



BRIGHAM AND WOMEN'S HOSPITAL

Study Title: Marijuana Use Among IBD Patients: An Investigation of Patient Perspectives

Principle Investigator:

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Why is this research being conducted?

On November 6, 2012, Massachusetts voters approved a referendum making Massachusetts the 18th state to allow the medical use of marijuana. The new law allows doctors to recommend medical marijuana for the following medical conditions: "Cancer, glaucoma, positive status for human immunodeficiency virus, acquired immune deficiency syndrome (AIDS), hepatitis C, amyotrophic lateral sclerosis (ALS), Crohn's disease, Parkinson's disease, multiple sclerosis and other conditions as determined in writing by a qualifying patient's physician." Studies have shown that patients with inflammatory bowel disease (IBD, which includes Crohn's disease and Ulcerative Colitis) are using marijuana for symptom relief. The purpose of this study is to better understand the use of marijuana among IBD patients, the symptoms marijuana seems to treat, and how this impacts the severity and treatment of their disease.

You are being asked to participate in the study because you have been identified as a patient of the BWH GI Unit with Inflammatory Bowel Disease. We obtained your contact information because you are treated at the BWH GI Unit. You will be one of 200-300 patients in this study.

What will happen in this research study?

You will complete one survey. The entire questionnaire should take less than 15 minutes. It includes two sections: (1) questions about your medical history and severity of IBD and (2) information about current or previous marijuana use. We will not obtain other information from your medical record.

Participation in the study is voluntary and choosing not to participate will not impact your care at BWH. Please answer these questions as honestly as possible as this information will help us with future research studies. We hope you will answer every question although you may skip those you are uncomfortable with. The information obtained from this survey will not be made a part of your medical record.

Privacy

We are required by the Health Insurance Portability and Accountability Act (HIPAA) to protect the privacy of health information obtained for research. This is an abbreviated notice, and does not describe all details of this requirement. During this study, identifiable information about you or your health will be collected and shared with the researchers conducting the research. In general, under federal law, identifiable health information is private. However, there are exceptions to this rule. In some cases, others may see your identifiable health information for purposes of research oversight, quality control, public health and safety, or law enforcement. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy.

If you decide to take part in this research study, your health information may be used within Partners and may be shared with others outside of Partners as explained below.

Health information about you that might be shared or used during this research:

- Information from your hospital or office health records within Partners that are reasonably related to the conduct and oversight of the research study.
- New health information obtained in this study.

Why health information about you might be used or shared with others:

- To do research as described above.
- To make sure we do the research according to certain standards set forth by ethical guidelines, relevant laws and by quality groups.

People or groups that might use or share your health information:

People or groups within Partners

- Researchers and the staff involved in this research study.
- The Partners review board that oversees the research.
- Staff within Partners who need the information to do their jobs (such as overseeing quality of care or research).

People or groups outside Partners

- People or groups that we hire to do certain work for us, such as data storage, companies, our insurers, or our lawyers.
- Federal and state agencies (such as U.S. Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health and/or the office for Human Research Protections) and other U.S. or foreign government bodies, if required by law or involved in overseeing the research.
- Organizations that make sure hospital standards are met.

Your privacy rights:

You have the right not to complete this survey permitting us to use and share your health information for research. If you choose not to complete the survey, you can't take part in this research study. This is because we need to use the health information of everyone who takes part in this research study. You have the right to withdraw permission from us to use or share your health information for this research study at anytime. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. You have the right to view and obtain a copy of your health information that is used or shared for treatment. To ask for this information, please contact the person in charge of this research study.

If you'd like to speak to someone not involved in this research, contact the Partners Human Research Committee at 617-424-4100.

Section 1

1. What is your age? years old

2. What is your gender?

- Male
- Female

3. Which race/ethnicity best describes you? (Please choose only one.)

- American Indian or Alaskan Native
- Asian or Pacific Islander
- Black, not of Hispanic origin
- Hispanic
- White, not of Hispanic origin

4. What is your diagnosis?

- Ulcerative Colitis
- Crohn's Disease
- Indeterminate Colitis

5. Have you ever undergone surgery for your Inflammatory Bowel Disease (IBD)?

- No
- Yes

6. Have you ever been hospitalized for your IBD?

No (proceed to question 8)

Yes ➔ 7. How many times have you been hospitalized for your IBD?

- 1-3 times
- 4-6 times
- 6-10 times
- more than 10 times

8. Are you currently taking a biologic agent for your IBD (ie. Remicaide, Humira, Cimzia, Stelara, Tysabri)?

- No
- Yes

9. Do you have chronic abdominal pain related to your IBD?

No (proceed to next page)

Yes ➔ 10. Have you ever needed narcotics for your abdominal pain (ie. oxycodone, Oxycontin, MS Contin, methadone)?

- No
- Yes

11. Are you currently taking narcotics for your chronic abdominal pain (ie. oxycodone, Oxycontin, MS Contin, methadone)?

- No
- Yes

12. How often do you require narcotics for your chronic abdominal pain?

- More than once a day
- Once a day
- A few times a week
- A few times a month
- Less than once a month or never

13. How would you describe your disease over the last year?

- In remission
- Periods of remission with a few flares
- Continuous mildly active disease
- Continuous significantly active disease

The next 10 questions are designed to find out how you have been feeling during the last 2 weeks.

14. How often has the feeling of fatigue or of being tired and worn out been a problem for you during the last 2 weeks?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- Hardly any of the time
- None of the time

15. How often during the last 2 weeks have you had to delay or cancel a social engagement because of your bowel problem?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- Hardly any of the time
- None of the time

16. How much difficulty have you had, as a result of your bowel problem, doing leisure or sports activities you would have liked to have done during the last 2 weeks?

- A great deal of difficulty; activities made impossible
- A lot of difficulty
- A fair bit of difficulty
- Some difficulty
- A little difficulty
- Hardly any difficulty
- No difficulty; bowel problems do not limit sports or activities

17. How often during the last 2 weeks have you been troubled by pain in the abdomen?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- Hardly any of the time
- None of the time

18. How often during the last 2 weeks have you felt depressed or discouraged?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- Hardly any of the time
- None of the time

19. Overall, in the last 2 weeks, how much of a problem have you had with passing large amounts of gas?

- A major problem
- A big problem
- A significant problem
- Some trouble
- A little trouble
- Hardly any trouble
- No trouble

20. Overall, in the last 2 weeks, how much of a problem have you had maintaining or getting to the weight you would like to be?

- A major problem
- A big problem
- A significant problem
- Some trouble
- A little trouble
- Hardly any trouble
- No trouble

21. How often during the last 2 weeks have you felt relaxed and free of tension?

- None of the time
- Hardly any of the time
- A little of the time
- Some of the time
- A good bit of the time
- Most of the time
- All of the time

22. How much of the time during the last 2 weeks have you been troubled by a feeling of having to go to the bathroom even though your bowels were empty?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- Hardly any of the time
- None of the time

23. How much of the time during the last 2 weeks have you felt angry as a result of your bowel problem?

- All of the time
- Most of the time
- A good bit of the time
- Some of the time
- A little of the time
- Hardly any of the time
- None of the time

Section 2**24. Do you support the legalization of medical marijuana?**

- No
- Yes

25. Did you vote in favor of legalizing medical marijuana?

- I voted in favor of legalization.
- I voted against legalization.
- I did not vote
- I do not live in Massachusetts / I am not eligible to vote in Massachusetts

26. Would you be interested in participating in a clinical trial that would test marijuana for symptom relief of your IBD?

- No
- Yes

27. Have you ever used marijuana?

- I currently use marijuana (proceed to question 30 below)
- I have used marijuana in the past, but am not currently using (proceed to question 37 on page 9)
- I have never used marijuana

28. Would you be interested in using marijuana medicinally when it is legally available? No (you have completed the survey) Yes**29. What symptoms would you use it to treat?**

- | | | |
|--------------------|---------------------------|--------------------------|
| a) Abdominal pain? | <input type="radio"/> Yes | <input type="radio"/> No |
| b) Diarrhea? | <input type="radio"/> Yes | <input type="radio"/> No |
| c) Appetite? | <input type="radio"/> Yes | <input type="radio"/> No |
| d) Nausea? | <input type="radio"/> Yes | <input type="radio"/> No |

You have completed the survey. Thank you so much for your participation.

Questions 30-36 are for CURRENT users of marijuana only**30. How do you consume marijuana? Select the method you use most frequently.**

- Smoking it in joints
- Smoking it in pipes
- Smoking it in bong
- Baking and eating it

31. How long have you been using marijuana?

- Weeks
- Months
- Years

For **CURRENT** users only (continued)

32. Are you currently using marijuana recreationally?

No (proceed to question 34)

Yes

33. How frequently are you using marijuana recreationally?

- Several times a day
- Once a day
- Several time a week
- Once a week
- Several times a month
- Once a month
- Less than once a month

34. Are you currently using marijuana medicinally to treat symptoms of your disease?

No (you have completed the survey)

Yes

35. How frequently are you using marijuana medicinally for symptom relief?

- Several times a day
- Once a day
- Several time a week
- Once a week
- Several times a month
- Once a month
- Less than once a month

36. If you are using marijuana to treat symptoms of your disease, do you use it to treat:

a) Abdominal pain?

No

Yes

How effective is it?

- Ineffective
- Slightly helpful
- Moderately helpful
- Very helpful
- Complete relief

b) Diarrhea?

No

Yes

How effective is it?

- Ineffective
- Slightly helpful
- Moderately helpful
- Very helpful
- Complete relief

c) Poor Appetite?

No

Yes

How effective is it?

- Ineffective
- Slightly helpful
- Moderately helpful
- Very helpful
- Complete relief

d) Nausea?

No

Yes

How effective is it?

- Ineffective
- Slightly helpful
- Moderately helpful
- Very helpful
- Complete relief

You have completed the survey. Thank you so much for your participation.

Questions 37-46 are for PAST users of marijuana only

37. How did you consume marijuana? Select the method you used most frequently.

- Smoking it in joints
- Smoking it in pipes
- Smoking it in bonges
- Baking and eating it

38. How long ago did you stop using marijuana?

- Weeks
- Months
- Years

39. Would you be interested in using marijuana medicinally when it is legally available?

No

Yes ➡ **40. What symptoms would you use it to treat?**

- | | | |
|--------------------|---------------------------|--------------------------|
| a) Abdominal pain? | <input type="radio"/> Yes | <input type="radio"/> No |
| b) Diarrhea? | <input type="radio"/> Yes | <input type="radio"/> No |
| c) Appetite? | <input type="radio"/> Yes | <input type="radio"/> No |
| d) Nausea? | <input type="radio"/> Yes | <input type="radio"/> No |

41. Did you use marijuana recreationally?

No (proceed to questions 43)

Yes ➡ **42. How frequently did you use marijuana recreationally?**

- Several times a day
- Once a day
- Several time a week
- Once a week
- Several times a month
- Once a month
- Less than once a month

43. Did you use marijuana medicinally to treat symptoms of your disease?

No (you have completed the survey)

Yes ➡ **44. How frequently did you use marijuana medicinally for symptom relief?**

- Several times a day
- Once a day
- Several time a week
- Once a week
- Several times a month
- Once a month
- Less than once a month

45. Why did you discontinue medicinal use of marijuana? Select the one reason that most applies.

- No longer effective for symptom relief
- No longer needed for symptom relief (ie. your symptoms had resolved)
- Too difficult to obtain
- Too risky

Continue on next page

For *PAST* users only (continued)

46. If you used marijuana to treat symptoms of your disease, did you use it to treat:

a) Abdominal pain?

No

Yes

➤ **How effective was it?**

Ineffective

Slightly helpful

Moderately helpful

Very helpful

Complete relief

b) Diarrhea?

No

Yes

➤ **How effective was it?**

Ineffective

Slightly helpful

Moderately helpful

Very helpful

Complete relief

c) Poor Appetite?

No

Yes

➤ **How effective was it?**

Ineffective

Slightly helpful

Moderately helpful

Very helpful

Complete relief

d) Nausea?

No

Yes

➤ **How effective was it?**

Ineffective

Slightly helpful

Moderately helpful

Very helpful

Complete relief

Thank you so much for completing the survey.