Early Survey Results from the Minnesota Medical Cannabis Program

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As part of its legislative mandate, the Minnesota Department of Health's Office of Medical Cannabis (OMC) is required to study and report on the state's medical cannabis program. This article describes preliminary findings from the OMC's research about who is using the program and whether patients and their certifying health care practitioners are noticing benefits and harms.

In May 2014, Minnesota became the 22nd state to create a medical cannabis program. Distribution of extracted cannabis products in liquid or oil form to qualified, enrolled patients began July 1, 2015. Minnesota's medical cannabis program is distinct from those in other states, as the Department of Health's Office of Medical Cannabis (OMC) is required by law to study and learn from the experience of participants. Its online registry, which integrates information from patients, certifying health care practitioners and manufacturers, is the mechanism used to capture data.

In Minnesota, medical cannabis treatment falls outside the traditional medical model. Physicians, physician assistants and advanced practice registered nurses certify patients as having conditions that by law qualify them for the program (Table 1). Those clinicians do not have a direct role in determining the dose or form of cannabis to be used. That is handled by pharmacists at the distribution centers (certifying clinicians can communicate their recommendation to the patient and the distribution center pharmacist, however).

In order to participate in the program, a patient is expected to have an ongoing relationship with their certifying clinician. Thus, our research seeks to integrate clinicians' and patients' observations in an attempt to understand the patient experience. This article describes what we have learned thus far about who is using the program, and what patients and their certifying health care practitioners are seeing in terms of benefits and harms. At this point, the numbers of patients and health care providers reporting are still small, and the findings must be considered preliminary.

TABLE 1

Qualifying conditions for Minnesota's medical cannabis program

Cancer (if disease or treatment causes severe/chronic pain, nausea or severe vomiting, cachexia or severe wasting)

Glaucoma

HIV/AIDS

Tourette syndrome

Amyotrophic lateral sclerosis (ALS)

Seizures (including those characteristic of epilepsy)

Severe and persistent muscle spasms (including those characteristic of multiple sclerosis)

Crohn's disease

Terminal illness (with a probable life expectancy of less than one year or if the illness or treatment causes severe/chronic pain, nausea or severe vomiting, cachexia or severe wasting)

Survey Tools and Process

We developed a patient experience survey to capture information about the benefits and harms of program participation. A parallel survey developed for certifying health care practitioners (HCPs) captures similar information from the clinician's perspective.

Both the patient and the HCP surveys include multiple choice and open-ended questions. They are administered through an online platform and are accessible through the patient or practitioner registry page and through emails that include links to them. The surveys are released three months after the patient's first medical cannabis purchase (starting July 1, patients will receive surveys at three months and six months after their first purchase, then approximately every six months thereafter for the duration of their participation in the program). Health care practitioners receive a survey six months after the patient's first medical cannabis purchase and approximately every six months thereafter, as long as they remain the certifying provider for that patient. Each online survey remains active for 45 days; if patients and practitioners do not complete it within two weeks, a paper version is mailed to them. To maximize response rates, the survey

can be submitted even if it is incomplete. (To see a copy of the survey, go to the "Print Materials and Forms" section of the Office of Medical Cannabis website: www.health.state.mn.us/topics/cannabis/index.html.)

Response Rates and Findings

A total of 435 patients made their first medical cannabis purchase during the first three months of the program (July 1 to September 30, 2015). Those patients were certified by 345 clinicians between June 1 and September 28, 2015. Of the 435 patients, 241 (55%) completed the survey. Of the 345 HCPs who certified the 435 patients, 94 (27.2%) completed surveys for 169 (39%) patients. Since enrollment in the program began, 29 (7%) of the 435 patients are known to have passed away; we included those patients in our report, as in some cases their caregivers or relatives and HCPs completed surveys. Patient demographics are shown in Tables 2, 3 and 4.

Patient response rate did not vary significantly by age group (Table 2), with the lowest response rate among patients 65 years of age and older. The response rate among HCPs was generally higher for younger patients. Distribution across qualifying medical conditions varied widely. Patient and HCP response rates tended to be lower for ALS and terminal illnesses (Table 3). Patients in the program are predominantly white (84.5%) and male (61.3%); we found no significant variation in response rates by race (Table 4).

Of the 435 patients, both a patient survey and HCP survey were completed for 98 (22.5%); neither survey was completed for 96 (22.1%).

Perception of Benefits from Medical Cannabis

Both the patient and HCP surveys asked respondents to rate the benefits experienced by the patient from medical cannabis on a scale of 1 (no benefit associated with treatment) to 7 (a great deal of benefit associated with treatment). For both patients and HCPs, perception of benefit was quite high (Figure); 209 patients (87.8%) and 97 HCPs (68.3%) indicated

TABLE 2

Patient and health care practitioner responses by age group

PATIENTS' AGE (YEARS)	NUMBER OF PATIENTS	PATIENT RESPONSES (RESPONSE RATE)	HCP RESPONSES (RESPONSE RATE PER PATIENTS IN AGE CATEGORY)
0-4	12	8 (67%)	7 (58%)
5-17	61	34 (56%)	29 (48%)
18-24	24	15 (63%)	13 (54%)
25-35	69	35 (51%)	22 (32%)
36-49	103	60 (58%)	39 (38%)
50-64	123	70 (57%)	41 (33%)
65+	43	19 (44%)	18 (42%)

TABLE 3

Patient and health care practitioner responses by qualifying medical condition*

QUALIFYING MEDICAL CONDITION	NUMBER OF PATIENTS	PATIENT RESPONSES (RESPONSE RATE)	HCP RESPONSES (RESPONSE RATE PER PATIENTS WITH CONDITION)
Glaucoma	6	4 (67%)	2 (33%)
HIV or AIDS	19	12 (63%)	11 (58%)
Tourette syndrome	8	6 (75%)	4 (50%)
ALS	9	3 (33%)	3 (33%)
Seizures	112	76 (68%)	45 (40%)
Muscle spasm	157	85 (54%)	61 (39%)
Crohn's disease	30	14 (47%)	13 (43%)
Cancer	103	44 (43%)	36 (35%)
Terminal illness	25	12 (48%)	6 (24%)

*Thirty-five patients are certified for multiple qualifying conditions and are represented more than once.

TABLE 4

Patient and health care practitioner responses by race*

RACE	NUMBER OF PATIENTS	PATIENT RESPONSES (RESPONSE RATE)	HCP RESPONSES (RESPONSE RATE PER PATIENTS IN EACH GROUP)
American Indian	3	1 (33%)	2 (67%)
Asian	8	3 (38%)	3 (38%)
Black	18	6 (33%)	6 (33%)
Hawaiian	0	0 (0%)	0 (0%)
White	368	216 (59%)	146 (40%)
Other	5	3 (60%)	3 (60%)
2+ Races	13	4 (31%)	4 (31%)
Unknown	24	8 (33%)	5 (21%)

*Hispanic ethnicity was captured as a separate question from race.

the patient experienced at least some benefit (score of 4 or higher) from medical cannabis.

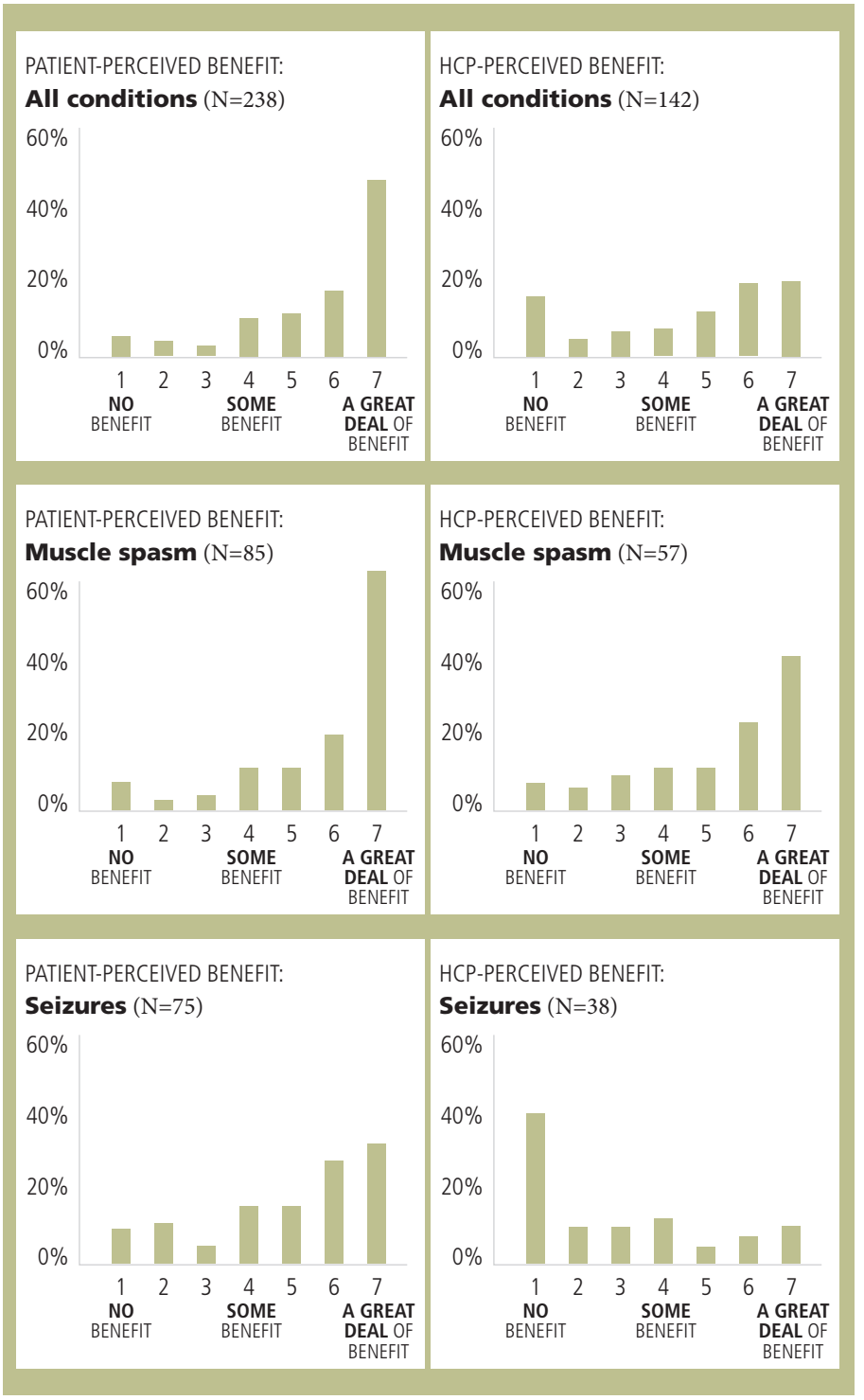
Notably, both patient and HCP scores varied by condition. HCPs reported that patients certified for muscle spasm seemed to have experienced a greater degree of benefit than the overall patient population. Patients certified for seizures reported experiencing less benefit than the overall patient population. Of the 38 HCPs who certified patients with seizures, only 36.8% reported at least some benefit for those patients.

HCP reports of benefit were generally more conservative than patient reports. We also looked at benefit scores for patients for which both the patient and HCP surveys were completed. Of the 78 patient-HCP pairs that provided benefit scale data, 3 (4%) agreed that there was no or little benefit to medical cannabis treatment (score of 1 or 2); 11 (14%) agreed that there was mild or moderate benefit (score of 3 to 5) and 35 (45%) agreed that there was significant benefit (score of 6 or 7).

Both patients and HCPs were asked to describe the most significant benefit to the patient. One hundred forty-four (59.8%) of the 241 patient surveys had listed improvement in symptoms related to qualifying medical conditions as the most significant benefit (Table 5). An additional 38 (15.8%) described indirect benefits such as improved sleep or reduced anxiety as the most significant benefit. Five patients (3%) reported access to legal and/or safe cannabis as the primary benefit. Of the 169 surveys HCPs completed, 80 (47.3%) listed improvement in symptoms as the most significant benefit for patients and 12 (7.1%) described indirect benefits as being the most significant benefit.

FIGURE

Distribution of reported benefit scores from patients and health care practitioners



Perception of Harms from Medical Cannabis

Patients and HCPs who responded to the survey also had the opportunity to rate harm from medical cannabis treatment on a scale of 1 (no harm) to 7 (a great deal of harm) and to describe the most significant harm as a result of medical cannabis treatment. To address the issue of medication cost separately, we asked patients to rate the cost of medical cannabis on a scale of 1 to 7 with 1 being "very affordable" and 7 being "very prohibitive." Many patients (177; 73%) reported that medical cannabis was unaffordable (score of 5 to 7). Despite our intention to have respondents exclude cost from their reporting on harm, 18 (7.5%) patients and 17 (10%) HCPs reported cost as the most significant harm. Another common response was distance to or inconvenience of visiting a cannabis distribution center (six patients; 2.5%).

TABLE 5

Summary of most significant benefits experienced by patients, as reported by patients and health care practitioners

	PATIENT REPORTS (% OF 241 COMPLETED SURVEYS)	HCP REPORTS (% OF 169 COMPLETED SURVEYS)
Direct benefits	144 (59.8%)	80 (47.3%)
Reduced muscle spasms	47 (19.5%)	16 (9.5%)
Reduced pain	32 (13.3%)	25 (14.8%)
Fewer/less severe seizures	28 (11.6%)	15 (8.9%)
Reduced symptoms relating to nausea, vomiting and cachexia	27 (11.2%)	23 (13.6%)
Reduced symptoms relating to Tourette syndrome	4 (1.7%)	1 (0.6%)
Reduced symptoms relating to Crohn's disease	4 (1.7%)	0 (0%)
Reduced symptoms relating to glaucoma	2 (0.8%)	0 (0%)
Indirect benefits	38 (15.8%)	12 (7.1%)
Improved quality of life	8 (3.3%)	4 (2.4%)
Improved sleep	11 (4.6%)	2 (1.2%)
Improved alertness/cognitive functioning	10 (4.1%)	0 (0%)
Improved mobility/general functioning	4 (1.7%)	1 (0.6%)
Improved comfort	3 (1.2%)	1 (0.6%)
Reduced anxiety	2 (0.8%)	4 (2.4%)

TABLE 6

Summary of most significant harms experienced by patients, as reported by patients and health care practitioners

HARMS	PATIENT REPORTS (% OF 241 COMPLETED SURVEYS)	HCP REPORTS (% OF 169 COMPLETED SURVEYS)
Physical side effects	39 (16%)	13 (8%)
Mental side effects	8 (3%)	14 (8%)
Access issues (cost/access to distribution center)	24 (10%)	17 (10%)

Forty-seven of the 241 patients who responded (20%) reported physical or mental harms associated with medical cannabis use (Table 6). Four reported an increase in seizures. Others described harms that mirrored the side effects reported in clinical trials of medical cannabis.[1,2] For those who experienced the highest levels of harm, the physical or mental effects they reported were as follows: hives (score: 7; n=1); stomach pains, increase in seizures, burning in mouth, dizziness, sedation and high (score: 6; n=5); lightheadedness, paranoia, sleepiness (score: 5; n=3). Another 24 (10%) reported a variety of other issues, including desire for different types of products (n=3); stigma or negative reactions from family or health care providers (n=6); wishing the cannabis were more effective (n=5); and experiencing other nonclinical effects (n=10).

Twenty-seven (16%) of the 169 HCPs who responded reported physical or mental harms resulting from medical cannabis treatment in patients; as with the patient reports, the harms generally mirrored side effects described in clinical trials. Two exceptions were a report of worsening symptoms of Parkinson's disease (with reported harm score of 4) and a report of some seizure types worsening (with a reported harm score of 5). The physical or mental effects associated with the highest levels of harm were abdominal discomfort (score: 7; n=1); sedation (score: 6; n=1); constipation and lethargy with worsened seizures and "too strong for patient" (score: 5; n=2). Another five HCP surveys indicated other issues, including lack of benefit (n=3).

Drug Interactions and Other Clinical Observations

The HCP survey includes space for practitioners to share insights about a patient's medical cannabis treatment. They used this space to report observations on clinical issues ranging from lack of efficacy (n=4) to difficulties in the patient obtaining other pain medications because of their medical cannabis use (n=2). Twelve stated that the patient reduced their pain medication dosage as a result of their medical cannabis use; six specifically mentioned decreased opioid use; another three indicated reduction of nonpain medications.

Other Feedback from Health Care Practitioners

The HCP survey also solicited feedback on the state's medical cannabis program. Some HCPs expressed a desire to see the program expanded to include new conditions and/or accommodate the addition of intractable pain (n=13) and to see published research and/or statistics on the program's patient population (n=2). Additionally, 18 respondents indicated concerns over the medication's cost.

Many HCPs also noted that they are seeking an in-depth understanding of their patient's medical cannabis treatment. Thirteen HCPs requested formulation and dosing information for their patients,

with some requesting detailed notes from the manufacturers' pharmacists. (Note: Certifying HCPs can see medical cannabis purchases made by their patients, along with their symptom score and side effect information; this feature became available after the program's launch.)

Learning from Early Experience

One of our goals was to keep the surveys short. As we reviewed responses, we realized that the surveys can be improved. We found some questions provided less granular information than desired and that the open-ended format of many questions required adjudication of each response. As a result, when the registry is updated to prepare for the addition of intractable pain as a qualifying condition, some survey questions will be eliminated and others will be consolidated. This should reduce the burden on HCPs.

The early results show that for many patients and HCPs, their experience with medical cannabis treatment and with the program itself are not easily separated. Complaints about the high cost of medical cannabis frequently appeared in both patient and HCP responses. Inability to find a certifying practitioner and having to travel long distances to a cannabis distribution center also were mentioned. Having learned from early results, we plan to revise the survey to more effectively separate responses related to the program from those related to the health consequences.

Future Directions

We plan to release a comprehensive report on the state's first-year experience in late 2016. This will include patient and HCP survey results along with information about patient characteristics, patient symptoms and side effects, medical cannabis product use, results from the SF-12 quality-of-life assessment at baseline and at three and 12 months after program initiation, medical history and other medication use. After reviewing the findings, we may conduct further studies of populations with specific diseases and their experiences with medical cannabis; those studies may include medical record data. A limitation of our current effort is that it relies on patient reports and clinician observations; however, those insights are invaluable for potential patients and for clinicians who are already caring for patients in the program and working with those who are interested in trying this treatment. MM

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