

MN Office of Medical Cannabis Research and Analytics Update

**Task Force on Medical Cannabis
January 6, 2017**

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Covered in today's presentation:

- Current counts of program statistics
- Early look at components of report on enrollees during first year of program (report will be completed end of March)
- Very early look at patients certified for intractable pain (report on first six months of intractable pain enrollees by end of 2017)

Research Data

- Separate from transactional registry
- Deidentified to protect patient privacy
- Security policies (examples: no remote access; no loading data onto PC; other)

As of December 23, 2016:

3936 Active Patients

- 56% Intractable pain
- 24% Severe and persistent muscle spasms
- 14% Cancer
- 8% Seizures
- 4% Inflammatory Bowel Disease
- 2% Terminal Illness
- 2% HIV/AIDS
- ≤ 1% each: Tourette syndrome, Glaucoma, ALS

Note: 12% of patients > 1 condition

As of December 23, 2016:

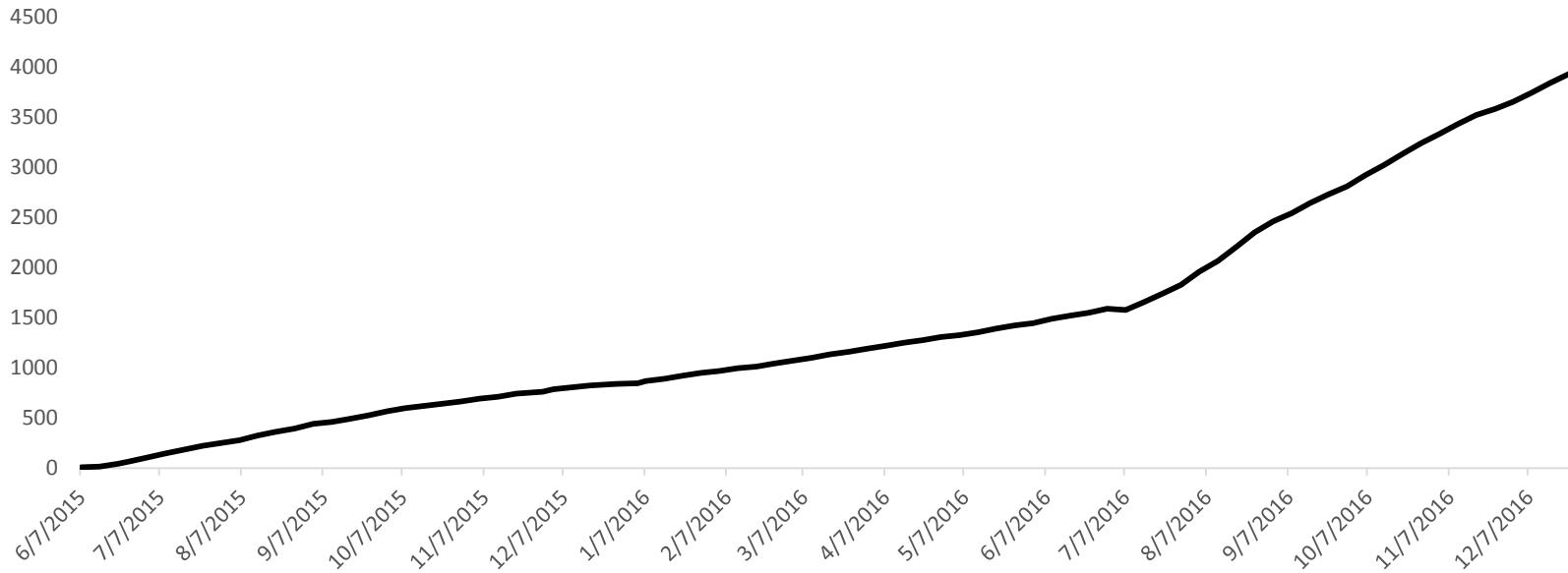
3936 Active Patients

Age distribution

- 0-4 (<1%)
- 5-17 (3%)
- 8-24 (4%)
- 25-35 (14%)
- 36-49 (24%)
- 50-64 (36%)
- 65+ (18%)

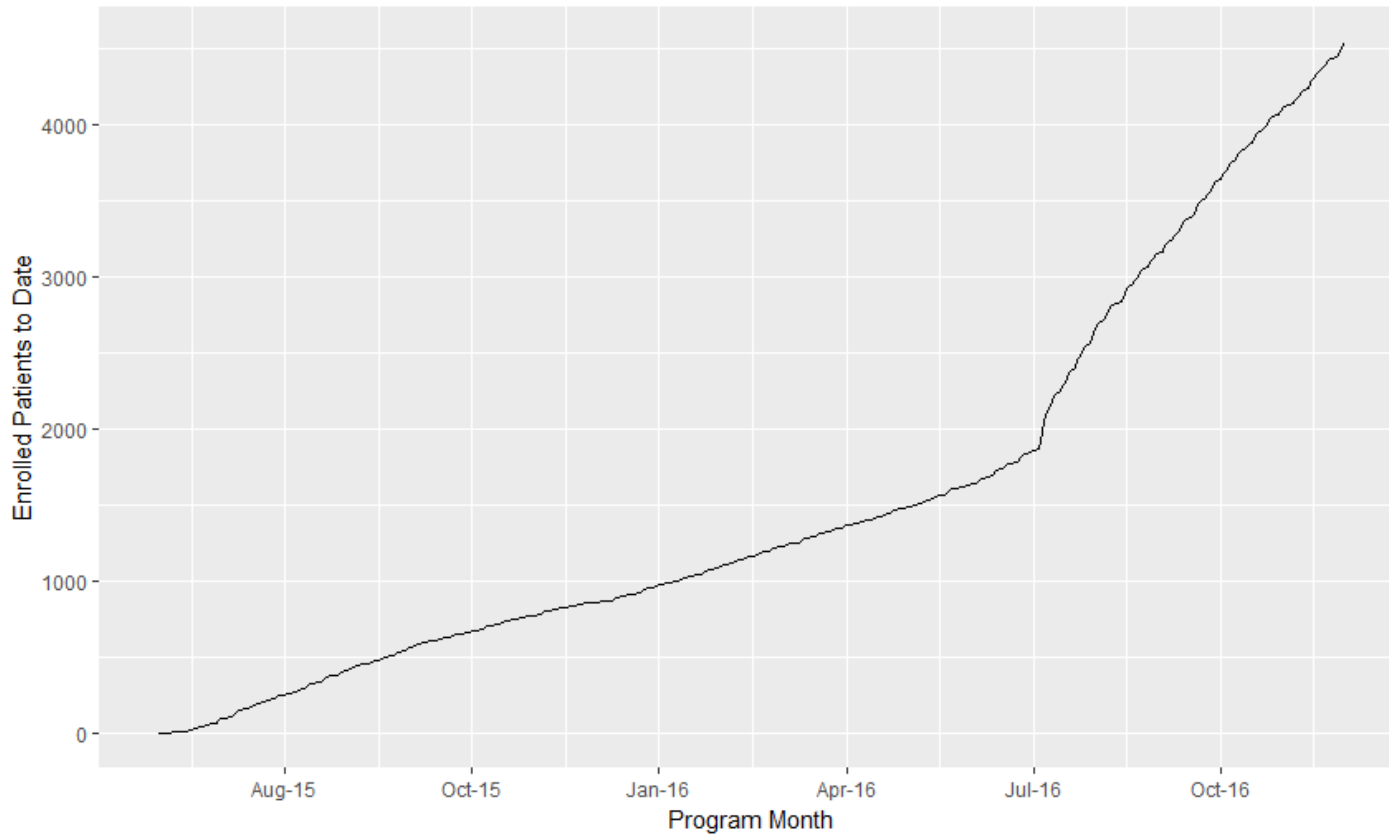
Active Patient Count

Number of Patients Active in Registry: June 2015-December 2016



Total Patient Enrollment

Cumulative Count of Patients Enrolled in Program



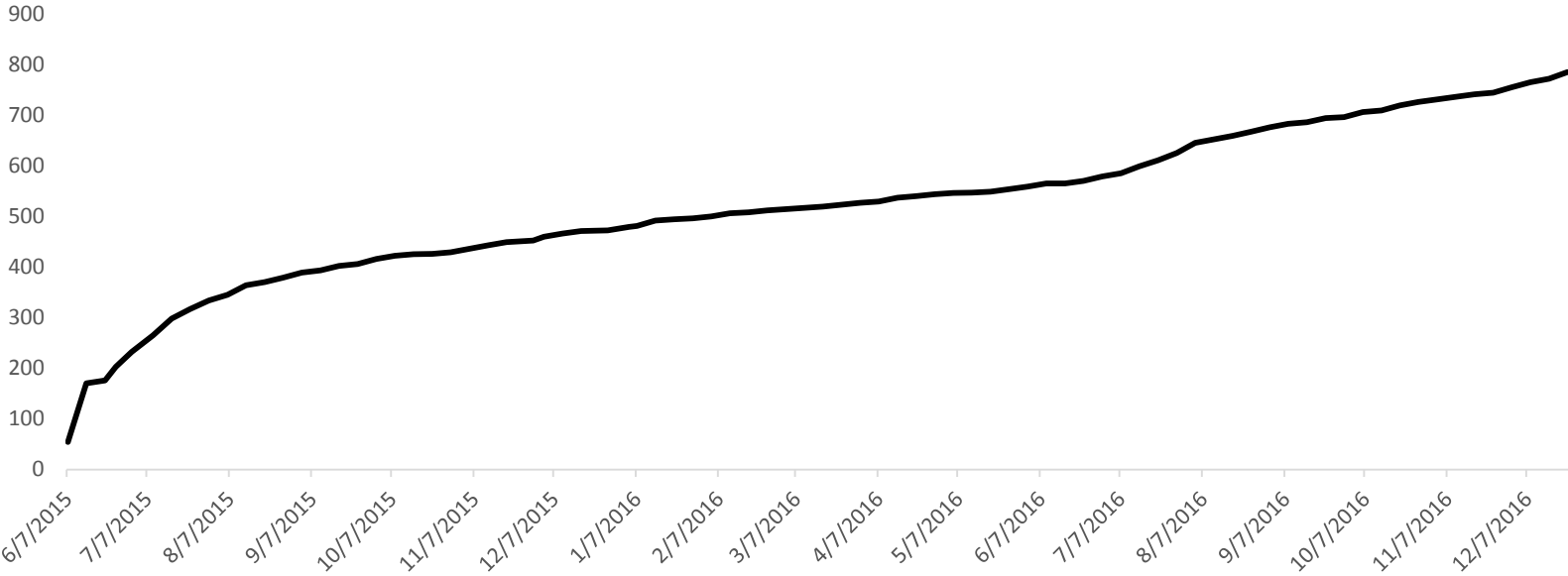
As of December 23, 2016:

786 Health Care Practitioners Registered:

- 81% Physicians
- 14% Advanced Practice Registered Nurses
- 6% Physician Assistants

Healthcare Provider Enrollment

Registered Healthcare Practitioners: June 2015-December 2016



Report on enrollees during the first year of the program – components:

- Description of patients, registered caregivers, and health care practitioners
- Purchasing patterns (including duration of participation)
- Medical Cannabis Use Patterns
- Changes in symptoms (and description of medical cannabis used when clinically significant improvement achieved)
- Side effects
- Survey results on benefits and harms – includes appendices with direct words of patients and their certifying health care practitioners

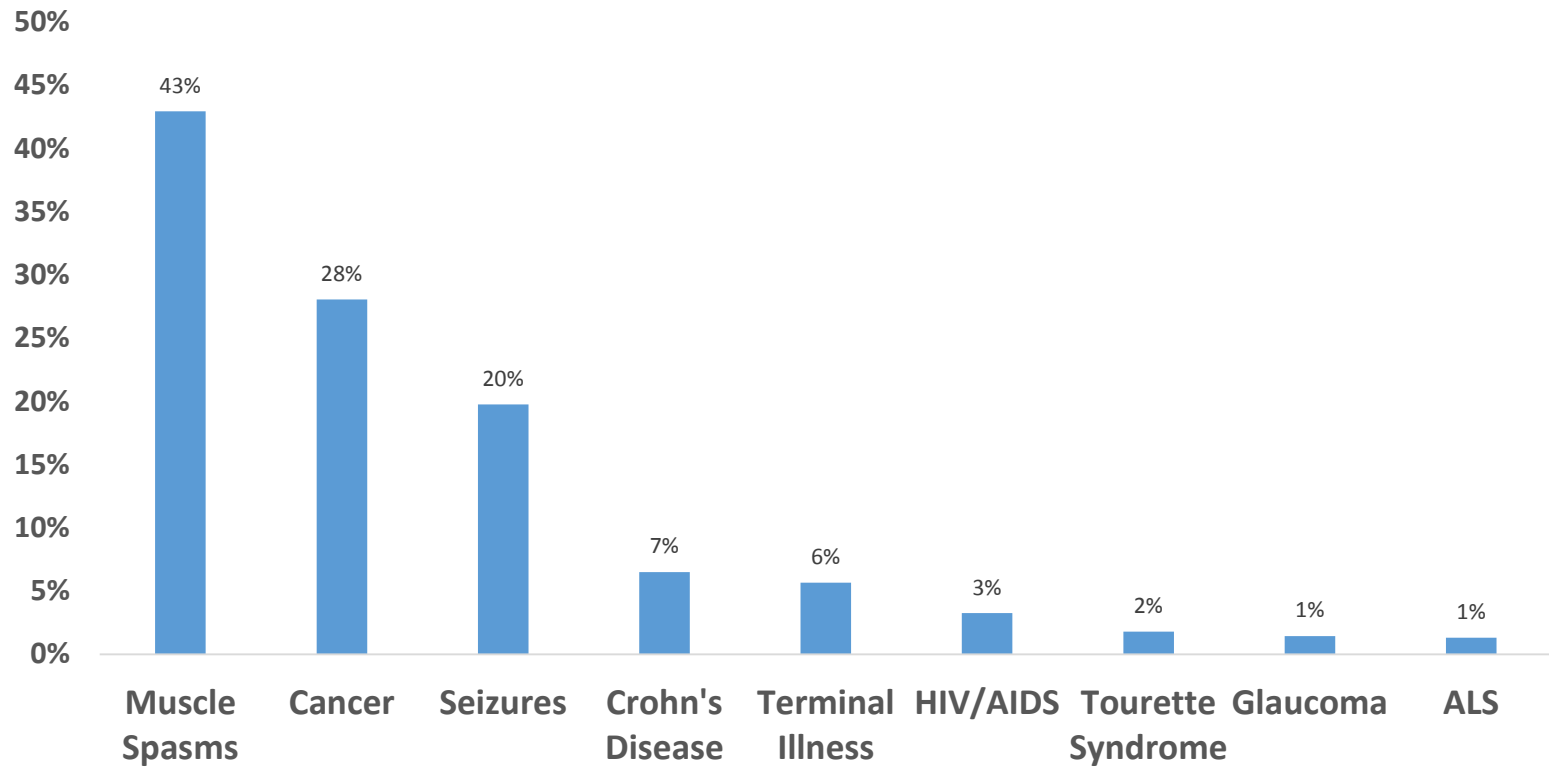
Minnesota Medical Cannabis Program

**Patient, Certifying Healthcare Provider and
Caregiver Statistics
July 2015-June 2016**

Program Year One Descriptives

Program Year One: 1660 Patients

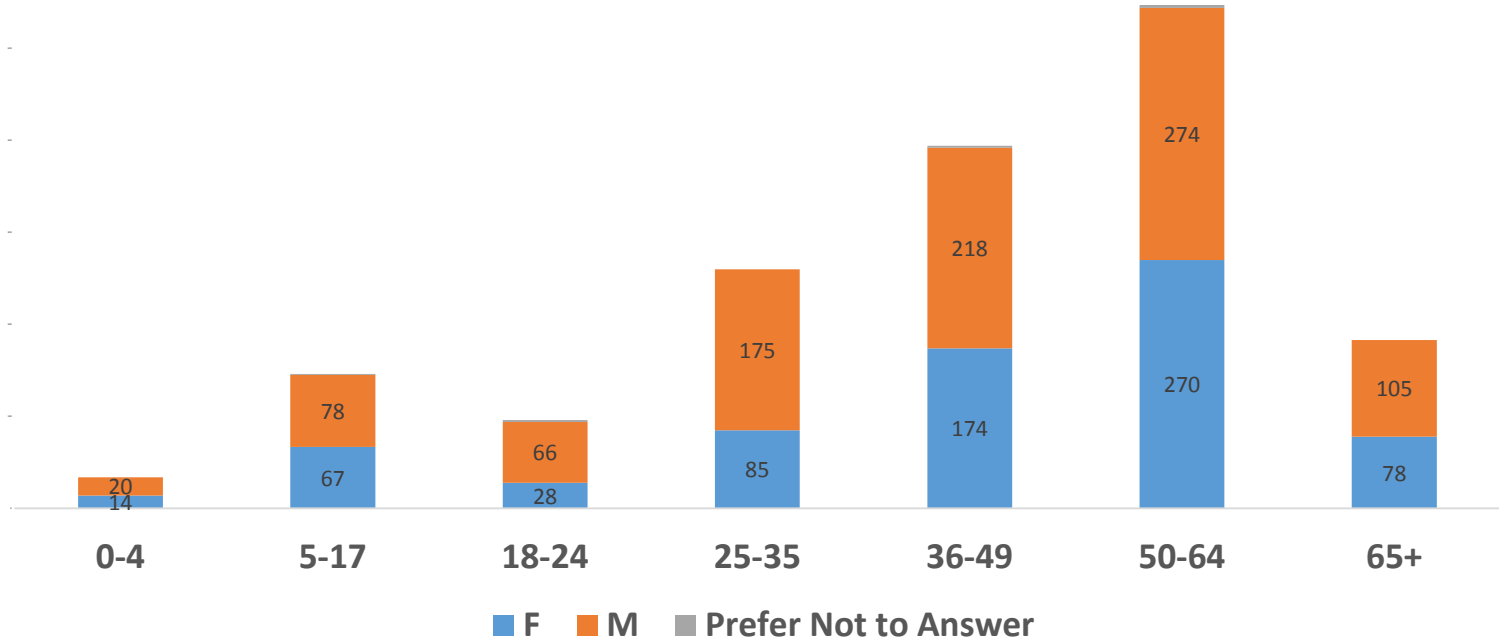
Enrolled Patients by Qualifying Condition





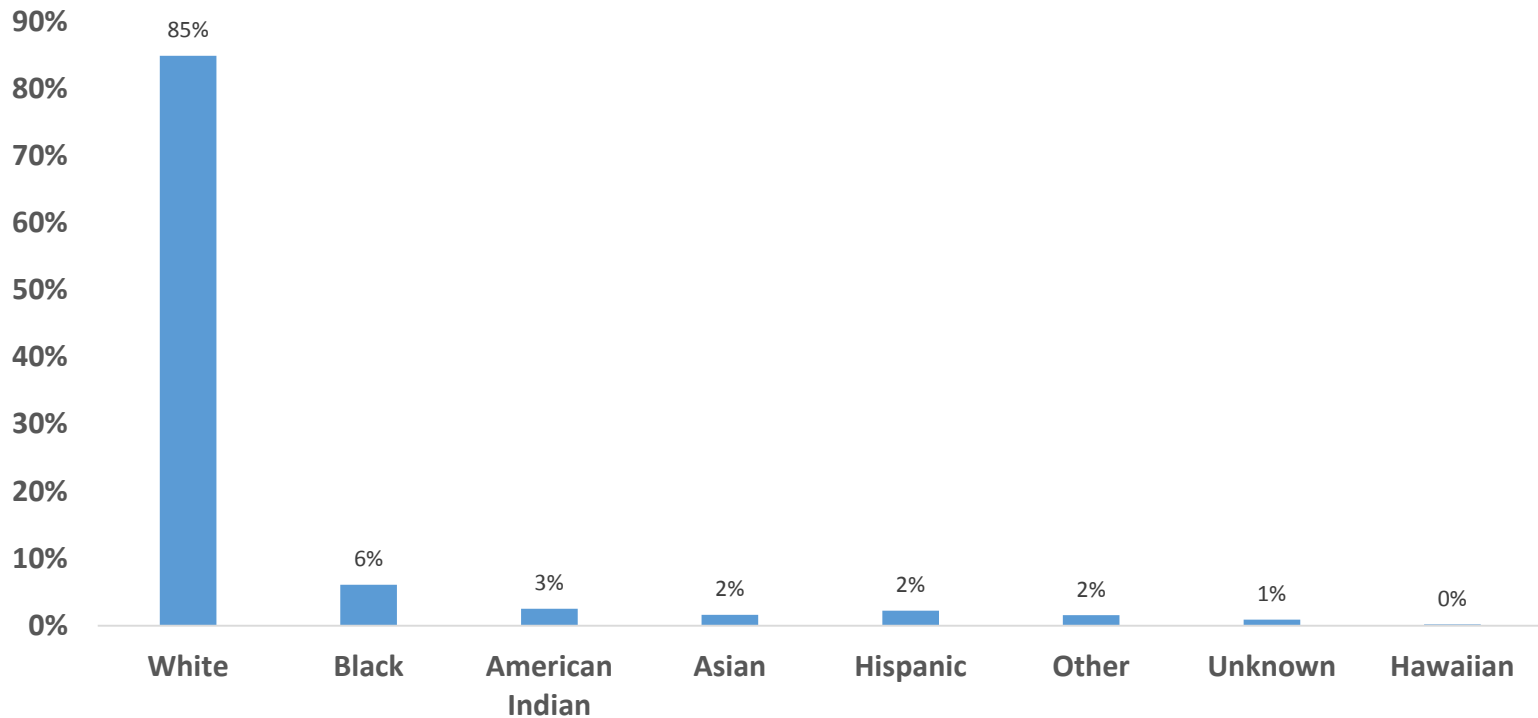
Program Year One: 1660 Patients

Enrolled Patients by Age and Gender



Program Year One: 1660 Patients

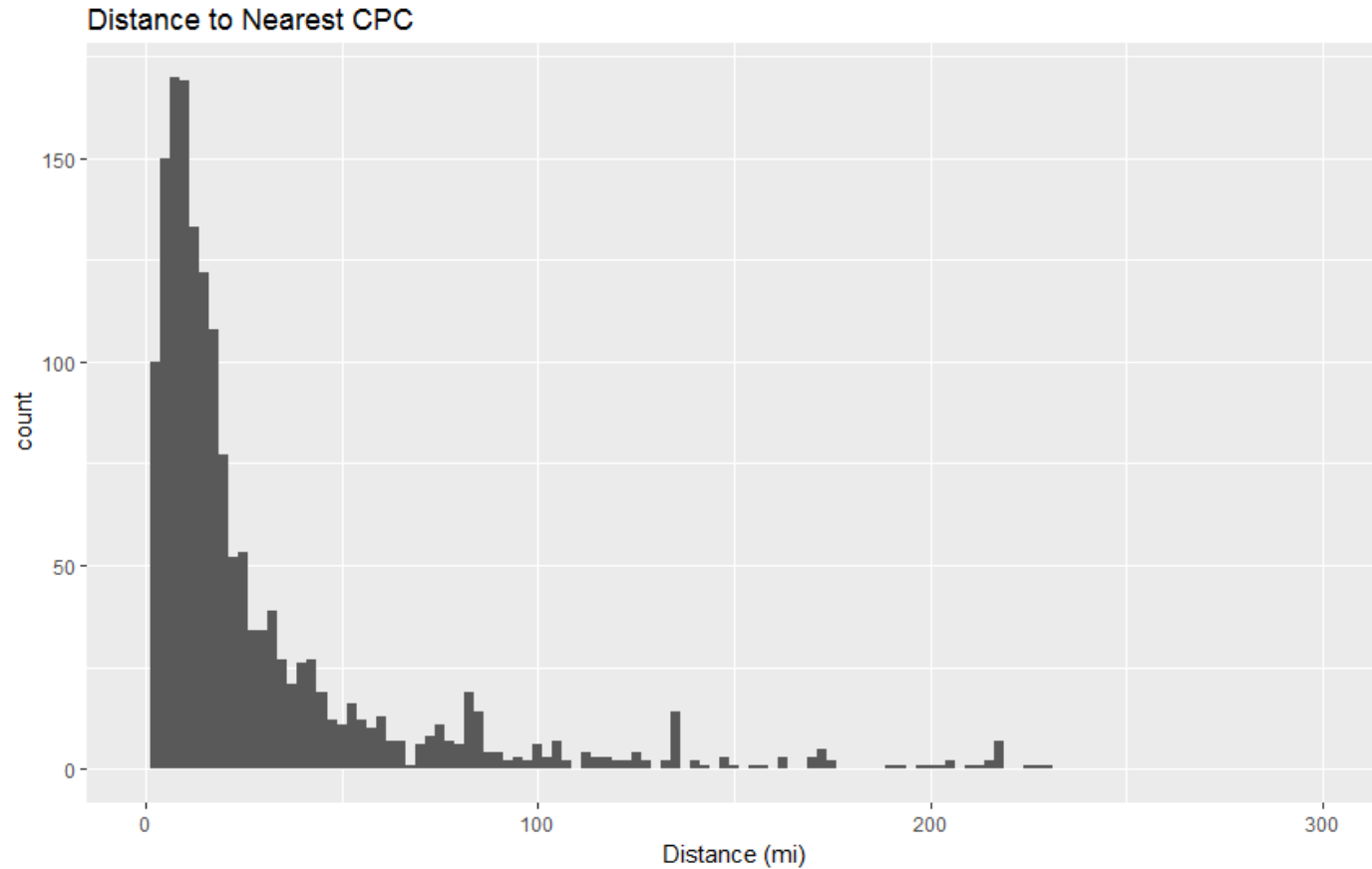
Enrolled Patient Race/Ethnicity



Program Year One: Patients with Caregivers

CONDITION	% Allowed Caregivers Per HCP	% With Registered Caregivers	% with Registered Parents/ Legal Guardians
All Conditions	41%	11%	17%
Cancer	40%	15%	5%
Terminal Illness	56%	15%	11%
Glaucoma	33%	13%	0%
HIV/AIDS	11%	2%	0%
Tourette Syndrome	40%	7%	53%
ALS	77%	32%	5%
Seizures	66%	10%	65%
Muscle Spasms	29%	10%	4%
Crohn's Disease	20%	6%	3%

One-Way Distance to Nearest Patient Center



Product Types Purchased (July 2015- Dec 2016)

Vapor	Capsule/Oral Solution	Tincture	N	%
x	x		542	33%
x	x	x	223	13%
	x		219	13%
x			213	13%
	x	x	197	12%
		x	66	4%
x		x	66	4%
			134	8%

Registered Healthcare Practitioners

HCP TYPE	N	%	MALE: N(%)	MEAN AGE (SD)
Physicians	475	82%	341 (72%)	50.3 (11.3)
Nurses	77	13%	9 (12%)	47.0 (9.4)
PAs	28	5%	6 (21%)	39.5 (9.6)
Total	580	100%	356 (61%)	49.4 (11.3)

Registered Physician Specialties

Registered Physician Specialties	N
Primary Care	177
<i>Family Medicine</i>	108
<i>Internal Medicine</i>	60
<i>Pediatrics</i>	8
Oncology	80
Neurology	62
Specialized Pediatrics	29
Hospice/Palliative Medicine	24
Physical Medicine and Rehabilitation	21
Gastroenterology	10
Psychiatry	10
Ophthalmology	9
Surgery	8
Infectious Disease	6
Pain Medicine	5
Radiology/Radiation Oncology	5
Nephrology	3
Rheumatology	2
Emergency Medicine	2
Geriatric Medicine	2
Obstetrics and Gynecology	2
Sports Medicine	2
Anesthesiology	1
Dermatology	1
Public Health and Preventive Medicine	1
Sleep Medicine	1

Patient and HCP Surveys: First 6 Months

Patient/Healthcare Practitioner Surveys

- Short survey asking patients and their healthcare practitioners about benefits and harms associated with medical cannabis
- Initial survey schedule: sent to patients and their healthcare practitioners 3 months after the patient's first medical cannabis purchase
- Revised survey schedule: sent to patients 3 months after the patient's first medical cannabis purchase; sent to patients and their healthcare practitioners every 6 months the patient is enrolled in the program

Benefits and Negative Effects

- Patients and HCPs asked to quantify benefits/harms related to medical cannabis use:

1. How much benefit, if any, have you experienced from taking medical cannabis?
(1- no benefit; 4- some benefit; 7- a great deal of benefit)

1

2

3

4

5

6

7

4. How much negative impact, if any, have you experienced by taking medical cannabis? (For this question, please do not consider the financial costs)
(1-no negative effects, 4-some negative effects, 7-great deal of negative effects)

1

2

3

4

5

6

7

- Patients and HCPs asked to describe the benefit(s)/harm(s) from medical cannabis

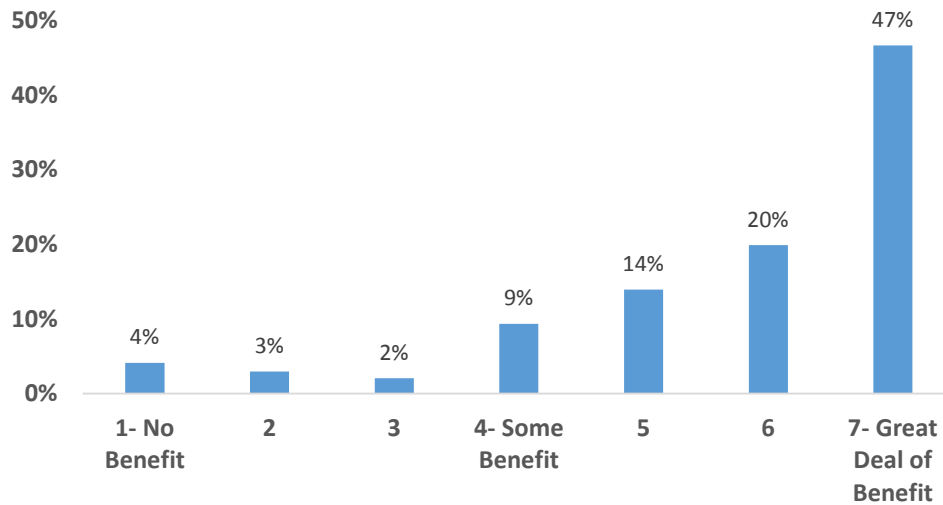
Patient/Healthcare Practitioner Surveys: First 6 Months

Patients who purchased medical cannabis July
2015-December 2015

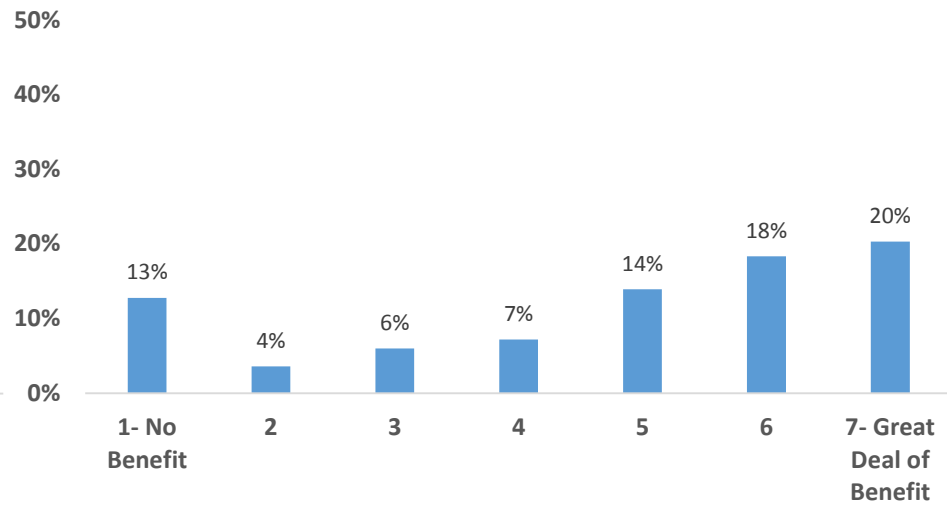
- **774 patients** and their certifying HCPs were sent surveys 3 months after the patient's first purchase
- **437 (56%) patient surveys** were completed
- **251 (32%) HCP surveys** were completed

3-Month Survey: Perception of Benefit

Patient-Perceived Benefit: All Conditions (N=437)



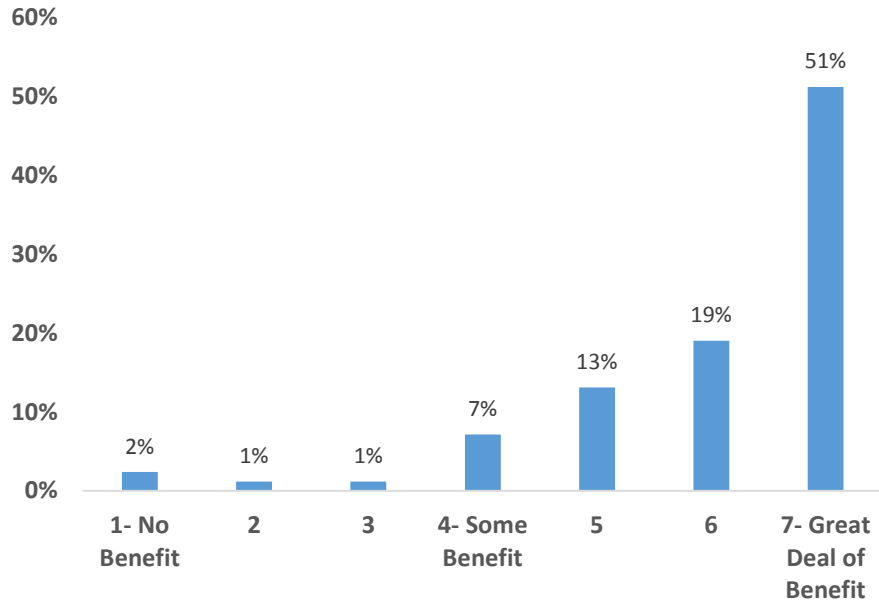
HCP-Perceived Benefit: All Conditions (N=251)



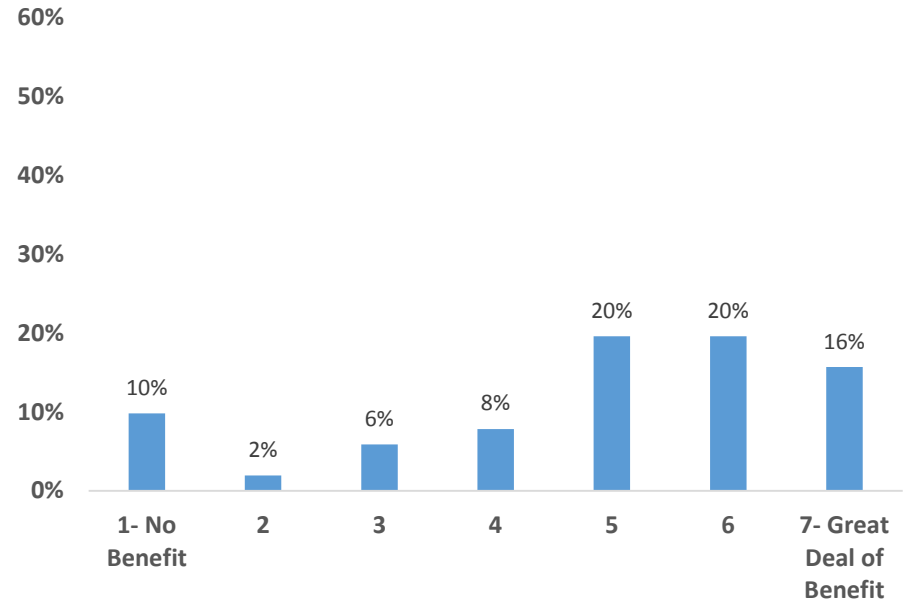


Perceived Benefits in Cancer Patients

Patient-Perceived Benefit: Cancer (N=84)



HCP-Perceived Benefit: Cancer (N=51)



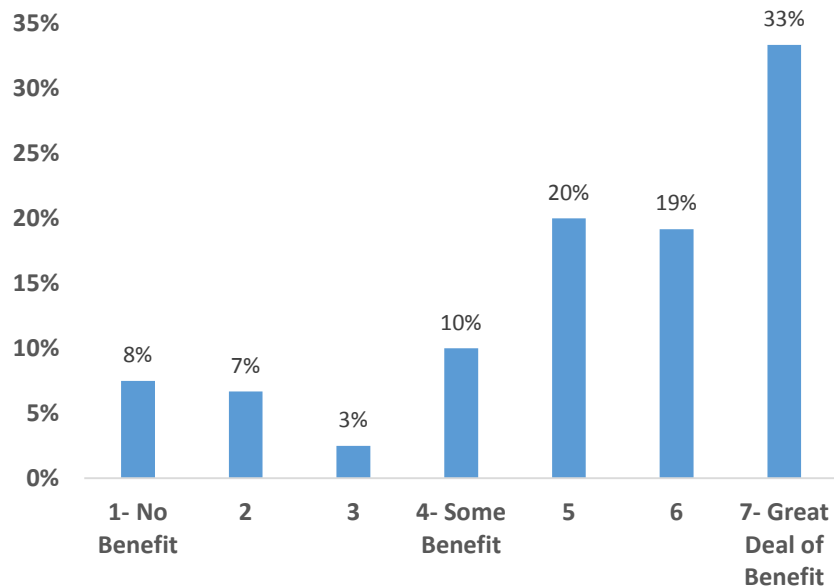
Patient Comments

“I was able to get off all my anti nausea medication which allowed me to Get off all the anti constipation medication. Prior to being in the cannabis program I had no appetite and had lost 35 lbs I have been able to put back on 15 lbs. My quality of life after chemotherapy treatments turned around substantial. An added bonus was the pain relief from a chronic back pain, it has helped significantly with my pain management.”

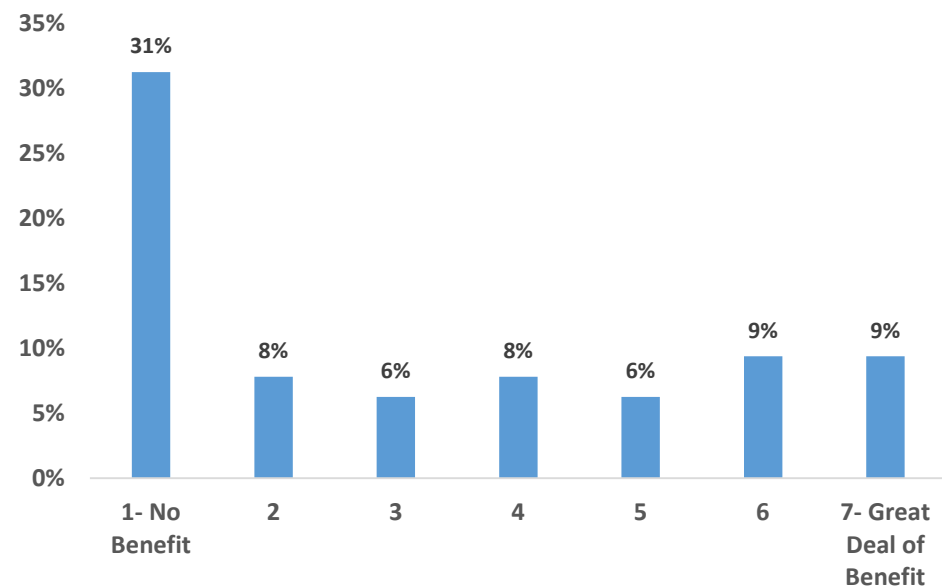
“One benefit was it helped with my nausea and vomiting but not as well as I would have hoped. I had to puff on the vape pen consistantly to relieve me of the nauseated feeling instead of the 1 to 2 puff recommended dose.”

Perceived Benefits in Seizure Patients

Patient-Perceived Benefit: Seizures (N=120)



HCP-Perceived Benefit: Seizures (N=64)



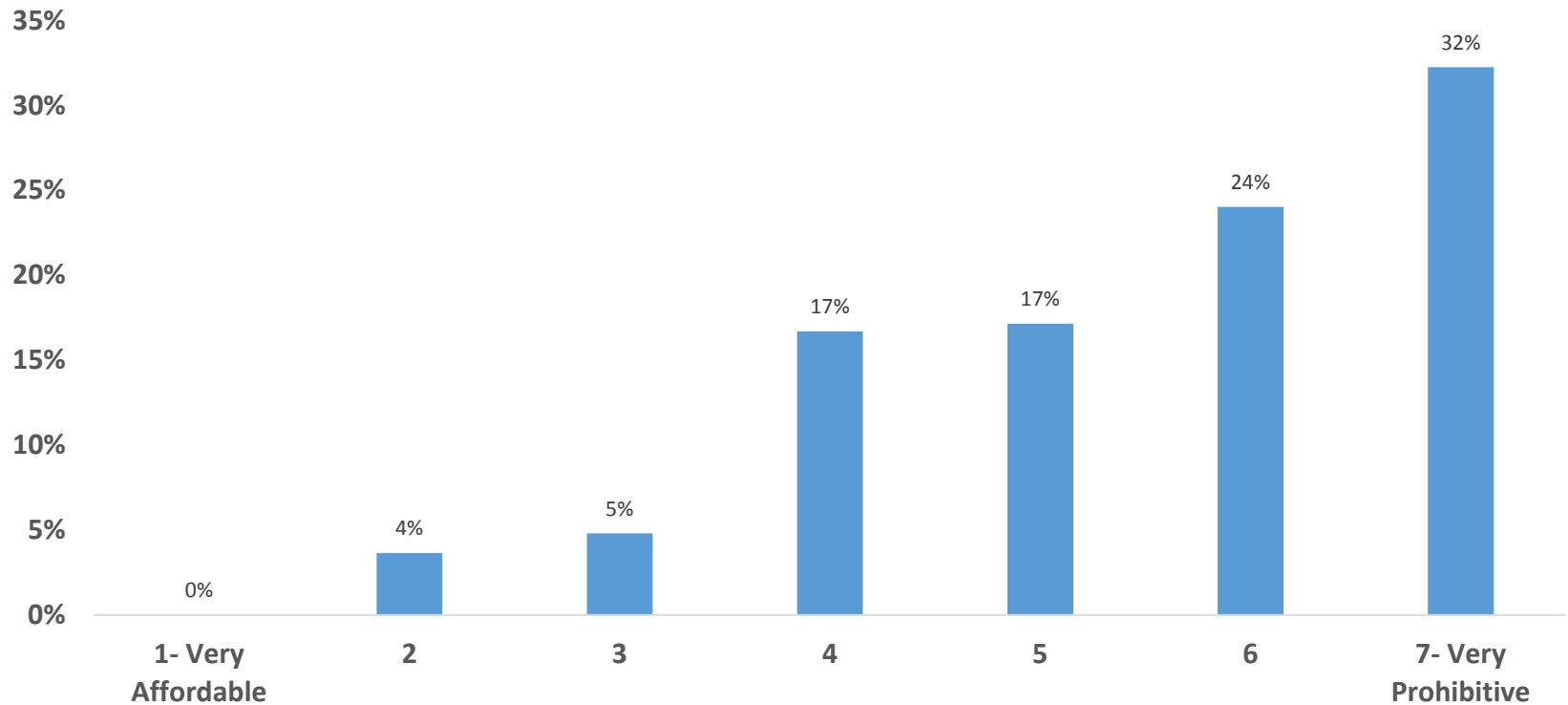
Patient Comments

“98% seizure reduction, elimination of persistent headaches, and we were able to wean 75% of child's benzodiazepines, meaning that her Quality of Life has significantly improved, as have all of her abilities.”

“My daughter went for the full month of September with NO seizures when she first started on cannabis. October and November were not so good. This past month we tried a different formula to see if we can get better control. Still more adjustments are needed.”

Attitudes Toward Cost

“Do you find the cost of medical cannabis to be affordable or prohibitive?”



Minnesota Medical Cannabis Program

Patient Self-Evaluation Data – Early Look

Patient Self-Evaluation

Patients complete a Patient Self-Evaluation prior to purchasing medical cannabis

- Negative side effects
- Symptom changes

Patient Self-Evaluation


Patients complete a Patient Self-Evaluation prior to purchasing medical cannabis

- **Negative side effects**
- Symptom changes

Side Effect Reporting

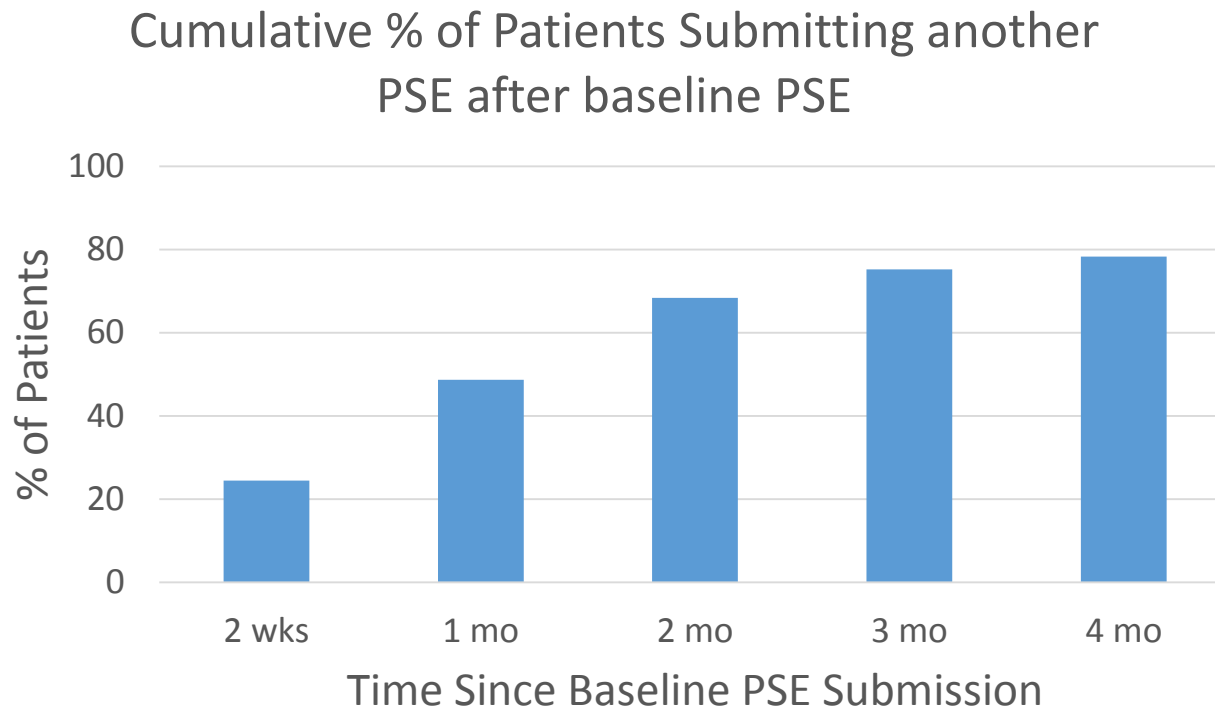
- What side effect(s) might be attributed to medical cannabis?

- How severely is side effect experienced?
 - Mild: Symptoms do not interfere with daily activities
 - Moderate: Symptoms may interfere with daily activities
 - Severe: Symptoms interrupt usual daily activities

-  Any additional comments on side effect?

What percentage of patients reported negative side effects within the 4 months following their first medical cannabis purchase?

Why within 4 months?

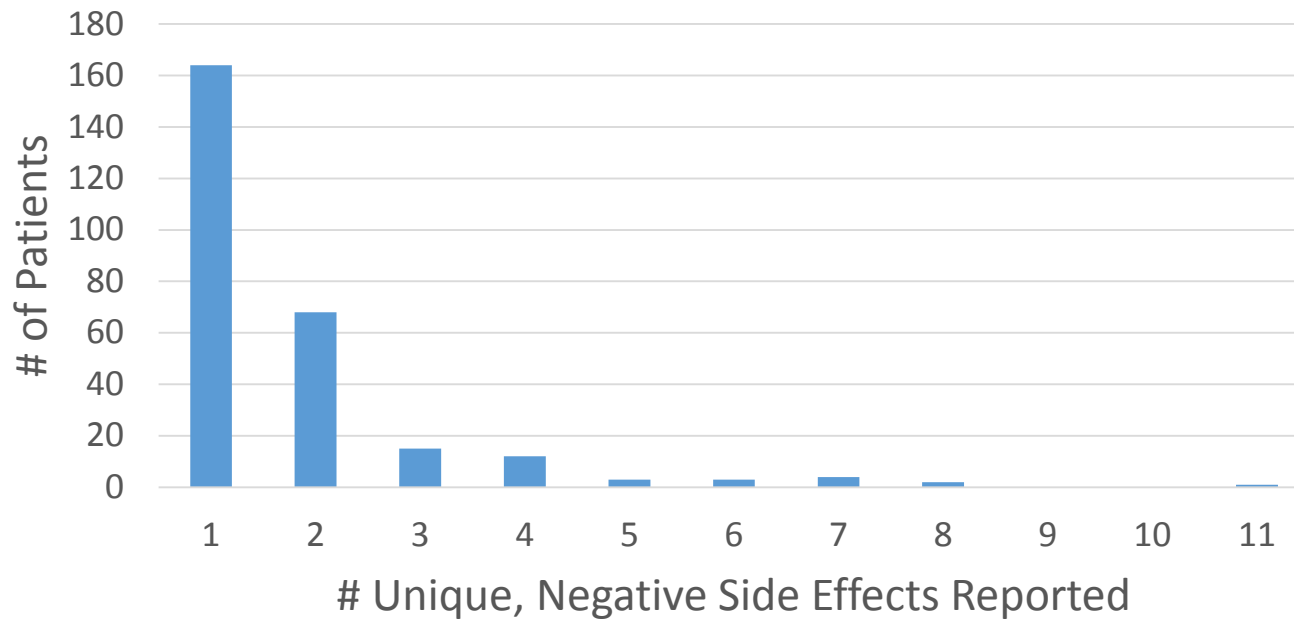


What percentage of patients reported negative side effects within the 4 months following their first medical cannabis purchase?

Out of the **1502** patients in the 1st cohort who could potentially report negative side effects, only 272 **(18.1)% reported any cases**

How many different, negative side effects do patients report?

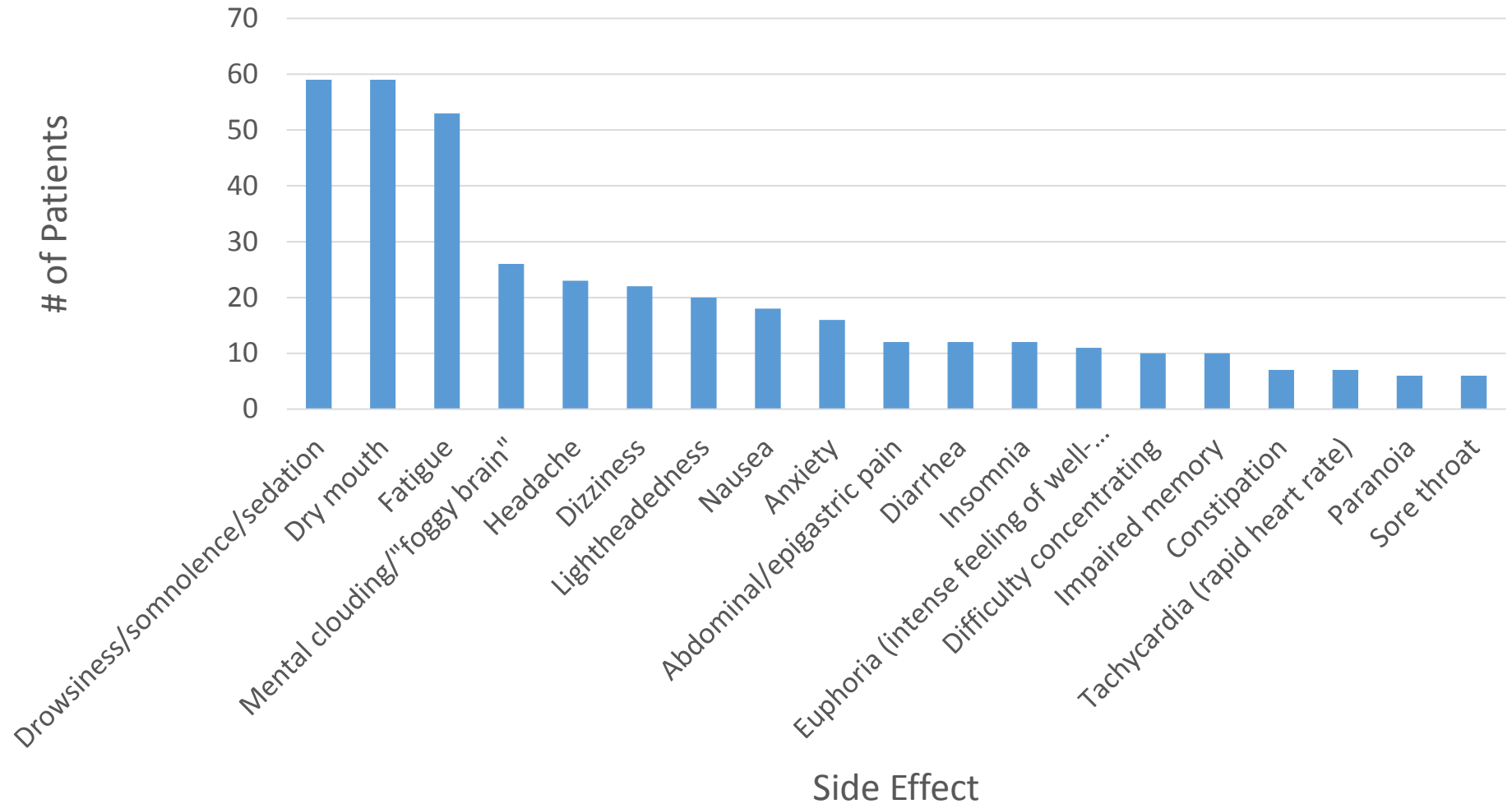
Frequency Distribution of Patients by Number of Unique Side Effects Reported





Most Commonly Reported Negative Side Effects ³⁸

Number of Patients Reporting Listed Side Effects



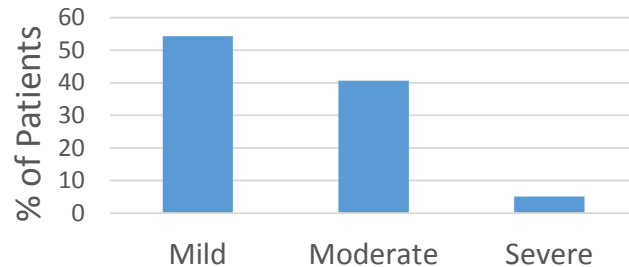
Side Effect	# Patients Reported
Asthenia (muscle weakness)	5
Chest pain	5
Confusion	5
Disorientation	4
Eye redness	4
Increased agitation	4
Lethargy	4
Blurred Vision	3
Decreased muscle coordination/balance	3
Increased seizures	3
Numbness	3
Panic attack	3
Personality/mood change	3
Tinnitus (ringing perception in the ears)	3
"Stoned" feeling	2
Body stiffness	2
Coughing/lung irritation	2
Decreased appetite	2
Dry eyes	2
Feeling cold	2
Tremors	2

Side Effect	# Patients Reported
"Wired" feeling	1
Bloating	1
Burping	1
Change in quality of seizures	1
Chest colds	1
Cognitive change	1
Cramping with bowel movement	1
Dysphoria (intense feeling of unease or unpleasantness)	1
Exacerbation of lymphedema	1
Eye muscle twitching	1
Hives	1
Hyperactive bowel sounds	1
Hypomania	1
Increase in mucus secretions	1
Increased aggression	1
Increased urine output	1
Increased yelling	1
Mouth irritation/burning	1
Rash on face	1
Repressed immune system	1
Sleep disturbance	1
Sneezing	1
Thrush	1
Urinary retention	1
Vomiting	1
Worsening acne	1

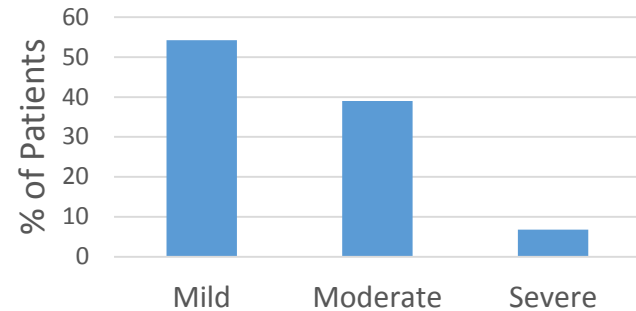
Negative Side Effect Severity

90.6% of all unique reported side effects are of mild to moderate severity

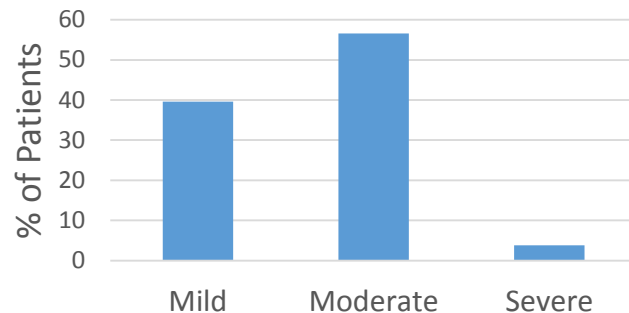
Drowsiness/somnolence/sedation
(n = 59)



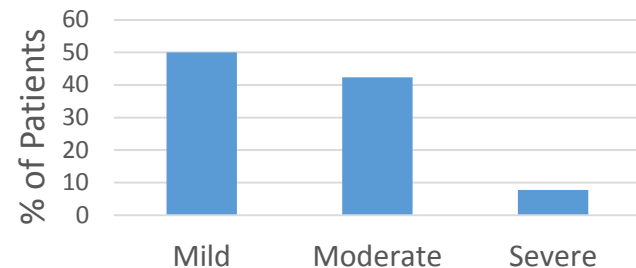
Dry mouth (n = 59)



Fatigue (n = 53)



Mental clouding/"foggy brain"
(n = 26)



Patient Self-Evaluation

Patients complete a Patient Self-Evaluation prior to purchasing medical cannabis

- Negative side effects
- **Symptom changes**

Symptom Changes on Patient Self-Evaluation

- Standard 8 symptoms
 - 0-10 numerical rating scale

e.g.,

Your disturbed sleep at its worst *



- Condition-Specific symptoms

What percentage of patients who experienced moderate to severe symptoms achieved $\geq 30\%$ reduction by the 4th month since their first medical cannabis purchase?

Symptom Changes – Early Look

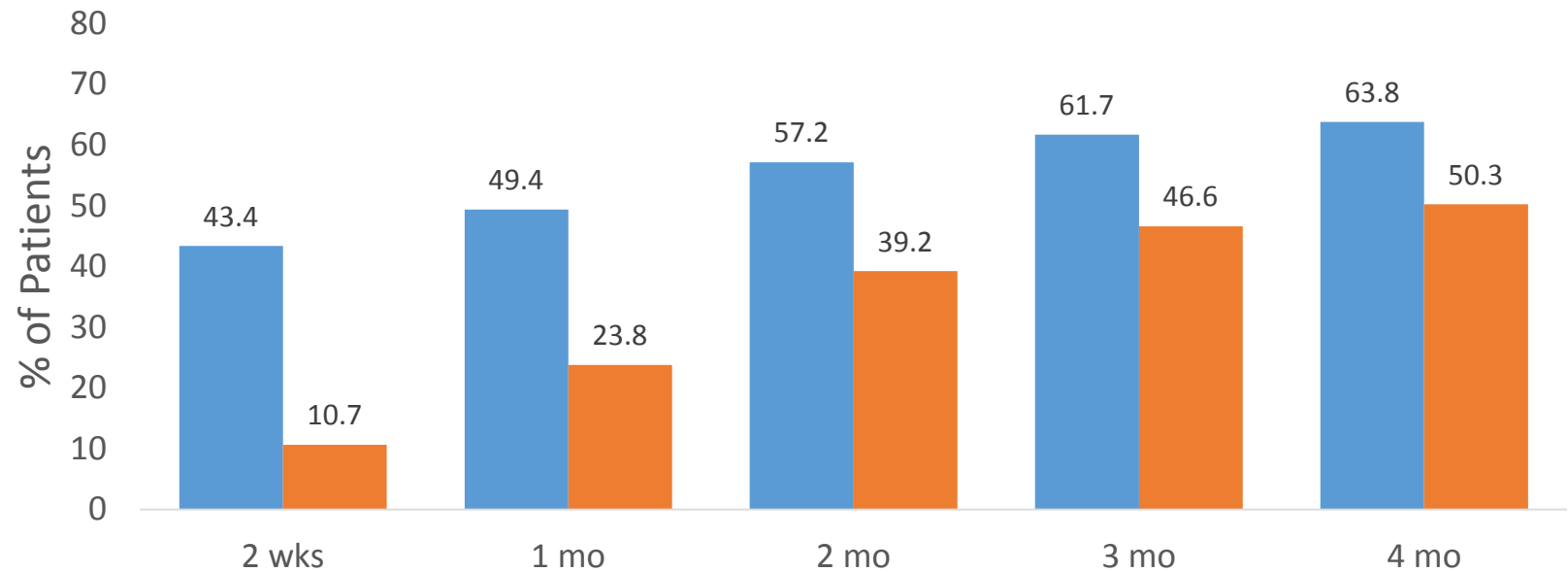
1512 out of 1660 (91.1%) patients enrolled in the 1st year have made some type of medical cannabis purchase AND have at least been enrolled for 4 months since their first medical cannabis purchase

Symptom Changes: Disturbed Sleep (Standard 8)

- **87.5%** of respondents (1323/1512) rated sleep disturbance at moderate to severe levels at baseline

Symptom Changes: Disturbed Sleep (Standard 8)

Cumulative 30% Symptom Reduction



■ Of all Moderate to Severe scoring patients submitting data by this time point

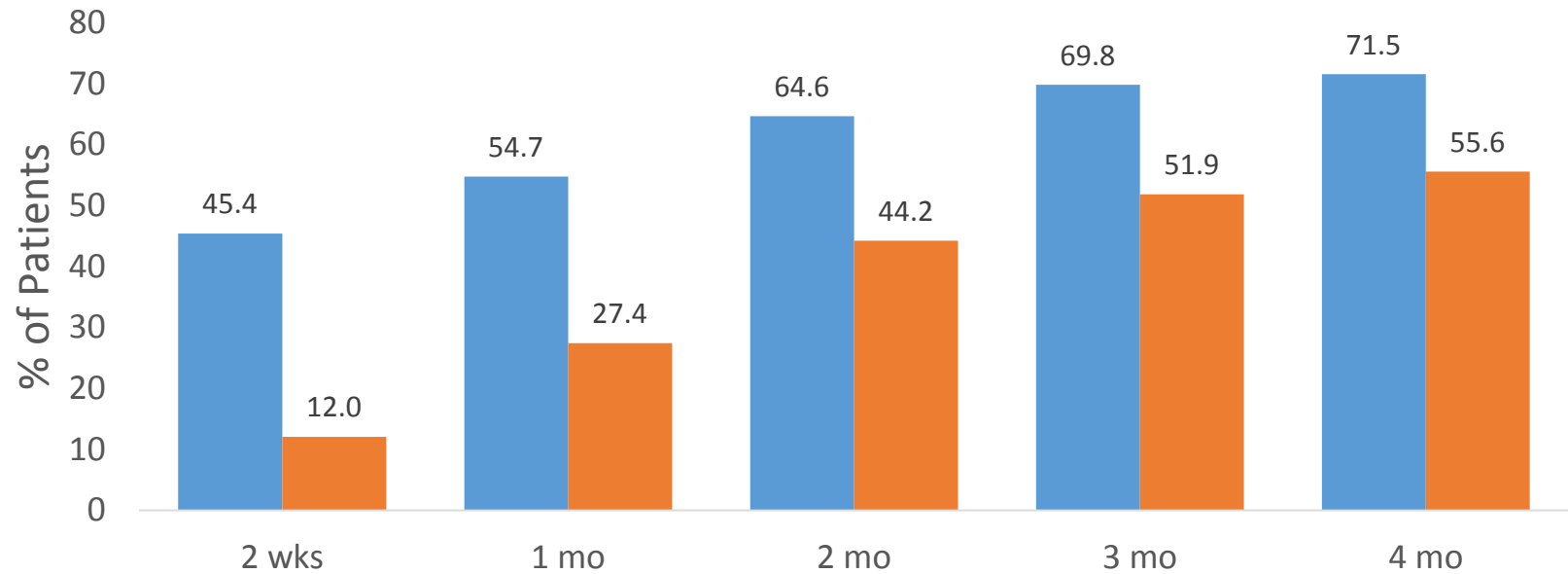
■ Of all Moderate to Severe scoring patients

Symptom Changes: Nausea (Standard 8)

- **57.1%** of respondents (864/1512) rated nausea at moderate to severe levels at baseline

Symptom Changes: Nausea (Standard 8)

Cumulative 30% Symptom Reduction



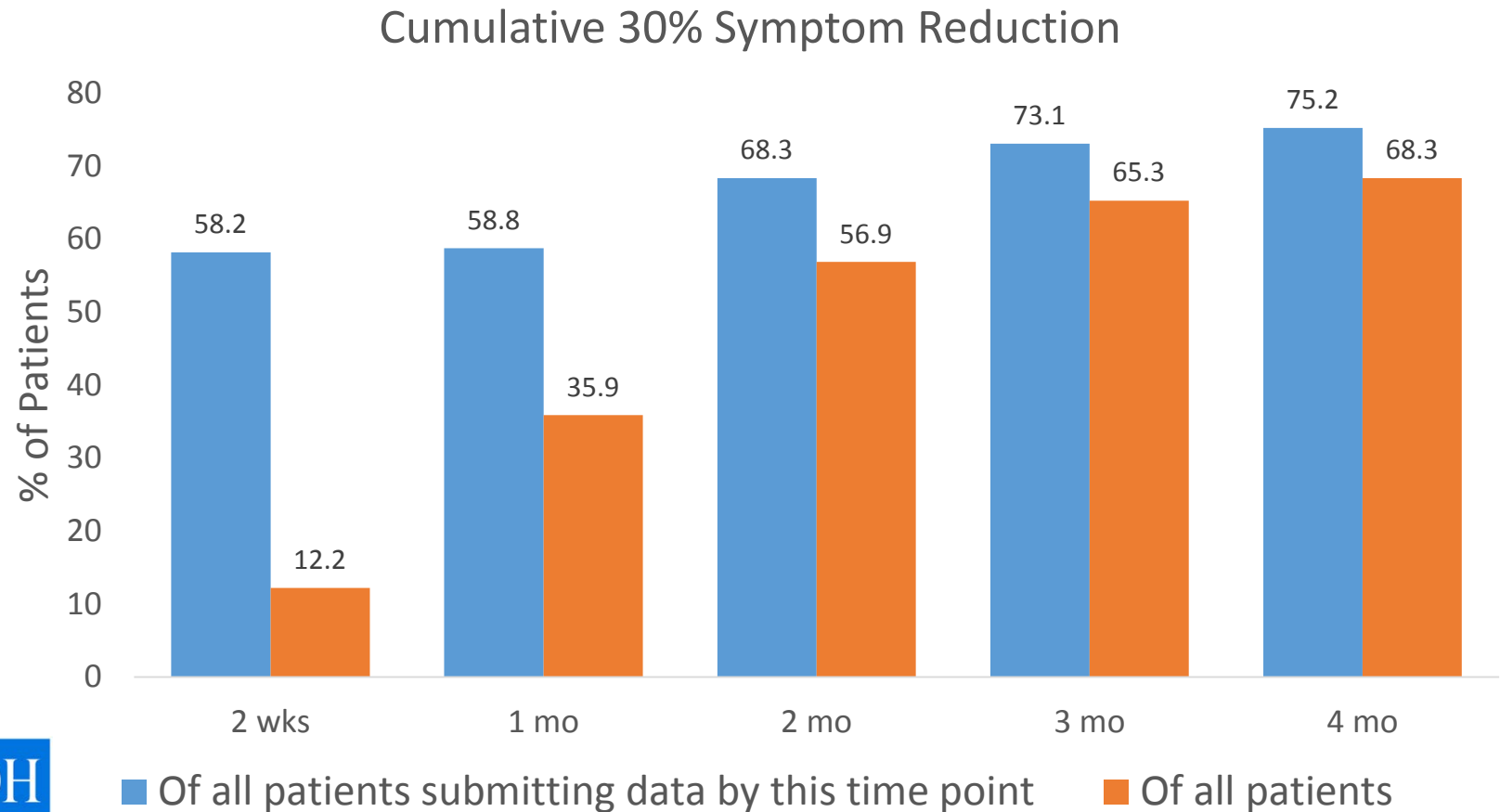
■ Of all Moderate to Severe scoring patients submitting data by this time point

■ Of all Moderate to Severe scoring patients

Symptom Changes: Weekly Seizure Frequency (Condition-Specific)

- 328 (19.8%) seizure patients enrolled within 1st program year
- **262** (79.9%) of them had weekly seizure responses at baseline

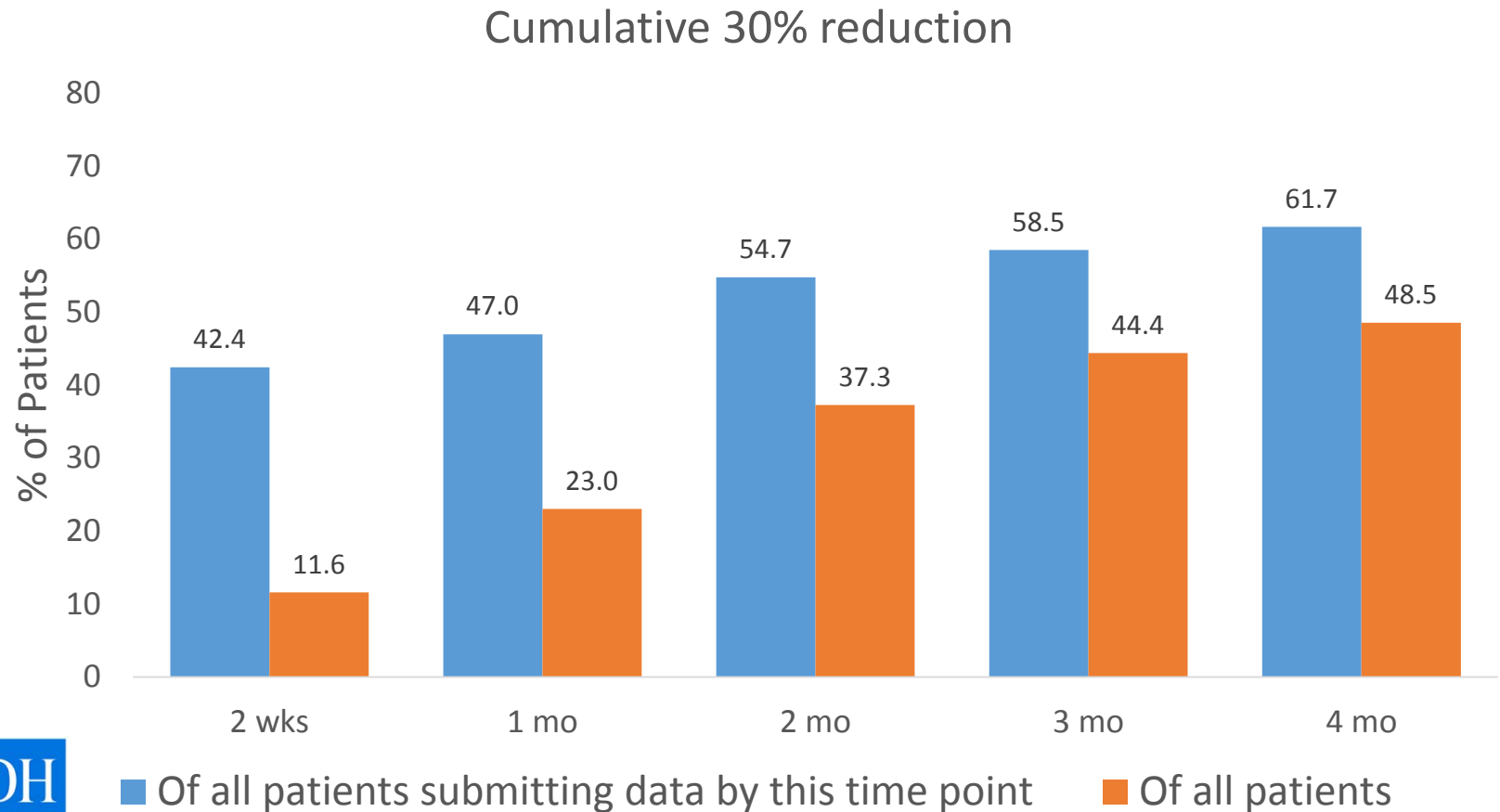
Symptom Changes: Weekly Seizure Frequency (Condition-Specific)



Symptom Changes: Weekly Spasms Frequency (Condition-Specific)

- 733 (44.2%) muscle spasm and/or ALS patients enrolled within 1st program year
 - 713 Muscle Spasm patients
 - 22 ALS
- **604** (82.4%) of them had weekly spasms responses at baseline

Symptom Changes: Weekly Spasms Frequency (Condition-Specific)



Symptom Changes

Additional information in 1st year report:

- Description of medical cannabis products patients purchased when patient first achieved 30% symptom reduction
- Description of symptom scores *after* achieving first 30% reduction

Preliminary Intractable Pain Results

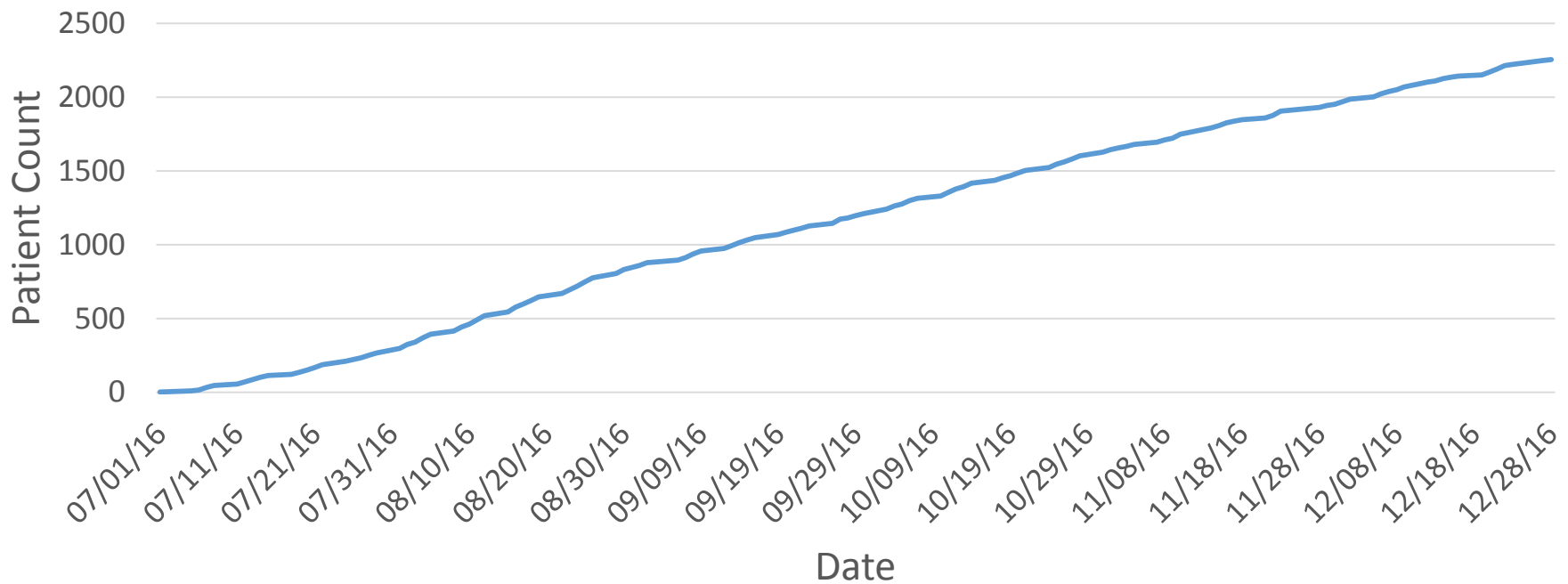
Intractable Pain Enrollments

2255 IP patients in Approved status (as of Dec. 28th, 2016)

- **Most common IP causes:**
 - Back pain
 - Axial
 - Radicular
 - Fibromyalgia/myofascial pain
 - Arthritis: osteoarthritis
 - Neuropathy that is not of HIV, diabetic, or post-herpetic origin

Patients Approved for Intractable Pain

Cumulative Number of Intractable Pain Patients Approved for the Medical Cannabis Program

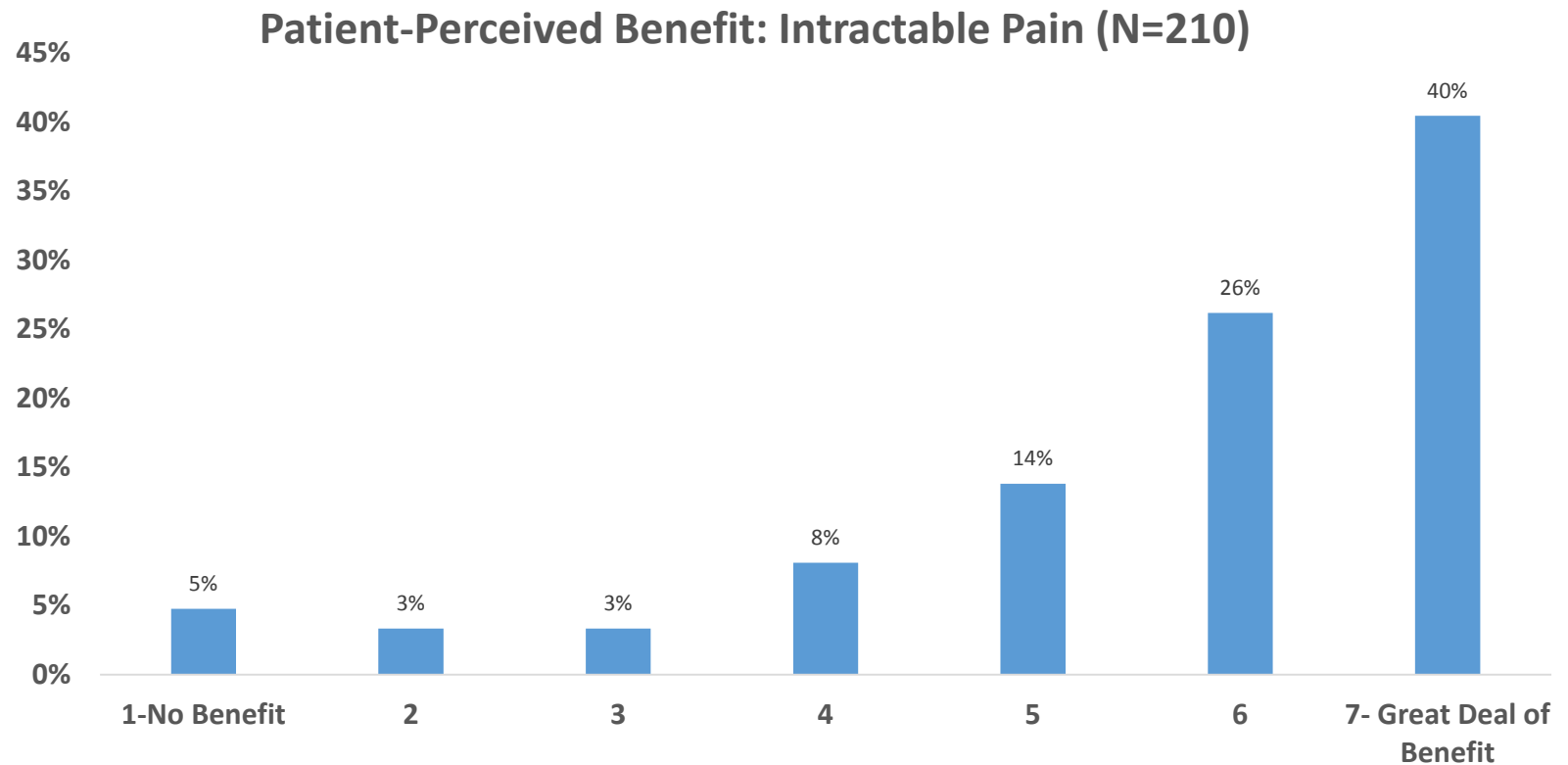


2255 IP patients currently active as of Dec. 28, 2016

Preliminary Intractable Pain Patient Survey Results

- **382 patients** certified for Intractable Pain began purchasing medical cannabis between **8/1/16 and 8/12/16**
- **210 (55%)** completed a survey 3 months after their first purchase

Patient Perception of Benefit: Intractable Pain



Perceived Benefits from Medical Cannabis

Benefit Types	N (%)
Pain Reduction	133 (63%)
Sleep Improvement	58 (28%)
Reduction of Other Medications/Related Side Effects	38 (18%)
Anxiety Reduction	33 (16%)
Quality of Life Improvement	20 (10%)
Mobility/Functional Improvement	16 (8%)
Appetite Improvement	16 (8%)
Nausea/Vomiting Reduction	14 (7%)
Spasm Reduction	11 (5%)
Improved Mood/Attitude	9 (4%)
Improved GI Function	2 (1%)
Improved Alertness/Cognition	1 (0%)
Crohn's Symptoms Reduction	1 (0%)

Patient Comments

- “1. I can play with my daughter without needing breaks or not being able to at all.**
- 2. I can go to school/work because I can be on my feet without needing to rest every hour or more.**
- 3. I can sleep through the night!**
- 4. I can take my daughter to the zoo or park etc without worrying about if I'll be able to get through it without needing breaks.**
- 5. I can get right up when I wake up without needing an hour or more to get the energy to move.**
- 6. My anxiety has been better, so my life is overall easier to manage**
- 7. It helps with my ovarian cyst pains I get monthly**
- 8. I don't have migraines anymore**
- 9. I can make plans again**
- 10. I'm not nauseous all the time.**

Honestly, I could keep going and going. The benefits I've experienced are overwhelming. I still have pain, but, it doesn't dictate my life. I feel like I finally have my life back.”

“Minimized leg cramps. Helps with daily pain but wish it worked better for how expensive it is.”

For more information:

Office of Medical Cannabis web site:
<http://www.health.state.mn.us/topics/cannabis/>

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