

Article Title: The Medical Cannabis Regulatory Framework in Canada: A Narrative Review

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Abstract

Introduction: In 2001, Canada became one of the first countries to legalize medical cannabis; since then, the Canadian government has released policies regulating this product. In 2018, Canada passed the Cannabis Act to also legalize cannabis for recreational use and placed the previous medical cannabis regulatory framework under this same act. The purpose of this review is to provide a current account of the Canadian medical cannabis regulatory framework by examining patient access, ethical implications, and regulatory compliance.

Methods: This narrative review, informed by searches conducted across academic databases and the grey literature, aims to provide a current account of the medical cannabis regulatory framework in Canada. Resources that discussed aspects of this framework were drawn upon to synthesize this review.

Results: Many resources were examined on the policies' ethical implications, and consequences for public health and on individual patients in the context of medical cannabis use. Additionally, studies conducted thus far highlight the fact that continued research to fill knowledge gaps in the clinical evidence for different medical conditions is still very much warranted. Furthermore, ethical concerns regarding the role of healthcare practitioners under medical cannabis regulations were also explored.

Conclusion: Opposing viewpoints towards the medicalization of cannabis and the effects of using medical cannabis continue to exist in Canada. Further research should examine the challenges and successes that were encountered under previous medical cannabis regulatory frameworks in order to ensure adequate production, distribution, and access to medical cannabis under the current and future frameworks and address existing accessibility concerns.

Keywords: Cannabis; Cannabinoids; Health Canada; Medical cannabis; Drug policy; Regulation

Abbreviations

ACMPR: Access to Cannabis for Medical Purposes Regulations

CMA: Canadian Medical Association

CPhA: Canadian Pharmacists Association

HCO: healthcare organization

MMAR: Marihuana Medical Access Regulations

MMPR: Marihuana for Medical Purposes Regulations

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1. Introduction

The use of cannabis as a therapeutic option for a number of conditions in the healthcare setting has received considerable attention over the past two decades. In recent years, medical cannabis has been recommended and used as an effective treatment option for certain ailments and symptoms including chemotherapy-induced nausea, spasticity associated with multiple sclerosis, and chronic and neuropathic pain [1], [2], [3], [4], [5]. Although many patients have reported on the effectiveness of medical cannabis for treating various symptoms across a variety of medical conditions, there is still a substantial gap in research surrounding the risks and benefits of this therapy, especially in the context of sedative and anxiolytic use [6].

In 1999, the Canadian government provided patients with legal access to dried marijuana for medical purposes using Section 56 exemption under the Controlled Drugs and Substances Act [7]. Following this, in 2001, Canada implemented the Marihuana Medical Access Regulations (MMAR), through which the government of Canada, provided patients with debilitating illnesses with an Authorization to Possess (ATP) medical cannabis under the recommendation of a physician, and a Personal or a Designated Production License (PPL/DPL) to produce medical cannabis [7], [8], [9]. The authorized patients could obtain their medical cannabis either from suppliers contracted to Health Canada, grow it themselves, or rely on designated suppliers growing on their behalf [1,8,9]. In June 2013, Health Canada released a new set of regulations called the Marihuana for Medical Purposes Regulations (MMPR) to replace the MMAR [8]. In order to enhance medical cannabis access for authorized patients, the MMPR aimed to create conditions for a commercial industry through which only licensed producers could cultivate and distribute medical cannabis products to authorized patients [1,8,9]. The regulation's licensed producer system was designed to

provide patients with consistent and quality-controlled products under regulated conditions [9]. Furthermore, under the MMPR, Health Canada's role in patient authorization for medical cannabis use was removed and delegated to healthcare practitioners which added a perceived burden of responsibility on physicians [9].

Until recently, the Canadian medical cannabis regulatory framework for healthcare practitioners, clients, and licensed producers was the Access to Cannabis for Medical Purposes Regulations (ACMPR), which was passed after the MMPR in 2016 [10,11]. Canada's Federal Court ruled that providing authorized patients with medical cannabis only through licensed producers was insufficient and unconstitutional [12]. Consequently, the ACMPR was carried out in parallel to the MMPR as an immediate solution to the problem. Along with designating healthcare practitioners as gatekeepers of medical cannabis and providing quality-controlled medical cannabis through licensed sellers, the ACMPR also allowed individuals to grow their own supply of cannabis or designate someone else to grow it on their behalf [7,11,13,14].

Based on the recommendations from the Task Force on Cannabis Legalization and Regulation, on October 17, 2018, the Canadian government carried out Bill C-45, also known as the Cannabis Act, in favour of the legalization of recreational marijuana [15], [16]. The main goals of the Cannabis Act from a public health standpoint were to protect youth from access to cannabis products, prevent criminals and illicit markets from profiting from the sale of cannabis, and protect the public by allowing adults to access quality-controlled cannabis products [15,17]. This Act creates a strict legal structure for tightly regulating the cultivation, distribution, and sale of cannabis products across Canada [15,16]. It is important to note that there are two separate frameworks for the medical and recreational systems under the

Cannabis Act, however medical cannabis patients can use both systems to obtain their medical cannabis. Some of the primary objectives under Bill C-45 included improved changes to patient medical cannabis access, increased investment in medical cannabis research, data monitoring, patient reviews, and continued reporting on benefits and adverse effects of medical cannabis by Health Canada [1,15,16]. Notably, patients originally registered under the ACMPR were automatically moved under the new Cannabis Act, and once registered with Health Canada, patients were still able to either self-produce the cannabis, designate someone to produce it for them, or buy from licensed sellers [15], [16], [17]. The Canadian market data reported that by the end of September 2019, 369 614 Canadians were registered with a licensed seller under the medical cannabis regulations and 29 193 Canadians were registered through Health Canada and thus granted access to cultivate their own medical cannabis [10].

Preliminary searches indicated that a limited number of research studies have evaluated the Canadian medical cannabis regulatory framework in the peer-reviewed literature, which represents an important knowledge gap. Since medical cannabis regulations have been historically subject to change, as depicted by the three aforementioned substantial changes in Canadian medical cannabis regulations, the purpose of the present narrative review is to provide a current account of the medical cannabis regulatory framework in Canada, which can serve as the basis for a future, more comprehensive systematic review on this topic as well as to help inform further research.

2. Methods

We conducted a literature search using the methodology informed by Ferrari's narrative review framework [18]. Both the peer-reviewed and the grey literature were searched to

provide a current account of the medical cannabis regulatory framework in Canada, including the history of how medical cannabis has been regulated, and identify efficacy, public safety, ethical, and accessibility considerations of the new regulations. Prior to beginning the synthesis of the literature included in this narrative review, JYN and SU conducted and reviewed results of preliminary searches of the academic literature leading up to and including the current regulatory framework of medical cannabis in Canada. Subsequently, JYN and PH conducted searches on MEDLINE, AMED, EMBASE, PsycINFO, and Google Scholar including results from database inception leading up to and including April 2020. The keywords used across different databases varied, however, across all searches these included: ‘cannabis’, ‘medical cannabis’, ‘marijuana’, ‘regulation’, ‘health policy’, ‘Canada’, ‘Canadian’ and ‘Health Canada’. We provide a sample search strategy in Table 1, however, no PRISMA diagram is provided as this study was not framed as a systematic review. JYN and PH also hand-searched for grey literature on the Health Canada website, as well as the websites of other organizations with a vested interest in medical cannabis regulation including Canadians for Safe Access, Medical Cannabis Canada, the Canadian Pharmacists Association, and the Arthritis Society; these were thoroughly searched for and reviewed in order to analyze and understand the history of different laws and regulations pertaining to the access and use of medical cannabis. All authors collectively reviewed and synthesized all of the items collected and included in this narrative review.

3. Results

3.1. Implications under Marijuana Medical Access Regulations (2001-2014)

In 2007, Belle-Isle et al. identified barriers to medical cannabis access, specifically for Canadians living with HIV/AIDS; in this survey, 86% of respondents reported reliance on illegal sources to obtain medical cannabis [19]. Although patients with HIV/AIDS had been

granted legal access to medical cannabis under MMAR, their low percentage of registration for medical cannabis, was suggestive of other barriers to their access [19]. They explained that although some of these patients reported lack of physician approval as the barrier to their legal medical cannabis access, the majority of patients relied on illegal sources due to a mistrust of government, intimidating requirements, concerns about repercussions, and lack of program awareness [19]. In 2014, Belle-Isle et al. reported the results of a survey from the Cannabis Access for Medical Purposes Survey, which identified barriers to medical cannabis access for all Canadians [20]. It was found that fewer than 5% of the estimated medical cannabis users were registered with the federal program to obtain legal medical cannabis [20]. This major discrepancy was explained to be the result of different factors posing as obstacles to access of medical cannabis from the federal program [20]. One obstacle was the lack of physician approval of patients for medical cannabis use [20]. In 2013, the Canadian Medical Association (CMA) reported that there was an insufficient amount of clinical evidence surrounding the risks, benefits and use of medical cannabis, and that the majority of physicians believed they lacked sufficient information to recommend medical cannabis [21]. Another barrier to medical cannabis access was described as the omission of cannabis dispensaries such as compassion clubs from the regulatory system; these dispensaries provided a significant amount of the illegally-obtained medical cannabis for patients [20].

Lucas conducted a critical policy analysis of several components of medical cannabis policy in Canada [22]. He illustrated that despite there being a record of 290 000 medical users in British Columbia, there were only 2838 applications received by Health Canada across Canada by 2004 [22]. This was followed by the decline of about 75% of registered medical cannabis users in 2004. It was noted that a reason for the decline in the number of applicants to access medical cannabis could have been attributed to the barriers and restrictions for

potential applicants under the MMAR. Lucas described that the reluctance of healthcare practitioners and the CMA to administer medical cannabis to patients (due to lack of clinical-based evidence and scientific knowledge) posed a barrier to medical cannabis access among patients [22]. Another discussed barrier to simplified access was the hurdle of completing the 29-page application requirement which took up to 12 months to be processed by Health Canada [22].

3.2. Implications under Marihuana for Medical Purposes Regulations (2014-2016)

Belle-Isle et al. also discussed the potential barriers that could remain after the phasing out of the MMAR to the MMPR, as they published their study a few months before the full transition to the MMPR [20]. They concluded that multiple barriers they discussed under the MMAR were not addressed under the new MMPR [20]. They explained that the problem of insufficient clinical evidence still remained for hesitant physicians who sought to authorize patients for legal access, and that physicians' hesitance could increase under the new regulations, as there were no plans to further improve medical cannabis research and knowledge under the MMPR [20,21]. Moreover, they mentioned that the affordability barrier could be exacerbated under MMPR as the prices offered by commercial licensed producers were subjected to increase from \$5 CAD/gram to anywhere between \$6-\$12 CAD/gram [20]. Lastly, it was noted that the MMPR's failure to include medical cannabis dispensaries under the new regulations also continued to impede medical cannabis access [20]. Valleriani et al. support this claim by providing a perspective from an Ontario-based licensed producer that highlights the importance of medical cannabis dispensaries on medical cannabis education and availability [23].

Ries analyzed some of the ethical and legal implications of medical cannabis regulations under the MMPR and explained that to some extent the new regulations could enhance medical cannabis access by eliminating a previously identified barrier: patient mistrust in government [24]. They clarified that with the new ‘gatekeeper’ role being transferred to healthcare professionals from the government, patients could instead seek access to quality-controlled medical cannabis through physicians [24]. However, Ries explained that physicians’ exercise of this role raised ethical and legal concerns for both them and the patient [24]. Ries further elucidated that shifting the judgement of identifying eligible patients to the healthcare professionals by requiring them to authorize the use of an unapproved and otherwise illegal product placed them in a difficult situation [24]. If the physicians did not authorize medical cannabis for their patients based on the reason of inadequate clinical evidence, they would pose an obstacle to legally accessing medical cannabis, resulting in potential illegal access [24]. Alternatively, if they authorized medical cannabis for their patients and the therapy resulted in harm, the physician may be deemed to have acted negligently [24,25]. Similarly, Ko et al., presented the barriers to medical cannabis use from both the patient and physician perspectives [26]. They suggested that increasing evidence-based research and providing evidence-based guidelines to physicians, in addition to training them for authorization practices, could increase their willingness to authorize medical cannabis for their patients and thus decrease the barrier of accessibility [26].

In a cost-benefit analysis of regulatory changes to medical cannabis access, Stambrook et al. presented concerns under the MMAR which were addressed by the regulatory proposals adopted in the MMPR [27]. They explained that a criticism of the MMAR policies documented by the Canadian law enforcement authorities was the difficulty of obtaining residential warrants for authorities to enter and inspect regulatory compliance of the

cultivation area where registered patients grew their own supplies [27]. The analysis further suggested that prohibition of personal cultivation licenses for registered patients under the MMPR, rendered residential cultivation illegal and made it easier for authorities to obtain residential warrants in order to oversee activities and prevent misuse and excessive production of cannabis for other purposes [27]. Moreover, Garis and Clare examined the newly proposed regulations under MMPR and explained the addressed and remaining concerns from the MMAR under the new regulation [28]. They reported that elimination of self-cultivation as a means of access to medical cannabis and its replacement by licensed commercial producers addresses multiple concerns (regarding residential growth of medical cannabis, the potential diversion of the self-cultivated medical cannabis to the illicit market, and its sale for illegal recreational use) raised under the MMAR [28]. However, it was also suggested that the MMPR did not completely eliminate the health and safety concerns under the MMAR, unless it was revised to demand a full disclosure and remediation of the land and residential areas previously used for medical cannabis self-cultivation under the MMAR [28]. This proposal was on the basis of various environmental and public health concerns such as the possibility of mould and fungi growth as well as the possibility of contamination of the property and surrounding water supplies with chemicals from pesticides and fertilizers previously used in the area [28]. These toxic chemical particles could remain in the air and contaminate surrounding areas which resulted in the proposal to revise the MMPR adding this extra requirement from previous residential growth sites [28]. The concern regarding consequences of self-cultivation in residential buildings have also been expressed by Johnson and Miller who noted that significant water vapour in an indoor environment could lead to mould as well as abiotic hazards such as carbon monoxide and pesticides [29]. Along with mould, other potential consequences that have been reported by fire departments include electrocution, combustion by-products, and explosion hazards [30], [31], [32].

3.3. Implications under Access to Cannabis for Medical Purposes Regulations (2016-2018)

One of the main reasons for replacing the MMPR with the ACMPR in 2016 was to facilitate greater access to medical cannabis by authorizing individuals to register with Health Canada and self-cultivate their own supply for consumption, or to outsource legally from a designated producer [33]. Although after delegation of the gatekeeping role to healthcare practitioners, multiple practice standards have been issued to guide physicians, there were no specific guidelines and policies for healthcare organizations (HCO) in the context of the ACMPR [33], [34], [35]. This concern for HCO policies was not unique to the ACMPR as healthcare practitioners (and thus organizations) were involved in recommending and dispensing medical cannabis to authorized patients under both the MMAR and the MMPR. Bean and Smith considered both policy issues and ethical implications to provide a systematic approach to carrying out potential regulations around medical cannabis use in Canadian HCOs [33]. They noted that regulation requirements in HCO settings posed unique concerns and that it was necessary to consider the medical cannabis locus of administration. For example, there are obvious conflicts between smoking or vaping medical cannabis inside an HCO building due to provincial legislations, workplace health policies and institutional policies that enforce a smoke-free environment [33]. Researchers also indicated that potential regulations must consider the routes of medical cannabis administration: smoking (although there is less evidence surrounding the potential harms of second-hand smoking compared to tobacco, there is a pungent odor associated with it); vapourizing; ingesting in the form of edibles or tea (delayed onset when ingested); and prescribed oral synthetic forms such as cannabinoids, which are pharmaceutically created cannabis products that contain active ingredients found in cannabis, such as tetrahydrocannabinol (THC) [33]. The policy considerations for the security of medical cannabis in an HCO environment entailed ensuring the use of patient

waiver and consent forms, along with creating guidelines for physicians to establish an environment preventing medical cannabis abuse and misuse through its appropriate storage [33].

Furthermore, Bean and Smith presented ethical considerations for potential HCO medical cannabis policies under the ACMPR [33]. They first considered the “harm principle” which states that "power should only be exercised over individuals against their will if it is in their direct best interest to prevent harm to others". When applied in the context of medical cannabis [33]. Bean and Smith suggested that HCOs should consider that one of its routes of administration includes smoking. Hence, HCO's may choose to prohibit the smoking of medical cannabis when considering that any negative effects of smoking the product would not only impact the individual but also those around them who would be susceptible to second-hand smoke [33], [34], [35], [36]. Given that there are alternative routes of administration to smoking medical cannabis such as edibles and synthetic cannabinoids that can be ingested and vaping, there is potential for HCO's to accommodate the needs of patients and the “harm principle” [33]. Next, they considered the principle of “respect for autonomy” which prioritizes a patient's ability to engage in a treatment regimen that meets their needs and therapeutic goals without restrictions. They argued that HCOs should strive to establish policies that consider patient autonomy, as restrictions on medical cannabis options could affect treatment and interfere with potential harm reduction measures [33]. Bean and Smith further explained that HCO policies must also consider the principle of “non-maleficence” in that any regulations preventing a patient from accessing their preferred route of administration for medical cannabis could directly or indirectly cause them unnecessary harm [33]. Lastly, they discussed the principle of “justice”, which refers to the equal treatment of cases that are similar to avoid inconsistency among policy approaches. As

examples, it would be unethical if medical cannabis were being held under stricter regulations in comparison to other pain-relieving drugs or if patients were subject to policies that did not reflect the uniqueness of medical cannabis itself [33]. By integrating these ethical principles among others, HCOs have the opportunity to use policy to mitigate negative outcomes associated with medical cannabis stigma and foster a more trusting environment for patients [33].

Another unaddressed concern under the ACMPR was the inadequate research and evidence-based scientific knowledge regarding the therapeutic efficacy, risks, interactions with medication, and safe dosing of medical cannabis [37]. This major concern had been presented to the federal government and discussed by the CMA multiple times throughout the evolution of Canada's medical cannabis regulations, however, it still posed ethical and legal concerns for physicians and was a significant obstacle for patients seeking access to medical cannabis [21,25,37]. In response to the primary concerns regarding quality, safety, and efficacy of medical cannabis use, the Canadian Medical Protective Association recommended that physicians who feel uncomfortable with the regulations or have limited medical cannabis knowledge, should refrain from authorizing medical cannabis for patients due to potential liability [37]. The CMA noted that these recommendations and the negative attitude of physicians regarding medical cannabis authorization were driven by the potential for patient harm and the possibility of misuse and abuse of the product [37]. A CMA recommendation that could partially address the physicians' hesitancy for authorization, was to carry out the same approval process for medical cannabis as pharmaceutical medications including clinical trials, holding it to the same safety and efficacy standards [37].

In contrast, the Canadian Pharmacists Association (CPhA) have mentioned in their position statements that the prohibition of pharmacies and medical cannabis dispensaries, such as compassion clubs, from the medical cannabis regulatory framework under the ACMPR prevented easier and more appropriate access to medical cannabis by patients [38]. Capler et al. analyzed the importance of dispensaries by comparing the patient experience obtaining medical cannabis from dispensaries versus other sources [39]. Their results showed that dispensaries were rated more favourably for medical cannabis accessibility, quality, and safety and concluded that dispensaries were highly endorsed by patients [39]. It was suggested that future medical cannabis regulations should be informed by patient's experiences accessing the product, in order to enhance access and eliminate cost and health barriers by including dispensaries under the legal framework [39]. Capler et al. argued that although dispensaries had remained illegal under the past few medical cannabis regulatory reforms, they had consistently been identified as beneficial and a preferred method of obtaining medical cannabis by patients, thus their inclusion under the legal framework could have further enhanced patient access [39].

The reintroduction of self-cultivation and designated producers to increase medical cannabis access under ACMPR, re-raised a number of concerns that existed under MMAR regarding residential cultivation [33]. Garis et al. [40] and Clare et al. [41] noted that the issues regarding diversion to illicit markets, medical cannabis production over authorized limits, and the inability of authorities to monitor cultivation and differentiate between legal and illegal medical cannabis, resurfaced again with the reintroduction of residential self-cultivation. They explained the fundamental requirements necessary for an indoor cannabis cultivation area and highlighted the health and safety risks associated with cannabis cultivation taking place in private homes and residential areas [40]. These fundamental requirements comprise

of extensive modifications to private homes and include altered ventilation, increased electrical power, structural changes and dehumidification conditions to enable indoor cultivation. Health and safety risks associated with these indoor growing conditions could include the development of mould, toxic chemical contamination and electrical, fire and structural hazards [40]. They concluded that considering the strong evidence of non-compliance among licensed medical cannabis cultivators, and the significant health, and safety hazards, cultivation in residential settings still carried a very high-risk and required a robust regulatory framework and monitoring [40]. Additionally, Clare et al. illustrated the limits of monitoring regulatory compliance of residential medical cannabis cultivation, as Health Canada did not inspect the cultivation activities of license holders [41]. Moreover, third party authorities were also unable to conduct regulatory inspections since Health Canada could not share the information of license holders due to privacy regulations [41]. The lack of regulatory oversight could lead to possible diversion to illicit markets, overproduction of medical cannabis products and illegal use of cultivated medical cannabis [27,41]. Their report suspected that one third of the residential medical cannabis cultivation sites contained moulds further adding to health and safety complications [41].

3.4. Implications under the Cannabis Act (2018-present)

Although the Cannabis Act has replaced the ACMPR, many of the regulations surrounding the pathways for access and use of medical cannabis have largely remained the same with minor changes to improve access [1,15]. With the legalization of recreational cannabis, there are now two separate streams for accessing cannabis legally: the medical system and the recreational system. Although patients have the option of accessing cannabis for medical purposes via the medical system, the recreational system provides an alternative route for them to legally obtain their medical cannabis [17]. However, under the Cannabis Act, some

concerns have been raised surrounding medical cannabis use such as a lack of clinical evidence and the gatekeeper role of healthcare professionals still remain, both of which can interfere with access to medical cannabis. Balneaves and Alraja explained that legalization of non-medical cannabis can have positive implications for patients who have experienced challenges in obtaining physician authorization for use [42]. They indicated that legalization can reduce the stigma surrounding medical cannabis use among the general public, thereby reducing such barriers that some patients faced before cannabis was legalized for recreational use [42]. Though the Cannabis Act intended to increase medical cannabis access for patients, the results of a medical cannabis survey carried out by the CPhA, reported that 26% of medical cannabis users found it harder to access medical cannabis post-legalization [43]. Shanahan and Cyrenne illustrated that long delivery wait times and poor customer service were factors that reduced patient access to medical cannabis under the Cannabis Act, thereby possibly redirecting them back to recreational outlets or illicit markets (including non-federally licensed sellers, and compassion clubs which are still illegal) to obtain their medical cannabis and also to receiving health advice from unregulated sources [44,45]. A systematic review on the implications of cannabis legalization conducted by Bahji and Stephenson reported that following the legalization of recreational cannabis, the illicit market for cannabis in Canada has increased [44]. These data were further supported by the CPhA survey which found that 48% of respondents declared accessing medical cannabis through illegal markets and 44% reported having purchased from recreational markets when they had reduced access to cannabis via the medical system [43]. Additionally, considering the decreased access to medical cannabis for patients and their increased reliance on recreational markets, patients under the legal age can be at a greater disadvantage since they cannot purchase the product from recreational markets legally [46].

Similarly, the price of medical cannabis sold legally is another barrier to its access as it has been noted to be more expensive in comparison to illicit markets. Both Bahji and Stephenson [44] and Fischer [48] noted that the difference in price of cannabis obtained from legal sources have remained relatively the same at \$10 CAD/gram versus illicit market prices that have decreased significantly to \$6.37 CAD/gram. The difference in affordability refers to the fact that cost is a driving force behind patient's decisions to obtain medical cannabis from illicit markets over federally licensed sellers [47]. In an article published by the Canadian Drug Policy Coalition, it was reported that in 2019 across Canada the cost of medical cannabis per gram was on average 75 cents higher than the price of recreational cannabis. Especially for patients requiring long-term, continuous prescriptions of medical cannabis, this cost represents another major obstacle to access [49]. Despite compassionate programs and organizations such as CanniMed that subsidize the cost of medical cannabis for those experiencing financial challenges, these solutions are outliers and do not treat the systemic issue of a lack of access for all individuals [49]. Furthermore, Shanahan and Cyrenne noted that although medical cannabis is treated like other medically-authorized treatments in certain aspects, it is subjected to additional taxes (unlike other medicines) which once again increases the cost for patients [45]. Geographical constraints, termed “postcode injustice” by the Canadian Drug Policy Coalition, mean that there is a further lack of access to medical cannabis in rural areas in comparison to urban ones, with reports indicating that patients have been known to travel hours outside of their community to fill prescriptions [49].

With the legalization of cannabis under the Cannabis Act, the CMA advised the federal government to eliminate the medical cannabis program and physicians’ gatekeeping role, and create a single system for cannabis access for medical and recreational users that would eliminate the ethical and legal concerns of healthcare practitioners [50]. However, the

Cannabis Act still requires healthcare practitioners to authorize patients for medical cannabis use, thus retaining these previously identified ethical concerns [15]. A commentary written by Kahan et al. highlighted the lack of extensive research and evidence for medical cannabis therapeutic efficacy, potential risks, side-effects and safe dosage [51]. Specifically, there is largely correlational and anecdotal evidence on the efficacy of medical cannabis for a range of conditions (e.g. depression and anxiety) [46]. Moreover, there is misrepresented information regarding the conditions for which cannabis is purported to have therapeutic effects, and this is especially seen in cannabis clinics [51]. Cannabis clinics can be described as private clinics staffed by physicians who sign necessary documentation authorising a patient access to medical cannabis for a fee, however, the ethics of charging for such a service has been debated. Moreover, another concern expressed regarding medical cannabis regulation under the Cannabis Act included the absence of regulatory oversight by Health Canada and the failure to publish indications, contraindications or dosing protocols for the medical cannabis being prescribed as a treatment at these cannabis clinics [51]. As a result of insufficient scientific knowledge and poor regulation and surveillance of medical cannabis clinics namely by Health Canada, several examples have been documented whereby patients were recommended to take unsafe doses [51].

4. Discussion

This narrative review provides a current account of the Canadian medical cannabis regulatory framework. Our findings not only indicate that limited information in the academic literature is available surrounding medical cannabis regulation in Canada, but also highlight conflicting opinions of healthcare professionals and committees on medical cannabis regulations set by the Canadian government. Insufficient clinical evidence coupled with stigmatization, and a

lack of training and educational resources have influenced physicians' hesitancy toward authorising medical cannabis for patients resulting in barriers to access.

Despite this, in recent years a large and rapid increase in global cannabis research has been observed, with studies originating from Canada being no exception, serving to grow the evidence-base surrounding its therapeutic properties [52,53]. However, physicians have been placed in a difficult position whereby they are responsible for advising patients on the use of medical cannabis without a full understanding of its benefits and risks [12]. Many physicians have expressed that it is difficult to meet such obligations to prioritize high quality care and ensure patient safety when they lack sufficient training in this field [12]. In the Task Force on Cannabis Legalization and Regulation's final report, it was noted that with this information regarding physicians' perspectives, the CMA and the Federation of Medical Regulatory Authorities of Canada expressed clear disapproval of physicians being the ones to authorize access to medical cannabis under the ACMPR [12]. Through analyzing the impact of medical cannabis on patients, healthcare providers and the public health system, this data can be used to inform policies that better suit the needs of the communities they aim to serve. Considering the implications of medical cannabis regulations under different reforms and certain concerns that have not been addressed following multiple regulation reforms, it is important to reflect on recurring concerns and their effects in order to address and improve them under subsequent reforms [54]. Careful analysis of these results highlighted the ongoing need to consider public safety concerns, ethical implications, and accessibility issues post-legalization.

4.1. Public safety considerations

4.1.1. Lack of research-based evidence

Following multiple reforms to the Canadian medical cannabis regulations, a major concern raised under all the regulations that still remain is the perceived lack of research-based evidence and scientific knowledge on the broad range of conditions for which medical cannabis has been claimed to have therapeutic effects [51,56]. Kahan et al.'s report highlighted the concern about misinformation surrounding the purported therapeutic potentials of medical cannabis that are presented to patients despite a lack of clinical research and evidence [51]. Contrary to this however, Lake et al. report that the CMA has also failed to acknowledge various peer-reviewed, clinical studies on the therapeutic application of cannabis, and has engaged in publicly discouraging the prescribing of medical cannabis attributing this stance to perceived insufficient clinical evidence [57]. Although there has been some promising evidence of the therapeutic effects of medical cannabis for neuropathic pain, multiple sclerosis spasticity, palliative care, and chemotherapy-induced nausea, the therapeutic potentials for other medical and psychiatric conditions have not been as extensively researched [44,51]. Additionally, it is evident that proposed beneficial effects of medical cannabis touted by cannabis clinics may be exaggerated or based on anecdotal evidence which warrants the need for further investigations [46].

4.1.2. Need for regulatory oversight

As Stambrook et al. explained, under the MMAR, allowing residential self-cultivation of medical cannabis supply raises issues regarding regulatory compliance, the possibility of over-cultivation, and diversion to illicit markets [27]. Garis et al. [40] and Clare et al. [41] illustrated the potential dangers and safety-risks associated with medical cannabis cultivation in inappropriate residential areas. A main shortcoming of the current medical cannabis

policies is the lack of inspections by Health Canada or third-party authorities for regulatory compliance [40]. With regards to patient care, Kahan et al. described how the lack of regulatory oversight on cannabis clinic protocols can result in patients being recommended unsafe medical cannabis doses [51]. The implementation of a regulatory surveillance protocol by Health Canada could address these safety concerns by monitoring regulatory compliance and safety measures used in residential medical cannabis cultivation sites, as well as overseeing medical cannabis clinics protocols and activities. Ultimately, with improved regulations surrounding legal cultivation of cannabis plants, this may positively impact patients living in rural communities who might otherwise face challenges with access to medical cannabis [49].

4.2. Ethical considerations

4.2.1. Physician's role

Since the removal of the Canadian government's role in authorizing patients and their assignment of this “gatekeeping role” to healthcare providers under the MMPR, the CMA has debated the idea of delegating this responsibility from the government to physicians [21,50]. They have stated that requiring physicians to authorize the use of medical cannabis, a substance whose medical potential and effects has not been excessively studied, places them in an unethical situation [21]. The ethical principles of beneficence and non-maleficence suggest that physicians should only recommend medical cannabis for conditions that have a strong evidence base [21]. However, physician willingness to engage in discussions surrounding medical cannabis with patients has been recommended as a facilitator to prevent the spread of misinformation and encourage patients’ safe and effective use of medical cannabis [58]. Under the Cannabis Act, the ethical concerns facing physicians still remain. Physicians also lack appropriate training and education surrounding medical cannabis which

adds to the possible ethical considerations [59]. Academic programs for health professionals are often unstructured and research indicates there exists some resistance among academic administrators to amend the medical curriculum to include medical cannabis. There are also limited standardized resources that facilitate an evidence-based education regarding medical cannabis [61]. Regulatory bodies in medical education in Canada do not offer guidance on how to improve this knowledge gap for physicians [60]. With regards to the training of physicians in particular, in an article discussing a model of care at a leading medical cannabis clinic in Canada, Prosk et al. discuss that peer support among healthcare providers, especially physicians, could facilitate greater support and mentorship within an often controversial and stigmatized form of treatment leading to better outcomes for patients [61]. With a better understanding of healthcare providers' concerns, we can use this information to develop guidelines, training, and education to provide them with resources and skills to be able to effectively discuss and prescribe medical cannabis to patients [62].

4.2.2. Health care organization policies

Bean and Smith's analysis of ACMPR in the context of ethical and policy implications for HCOs, considered the harm principle and the harm reduction paradigm [33]. With the legalization of recreational cannabis in 2018, a guideline was released by the Ontario Hospital Association, to aid hospitals with the development of necessary policies around cannabis and update any existing policies on drug use by including cannabis [63]. A legislative update on the Cannabis Act was also issued which highlighted key points from the bill for long-term care homes, hospitals, and other workplaces [63]. However, beyond these documents, further resources would be of value in outlining the policies and regulations, in relation to the Cannabis Act, specific for hospitals with patients who use medical cannabis.

4.3. Regulatory considerations

4.3.1. Medical Cannabis accessibility post-legalization

Under the Cannabis Act, it was reported that 26% of individuals using medical cannabis found it harder to access the medical cannabis [43]. Between 2018 and 2019, 40.1% of Canadians aged 15 or older were still accessing cannabis through illegal means, despite it being available legally [64]. The CPhA's survey found that out of the patients that experienced reduced access to medical cannabis, 48% reported accessing cannabis through illegal markets, and 44% accessed cannabis through recreational markets, while 31% waited for the supplies to be restocked [43]. These data suggest that recreational cannabis legalization not only has had negative effects on the patients' accessibility to medical cannabis, but it has also contributed to the growth of illicit markets [43,65]. Hawley et al. found that following the legalization of recreational cannabis in Canada, 18% of current medical users with cancer surveyed reported more problems getting cannabis, compared to 8% pre-legalization, with common barriers cited as lack of available dispensaries and cost [65]. The higher price and taxation associated with medical cannabis also pose affordability barriers to accessing medical cannabis [65]. Shover and Humphreys emphasize that public health will be maximized if medical cannabis truly functions as medicine with clear indications, dosing protocols and tight regulations, or if it is weaved into the recreational system [66]. They found that with a few exceptions, the cannabis products that are available for purchase through the medical system and the recreational system are the same [65]. In Canada, there are province-sanctioned cannabis retail stores that constitute the recreational system, whereas the medical system ensures that medical cannabis can only be purchased through federally licensed producers [64]. Medical cannabis can often be less expensive than recreational cannabis as in addition to compassionate programs that subsidize costs, federally licensed producers will absorb the federal tax for their customers making it more affordable

[64]. Shover and Humphreys suggest that combining the systems for medical and recreational cannabis into one may streamline regulation and increase tax benefits by preventing recreational users from entering the more lightly taxed medical system [66]. Although the desired goal of regulation may be to reduce harms resulting from illegal cannabis use, this is unlikely to be achieved unless the legal system allows patients greater accessibility and affordability [65]. Effective policies should provide information about product sources and how to access them legally to prioritize patient safety and reduce the risk of punishment, which in turn could address part of the stigma associated with medical cannabis [67]. Evaluations are warranted to assess whether treating medical cannabis like other medically authorized treatments, improving insurance coverage, and/or providing more convenient distribution methods, could help to alleviate barriers to medical cannabis access.

4.3.2. Dedicated medical program

Although recreational cannabis was legalized under the Cannabis Act, two separate systems under this Act still remain in order to obtain cannabis depending on the purpose of use; there is a recreational system and a medical system which were developed from the ACMPR. To obtain cannabis for medical purposes, the patient is still required to present a physician's recommendation; furthermore, the chemical content of the cannabis used for medical purposes may be different than when it is used for recreational purposes (the latter typically containing higher levels of tetrahydrocannabinol). Following the legalization of recreational cannabis, physicians were conflicted about their role in light of these changes in regulation; Dr. Jeff Blackmer, the CMA vice-president of medical professionalism stated that there was no need to separate medical cannabis regulations once Bill C-45 came into effect, while other physicians argued that a separate medical access was necessary to ensure registered medical cannabis patients did not lose access [55,68]. One important implication of combining the

recreational and medical system would be streamlined product quality due to the varying chemical composition of the products based on the intended use [69]. This argument was presented to the House of Commons of Canada by the Canadian Nurses Association program leader, Karey Shuhendler, noting that maintaining a designated medical system ensures adequate patient access to appropriate cannabis products used for medical purposes [69]. Furthermore, without a separate system to access cannabis for medical purposes, patients would be less likely to discuss or disclose their cannabis use to their physician, and that a lack of communication could result in unfavourable drug interactions or the reduced efficacy of their other medications [42]. Lastly, the maintenance of a separate medical system under the Cannabis Act could place additional importance in addressing the paucity of evidence-based research, since it creates an emphasis on the research for medical cannabis use while legalizing the product, whereas eliminating the medical system could prevent further research on the therapeutic efficacy of medical cannabis for different medical conditions.

4.4. Limitations

While our findings did not result from a systematic search strategy, we purposefully selected a narrative review methodology given its appropriateness in capturing information from very broad and diverse types of literature (both peer-reviewed and grey) on this topic. Thus, this work may serve as a starting point informing future and topic-targeted systematic reviews. The literature included in this review were limited to articles published in English, as our team lacked the human and financial resources for translation. It should be noted, however, that many Canadian government documents are published in both English and French, and that the vast majority of peer-reviewed literature is published in English.

5. Conclusions

This narrative review involved a search and synthesis of both the peer-reviewed and grey literature to provide a current account of the medical cannabis regulatory framework in Canada, providing an overview of studies evaluating the MMAR, the MMPR, the ACMPR, and the Cannabis Act. Despite the change in regulations over time, the collective information reported by the literature included in this review suggest that each framework has struggled to address the needs of patients requiring medical cannabis. As medical cannabis regulation is an evolving topic, it can be expected that changes will continue to be made in the future, based on new and emerging evidence. This review highlights a number of scientific, social, and policy knowledge gaps which may serve as a starting point for future targeted research.

Declarations

Financial support

This study was unfunded.

CRedit authorship contribution statement

Jeremy Y. Ng: Conceptualization, Methodology, Validation, Investigation, Supervision, Writing – review & editing, Funding acquisition. Pargol Homayouni: Formal analysis, Investigation, Writing – original draft. Sana Usman: Formal analysis, Investigation, Writing – original draft. Zoya Gomes: Writing – review & editing.

Declaration of Competing Interest

All authors declare that they have no competing interests.

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Data availability

Not applicable

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POSTPRINT

Tables Legend

Table 1: Sample Search Strategy Informing Narrative Review Synthesis

POSTPRINT

Tables

Table 1. Sample Search Strategy Informing Narrative Review Synthesis

Database–AMED (Allied and Complementary Medicine) <1985 to April 2020>, Embase <1974 to 2020 April 21>, APA PsycInfo <1806 to April Week 2 2020>, Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946 to April 21, 2020> Search Strategy:
1 cannabis.mp. or Cannabis/ (83560)
2 marijuana.mp. or Marijuana/ (78241)
3 Health Policy/ or health policy.mp. (265741)
4 or/1-2 (106011)
5 3 and 4 (1187)
6 limit 5 to English language (1134)
7 limit 6 to humans [Limit not valid in AMED,APA PsycInfo; records were retained] (1011)
8 remove duplicates from 7 (774)
9 canada.mp. [mp=ab, hw, ti, tn, ot, dm, mf, dv, kw, fx, dq, tc, id, tm, mh, nm, kf, ox, px, rx, an, ui, sy] (414944)
10 canadian.mp. [mp=ab, hw, ti, tn, ot, dm, mf, dv, kw, fx, dq, tc, id, tm, mh, nm, kf, ox, px, rx, an, ui, sy] (176320)
11 or/9-10 (497843)
12 8 and 11 (79)