Medical marijuana: Canada's regulations, pharmacology, and social policy

New policy reflects contradictions in social and medical trends

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Introduction: This paper gives an introduction to important aspects of Canada's medical marijuana policy. It reviews the history and the physiological effects of marijuana, as well as four social theories that have contributed to the traditional view of marijuana use as "drug abuse."

Methods: A PubMed search was conducted using the search words "medical marijuana Canada" for the period 1980 to 2002. Articles were included if they contained information on marijuana's physiological effects or social issues. An internet search using www.Google.com and the same search words was conducted. Websites were included if they contained information on medical marijuana policy in Canada. Secondary literature provided background on social theory.

Setting: Canada's federal policy on medical marijuana.

Results and Discussion: In 2001, Canada became the first nation to implement a national policy allowing for the use and paid supply of marijuana for medicinal purposes, and this policy generated both vigorous debate and general public support. The new policy has been accompanied by a cooperative research effort between Health Canada and the Canadian Institutes of Health Research to prove marijuana's therapeutic efficacy.

In July 2001, Canada became the first nation to implement a national policy allowing for the legal use and paid supply of marijuana for medicinal purposes.[1,2] Broadly speaking, this development represents increased emphasis on patient rights, on pain control, and on the importance of quality of life and palliative care. It demonstrates that Canadians generally accept the patient's right to access pain control medications of their choice (see Guest Editorial, p. 17). The implementation of this policy has not been without considerable controversy, opposition, and support from many aspects of society, including law enforcement, physicians' groups, health researchers, and sociologists. The controversy is often fuelled by media reports, and studies have shown that the mass media can affect public opinion dramatically.[3]

This paper reviews the background on marijuana status in Canada, the medical marijuana policy set forth by Health Canada, current research on physiological effects of marijuana, and four social theories that have supported prohibition of marijuana, but which are now largely discredited in relation to medical marijuana.

Background

In 1999 Canada embarked on a novel policy allowing the medical use of marijuana. It was first announced in 1999 by Health Canada as a way to allow patients to receive marijuana for medical purposes. It created a contradiction within Canadian law that allowed patients to use marijuana medicinally but prohibited its use outright under other statutes. This situation was resolved through the courts and the current policy was unveiled in 2001.

The majority of Canadians support making marijuana available for medical purposes,[4] however, the lack of research evidence proving efficacy for this use makes medical and pharmacy associations reluctant to fully endorse the changes.

The recent history of the status of marijuana in Canada dates back to 1923. Marijuana then was banned under the Opium and Drug Act and its possession or use was deemed illegal.[5] In May 1997, the act governing marijuana was changed to the Controlled Drugs and Substances Act,[5] however, its status as an illegal substance to use or possess remained. In 1999, Health Canada made provisions for the use of marijuana for medical purposes, through a special application process granting permission for medical marijuana use.[6,7] This provision, however, did not supercede the 1997 Controlled Drugs and Substances Act.

The contradiction between federal regulations left patients in a Catch-22 situation. They were permitted, by Health Canada, to use marijuana for medical purposes, but under the Controlled Drugs and Substances Act it was still considered an illegal activity.[5] This legal ambiguity left many patients and citizens in a very precarious situation.

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Not only were patients at risk of being arrested for use of marijuana under the Controlled Drugs and Substances Act, but they were also at risk of undesired effects of street marijuana (since Health Canada had not provided a supplier of the drug). Similarly, they were at risk of prosecution if they chose to grow their own marijuana.[7]

Prior to 1999 it is estimated that 3,000 patients were using marijuana, illegally, for health purposes,[7] and between the years 1999 and 2001 there were 292 patients approved by Health Canada to use marijuana medicinally, with 500 applications pending.[1]

Choice of health or imprisonment

In August 2000, the Ontario Court of Appeal ruled that the banning of marijuana for medicinal purposes, as defined in the Controlled Drugs and Substances Act, was unconstitutional.[5,6] Specifically, the court ruled that the Controlled Drugs and Substances Act forced the accused "to choose between his health and imprisonment."[8] This ruling had the effect of forcing the federal government to amend its laws to allow the use of marijuana for medical purposes. It gave the politicians one year to change the law or else the growth and use of marijuana in Ontario, Canada's most populous province, would no longer be illegal.[8]

In the spring of 2001, the Canadian government announced its new policy on medicinal use of marijuana. This policy made Canada the first health system in the world that included a government-approved and funded supply of marijuana for medicinal purposes.[1,2] Patients who qualify under the policy fall into three categories:

- Prognosis of death within 12 months
- Suffering from nausea, vomiting, wasting syndromes, muscle spasms, intractable hiccups, pain associated with serious diseases (cancer, AIDS, multiple sclerosis)
- Suffering epileptic seizures, glaucoma, spasticity caused by spinal cord injury[1,2,6,9]

The intent of the new policy was summarized by then–Health Minister Allan Rock: "Canada is acting compassionately by allowing people who are suffering from grave and debilitating illness to have access to marijuana for medical purposes," he said. "Today's announcement is the next important step. . . . It will bring greater clarity to the process for Canadians who require the use of this drug to alleviate symptoms."[6] The Senate Special Committee on Illegal Drugs also stated that support among Canadians for medicinal use of marijuana is strong.[4]

The responsibility for the coordination, development, and administration of the policy fell on the Office of Cannabis Medical Access within Health Canada.[10] Among other daunting tasks, they were responsible for clinical research into marijuana, working with the Canadian Institutes of Health Research, and the establishment of a reliable Canadian source of medical-research–grade marijuana.[10]

Criticism from physicians

The announcement drew immediate criticism. The Family Research Council said the new rules sent the wrong message to children "that marijuana has positive benefits and that it is a so-called medicine … We believe the best way to help people who are sick and dying is to utilize the drugs we have that are approved for relief."[6] Canadian Medical Association and Saskatchewan College of Physicians and Surgeons (SCPS) also voiced their opposition to the policy.[1,2,9] Both stated that marijuana will be difficult to prescribe because little clinical research has been done and the government is expecting too much from physicians with respect to patient counselling.[9]

SCPS stated, "We would encourage physicians to be cautious in relation to any new form of therapy for which there is, frankly, very little evidence in regards to its safety and effectiveness." It was also concerned about the requirements for physicians to counsel patients that the long-term effects of marijuana are unknown, and the need for the physician to document reasons for prescribing marijuana and other treatments that have failed.[9]

Research and pharmacology

Marijuana or *Cannabis sativa* is a cannabinoid-containing plant that can be an antinauseant, an appetite stimulant, an antispasmodic, and an analgesic.[11,12] It has also been shown to have a significant, but short-term, effect on lowering intraocular pressure.[11,12] Marijuana causes central nervous effects (a "high") that can be profound and are considered to be clinically unacceptable.[11]

Patients were left in a Catch-22 situation

When Canada introduced its policy to approve the use of marijuana for medicinal purposes it did so based on very scant clinical research.[11-14] Even though marijuana has been used both medicinally and recreationally for thousands of years it has not been put through the rigours of double-blind clinical trials to test its efficacy against placebos or other agents.[11] The lack of research is attributed to a lack of interest on the part of pharmaceutical companies to research a medication that occurs naturally and cannot be patented.[11,13] It has been suggested that perhaps plant extracts may be a more lucrative proposition for the pharmaceutical manufacturers since the processes in the formulation of extracts can be patented.[13]

The task of coordination of research into medicinal marijuana in Canada has been taken up by both Health Canada, through the Office of Cannabis Medical Access, and the Canadian Institute of Health Research.[14] Their primary focus is a five-year plan that will encourage research into clinical treatments with both smoked and non-smoked forms of marijuana and other cannabinoids.[14]

Until this research has been completed, however, current knowledge will be relied on for guidance. This section will review the pharmacology of the effects of cannabinoids, the current indications of marijuana in contrast to

ACTIVE INGREDIENTS

The physiological effects of cannabinoids have been attributed to the CB_1 and CB_2 receptors.[11] Most of the undesirable central nervous system (CNS) effects that marijuana exhibits have been linked to the CB_1 receptor.[11] It has been suggested, therefore, that a more appropriate agent would have activity at the CB_2 receptor site exclusively. One such agent that shows promise is cannabidiol, which has very few psychoactive CNS effects due to its CB_2 receptor affinity.[11]

The primary active ingredient in marijuana, 9-tetrahydrocannabinol (THC), is available as a purified formulation in a soft gelcap formulation, dronabinol.[11]

other agents, the delivery systems of marijuana, and its harmful effects.

Gelcaps

Gelcap formulations are not widespread due to several problems associated with absorption, metabolism, and tolerability.[12,13] The absorption of dronabinol and the onset of action is slower than that of smoked marijuana. Patients who use marijuana for the immediate relief of symptoms find this to be unacceptable. The dose of dronabinol is not easily titrated, whereas smoked marijuana can be inhaled and, since it has a swift onset of action, the smoking can be discontinued once the desired relief is experienced.[12,13]

Dronabinol has been associated with an increased incidence of psychotic overdose symptoms compared to smoked marijuana.[13] This has been attributed to the first-pass metabolism that the oral dronabinol must undergo.[13] The metabolite, 11-hydroxy-THC is four times as psychoactive as the parent THC, and is not found in significant amounts with inhaled marijuana since first pass metabolism is avoided.[13]

Patients suffering from anorexia, nausea, and vomiting who are using marijuana to prevent weight loss have reported dissatisfaction with the oral THC formulation, stating that it is difficult to keep down.[13]

Inhaled marijuana

The harmful effects of the smoked form of marijuana have been documented more completely in the literature. The smoke has been shown to contain more than 200 additional compounds, many of which damage cilia in the lungs.[11,13] There are also increased risks of bacterial pneumonia in immunocompromised individuals, as marijuana has a negative effect on the immune system.[11] (Other sources have described the effect as immuno-modulating,[13] but the risk of infection is still present.)

Health Canada has expressed concern about these harmful effects and is pursuing research into other delivery systems.[14] Other systems that are being studied are suppositories, aerosols,[11] and vaporizers.[13] Proponents of marijuana or extracts of marijuana state that the non-purified plant form contains over 400 substances, including other cannabinoids, that act synergistically and have a greater effect than THC alone.[11,13] They also call for more research into vaporizers because they evaporate the cannabinoids and other volatile oils in the marijuana and avoid the harmful side effects caused by combustion.[13] Current vaporizer technology, however, does not eliminate the risk of bacterial or fungal infections and therefore more research is needed.[13]

Arguments of the opposition

Opponents of the use of marijuana for medicinal purposes argue that some of the uses that have been approved by Health Canada are more effectively treated with other medications. Examples include the use of 5HT antagonists such as antiemetics, and beta-blockers for glaucoma.[11] They also cite a number of side effects, such as decreased energy,[11] decreased short-term memory[11,13] (impairing at least three neurotransmitters[13]), and most disturbingly, a potentially addictive property through effects on the m_1 receptor.[13] (Potentially addictive properties are of concern — see box p. 26).

It is imperative that Health Canada prove or disprove the efficacy of medicinal marijuana

Pragmatists among the opponents of marijuana have welcomed research into its medicinal uses, as they feel that clinical efficacy will not be proven and, like the Laetril cancer treatment debate of 1980, medicinal marijuana will end up as a non-issue.[11]

Health Canada has approved the use of marijuana for medicinal purposes. It is clear that the approval has sidestepped many of the standard clinical trials that medications must undergo to show effectiveness. It is now imperative that Health Canada and the Canadian Institutes of Health Research prove, or disprove, medicinal marijuana's efficacy.

Theory and debate

Policy changes regarding the use of marijuana as a medication in Canada prompted debate between supporters of its therapeutic benefits and/or of patient rights to access treatment of their choice, and detractors who cite dangers of addiction and models of deviant behaviour. The debate itself, and its outcome, demonstrate that social acceptance of patient rights, on the one hand, and medical marijuana use, on the other, makes the "deviance" model in relation to medical marijuana virtually obsolete. Marijuana use for medical purposes is no longer perceived

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as deviant behaviour in Canada and Canadians do not want it positioned as "drug abuse."

It is incumbent upon the researcher to demonstrate causality between the initial use of marijuana for medical purposes and the end effect of drug "abuse" by the patient. This alleged relationship has been the subject of many studies.[17-19] The United States' Drug Enforcement Agency consistently maintains that marijuana is a gateway drug that leads to more serious drug use, and that the legalizing of marijuana for medical purposes would send the wrong message to society: that marijuana use is beneficial to the individual. These premises were analyzed by a panel of 11 independent researchers who were commissioned by the Institute of Medicine in the largest literature review to date,[17] and reported "no evidence that giving the drug to sick people would increase illicit drug use in the general population. Nor is marijuana a 'gateway drug' that prompts patients to use harder drugs like cocaine and heroin."[17] The Report of the Senate Special Committee on Illegal Drugs states that marijuana is not considered a gateway drug.[4]

The research has, in fact, shown that marijuana use is negatively associated with depression when its use for coping is controlled.[19] The use of marijuana, when smoked in the company of trustworthy friends, has been shown to improve the user's mental state.[19] This finding should add credibility to medical marijuana use since the guidelines and doses that are recommended are the lowest possible effective doses.[20]

Four traditional social theories (see below) attempt to predict the effects that marijuana use will have on the user. They predict that the user, who is in some way distressed or deviant from society's norms, will turn to drug use. This may start as occasional marijuana use but as the user becomes more estranged from society the pattern of drug use will become more serious. These theories are often used to describe the actions of adolescents, however, the description of the situations of the users fits the profile of the patient in need of medical marijuana.

TRADITIONAL THEORIES OF DRUG ABUSE

Social theories relating to drug use and abuse in the 1960s, 1970s, and 1980s generally characterize the use of marijuana as deviant behaviour, and seek to understand the causes and possible results of such use. They do not focus specifically on medical marijuana — an important distinction.

Traditional social theories that attempt to explain drug addiction include anomie, differential association, symbolic interactionism,[15] and general strain theory.[16]

Anomie was used in the first part of the twentieth century to explain the social abnormality that occurs when society is weakened by some crisis. On an individual level, it means that when a person's goals are limited by their resources, they may become estranged from society and therefore act in their own interests. This, in turn, leads to retreatism and ultimately "deviant" behaviour.[15] The crisis that the individual experiences through the diagnosis of a life-threatening or debilitating disease could start the cascade whereby the person would seek to use marijuana for medicinal purposes whether it is approved or not. The worst case would see the individual withdrawing from society and pursuing their deviant drug behaviour either through the continued use of marijuana or with other illicit substances.

The differential association theory of drug abuse focuses mainly on deviant and criminal behaviour that is attributable to anti-social associations. It has been modified and renamed "*differential association reinforcement theory*."[15] It maintains that the first exposures to drug use are initiated by persons who are known intimately by the user, possibly even a family member.[15] Although this theory has been used to describe adolescent behaviour, its application to patients looking to family members and close friends for support appears to be a logical extension. According to this theory, once the pattern of the use of illicit substances has been established, the patient is at risk of descending into the use of more powerful and addictive substances.

Symbolic interactionism is the most interesting of the theories, as it applies to the use of marijuana for medical purposes. In 1966, Kai Erikson wrote, "Deviance is not a property inherent in any particular kind of behaviour; it is a property conferred upon that behaviour by people who come into direct or indirect contact with it."[15] In essence, individuals who smoke marijuana for medical purposes are considered deviants because of the label that North American society places on the use of illicit substances. This labeling of ordinarily law-abiding citizens can stigmatize these people, and cause the person to continue in behaviours that are more deviant. If the deviant label were to be removed the behaviour would be regarded as acceptable. Much of the risk of continued, more serious, drug use would therefore be abated, since the patient would never have been labeled deviant.

General strain theory draws from anomie as it focuses on discrepancies between aspirations and reality. The patient's perception of the injustice of having their good health and possible future aspirations stripped away and replaced by suffering creates strain. This strain, in turn, causes the patient to focus on the immediate relief of suffering rather than the attainment of future goals.[16] The illegal use of marijuana for the relief of suffering is one of the manifestations of the patient's desire for relief from their strain.

All of the theories agree that, once a patient has deviated from social norms through the use of marijuana, there is an increased risk of the patient pursuing further use of illicit substances. The theories propose that this in turn can initiate a cascade that leads the patient to addiction and drug abuse.

Conclusion

When considering the debate about medical marijuana policy, we note many parallel streams of discussion on diverse topics, including law enforcement issues, increased credence given to patient rights, increased awareness of the burden of chronic pain, drug abuse and addiction, and medical evidence for and against medical marijuana use. Understandably, health professionals tend to focus on fears of addiction, concerns over malpractice, and medical evidence, which are not necessarily the focus of patient or political groups.

A focus for health professionals is the fact that we have anecdotal evidence but no clinical trial evidence in support of medical marijuana. Both private (pharmaceutical) and public (government and university) researchers have been reluctant to fund large-scale research in medical marijuana. In 1999, Health Canada and the Canadian Institutes of Health Research addressed the lack of clinical evidence by instituting a $7.5-million research program to determine the safety and efficacy of marijuana and related cannabinoids in the management of symptoms in patients unresponsive to usual treatment modalities. The research program is projected to be completed in 2004.[21] While the Drug Enforcement Agency in the United States has maintained that marijuana is a gateway drug, this view is neither shared by the scientific community nor the Senate of Canada. Canada has approved a policy that has considerable public support.

The non-purified plant form contains 400+ substances (including cannabinoids) that are said to act synergistically with a greater effect than THC alone

More research into the effects of marijuana on the m_1 receptor as well as effects on dopamine levels in the brain is necessary.[17,20] If marijuana is found to be addictive or to serve as a gateway drug, then review of indications for its use would be warranted. Policy-makers should be cognizant, however, of the needs of the population that medical marijuana serves. If a patient is progressing through the end stages of a degenerative disease, then the possible addictive effects of marijuana could be considered irrelevant and its use would be appropriate. ■

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