

CMAJ September 11, 2007 vol. 177 no. 6 doi: 10.1503/cmaj.071044

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News

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New dosage limits for medical marijuana: But where's the science?

by Pauline Comeau

September 11th, 2007

New evidence-based guidelines are urgently needed to help doctors negotiate Canada's hazy medical marijuana landscape, particularly in light of Health Canada's efforts to impose new dose limits, say the nation's leading cannabis researcher and doctors who have been queried about their marijuana authorizations.

Canada should also re-establish a formal process for developing responsible dosing strategies, says Mark Ware of McGill's University Health Centre, the sole researcher funded under the now defunct Medical Marijuana Research Program (CMAJ 2006;175:[12]: 1507-8).

The 1053 doctors now authorizing marijuana use for 1816 patients need "more evidence" regarding rational dose levels, he says. And Ware suggests the Canadian Consortium for the Investigation of Cannabinoid could lead such an effort.

"There is more research, more trials, formulations that could be done," says Ware. "If we had a couple of days in a room with people and pharmacologists then we could sit around and say, here is the best we can come up with, here are some guidelines."

Under current medical marijuana rules, doctors authorize the amount of marijuana they and their patients feel is necessary. However, several who have recommended above 5 g per day were recently telephoned by a Health Canada medical marijuana program officer, and advised that the department recommends no more than 1-3 g per day, irrespective of the medical condition or means of consumption (inhaled, ingested or both). Health Canada also posted that recommendation on its Web site in October 2006, after officials noted the number of authorized users prescribed at more than 5 g per day had increased to 15% in June, 2006 from 10% a year earlier.

Alison Myrden of Burlington, Ont., is authorized to take 20-28 g of marijuana per day to alleviate pain from multiple sclerosis and trigeminal neuralgia. Her physician did not alter her dosage after a Health Canada phone call, but Myrden says, "I've been prescribed heroin and cocaine, and I've never had the issues I've had with marijuana."

The lower 1-3-g dose recommendation stems from "an examination of current available evidence on daily amounts," stated unnamed officials in an email exchange coordinated by Health Canada

spokesperson, Renée Bergeron. Asked to provide the scientific basis for the dose recommendations, the officials cited 3 studies and "preliminary Canadian research findings."

In the first study, *Medical Cannabis: Rationale Guidelines for Dosing* (IDrugs 2004;7:464-70), Health Canada selectively noted that users in Washington and California consumed 1.42-2.86 g per day. However, the study authors go on to recommend a dose range of 0.05-7.40 g per day, and that was for a more potent form of cannabis currently produced by Health Canada's grower (15% tetrahydrocannabinol content compared to 12%-plus). Moreover, the study concluded that considering the complexity of marijuana dosing, from tolerance to mode of ingestion, the guidelines should be viewed only "as a construct to allow the physician and patient to develop an individual, self-titration dosing paradigm."

The second study surveyed 916 users in the United Kingdom; a third documented use among 34 multiple sclerosis patients in Nova Scotia. In the latter 2 studies, consumption was less than 1-2 g per day.

Ware authored the UK study and coauthored the Nova Scotia one. In both, he says, nothing more than a range of use was documented. He notes that marijuana strength and its form of use can alter its therapeutic effectiveness.

Susan Russell, acting director for Health Canada's Office of Controlled Substances, says ordering patterns under the existing medical marijuana program support the 1-3-g limit as does "preliminary" Canadian information gleaned from an "unpublished study."

Those preliminary research findings are data from a study by Ware, funded by the Medical Marijuana Research program, which is not complete. "It is therefore premature to make any public statements about the study data; our estimates could yet change with further data collection," says Ware.

And while 1-3 g seems reasonable, based on the literature, more research is needed to be definitive, he says.

Medicinal marijuana users are frustrated by the latest twist. Tony Adams of Victoria, BC, is "furious" about the government's failure to respond to his letters regarding dosage reductions. Adams, 60, who suffers from degenerative disc disease and severe arthritis, was licensed for 7 g per day. He was seeking a boost to 10 g to use as tea, but got approval for 5 g.

Health Canada's Russell says the goal of the calls to doctors is merely to "verify or clarify the proposed daily amount." But some physicians say they have felt challenged, and have either prescribed lower doses or withdrawn from the program altogether. "You wonder, like with the narcotic control program, if they're going to flag the doctors that have high [tetrahydrocannabinol authorization] practices or something; if you're going to be under scrutiny," said one physician on condition of anonymity.

"In the pain practice, there is enough potential heat on this that I do not want to stand out too much," says Dr. David Boyd of Victoria Hospital's London Health Sciences Centre, London, Ont. He has 50-plus patients using marijuana, and no longer authorizes more than 5 g per day.

University of Ottawa Director of Health Services, Dr. Don Kilby is sympathetic to Health Canada's dilemma in managing a program that can include people seeking marijuana without true need, and he also sees the difficulty doctors face in helping patients whose ailments indicate a need for higher marijuana doses. Guidelines are needed, Kilby says.

Russell says Health Canada doesn't plan to develop guidelines, and doesn't have any "evidence" that doctors are intimidated by the calls. A small, informal survey of doctors is, however, underway.

The CMA received a letter from Health Canada on May 18 indicating that the department believes scientific evidence supports lower dose recommendations, that some patients receive considerably more and that the "apparent discrepancy" is motivating a partial review of the Medical Marijuana Access Regulations. Health Canada told CMAJ that amendments may be presented for consultation in 2007 or 2008.

CMA Director of the Office of Public Health Dr. Sam Shortt says the CMA does not approve of how medicinal marijuana is regulated considering the lack of studies correlating outcomes and dosages. Shortt advises doctors to read credible studies before authorizing marijuana use and to keep detailed clinical notes. The Canadian Medical Protective Association recommends physicians ask applicants to sign a release from liability.