMJ and marijuana politics; and the current gold rush mentality extends far beyond Thailand. Cannabis is a global industry with a value projected to be between 2- and 3-digit billion dollars (Pellechia, 2018), and many countries and their governments believe they can get their share, if they allow the use of MMJ immediately.

Germany: a case study

In Germany, substantial changes to the provision of MMJ have recently been undertaken, providing an excellent case study to learn from. Up until 2017, the only way to be granted access to MMJ in

Germany was to seek a special individual exemption ('Ausnahmegenehmigung') from the Federal Opium Agency. To receive this special permit, patients had to overcome several medical, economic and bureaucratic barriers, including but not limited to obtaining a medical certificate stating that no other therapy was effective in treating their symptoms, showing the full support of their physician, and agreeing to take precautionary measures ensuring that MMJ could not be stolen from their homes (Grotenhermen, 2014). If patients were granted access to obtain MMJ, they had to find a pharmacy willing to import the MMJ (usually from The Netherlands). The average price of 15–18 € per gram of MMJ had to be covered by the patients themselves. As of February 1, 2017, only 1080 patients had been granted the special permit to legally use marijuana for medical purposes (Stafford, 2017).

In January 2017, a formal MMJ program was voted for by Germany's lower house of parliament (Deutscher Bundestag, 2017). This move came in response to a verdict criticizing the then-common practice of routinely dismissing applications for special permits (see details above) and was further justified by the huge financial burden put on patients accessing MMJ through the use of special permits. The law came into effect on March 10, 2017 and equated MMJ with other cannabinoid-based medicines which had been authorized prior to 2017. It included the following measures:

- To provide MMJ for patients with "severe illnesses" if prescribed by a medical professional under 2 conditions:
  - a recognized standard treatment option was not available or the treating physician considered the standard treatment not to apply to the their patient, AND
  - the prospect of a positive impact of MMJ therapy was not entirely implausible (Deutscher Bundestag, 2017; Müller-Vahl & Grotenhermen, 2017);
- To cover the costs for prescribed MMJ through the public health insurance system;
- To coordinate the production of MMJ in Germany and to investigate the medical effects of MMJ, a cannabis agency was formed within the government-run 'Federal Institute for Drugs and Medical Devices (Stafford, 2017).

In summary, the main changes in access to MMJ were: (1) the coverage of costs by insurance, and (2) the increased number of patient groups qualifying for inclusion in the program. Data from a major health insurance company indicate that access to MMJ has grown exponentially since the passing of the new law: from 44,000 MMJ units dispensed in the first ten months after amendment in 2017 to 145,000 MMJ units in 2018 (Sturm & Shemyakova, 2019). As more extensive monitoring data have not been published yet, a definite number or description of patients with access to MMJ is not yet available. However, four of the largest public health insurance companies received nearly 20,000 claims to cover costs for MMJ in 2018 (Sturm & Shemyakova, 2019).

While the number of patients seems to have grown rapidly, several barriers hinder further rates of increase:

(1) The demand for MMJ exceeded Germany's import capacities (Jung, 2018a).
(2) Despite the new law, only about 60% of the MMJ therapy claims are currently reimbursed by health insurance companies (Jung, 2018b).
(3) A sizeable number of physicians are hesitant to prescribe MMJ (Borsch, 2018).

The first barrier will largely be overcome in the near future as the cannabis agency has just issued licenses to produce domestic MMJ (Bundesinstitut für Arzneimittel und Medizinprodukte, 2019), yet the licenses are not expected to fully cover domestic demand, so some import will still be necessary. With regard to the other barriers, the current government does not intend to overhaul the reimbursement procedures, and physicians as well as other medical professionals remain skeptical about the new law, citing insufficient knowledge among physicians, the lack of a list of medical conditions, and inconclusive evidence of any benefit to patients (Bühring, 2016; Hauth et al., 2016). In contrast, opposition parties suggest treating cannabis in the same manner as any other medication in order to facilitate routine reimbursement (Kappert-Gonther et al., 2019; Movassat et al., 2019), and this is echoed by the Association for Cannabinoid Medicines (Arbeitsgemeinschaft Cannabis als Medizin e.V., 2019).

While it is too early to fully evaluate the MMJ program in Germany, the available data suggest that the amendment was followed by an increase of MMJ patients, and this number could rise even further. As the MMJ program has been introduced by a coalition of Conservatives and Social Democrats, who oppose legalization of nonmedical cannabis use (at the federal level), the MMJ program is not believed to pave the way to legalization of cannabis at this point. Further, and unlike in North America, MMJ has always been dispensed through licensed pharmacies in Germany, resulting in a stricter separation of the medical and recreational system.

Given the preliminary evidence base, what can be learned from the implementation of the German MMJ program? As with other countries, there was enough pressure applied on the government to broaden existing regulations. However, these regulations were loosened without systematically determining actual need, which is impossible without a clear set of medical conditions. The regulations, without identifying specific conditions, led to a situation where some patients who could benefit from MMJ did not receive it, as many medical doctors refused to prescribe it, in part because of the highly bureaucratic procedures required of them for reimbursement, or out of fear of being liable for prescribing overly high doses. At the same time, other patients were prescribed MMJ for conditions for which there was no evidence of it being effective, or for those where it had even been shown to have a detrimental effect. Finally, amending regulations without proper planning led to a shortage in the MMJ supply.

Similar to other countries, the cannabis industry, or organizations closely linked to it, are trying to exploit the situation. Physicians have been invited to production plants in order to meet experts, and so-called "consensus papers" claiming MMJ to be effective for a large number of diseases have been delivered to congresses and even inserted as a supplement to a scientific journal (Häuser et al., 2019). Furthermore, industry has supported an organization that calls itself the "Deutsche Hanfverband" (Deutscher Hanfverband, 2019b); "German Cannabis Association"). The term Verband means "association" and denotes a typical German advocacy organization without any clear legal definition (Voelzkow, 2007). In fact, the "Deutsche Hanfverband" is a for-profit company with close links to nearly 200 cannabis-related companies (Deutscher Hanfverband, 2019a). It describes itself as the largest advocacy group for cannabis legalization in Germany, and has become one of the main voices in the public discussion of the legalization of cannabis. While the links to cannabis-related companies can be found on its website, the group has positioned itself more as a grass-roots non-governmental organization.

Considerations for countries who would like to start medical marijuana programs

As pressure mounts in many countries for changes to MMJ policy, the first consideration is whether or not to install a strict medical model comprised of only the medical indications with clear evidence of benefit from randomized controlled trials. While the burden of disease of cannabis—in part due to overall low prevalence—is less than the burden of other legal substances (alcohol, tobacco) or illegal drugs (opioids, stimulants) globally and in most countries (for comparative risk assessments with different methodologies see GBD 2017 Risk Factor Collaborators (2018) and Lachenmeier & Rehm (2015)), this burden of disease is not zero (Imtiaz et al., 2016). The most relevant

disease outcomes for public health in this respect will be due to traffic injuries and fatalities, cannabis use disorders, and respiratory illnesses including lung cancer. For the latter, quantification is difficult, as cannabis has traditionally been consumed together with tobacco, or by people who were also smokers. However, exposure to any kind of combustible product will have adverse respiratory effects.

The negative consequences of cannabis will have to be assessed against the medical benefits for any change in MMJ legislation. Such considerations may be only temporary, since research on the detrimental consequences of cannabis, and even more so for potential benefits of it, has been exploding.

However, the exact formulation of MMJ programs may have far-reaching consequences in terms of the prevalence of non-medical cannabis use as well. Thus, prevalence of non-medical cannabis use may be one of the decision criteria in jurisdictions with low prevalence who choose a more restricted medical model in order to avoid increases in prevalence and attributable burden.

For all jurisdictions, an exhaustive list of conditions should be created based on evidence. This would garner some resistance from industry and users, but from a public health perspective there is no rational reason why MMJ should be extended to diseases for which cannabis use has no evidence to be effective, or for which it is likely detrimental (e.g., depression). In sum, the current evidence for medical indications is not that strong (Abrams, 2018; National Academies of Sciences Engineering & Medicine, 2017), especially for the classic medical conditions of pain or epilepsy (Häuser et al., 2019; Stockings, Campbell et al., 2018, Stockings, Zagic et al., 2018). However, pain has been cited as the main indication among MMJ users in several US states (Park & Wu, 2017) and in Germany (Schmidt-Wolf & Cremer-Schaeffer, 2019). Further, it should be noted that a large proportion of the evidence base is derived from cannabinoid-based medicines such as Dronabinol and not from MMJ directly (e.g., only 8 out of 47 studies on pain management reviewed by Stockings, Campbell et al. (2018) involved MMJ).

Given these limitations, a strict MMJ model may cover treatment of the listed conditions, and for most countries these would allow medical use for several hundred or thousand patients only (such as was the case in the early days of the MMJ model in Canada). Such a model would also avoid setting undesirable precedents. One such precedent, which has already been seen in Thailand involves pharmaceutical companies creating their own market—without any state control—simply by demonstrating effectiveness from testimonials from cannabis user groups. These precedents could then also be applied to other types of herbal and non-herbal medicines. Finally, there are equity issues in allowing MMJ in health care systems that include subsidizing medication costs. Relying on governments or health insurers to subsidize the costs of MMJ for uses where there is no evidence for effectiveness will create inequity and potentially scarce resources for evidence-based treatments.

Another consideration in the implementation of MMJ programs would be the role of cannabinoid-based medicines, which represent adequate treatment solutions for many conditions, depending on the relative concentration of THC and CBD. These medicines should routinely be preferred over MMJ given the available evidence from clinical trials prior to their approval, including standardized dosage levels, and least harmful mode of administration (orally or as a spray). If MMJ is to be introduced alongside cannabinoid-based medicines, the preference of MMJ over cannabinoid-based medicines needs to be justified in detail. The main argument to prefer MMJ over cannabinoid-based medicines is the so-called 'entourage effect', which suggests that the effects of MMJ are driven by the interaction of THC, CBD, other cannabinoids and terpenes (Grof, 2018; Russo, 2019). As cannabinoid-based medicines contain only THC and/or CBD, a full therapeutic effect is believed to be only achieved by MMJ. However, solid evidence for this hypothesis is still lacking.

With respect to traffic injury risk (Rogeberg & Elvik, 2016), decisions will have to be made, such as whether a *per se* law for cannabis levels detected in blood should be enacted as it has been for alcohol (Wolff & Johnston, 2014), and/or whether the driver's licenses of patients should be suspended during MMJ therapy.

In any case, monitoring and surveillance are important to assess needs, measure potential diversion of medical cannabis, and establish a public health balance. In a situation with evolving evidence, it is best to see laws such as those found in the establishment of MMJ programs in the light of an experimenting society, where new evidence will lead to the correction and refinement of laws as new information emerges (Campbell, 1969, 1973; Fischer et al., 2015).

Conclusions

Many countries are currently faced with decisions about implementing MMJ regulations. While there is evidence that MMJ can be effective in treating some diseases, the implementation of MMJ programs has broader implications for drug policies which need to be considered. Accordingly, MMJ should only be implemented with a strict monitoring and surveillance program of these implications.

Declaration of Competing Interest

None.

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Supplementary material

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