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What is This?

Prospectively Surveying Health-Related Quality of Life and Symptom Relief in a Lot-Based Sample of Medical Cannabis-Using Patients in Urban Washington State Reveals Managed Chronic Illness and Debility

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Abstract

Objectives: To characterize health-related quality of life (HRQoL) in medical cannabis patients. **Methods:** Short Form 36 (SF-36) Physical Health Component Score and Mental Health Component Score (MCS) surveys as well has CDC (Centers for Disease Control) HRQoL-14 surveys were completed by 37 qualified patients. **Results:** Mean SF-36 PCS and MCS, normalized at 50, were 37.4 and 44.2, respectively. Eighty percent of participants reported activity/functional limitations secondary to impairments or health problems. Patients reported using medical cannabis to treat a wide array of symptoms across multiple body systems with relief ratings consistently in the 7-10/10 range. **Conclusion:** The HRQoL results in this sample of medical cannabis-using patients are comparable with published norms in other chronically ill populations. Data presented provide insight into medical cannabis-using patients' self-rated health, HRQoL, disease incidences, and cannabis-related symptom relief.

Keywords

complementary and alternative medicine, cannabinoid medicine, medical cannabis, cannabinopathic medicine, health-related quality of life, symptom management, SF-36, CDC HRQoL-14

Introduction

In states with active medical cannabis programs, health care practitioners are familiarizing themselves with the wide safety margins¹ and broad clinical efficacies² of cannabinoid botanicals by authorizing their use and receiving feedback from patients. This health care phenomenon is driven by rising awareness of accumulated knowledge in the field of cannabinoid medicine or cannabinopathic medicine, a term coined by pioneer Dr Lester Grinspoon, which has arisen out of clinical experience and modern research on the mechanisms of action of cannabis' effects in the body, in part via the endogenous cannabinoid signaling system.^{3,4}

Despite this, to date, little is known about the characteristics of this patient population. Much of the information in the public domain about characteristics of patients who seek medical authorization to use cannabis or who go to access points where medical cannabis is dispensed is garnered through media reports and public campaigns by proponents and opponents of medical cannabis systems. While there are some state registries and a number of noteworthy studies and reports that have

examined delivery points of medical cannabis in the United States using community-based and patient-centered

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perspectives, 5-13 none have used standardized health-related quality of life (HROoL) tools or employed systematic sampling strategies. The present research project is significant as the only study using standard tools to assess self-rated health and HROoL in a uniquely drawn sample of patients using medical cannabis. With such instruments, a valid comparison to state and national normative population samples can be made.

The concept of HRQoL refers to a person or group's perceived physical and mental health over time and helps us to understand how illness interferes with day-to-day life. 14 A variety of psychometric instruments have been developed over the last several decades for gauging this type of perceived health status. 15 Such indicators are utilized extensively in health surveillance and are considered valid instruments to gauge service needs and intervention outcomes, especially given that selfassessed health status has proven to be a better predictor of mortality and morbidity than many objective measures of health, as shown in a review of 27 prospective, longitudinal community studies from the United States and abroad, in which 23 showed, with large effect sizes, that self-ratings of health reliably predicted survival in populations, even when known health risk factors have been taken into account.¹⁶

The following are key HRQoL metrics used in this study. First, the SF-36 (short form, 36 questions), developed in 1992, is the most widely used survey instrument worldwide to gauge self-reported health status. 17 Its questions explore a person's physical functioning, role limitations due to physical problems, social functioning, bodily pain, general mental health, role limitations due to emotional problems, vitality, and general health during the past year, past month, and in current day-to-day life. All the scales are scored so that the least health has a value of 0 and the greatest health has a value of 100. From 8 scales, 2 linear combinations are commonly computed: a Physical Component Summary (PCS) and a Mental Component Summary (MCS), with the normative value set at 50 for each based on a 1990 US general population survey. 18 Second, the Centers for Disease Control and Prevention (CDC) HRQoL-14 (14 questions) developed in 1993 is a set of survey measures developed by the CDC and its partners for use in tracking population health status and HRQoL in states and communities.¹⁹ It combines 3 modules: the Healthy Days Core Module, the Activity Limitations Module, and the Healthy Days Symptoms Module. These include 1 health status measure (self-rated health), 3 HRQoL measures (recent physical health, recent mental health, and recent activity limitation), 5 activity limitation questions, and 5 questions that measure recent symptoms of pain, depression, anxiety, sleeplessness, and vitality. The activity limitations questions are designed to measure "the presence of any self-reported current limitation and, if present, its main cause and duration, as well as whether the help of another person is needed to perform basic activities of daily living (ADLs) or other routine instrumental activities of daily living (iADLs)."20 The CDC HRQoL-14 normative data are available as components of the instrument are administered annually by telephone to large samples of the general population of adults in Washington State and others states.

This purpose of this study was to further characterize this sparsely studied patient population by analyzing data collected on legally qualified medical cannabis using patients who accessed cannabis at a cooperative dispensary in Washington state. Specific aims included quantifying HROoL in this increasingly accepted, albeit not mainstream, medical care system by evaluating patient health characteristics at one site in Washington state, where cannabis is delivered to qualifying patients for their use in treatment under medical supervision.

Methods

The study was approved by the Human Subjects Division at the University of Washington, Application No. 33070 on October 23, 2007, and a federal Certificate of Confidentiality (NCCAM 08-01) was issued by the National Institutes of Health's National Center for Complementary and Alternative Medicine on December 4, 2007. The Certificate ensures that any sensitive information collected as part of this study will remain shielded from outside parties and that those involved in conducting the study "cannot be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify" study participants or otherwise compromise their privacy. The first author was a recipient National Science Foundation Graduate Research Fellowship, but there was no specific funding for this study which was conducted as part of that author's dissertation field research.

The exact location of the dispensary where the study was conducted will remain anonymous and undisclosed to protect participants' privacy and must remain so as per Human Subiects review. Patient sampling was conducted on consecutive days during operating hours from 2007 to 2008. The sampling strategy used was place based and germplasm based. This means that all patient participants recruited for enrollment visited the dispensary during the time the study was taking place and chose, out of the several cannabinoid botanical medicine strains available, to purchase and treat themselves with "plum," a strain preselected for study unbeknownst to patients. Patients were in no way influenced to choose one strain over another and those who solely chose other strains were not recruited. Patients were recruited with the assistance of staff who directed willing potential participants to the researcher. They were told explicitly that they are under no obligation to participate, that participation is entirely voluntary, and that they were free to discontinue participation at any time. The study inclusion criteria were one had to be a qualified medical cannabis patient (preverified by dispensary and asked of subjects as initial survey item) delivered part of the "plum" study lot, aged 18 or older, and proficient in English. The sole study exclusion criterion was anyone taking a cannabinoid receptor blocker drug (none mentioned). Patients were given no gifts, payments, or services for participation.

After oral informed consent, willing patients were enrolled, assigned a random number, and asked to fill out an on-site questionnaire in a quiet area, which assessed medical marijuana treatment history and HRQoL using the SF-36¹⁷ and the

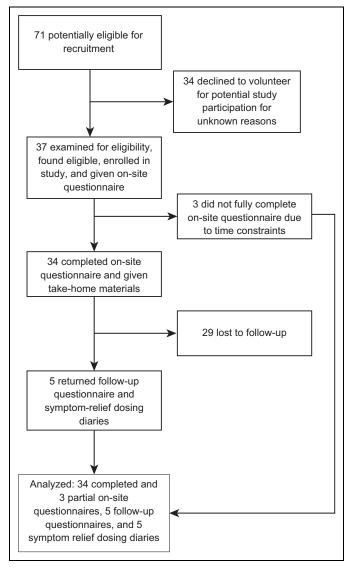


Figure 1. Participant sampling strategy flowchart.

CDC HRQoL-14 + Activity Limitations Module¹⁹ instruments. To assess symptom control, patients were given a list of symptom control choices from the standard review of systems of a medical history divided into categories by body system. Symptom relief options presented were chosen based on the known clinical database of medical cannabis effects. Patients were asked to indicate the ones that applied to them and to indicate on a scale of 1 to 10 what degree of symptom relief they get, where $10 = absolute \ symptom \ control$ and $1 = minimum \ symptom \ control$.

After completing the on-site questionnaire, participants were also given a take-home questionnaire and instructed to complete the second half of this questionnaire after consuming the physician-authorized medical cannabis received during their visit. This questionnaire focused on patient satisfaction with cannabinoid botanical medicines vis-à-vis their use of other medications²¹; it queried symptomatic relief achieved with self-titrated dosing of their supply of the cannabinoid

botanical medicine strain under investigation and repeated some HRQoL items from the on-site questionnaire and adapted items from prior surveys. Participants were also given a symptom-relief dosing diary with instructions and an addressed and stamped envelope to return the materials by mail or in person. Over 2 months after the initial patient sampling, a sign was posted by dispensary staff behind the counter for 2 weeks to increase the return rate of the study materials.

Collected study materials were then analyzed. The SF-36 questionnaire used in this study was inadvertently modified from the standard version in that item 7 which queried "bodily pain during the past 4 weeks" had 5 response choices rather than the standard of 6; therefore, this item was dropped in the scoring and treated per protocol as unanswered. In cases in which the SF-36 questionnaire was only partially completed, scoring was calculated per protocol regarding missing data. Physical Health Component Score (PCS) and Mental Health Component Score (MCS) were derived using the SF-36 norm-based calculator (www.sf-36.org/nbscalc) using the 1990 normed data when the scores for all 8 scales of the SF-36 were available.

Results

Thirty-seven participants were enrolled. Figure 1 shows the study flowchart. Table 1 shows the demographic characteristics and medical marijuana patient-years of study sample. There was a wide variation in the length of time participants identified as being qualifying medical marijuana patients, averaging 3.84 ± 3.99 years and ranging from 4.4 months to 16 years. While all were verified medical marijuana patients under Washington law, one identified as also having been a qualifying patient in California and another in Oregon. There were over 138 medical marijuana patient-years in the study sample. Table 2 shows the qualifying conditions for the medical use of marijuana in Washington State, with which participants identified as being diagnosed. See Supplementary Data for particispecifiers and comments on their qualifying conditions. All 10 qualifying condition categories were represented: 4 (10.8%) had cancer, 6 (16.2%) had HIV, 6 (16.2%) had multiple sclerosis, 3 (8.1%) had epilepsy or other seizure disorder, 8 (21.6%) had spasticity disorder, 16 (43.2%) had intractable pain, 2 (5.4%) had glaucoma, 1 (2.7%) had Crohn disease, 4 (10.8%) had hepatitis C, and 14 (37.8%) had any other disease, including anorexia, resulting in nausea, vomiting wasting, appetite loss, cramping, seizures, muscle spasms, and/ or spasticity. Half of the patients identified more than one qualifying condition. Table 2 also shows a list of symptoms and illnesses that go beyond Washington State's list of qualifying conditions that are theoretically responsive to cannabinoid medical treatment, based on cannabinoid physiology studies, clinical experience, other regional medical cannabis access policies, or population surveys. ^{23–29} Patients were not told that this was a list of conditions that may be responsive to cannabinoid treatment. They were simply asked whether they had any of these conditions or had ever been diagnosed with them. In

Table 1. Sample Demographics Summary Statistics

Gender, n (%)	
Male	24 (65)
Female	13 (35)
Years as qualifying patient	()
Male	
Mean \pm SD	3.95 ± 4.31
Range	4.4 months to 16 year
Female	, , , , , , , , , , , , , , , , , , , ,
Mean \pm SD	3.63 ± 3.48
Range	6 months to 7.75 yea
Total	,
Mean ± SD	3.84 ± 3.99
Range	4.4 months to 16 yea
Age, years	, , , , , , , , , , , , , , , , , , , ,
Male	
Mean \pm SD	38.3 ± 9.4
Median	39
Range	21-59
Female	_, _,
Mean \pm SD	47.3 ± 10.5
Median	51.4
Range	29-51.8
Total	2. 55
Mean ± SD	41.4 ± 10.6
Median	39
Range	21-61
Ethnicity, (n identifying as) (%)	•.
Caucasian	25 (65.8)
African American	5 (13.2)
Native American	3 (2.6)
Hispanic	2 (5.3)
Other	3 (2.6)
Annual income, n (%)	3 (2.0)
<\$20 000	13 (39.4)
20 000-34 999	11 (33.3)
35 000-49 999	3 (9.1)
50 000-99 999	5 (15.2)
>100 000	I (3.0)
Health insurance, n (%)	1 (3.0)
Yes	31 (88.6)
No	4 (11.4)
Type of health insurance, (n claiming) (%)	1 (11.1)
HMO	4 (3.0)
PPO	9 (27.3)
Medicare/Medicaid	18 (54.5)
Other (EIP, Virginia, etc)	2 (6.1)
Carci (En , virginia, etc)	2 (0.1)

Abbreviations: HMO, health maintenance organization; PPO, preferred provider organization; SD, standard deviation; EIP, Early Intervention Program.

over 90\% of the cases, participants endorsed using marijuana to treat the given condition.

Table 2 additionally displays the cumulative results of the question: "Thinking now about your qualifying condition, for which of the following symptom-relieving purposes do you use medical marijuana?" Notable trends include the fact that the patients use medical cannabis to treat a wide array of symptoms across multiple body systems with symptom control ratings consistently in the range of 7 to 10. With regard to the main symptom/symptoms that led participants use medical cannabis

to treat (see Supplementary Data), 14 patients (40%) reported psychiatric symptoms not covered under Washington State's law such as stress, depression, anxiety, insomnia, posttraumatic stress disorder exacerbation, and rage. Table 3 summarizes HROoL metrics using the standard survey instruments of the SF-36 and the CDC HRQoL-14. For comparison, normative from the general population and chronic illness subpopulations is shown. With regard to the results of the Activity Limitations Module, patients were asked whether they were "limited in any way in any activities because of any impairment or health problem." Twenty-nine participants (85.3%) endorsed activity/ functional limitations secondary to impairments or health problems. Of these, 17 (50%) needed help with iADLs (as everyday household chores, doing necessary business, shopping, or getting around for other purposes, etc) and 7 (20.6%) needed help with ADLs (eating, bathing, dressing, toileting, or getting around the house).

Five participants returned the take-home survey materials (15\% response rate). They were a 41-year-old Caucasian male with HIV (Pt#2), a 49-year-old Caucasian male with multiple sclerosis (Pt#15), a 37-year-old African American male with neck muscle spasms and chronic headaches (Pt#16), a 52year-old Native American/Caucasian female with multiple sclerosis (Pt#20), and a 39-year-old Hispanic/Caucasian male with AIDS-stage HIV (Pt#37). All reported that medical marijuana treatment is a major component of their health/disease management. With regard to symptom management, all but one of the respondents endorsed the ability of medical cannabis to synergize or improve the effectiveness of other medications that they take, such as antidepressants, anti-spasmodics, and analgesics. Of the 5 respondents, 3 endorsed cannabis' ability to improve the tolerability of other medications.

With regard to HRQoL indicators, the questions for which participants were instructed to answer only after consuming the "plum" strain cannabis, there were no changes seen in overall general self-rated health. The SF-36 physical health component scores increases, ranging from 1.7 to 8.4 in magnitude, were seen in all but one (Pt#20) case (80%), where a decrease by 3.6 was seen. Mental health component summary scores showed no definite pattern, with scores rising in 3 cases and dropping in 2. Changes in 6 of the 9 CDC HRQoL-14 Healthy Days modules were more uniform and were as follows. In 65% of the cases, the number of reported "unhealthy days," "depressed days," "anxious days," and "days mental health was not good" in the last 30 days showed a decrease, ranging from 1 day fewer to 29 days fewer, and in the remaining 35% of the cases, there was no change. The number of days reported in the last 30 days to be days with "not enough rest or sleep" either did not change (in 60%) or increased by 2 or 5 days. The number of days reported in the last 30 days to be "very healthy and full of energy" increased by 5 days or more for all respondents except one for whom it decreased by 2 days. Eighty percent of respondents affirmatively endorsed the statement that consuming the study medical cannabis helped to "maintain their functional status," and 80% were able to indicate specific quality-of-life improvements connected to the consumption of

Table 2. Select Medical Conditions and Cannabis Use–Related Symptom Control Reported in Study Sample

Qualifying diagnoses for medical use of marijuana in WA 16 (25.0) Intractable pain 16 (25.0) NN/VApp loss/cramping/sz/spasm/spasticity 14 (21.9) Spasticity disorder 8 (12.5) HIV 6 (9.4) Multiple sclerosis 6 (9.4) Cancer 4 (6.3) Hepatitis C 4 (6.3) Epilepsy or other seizure disorder 3 (4.7) Glaucoma 2 (3.1) Crohn's disease 1 (1.6) Symptom control reported n (%) To reduce anxiety 25 (71.4) To improve mood 24 (68.6) To reduce nausea 23 (65.7) To stimulate appetite 19 (54.3) To reduce muscoloskeletal pain 18 (51.4) To reduce neurological pain 16 (45.7) To reduce HEENT pain 13 (37.1) To reduce dermatological pain 11 (31.4) To reduce dermatological pain 11 (31.4) To manage/gain weight 9 (25.7) To reduce dermatological pain 7 (20.0) To reduce dizziness 7 (20.0) <tr< th=""><th>Diagnoses and symptoms queried</th><th>Number reporting (%)</th></tr<>	Diagnoses and symptoms queried	Number reporting (%)
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Table 2. (continued)

Diagnoses and symptoms queried	Number reporting (%)
Osteoporosis	3 (1.8)
Head trauma	3 (1.8)
Bipolar disorder	3 (1.8)
Substance use disorder/disorders	3 (1.8)
Fibromyalgia	2 (I.2)
Diabetes	2 (1.2)
Incontinence	2 (1.2)
Other neurological disorder	2 (1.2)
Muscular dystrophy	I (0.6)
Spinal cord disease	I (0.6)
Psychotic episodes	I (0.6)
Tourette syndrome	I (0.6)
Pruritis (severe itching)	I (0.6)
Lou Gerhig disease (ALS)	0 (0)
Ankylosing spondylitis	0 (0)
Convulsions	0 (0)
Alzheimer disease	0 (0)
Parkinson disease	0 (0)
Huntington disease	0 (0)
Stroke	0 (0)
Schizophrenia	0 (0)

Abbreviations: HEENT, head, ears, eyes, nose, throat; GU, genitourinary; GI, gastrointestinal; N/V/App loss, nausea, vomiting, appetite loss; sz, seizures; HIV, human immunodeficiency virus; PMS, premenstrual syndrome; ALS, amyotrophic lateral sclerosis.

Supplementary Data: Qualifier phrases participants voluntarily added to medical marijuana qualifying diagnosis query; qualifier phrases participants voluntarily added to cannabinoid-responsive conditions query; complete results from the open-ended question: "Overall, what would you say are the main symptoms that you regularly use medical marijuana to treat (not necessarily limited to those stemming from your qualifying condition)?"

the study medical cannabis such as an ability to work, increased productivity and life satisfaction, and symptom abatement such as decrements in anxiety and bolstering of appetite. Specific symptom relief reports as summarized in participants' dosing diaries are shown in Table 4.

Discussion

Demographically, the sample median age was 2.32 years higher than the state-level median age; however, the gender—median age differential seen in the patient sample was 6 times greater in magnitude in the than that in the state population,³⁰ revealing a male skew in the sample. In terms of ethnicity, the study sample had an approximately 17% lower white representation and included a higher proportion of all nonwhite ethnicities, except Hispanic, than that seen at the state level.³¹ The midpoint of the sample's median income range was approximately \$27 000 lower than the median household income for the state overall, which was projected to be \$56 462 in

^a Patients were asked whether they suffered from or had been diagnosed with any of these conditions and not told that these conditions may be responsive to cannabinoid treatment

Table 3. Health-Related Quality of Life^a

HRQoL indicator	Sample average ± standard deviation, median ^b	Normative values (SF-36: 1990 US gen pop survey, n = 2474; CDC: VVA 2007 survey, n = 24 848)		Norms for congestive heart Norms for failure (US gen cancer: (US gen pop) ^c pop) ^d	Norms for limitation in the use of an arm/arms or Norms for depression leg/legs: (US gen pop) screener (US gen pop)	Norms for depression screener (US gen pop) ^f
SF-36 PCS SF-36 MCS	37.4 ± 13.0, 32.8 44.2 + 12.3, 44.3	50	31.0	45.1 48.8	37.7	47.9
General health	Fair to good	Good to very good	i	2	į	2
Days physical health not good	$12.4 \pm 10.5, 10$	3.7				
Days mental health not good	$11.0 \pm 10.7, 6$	3.2				
Unhealthy days	$18.2 \pm 11.5, 21.5$	9.9				
Limited days	$8.7 \pm 8.7, 6$	2.3				
Pain diff. days	$12.0 \pm 11.0, 10$					
Depressed days	$9.2 \pm 9.5, 5$					
Anxious days	$9.7 \pm 10.6, 4.5$					
Not enough sleep/rest days	$12.9 \pm 11.2, 8.5$					
Very healthy and full of energy	11.9 \pm 9.9, 10					
days						

Abbreviations: PCS, Physical Health Component Score; MCS, Mental Health Component Score; CDC, Centers for Disease Control and Prevention; gen pop, general population.

^a Data collected from on-site survey with comparison normative values and chronic illness values presented. 11,23 SF-36, CDC Healthy Days Core and Symptoms Modules; CDC days measurements are all out of

<sup>30.

&</sup>lt;sup>b</sup> In 2 cases in which the SF-36 questionnaire was only partially completed (missing 2 and 14 items, respectively), scoring was calculated per protocol regarding missing data. Two participants' summary score results were excluded due to missing data.

^c Based on self-report.

^d Based on self-report, except skin cancer.

^e Based on self-report of limitations in the use of an arm or leg (missing, paralyzed, or weakness).

^f Based on self-report of 2 weeks or more feeling sad, blue, or depressed in the past year, or 2 years or more feeling sad or sad much of the time in the past year.

Table 4. Symptom Relief Dosing Diary Summaries^a

	Participant number					
	2	15	16	20	37	
Medical cannabis amount, g	3.5	28.35	0.5	3.4	5	
Degree of symptom relief provided on average	75% depression relief for 12 hours, 62% nausea relief for 12 hours, 88% appetite stimulation for 10.5 hours	22% spasm relief for 97 hours	67% head pain relief over 2 hours	98% nausea relief for 60 hours; 100% spasm relief for 72 hours, 97% pain relief for 65 hours	23% appetite stimulation for 10 hours, 23% nausea relief for 10 hours, 23% depression relief for 10 hours, 23% pain relief for 10 hours	
Percentage symptom relief \times hours relief/ grams of medical cannabis	257 depression; 213 nausea; 264 low appetite	75 spasm	268 pain	1729 nausea; 2118 spasm	46 low appetite; 46 nausea; 46 depression; 46 pain	

^a Participants were instructed to fill out dosing diaries for the symptoms they described as the main one/ones for which they used medical cannabis to treat. They were asked to rate the symptom severity on a scale of 1 to 10 before and after administration of a portion of the "plum" strain medical cannabis under study. They were asked to document the amount used and the time period over which the relief was sustained. The table shows, for each subject, the overall average reported symptom relief over the total time periods recorded in the dosing diaries with the total medical cannabis amount used over that time. For interparticipant comparison, a symptom relief duration—cannabis amount ratio is calculated.

2007.³⁰ In all, 88.6% of the patients in the sample had some form of health insurance—very close to the 86% health care access/coverage rate in Washington State overall³²—and of these, 64.5% held health insurance from the public sector (eg, Medicare, Medicaid, Early Intervention Program, Virginia). This demonstrates a similar degree of economic access to health care resources among the patient sample compared with the general statewide population.

The sample showed cross-sectional representational strength, as all 10 (at that time) qualifying medical conditions for the use of medical marijuana enumerated in Washington state law and set forth by the Medical Quality Assurance Commission were reported as being present in the patient sample, with the majority reporting "intractable pain" or "any disease, including anorexia, which results in nausea, vomiting, wasting, appetite loss, cramping, seizures, muscle spasms, and/or spasticity" qualifying conditions. As predicted, a high concentration of cannabinoid-responsive conditions was found in patients who frequented a cannabinoid medical delivery space. Thirty out of 38 of the conditions that have been identified in prior studies as likely cannabinoid-responsive were reported present in the sample. These included self-reported migraine, depression, sleep apnea, and arthritis sufferers, among others, consistent with data reported in a medical cannabis use survey in Australia.²⁶ In that survey of 128 people (63% male, median age 45 years), authors reported "a wide range of medical conditions and symptoms associated in the literature with the use of medicinal cannabis most commonly chronic pain (53%) and arthritis (38%) ... migraine (22%), weight loss (21%) and persistent nausea (20%)."²⁶ Consistent with current biomedical science, patients reported treatment of symptoms across multiple body symptoms owing to the widespread nature of the body's endogenous cannabinoid system which serves as a central homeostatic

modulator.^{3,4} With such a high rate of psychiatric symptoms being treated with cannabis, it would be sound health policy to include selected mental disorders as qualifying conditions for medical cannabis use in state programs.

By all measures, patients had a much lower HRQoL compared with state and national averages as shown in Table 3. Physical and Mental Health Component Score averages in the study sample are comparable with scores found in participants with self-identified chronic illnesses seen in previous studies. Self-rated health in the study sample was on average one full notch below the state average of good to very good. 32 The average number of days in the last 30 days reported in the sample in which physical health was not good and in which mental health was not good were both 3.4 times higher than the state average.³² With regard to functional status, the average number of days reported in the last 30 days in which poor physical or mental health kept them from doing their usual activities such as self-care, work, or recreation was 3.9 times higher in the sample than the average number reported in a state-level survey.³² The percentage of participants reporting activity/functional limitations secondary to impairments or health problems, 80%, was 3.8 times higher than that found in the state-level survey (22.8%).³²

The prospective portion of the study showed a response rate of 15%; it is unclear why the study materials from the other 29 patients were not returned, even after a sign was placed for 2 weeks in the clinic, reminding patients to return the study materials. The patients who returned the materials mostly had differing ethnic backgrounds—2 were Caucasian and the rest reported partial or full minority ethnicities. They ranged in age from 37 to 52 years old. Of the 5, 4 reported an average annual income of less than \$20 000. This means that no patients who reported average annual incomes higher than \$20 000 returned

their take-home materials, with the exception of 1 patient with multiple sclerosis who reported an annual income in the range of \$50 000 to 99 999. Put another way, the <\$20 000 annual income quintile had the highest survey return rate of 4 (31%) of 13, and the \$50 000 to 99 999 quintile had a second highest survey return rate of 1 (20%) of 5, and all other quintiles had a survey return rate of 0%. It is interesting to note that no patients who were recruited on day 3 of the study, the day with the heaviest subject recruitment, returned the take-home materials.

Six of the 9 CDC HRQoL-14 measures nearly all uniformly improved or stayed the same in the prospective sample patient data over the time period that the study occurred. During this period, all patients indicated on the study questionnaire that medical cannabis was a major component of their health/disease management. However, it should be noted that it is unclear whether these validated HRQoL instruments, while designed to be reliable and responsive over time, can acutely gauge the short-term effects of taking a new supply of a chronically self-administered treatment in a chronically ill patient. Subjects' indication that medical cannabis use was a major component of their health/disease management. There is also potential for iatrogenic bias since the patients' physicians authorized them to use medical cannabis. When a provider hands the patient a prescription and says (or implies), "take this to get better," this may induce a placebo effect. However, this was a longitudinal, observational study with multiple stages of data collection. This methodological design reduces bias by examining multiple outcome variables over time.³³ Summary data from the dosing diaries shown in Table 4 does capture some meaningful information on dose-by-dose symptom relief patients experienced with the botanical medicine.

The participants in the study constituted a convenience sample that may or may not have been representative of all patients utilizing the dispensary or all medical cannabis patients in Washington state generally, and there is no way of knowing as no uniform state-level data are available. The study was limited by the difficulties inherent in generalizing from a convenience sample, the small return rate of prospective study materials, lack of a control group, recall bias, and lack of corroborating medical records. The latter limitation is minimized by the fact that the dispensary site verified the qualifying condition status of each patient with their respective physicians during their initial registration.

Conclusion

The aim of this research was to investigate and uncover information regarding self-rated health and HRQoL for patients participating in the cannabinoid botanicals delivery system in Washington state, a unique system of health care delivery that is subject to peculiar constraints. This study sought to document the health outcomes and characteristics of a convenience sample of qualifying patients. The sample's health characteristics, when compared with the general population, help to quantify and qualify the frail and diminished health status of a representative sample of qualifying patients who appear to be successfully using cannabinoid botanicals to

relieve diverse symptoms and improve and maintain their health-related quality of life.

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Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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