Background & Methodology: Benefits Reported on the Patient Self-Evaluation

Background

The patient self-evaluation is required for patients to complete prior to each medical cannabis purchase. It includes questions to assess symptom severity, some of which are administered to all patients (standard set of 8 symptom measures) and some of which are tailored to symptoms for a given condition (condition-specific symptom measures). Since symptom data is collected prior each patient's first medical cannabis purchase, symptom changes can be assess over time and compared to baseline (baseline = patient responses to symptom questions just prior to their first medical cannabis purchase).

Methodology: Standard 8 Symptom Measures

The standard 8 symptom measures that all patients receive are answered on a 0-10 numerical rating scale (NRS), with 0 indicating absence of the symptom to 10 indicating that the symptom is as bad as the patient can imagine (see Box 1). Therefore, higher scores on these measures indicate poorer management of these symptoms. Patients are asked to rate symptom severity over the past 24 hours.

Box 1. Listing of the Standard 8 symptom measures that all patients answer, including the responses options available to patients.

Standard 8 Symptom Measures:

Anxiety; Lack of appetite; Depression; Disturbed Sleep; Fatigue; Nausea; Pain; Vomiting

Response Options (0-10 Numerical Rating Scale):

0 = Symptom not present;

10 = Symptom as bad as one can imagine

To understand whether patients derived any symptom benefits during their participation in the program, the following two questions were explored for each Standard 8 symptom measure:

QUESTION 1

Of those patients who experienced moderate to severe symptoms at baseline (score of 4 or higher at baseline), what percentage of them experienced at least a 30% improvement in symptoms within four months of their first medical cannabis purchase? The threshold of $\geq$30% reduction on a 0-10 point scale was chosen because this threshold has been documented in clinical trials to represent clinically meaningful change – especially for pain reduction and

spasticity reduction. Examples of ≥30% change include moving from a score of 10 to a score of 7, from 9 to 6, from 8 to 5, from 7 to 4, etc.

To address Question 1 the following procedure was adopted for each standard 8 measure: all patients who scored 4 or higher at baseline were identified as those experiencing moderate to severe symptoms, and all standard 8 responses that were submitted within 4 months of their first medical cannabis purchase were retained. From this dataset, each patient's standard 8 responses were compared to their baseline response over time. The first instance a patient achieved at least a 30% symptom improvement was recorded, effectively demonstrating when – during the first 4 months following their first medical cannabis purchase – the patient achieved symptom improvement, if at all.

Calculating the percentage of patients who achieved ≥30% symptom improvement within 4 months of their first medical cannabis purchase (Question 1) was done as follows: the number of patients who achieved ≥30% symptom improvement within 4 months was divided by the total number of patients that ever made a first purchase (patients with baseline PSE data). This allows for a conservative estimate on the proportion of patients achieving symptom improvement, since not all patients who made a first purchase will have continued in the program after that initial purchase. Reasons for a patient to make no additional purchases after their first purchase may include discontinuation due to lack of effectiveness, though they may have discontinued use for other reasons as well (i.e., medical cannabis cost, side effects, etc.).

QUESTION 2

If a patient achieved at least a 30% improvement on symptoms within 4 months of their first medical cannabis purchase (determined in Question 1), what percentage of them will, on average, still maintain that level of improvement in the four months following that initial 30% symptom improvement? [Four-month follow-up period]

Question 2 was addressed by observing the 4 month period that followed the patient's initial achievement of a≥30% reduction in symptoms. For each patient, all responses for a given symptom measure were identified during that 4-month follow-up period and averaged together. Patients who, on average, still maintained at least a 30% symptom improvement from baseline were identified as those showing persistence in their symptom benefits.

Methodology: Condition-Specific Symptom Measures

Besides the Standard 8 measures which are administered to all patients, some patients receive additional symptom questions on the PSE to more adequately address condition-specific symptoms. These include, among others, questions on seizure frequency for seizure patients, questions on spasm frequency for muscle spasm and ALS patients, and Crohn's activity in Crohn's patients. While patients received the same response options on the Standard 8 measures (respond from 1-10 on a numerical rating scale), response options for condition-specific measures vary and are captured in Table 1. In addition inclusion criteria to be included in the analysis varied by the condition-specific symptom measures (see Table 1).

All condition-specific measures were investigated within the same framework as the Standard 8 measures with the : 1) what percentage of patients achieved symptom improvement within the four months since their first medical cannabis purchase compared to their baseline responses, and 2) what percentage of those achieving symptom improvement showed general persistence, on average, in the 4-month follow-up period.

Table 1. Condition-Specific Measures and Target Patient Population: Inclusion Criteria for Analysis and Operational Definition for Symptom Improvement

Condition-Specific Measure	Who	Patients Included in Analysis at Baseline	Threshold to Indicate Symptom Improvement
Weekly spasms	Muscle Spasms; ALS	All	≥30% symptom improvement compared to baseline
Spasticity Scale (0-10 NRS)	Muscle Spasms; ALS	Score ≥4	≥30% symptom improvement compared to baseline
Body Weight	Cancer: Cachexia and Severe Wasting; IBD; Terminal Illness: Cachexia and Severe Wasting; HIV/AIDS		≥3% body weight increase compared to baseline
Weekly seizures	Seizures	All	≥30% symptom improvement compared to baseline
Number of Liquid Stools	Inflammatory bowel disease, incl. Crohn's Disease	≥5 liquid stools	
General Well-Being	Inflammatory bowel disease, incl. Crohn's Disease	"Very Poor" or "Terrible" response	Achieve ""Slightly Below Par" or "Very Well" response
Abdominal Pain	Inflammatory bowel disease, incl. Crohn's Disease	"Moderate" or "Severe" response	Achieve "Mild" to "No" response
Weekly tics	Tourette	All	≥30% symptom improvement compared to baseline
Intraocular pressure	Glaucoma	All	--

Methodology: PEG Tool for Intractable Pain Patients

Patients who were certified for Intractable Pain received the PEG Scale[1] in addition to the standard 8 symptom questions on the Patient Self-Evaluation. The PEG consists of three items to assess pain intensity and its interference with the patient's enjoyment of life and general activity (P = pain; E = enjoyment of life; G = general activity). As a validated tool, it has been proposed as an alternative to longer pain assessments that are administered in clinical settings. The scale asks patients to think back on their last week and rate the following on a 0-10 numerical rating scale (NRS): their average level of pain, pain interfering with their enjoyment of life, and pain interfering with general activity. A composite PEG score is derived by adding the scores on the three items and dividing by three. The three individual items on the PEG can also be analyzed on their own. For these cohort reports, the composite PEG score and individual PEG items are analyzed in a similar fashion to the Standard 8 symptom questions (improvement operationalized as ≥30% improvement on PEG in the composite and individual PEG items).

Methodology: Intraocular Pressure Test Results for Glaucoma Patients

Glaucoma patients are asked to provide the date of their most recent intraocular pressure test and results on the Patient Self-Evaluation. However, these results are not analyzed according to the symptom improvement framework discussed earlier in this section. Intraocular pressure test data is instead provided in table format for each eye along with the length of time that has lapsed between the intraocular pressure test and the patient's first medical cannabis purchase (time lapse depicted in months).

Limitations

There are some limitations with self-reported symptom data. Self-reported patient data is not verified by clinician assessment, for example. In addition, we may not adequately capture symptom data from patients who decide to no longer purchase medical cannabis (or to pause in purchasing medical cannabis for extended periods of time), leading to response bias.

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[1] Krebs EE, Lorenz KA, Bair MJ, et al. Development and initial validation of the PEG, a three-item scale assessing pain intensity and interference. Journal of General Internal Medicine. 2009; 24(6): 733-738. doi:10.1007/s11606-009-0981-1

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