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Cannabis health survey on usage in women with spinal cord injury and knowledge among physicians

Lee, Amanda H.X; Tse, Emmanuel; Nightingale, Tom E.; Sachdeva, Rahul; Walter, Matthias; Krassioukov, Andrei

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The Journal of Spinal Cord Medicine

Cannabis health survey on usage in women with spinal cord injury and knowledge among physicians: A cross-sectional study --Manuscript Draft--

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Corresponding Author:	Andrei V. Krassioukov, M.D., Ph.D, FRCPC The University of British Columbia Faculty of Medicine Vancouver, BC CANADA		
Corresponding Author Secondary Information:			
Corresponding Author's Institution:	The University of British Columbia Faculty of Medicine		
Corresponding Author's Secondary Institution:			
First Author:	Amanda HX Lee, MSc		
First Author Secondary Information:			
Order of Authors:	Amanda HX Lee, MSc		
	Emmanuel K Tse, BSc		
	Thomas E Nightingale, PhD		
	Rahul Sachdeva, PhD		
	Matthias Walter, MD, PhD		
	Andrei V. Krassioukov, M.D., Ph.D, FRCPC		
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Abstract:	Objective : Individuals with spinal cord injury (SCI) report using cannabis to self- manage chronic pain and spasticity. However, its safety and efficacy are not well understood. As more women with SCI are pursuing motherhood, clinicians must consider the possibility of maternal cannabis use and its impact on fetal development. Moreover, due to the lack of current evidence for cannabis, it is important to characterize the perceptions and knowledge of physicians towards both recreational and synthetic cannabinoids.		
	Design : Two anonymous surveys (10-items each) were conducted.		
	Setting and Participants : Women with SCI (n=20) completed an anonymous, online survey regarding cannabis use. Physicians at a Canadian SCI rehabilitation centre (n=15) completed a survey on their knowledge of recreational and synthetic cannabinoids among individuals with SCI.		
	Outcome measures : Survey 1 evaluated cannabis use patterns and perceptions before/after SCI in women, including during pregnancy and breastfeeding. The aim of Survey 2 was to understand the perception and current knowledge of physicians regarding recreational cannabis and synthetic cannabinoid use by patients with SCI.		
	Results : At the time of survey, 7 women with SCI reported use of cannabis, only 4 of them used prior to injury. Managing tone/spasticity (n=5) was the major reported		

benefit of cannabis use. Women used cannabis during pregnancy and/or breastfeeding as a sleep aid or relief for morning sickness (n=1 pregnancy, n=1 breastfeeding, n=1 both). The most reported challenge with cannabis use was difficulty obtaining consistent, desirable effects (n=5). Almost all physicians (n=13) described their knowledge on recreational cannabis products as "none, very little or poor", with greater overall comfort and knowledge of synthetic cannabinoids.
Conclusion : Due to the reported use of cannabis during pregnancy/breastfeeding and current impoverishment of physicians' knowledge (particularly regarding recreational cannabis products), it is imperative to further investigate the safety and efficacy of cannabis use in women with SCI.

December 8, 2021

Editor-in-Chief Dr. Florian P. Thomas Hackensack University Medical Center Seton Hall-Hackensack Meridian School of Medicine Hackensack, NJ, USA

Re: Second revisions of first revisions JSCM-D-21-00201R1 – cannabis use by women after spinal cord injury

Dear Dr. Thomas,

We are writing to you regarding our recently submitted revised manuscript entitled 'Cannabis health survey on usage in women with spinal cord injury and knowledge among physicians: A cross-sectional study' for submission in the Journal of Spinal Cord Medicine.

Once again, we would like to thank the Editorial Board and reviewers for their time, and the opportunity to submit our second revisions for further consideration. We hope our responses will help elucidate our efforts and the barriers faced for suggestions that we were unfortunately unable to incorporate. Please find below our complete response (in italics) to the comments from the Managing Editor (in bold) and Associate Editor (in bold) as well as to the reviewers' comments (in bold) for your consideration. Edits to the manuscript are highlighted in yellow.

COMMENTS FROM THE EDITORIAL:

* Reference citations should be in superscript, without parentheses or brackets. Reference citations should come after punctuations, such as commas or periods, and before semicolons or colons, with no spaces between the citation number and the punctuation mark. <u>Response:</u> Thank you. We revised the manuscript accordingly.

* Please italicize ''et al.'' wherever it appears in the paper, including references and tables. <u>Response:</u> Thank you. We revised the manuscript accordingly.

* No commas following "e.g." <u>Response:</u> Thank you. We revised the manuscript accordingly.

* For P values use the upper-case Roman P not italics, including tables and table legends. <u>Response:</u> Thank you. We revised the manuscript accordingly.

* Figure legend (caption) text should appear in the manuscript file after References and before any Tables

Response: Thank you. We revised the manuscript accordingly.

ASSOCIATE EDITOR'S COMMENTS:

I thank the authors for their careful consideration of comments previously offered, and for their letter, which provided important context for this review. I hold the view (shared by the reviewers) that his manuscript would add value to the field given the dearth of knowledge about cannabis use among women with SCI, but that the findings must be interpreted cautiously given sample size and other methodological limitations.

The reviewers have identified areas where additional clarification would be helpful as well as limitations to acknowledge. I thank the authors in advance for adding clarification and augmenting the limitations section in light of the suggestions offered below.

There was a helpful description of the reasons for not seeking more surveys in the letter that accompanied the manuscript. I recommend that the authors incorporate those reasons in the limitations section to provide context for readers. (Also, I suggest modifying or qualifying the statement indicating that "Future studies should attempt to replicate similar results with larger samples." Your own experience indicates how challenging that may be for a single center--offering suggestions for how that might be accomplished would be helpful, including multi-center studies or perhaps using qualitative designs to gain greater depth of knowledge when the population of interest is small.)

Thank you and your colleagues for your consideration during the review process, and for your work in this important area.

<u>Response:</u> Thank you. We appreciate the Associate Editor's feedback and suggestions. Thus, we have revised our manuscript accordingly. The Associate Editor acknowledged numerous crucial limitations that our team faced in conducting this study that was focus on women with SCI, a very small and poorly investigated cohort.

Lines 190 to 192:

Considering the aforementioned limitations of this study, future research may want to consider utilizing an international, multi-center, qualitative study design in order to gain a greater depth of knowledge into the population of interest, which is relatively small.

REVIEWER #2:

Summary

The authors of this study performed two anonymous surveys including women with SCI and physicians at a SCI rehab center. Cannabis use patterns before/after SCI in women, including pregnancy and breastfeeding were evaluated in Survey 1. The perception and current knowledge of physicians regarding cannabinoid use by patients with SCI was evaluated in Survey 2. 7 women reported use of cannabis mostly for managing tone/spasticity. Cannabis was used during pregnancy and/or breastfeeding as a sleep aid or relief of morning sickness. Most physicians described their knowledge of recreational cannabis products as none or very poor. The authors concluded that the safety and efficacy of cannabis use in women with SCI should be investigated.

<u>Response:</u> Thank you.

General Comments:

The manuscript is generally well written and easy to follow. The survey content appears thorough and complete.

<u>Response:</u> Thank you.

This is an entirely descriptive study in a very small population group. Consequently, it is very difficult to derive any firm conclusions or recommendations. Moreover, the findings appear quite predictable. For example, it is not surprising that women with SCI use cannabis, particularly since it well known that many SCI patients use this compound. As the authors indicate, pregnant women in the general population often use cannabis and there are reported negative consequences. Not surprisingly therefore, some women with SCI also use cannabis during pregnancy, although the extent of use in this group is entirely unknown as only 2 subjects were identified in this study. It is also not surprising that physicians described their knowledge of recreational cannabis products as poor given the poor regulation of this substance, myriad of different delivery methods, variety of dosages, etc. and other issues that the authors raised. Is there any group, for comparison, that has this knowledge?

<u>Response:</u> Thank you for your comment. To our knowledge, there is no group (i.e. comparators) that had this knowledge at that moment in time. Nevertheless, while the reviewer makes the assumption that no group has this knowledge, we have described the fact that it is lacking amongst a group of physicians that work with the SCI population, which we feel would be of interest to the JSCM readership.

Specific Comments:

The description of the women who used cannabis during pregnancy and /or breast feeding is hard to follow. Would stick to the abstract description: one during pregnancy, one during breastfeeding and one during both.

<u>Response:</u> Thank you. We agree with the reviewer and have changed the manuscript accordingly.

Lines 100 to 102:

Among the 20 women with SCI that started the survey, only seven completed the survey since 13 never used cannabis (Table 1). Notably, two women used cannabis, i.e. one during pregnancy, one during breastfeeding, and one during both.

In the Discussion, the use of percentages, given the small numbers, is misleading - recommend sticking to whole numbers.

<u>Response:</u> Thank you. We added the whole numbers in line 325 but kept the percentages as we are comparing the percentages of women to another study on that matter (i.e. reference 14: Demont-Heinrich et al.). The revised discussion reads as follows:

Lines 136 to 137:

Of the 20 women originally surveyed, seven (35%) were using cannabis and two (10%) women with SCI used cannabis during both pregnancy and breastfeeding.

The conclusion that use of cannabis during pregnancy and breastfeeding was more prevalent in your sample cannot be drawn given your very small sample size.

<u>Response:</u> Thank you. We agree with the reviewer and corrected the discussion accordingly.

Lines 142 to 147:

Demont-Heinrich et al. reported a more frequent use of cannabis use in the general population during pregnancy and breastfeeding in current cannabis users (i.e. 36% during their most recent pregnancy and 14% used while breastfeeding) compared to past users (5% during pregnancy and <1% while breastfeeding).¹⁴ With respect to the former study, our cohort of women with SCI had a percentage of cannabis use during pregnancy and breastfeeding somewhere in between.

In the Discussion, it is indicated that this study had reports of cognitive issues, but this is not provided in the Results section.

<u>*Response:*</u> Thank you. We agree with the reviewer as we only report on fatigue (in Table 2), Thus we revised our manuscript accordingly.

Lines 150 to 151: Our study also reported cannabis use-associated fatigue, which potentially could have a negative effect on cognitive function.

The recommendations in the final paragraph concerning the monitoring of SCI women for cannabis use and evaluations of the safety/efficacy of cannabis use in pregnant women are quite valid - but didn't we know this before your study.

<u>Response:</u> Thank you. We agree with the reviewer that certain professions including physicians, health care providers, and psychologists might be more aware of the potentially beneficial, as well as harmful, consequences associated with cannabis use. However, we strongly feel that consumers as well as healthcare professionals (in line with our results) are apparently not very aware of these issues and that education and future research on that topic are warranted.

REVIEWER #3:

The following manuscript reports on a cross-sectional internet-based study to elicit information on cannabis use among women with an SCI and knowledge and comfort level of prescribing and monitoring cannabis use by patients with SCI among rehabilitation physicians. The comments offered are meant to strengthen the article and are broken down by section:

<u>Response:</u> Thank you.

Introduction - provides a succinct overview of current state of knowledge about cannabis use among women with SCI; no suggestions.

<u>Response:</u> Thank you.

Methods - Addresses study timeline and human subjects' procedures. Concern: data was collected over August and September 2018, 3 years ago, and the response rate was <50%, yet there was no attempt to re-send the link or contact the potential participants. Please address why there were no further efforts undertaken to increase the number of responders.

<u>Response:</u> Thank you. We agree with the reviewer and would like to inform the reviewer that we have previously addressed similar inquiries raised by the Associate Editor in the last peer-review

round in February 2021. With respect to undertaking efforts "to increase the number of participants" by sampling more regions in Canada, North America or other even countries, we believe that any increase in sample size would be modest. Over the years we have compiled arguably the largest repository of prospective research participants who identify as female and have attempted breastfeeding at any point after sustaining a spinal cord injury, which is key to the overall conclusions of this paper. This is primarily due to our previous work on women's health issues and SCI which recruited participants from all across Canada. The research team members are also affiliated with acute SCI rehabilitation centres, through which they are able to reach out to new members of the SCI community to invite them as research participants. Despite these fortuitous connections, the response rate to our initial invitation remained just over 35%. Furthermore, expanding recruitment and data collection nearly three years after the survey was first developed will introduce a time lapse. We believe this would confound data interpretation of a study that was originally meant to be a small cross-sectional pilot survey. As legislation and attitudes surrounding cannabis use are rapidly changing in Canada, results obtained a year from now may not be entirely reflective of current perspectives and cannabis use patterns, if collated with data collected at the inception of this study.

Results: Clearly stated with adequate tables/figures.

<u>Response:</u> Thank you.

Discussion: The discussion is aligned with the reported results and within the context of current research in the field. However, the authors should also address the potential reasons for the rate of non-responders, which could be due to stigmatization of cannabis use, especially during pregnancy, and the possible hesitancy of women of child-bearing age to disclose cannabis use.

In addition, while decriminalization of cannabis is currently ongoing, there remain laws that criminalize substance use, including marijuana, for pregnant women and women with children. Such laws can work against full disclosure of patients with their physician, hinder research efforts, and patient/infant treatment.

Additional limitations include the cross-sectional and internet-based design of the study, which prohibited understanding the patterns of cannabis use/dose (daily/weekly) or confirmation of cannabis levels, which may influence maternal side-effects and infant physiologic effects.

<u>*Response:*</u> We thank the reviewer for their excellent suggestions. We have added / revised our limitations accordingly.

Lines 174 to 184:

There are several limitations to our work which should be considered including the small sample size of this pilot study, from which definitive conclusions regarding patterns of cannabis use cannot be drawn. It has to be noted that women with SCI represent only about 20% of all individuals with SCI³⁷, so information is limited related to their health and wellness.

Furthermore, the relatively high number of non-responders (i.e. almost two-thirds of women with SCI did not respond to the invitation), which could be due to stigmatization of cannabis use, especially during pregnancy and breastfeeding. Moreover, at the time when we invited women to

answer the survey, there were still laws that criminalized cannabis use which could have been a reason to not fully disclose cannabis use (i.e. frequency, dose, and occasion). Furthermore, the study design (i.e. cross-sectional and internet-based) does not allow to understand the pattern of cannabis use or confirm cannabis blood levels (i.e. the influence of maternal side-effects and infant physiology).

Thank you for allowing me to review the manuscript and best wishes to the investigators in their future endeavors.

<u>Response:</u> Thank you.

We once again thank you for your time and feedback.

Kind regards, the authors

Cannabis health survey on usage in women with spinal cord injury and knowledge among physicians: A cross-sectional study Abstract **Objective:** Individuals with spinal cord injury (SCI) report using cannabis to self-manage chronic pain and spasticity. However, its safety and efficacy are not well understood. As more women with SCI are pursuing motherhood, clinicians must consider the possibility of maternal cannabis use and its impact on fetal development. Moreover, due to the lack of current evidence for cannabis, it is important to characterize the perceptions and knowledge of physicians towards both recreational and synthetic cannabinoids. **Design**: Two anonymous surveys (10-items each) were conducted. Setting and Participants: Women with SCI (n=20) completed an anonymous, online survey regarding cannabis use. Physicians at a Canadian SCI rehabilitation centre (n=15) completed a survey on their knowledge of recreational and synthetic cannabinoids among individuals with SCI. **Outcome measures:** Survey 1 evaluated cannabis use patterns and perceptions before/after SCI in women, including during pregnancy and breastfeeding. The aim of Survey 2 was to understand the perception and current knowledge of physicians regarding recreational cannabis and synthetic cannabinoid use by patients with SCI.

Results: At the time of survey, 7 women with SCI reported use of cannabis, only 4 of them used prior to injury. Managing tone/spasticity (n=5) was the major reported benefit of cannabis use. Women used cannabis during pregnancy and/or breastfeeding as a sleep aid or relief for morning sickness (n=1 pregnancy, n=1 breastfeeding, n=1 both). The most reported challenge with cannabis

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use was difficulty obtaining consistent, desirable effects (n=5). Almost all physicians (n=13)
described their knowledge on recreational cannabis products as "none, very little or poor", with
greater overall comfort and knowledge of synthetic cannabinoids.

Conclusion: Due to the reported use of cannabis during pregnancy/breastfeeding and current

29 impoverishment of physicians' knowledge (particularly regarding recreational cannabis products),

30 it is imperative to further investigate the safety and efficacy of cannabis use in women with SCI.

32 Keywords: spinal cord injury, cannabis, survey, women, physicians

Introduction

Negative sequelae such as chronic pain and spasticity are experienced in approximately 60% and 80% of Canadians with spinal cord injury (SCI), respectively.¹ These secondary conditions can detrimentally impact activities of daily living and health-related quality of life (HRQOL)¹, but current therapeutics have demonstrated limited efficacy.² Therefore, many individuals with SCI are open to exploring cannabis as an alternative therapy to improve HRQOL.^{3,4} However, despite the rise of cannabis use among the wider general Canadian population since its legalization⁵, its effects are poorly understood in the SCI population. Individuals with SCI have rated cannabis as the most effective pain medication, even above opioids, and with fewer adverse drug reactions.⁶ Cannabis was also described as effective in treating spasticity in this unique population.⁷ However, negative consequences of cannabis use include fatigue, confusion, impaired memory, and nausea, which have been reported among individuals with SCI⁸, and increased risk of psychosis in the general population.⁹

Since the majority of individuals who have sustained a traumatic SCI are men¹⁰, women with SCI are often understudied; however this represents a substantial population roughly estimated to be 715,000-850,000 worldwide.^{11,12} Furthermore, women with SCI face sex-specific health challenges, including concerns relating to pregnancy and breastfeeding.¹³ Pregnant women may use cannabis to ameliorate pregnancy-related symptoms such as mood changes, pain, nausea and/or vomiting (morning sickness).¹⁴ A recent study demonstrated increased medicinal and nonmedicinal cannabis use among pregnant women from 2002-2017, particularly in the first trimester, a sensitive period for developmental toxicity.¹⁵ Cannabis use during pregnancy has been reported to have negative impacts on offspring, including impaired cognitive function¹⁶, disrupted attention and visual-motor coordination, greater impulsivity¹⁷ and increased rates of: depression¹⁸, anemia,

57 low birth weight¹⁹ and preterm birth.²⁰ Nonetheless, the scarcity of literature precludes a clear 58 understanding of the patterns and modes of cannabis ingestion, as well as putative therapeutic 59 efficacy and adverse drug reactions among women with SCI. Consequently, it is exceedingly 60 difficult for physicians to manage patient care.

61 Therefore, we conducted a two-part cross-sectional study. For part 1, the aim was to 62 determine cannabis use patterns and perceptions before/after SCI in women, including during 63 pregnancy and breastfeeding. For part 2, the aim was to understand the perception and current 64 knowledge of physicians regarding recreational cannabis and synthetic cannabinoid use by patients 65 with SCI.

67 Methods

The two-part study was approved by the Behavioural Research Ethics Board of the University of British Columbia (H16-02495) and utilized a nonprobability purposive sampling design. Part 1 involved an online survey with a maximum of ten items over three pages, developed by our research team (Appendix A). The survey was distributed through email to women with SCI who had previously consented to being approached as prospective participants for future research studies. Primary outcomes of the survey included cannabis use patterns before and following SCI, and secondary outcomes included reasons for use, routes of administration, and perceived positive and negative outcomes of cannabis for three timepoints: 1) following SCI, 2) during pregnancy and 3) during breastfeeding. Data was collected from August to September of 2018. The email provided an external internet hyperlink to a secure website host that complies with the British Columbia (BC) Freedom of Information and Protection of Privacy Act (FOIPPA).²¹ The informed consent form was on a separate page, allowing women to express their wish to participate or exit

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80 the survey. Further information on the survey administration was provided in accordance with the 81 Checklist for Reporting Results of Internet E-Surveys (CHERRIES) (Appendix B). Basic 82 frequency descriptive statistics for each question comprised the planned statistical analyses, 83 including range as a measure of variability.

Part 2 included a ten-item hardcopy survey for physicians, which was also developed by our research team (Appendix C-D). Physicians working at a SCI rehabilitation centre in BC, were contacted by telephone calls and in-person recruitment. Survey distribution and collection occurred from September to October 2018. Primary outcome measures of the physician's survey included knowledge on therapeutic and adverse drug reactions of synthetic and recreational cannabis. Moreover, we also enquired about physicians' years of experience, volume of patients, comfort prescribing cannabis, and physicians' perceptions of reasons for use and areas requiring more research as secondary outcomes. Statistical analyses included frequency descriptive statistics, including range, as well as Spearman's rank-order correlations between total number of years of practice, total daily patients and total number of patients with SCI seen daily, and comfort prescribing medical cannabis, knowledge of cannabis benefits and knowledge of cannabis side effects.

Results

98 Part 1: Women with SCI cannabis use

Among the 59 women with SCI emailed for part 1, 21 women visited the link, and 20 completed the survey (one woman did not continue to the survey). Among the 20 women with SCI that started the survey, only seven completed the survey since 13 never used cannabis (Table 1). Notably, two women used cannabis, i.e. one during pregnancy, one during breastfeeding, and one during both.

Most current users reported using cannabis for both medicinal and recreational purposes (n=4), while some used cannabis only for either medicinal (n=2) or recreational (n=1) purpose. The most common route of cannabis administration included edible products (i.e. baked goods infused with cannabis) (n=5) followed by inhalation/smoke (n=4), oral use of oils (n=2), topical use of oils (n=1) and other unspecified means (n=1).

The most commonly reported benefits of cannabis use following SCI included a reduction of tone and spasticity, pain, and depression/anxiety, improved sleep, and decreased morning sickness (Table 2). The same results were also observed among the two women who used cannabis during pregnancy, and likewise with women during breastfeeding, excluding sleep aid. Perceived negative impacts included inconsistency of effects, the legality of obtaining cannabis, fatigue, and issues with mobility.

Part 2: Physician perceptions and knowledge of cannabis

Fifteen physicians were recruited for part 2. At the time of survey completion, this group had practiced for a mean of 14 years, with all but one physician having seen patients with SCI in their practice (Table 3). Most physicians strongly agreed that they felt comfortable prescribing synthetic cannabinoids (Figure 1) and rated their knowledge of its therapeutic and side effects as excellent (Figure 2). Physicians considered pain relief as the most common reason for medical cannabis use, followed by spasticity relief and appetite stimulation. The majority of physicians reported their knowledge across five recreational cannabis products as being "none, very little or poor", as shown in the distribution of physician knowledge of recreational cannabis products (Figure 3).

No significant Spearman's rank-order correlations were found between the number of total years of practice, total daily patients or total patients with SCI, and comfort or knowledge with

medicinal synthetic cannabinoid therapeutic benefits or side effects (Table 4). Physicians then indicated priority areas to address, that would help guide their practice regarding cannabis use. Physicians were able to indicate more than one topic due to the open-text entry format of the question. Priority areas indicated were: further research on compound composition (n=6), product quality (n=4), a comprehensive database of available products (n=3), side effect profiles (n=2), evidence of efficacy (n=1) and impaired driving (n=1) (multiple reasons permitted).

33 Discussion

This study provides preliminary insight on cannabis use in women with SCI from the perspective of patients and knowledge of recreational cannabis and synthetic cannabinoids among physicians. Of the 20 women originally surveyed, seven (35%) were using cannabis and two (10%) women with SCI used cannabis during both pregnancy and breastfeeding. Spasticity and pain management were the most common reasons for use. The most frequent challenges were inconsistent effects and issues acquiring cannabis legally, since retrospective responses likely reflected a prelegalization period. Physicians reported a high level of knowledge and comfort prescribing synthetic cannabinoids and the contrary for recreational cannabis products.

Demont-Heinrich *et al.* reported a more frequent use of cannabis use in the general population during pregnancy and breastfeeding in current cannabis users (i.e. 36% during their most recent pregnancy and 14% used while breastfeeding) compared to past users (5% during pregnancy and <1% while breastfeeding).¹⁴ With respect to the former study, our cohort of women with SCI had a percentage of cannabis use during pregnancy and breastfeeding somewhere in between. Consistent with the literature, women with SCI in our study reported perceived benefits of cannabis use such as management of pain, spasticity^{22,23}, depression and anxiety. These findings

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follow a recent study suggesting higher rates of postpartum depression and anxiety in mothers with SCI compared to the general maternal population.²⁴ Our study also reported cannabis useassociated fatigue which potentially could have a negative effect on cognitive function. This is especially concerning as SCI can significantly impair various cognitive domains including; executive function, memory, attention, language and visuospatial domains.^{4,25-27}

Women with SCI most commonly consumed edibles, contrary to two studies examining routes of administration across the general SCI population.^{28,29} Notably, edible products were consumed by all three individuals who used cannabis during pregnancy and/or breastfeeding. It is possible that edibles were utilized intentionally to avoid harms of smoking cannabis, such as carcinogen exposure and increased risk of cancers.^{30,31} However, we did not examine participant attitudes on different routes of administration or perceived impact on their infants. The high prevalence of edibles may account for the reported inconsistent effects; both retail and homemade edibles are poorly regulated and vary widely in cannabinoid concentrations.³² Ingestion of edibles can have a delayed onset of both initial (30-90 minutes) and peak subjective effects (2-4 hours), which complicates appropriate dosing.³³

Our sample of physicians reported a substantially greater level of knowledge of medicinal synthetic cannabinoids than similar surveys, potentially due to their focus on SCI care.³⁴⁻³⁶ However, up to 87% of physicians self-reported their knowledge of recreational cannabis products as limited. As individuals with SCI continue to explore alternative treatments to manage secondary conditions, the state of clinician knowledge on these now legal compounds seems alarmingly inadequate. This paucity of physician knowledge regarding recreational cannabis may be due to the myriad of such products available, the rapidly evolving nature of product development, the lack of transparency and regulation regarding composition, and the absence of a central Cannabis health survey on usage in women with spinal cord injury and knowledge among physicians: A cross-sectional study

172 recreational cannabis database. Clarity on THC:CBD ratios and compositional details in173 recreational cannabis products were identified as a clear area of need.

There are several limitations to our work which should be considered including the small sample size of this pilot study, from which definitive conclusions regarding patterns of cannabis use cannot be drawn. It has to be noted that women with SCI represent only about 20% of all individuals with SCI³⁷, so information is limited related to their health and wellness. Furthermore, the relatively high number of non-responders (i.e. almost two-thirds of women with SCI did not respond to the invitation), which could be due to stigmatization of cannabis use, especially during pregnancy and breastfeeding. Moreover, at the time when we invited women to answer the survey, there were still laws that criminalized cannabis use which could have been a reason to not fully disclose cannabis use (i.e. frequency, dose, and occasion). Furthermore, the study design (i.e. cross-sectional and internet-based) does not allow to understand the pattern of cannabis use or confirm cannabis blood levels (i.e. the influence of maternal side-effects and infant physiology). Moreover, participants were limited to Vancouver, which may yield greater rates of cannabis use than rural settings, due to varying attitudes or access.³⁸ Similarly, physicians who work in a major city may be more knowledgeable and comfortable with cannabinoid prescriptions due to greater exposure to patients using cannabis. The self-reported nature of survey data may furthermore affect the representation of knowledge among physicians on cannabis products.

190 Considering the aforementioned limitations of this study, future research may want to 191 consider utilizing an international, multi-center, qualitative study design in order to gain a greater 192 depth of knowledge into the population of interest, which is relatively small. Moreover, it would 193 be beneficial to conduct longitudinal studies on the impact of maternal cannabis use on pre- and 194 post-natal development with an emphasis on neurocognitive function. Emerging evidence has

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shown that cannabinoid exposure in utero or via lactation induces perturbations of brain circuitry that cause long-term disruption of cognition and increased psychiatric vulnerability.³⁹ Furthermore, infants of women with SCI are often born preterm⁴⁰⁻⁴², with low gestational length⁴² and birth weight.^{42,43} As cannabis use has been documented to exert similar effects, cannabis exposure during early development may exacerbate these issues in neonates.^{19,44} Different routes of administration, including edibles, should also be evaluated to better represent the effects of everyday cannabis use.

This study demonstrated for the first time that cannabis use occurs during pregnancy and breastfeeding among women with SCI, potentially at a greater frequency than the general population.¹⁴ Moreover, it revealed a need for more information on recreational cannabis products to guide patient care. It is advisable for physicians of patients with chronic conditions such as SCI to closely monitor for cannabis use during the reproductive period. We advocate for further education of clinicians and additional research regarding safety and efficacy of cannabis use in women with SCI and their impacts on offspring, to improve long-term intergenerational health outcomes.

1 2 3		Cannabis health survey on usage in women with spinal cord injury and knowledge among physicians: A cross-sectional study
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14 15	215	provided to the editorial office in a separate file, hence it will be displayed in the final version in
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19 20	217	Declaration of author(s)' competing interests
21 22 23	218	The authors do not report any conflict of interest.
24 25	219	Author contributions
26 27 28	220	All authors contributed to conception, study design, and surveys. Authors 1, 2, 3, and 5 analysed
29 30	221	the data. All authors interpreted the data. Authors 1 and 2 drafted the manuscript. Authors 3, 4, 5,
31 32	222	and 6 revised the manuscript. Authors 1 and 2 contributed equally (i.e. shared first author) and
33 34 35	223	authors 5 and 6 contributed equally (i.e. shared senior author).
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${}^{4}_{5}$ 224	FIGURE LEGENDS
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7 225 8	Figure 1 – Comfort prescribing synthetic cannabinoids among physicians.
9 10 226	Physicians generally reported comfort in prescribing synthetic cannabinoids to patients with SCI.
11 12 227 13	
$^{14}_{15}$ 228	Figure 2 – Knowledge of synthetic cannabinoids among physicians.
16 17 22 0	Develoises self reported having fair to excellent browledge of conthetic convolutionids within the
17 229 18	Physicians self-reported having fair to excellent knowledge of synthetic cannabinoids within the
¹⁹ ₂₀ 230	context of therapeutic cannabinoid use by patients with SCI.
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²⁴ 232 25	Figure 3 – Physician knowledge of recreational cannabis products.
26 27 28 233	Between 47-87% of physicians reported their knowledge across five recreational cannabis
29 234 30	products as being "none, very little or poor". Between 13-53% of physicians reported "fair, good
$^{31}_{32}$ 235	or excellent" knowledge. No physician reported "excellent" knowledge for any listed product.
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TABLES

Table 1

Frequency statistics of cannabis use

annabis use Frequency reported			
	Yes (n)	No (n)	
Lifetime use among women with SCI	7	13	
Pre-SCI use among users	4	3	
Current post-SCI use among users	7	0	
Use during pregnancy	2	5	
Use during breastfeeding	2	5	

SCI = spinal cord injury.

Table 2

Perceived impact	TS	Frequency reported (n)
Benefits		
	Tone and spasticity	5
	Pain management	3
	Depression/anxiety	2
	Sleep aid	2
	Morning sickness	1
Negative impacts		
	Inconsistent effects	5
	Illegal to obtain	4
	Fatigue	2
	Mobility	1

245 Perceived benefits and negative impacts of using cannabis after SCI

breastfeeding. Negative impacts specifically experienced during pregnancy and breastfeeding

50 were not inquired.

Table 3

253 Characterization of physician experience and practice

Mean ± SD	Range
14 ± 12	2 - 40
9 ± 4	4 - 20
5 ± 4	0 - 12
	9 ± 4

SCI = spinal cord injury, SD = standard deviation.

Table 4

Spearman's rank-order correlations between characteristics of physician practice and

comfort and knowledge of synthetic cannabinoids

Physician characteristics	Comfort	Knowledge of SC	Knowledge of SC
	prescribing SC	therapeutic effects	side effects
Total years practiced	$R_s = 0.1, P = 0.7$	$R_s = 0.5, P = 0.09$	$R_s = 0.5, P = 0.1$
Daily patients	$R_s = 0.2, P = 0.5$	$R_s = -0.1, \frac{P}{P} = 0.6$	$R_s = 0.001, \frac{P}{P} = 1.0$
Total SCI patients	$R_s = 0.5, \frac{P}{P} = 0.07$	$R_s = -0.5, P = 0.09$	$R_s = -0.3, \frac{P}{P} = 0.3$

SC = synthetic cannabinoids, SCI = spinal cord injury.

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Cannabis health survey on usage in women with spinal cord injury and knowledge among physicians: A cross-sectional study

1 Abstract

Objective: Individuals with spinal cord injury (SCI) report using cannabis to self-manage chronic pain and spasticity. However, its safety and efficacy are not well understood. As more women with SCI are pursuing motherhood, clinicians must consider the possibility of maternal cannabis use and its impact on fetal development. Moreover, due to the lack of current evidence for cannabis, it is important to characterize the perceptions and knowledge of physicians towards both recreational and synthetic cannabinoids.

Design: Two anonymous surveys (10-items each) were conducted.

Setting and Participants: Women with SCI (n=20) completed an anonymous, online survey regarding cannabis use. Physicians at a Canadian SCI rehabilitation centre (n=15) completed a survey on their knowledge of recreational and synthetic cannabinoids among individuals with SCI.

Outcome measures: Survey 1 evaluated cannabis use patterns and perceptions before/after SCI in women, including during pregnancy and breastfeeding. The aim of Survey 2 was to understand the perception and current knowledge of physicians regarding recreational cannabis and synthetic cannabinoid use by patients with SCI.

Results: At the time of survey, 7 women with SCI reported use of cannabis, only 4 of them used
prior to injury. Managing tone/spasticity (n=5) was the major reported benefit of cannabis use.
Women used cannabis during pregnancy and/or breastfeeding as a sleep aid or relief for morning
sickness (n=1 pregnancy, n=1 breastfeeding, n=1 both). The most reported challenge with cannabis

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use was difficulty obtaining consistent, desirable effects (n=5). Almost all physicians (n=13)
described their knowledge on recreational cannabis products as "none, very little or poor", with
greater overall comfort and knowledge of synthetic cannabinoids.

Conclusion: Due to the reported use of cannabis during pregnancy/breastfeeding and current

29 impoverishment of physicians' knowledge (particularly regarding recreational cannabis products),

30 it is imperative to further investigate the safety and efficacy of cannabis use in women with SCI.

32 Keywords: spinal cord injury, cannabis, survey, women, physicians

Introduction

Negative sequelae such as chronic pain and spasticity are experienced in approximately 60% and 80% of Canadians with spinal cord injury (SCI), respectively.¹ These secondary conditions can detrimentally impact activities of daily living and health-related quality of life (HRQOL)¹, but current therapeutics have demonstrated limited efficacy.² Therefore, many individuals with SCI are open to exploring cannabis as an alternative therapy to improve HRQOL.^{3,4} However, despite the rise of cannabis use among the wider general Canadian population since its legalization⁵, its effects are poorly understood in the SCI population. Individuals with SCI have rated cannabis as the most effective pain medication, even above opioids, and with fewer adverse drug reactions.⁶ Cannabis was also described as effective in treating spasticity in this unique population.⁷ However, negative consequences of cannabis use include fatigue, confusion, impaired memory, and nausea, which have been reported among individuals with SCI⁸, and increased risk of psychosis in the general population.⁹

Since the majority of individuals who have sustained a traumatic SCI are men¹⁰, women with SCI are often understudied; however this represents a substantial population roughly estimated to be 715,000-850,000 worldwide.^{11,12} Furthermore, women with SCI face sex-specific health challenges, including concerns relating to pregnancy and breastfeeding.¹³ Pregnant women may use cannabis to ameliorate pregnancy-related symptoms such as mood changes, pain, nausea and/or vomiting (morning sickness).¹⁴ A recent study demonstrated increased medicinal and nonmedicinal cannabis use among pregnant women from 2002-2017, particularly in the first trimester, a sensitive period for developmental toxicity.¹⁵ Cannabis use during pregnancy has been reported to have negative impacts on offspring, including impaired cognitive function¹⁶, disrupted attention and visual-motor coordination, greater impulsivity¹⁷ and increased rates of: depression¹⁸, anemia,

57 low birth weight¹⁹ and preterm birth.²⁰ Nonetheless, the scarcity of literature precludes a clear 58 understanding of the patterns and modes of cannabis ingestion, as well as putative therapeutic 59 efficacy and adverse drug reactions among women with SCI. Consequently, it is exceedingly 60 difficult for physicians to manage patient care.

61 Therefore, we conducted a two-part cross-sectional study. For part 1, the aim was to 62 determine cannabis use patterns and perceptions before/after SCI in women, including during 63 pregnancy and breastfeeding. For part 2, the aim was to understand the perception and current 64 knowledge of physicians regarding recreational cannabis and synthetic cannabinoid use by patients 65 with SCI.

67 Methods

The two-part study was approved by the Behavioural Research Ethics Board of the University of British Columbia (H16-02495) and utilized a nonprobability purposive sampling design. Part 1 involved an online survey with a maximum of ten items over three pages, developed by our research team (Appendix A). The survey was distributed through email to women with SCI who had previously consented to being approached as prospective participants for future research studies. Primary outcomes of the survey included cannabis use patterns before and following SCI, and secondary outcomes included reasons for use, routes of administration, and perceived positive and negative outcomes of cannabis for three timepoints: 1) following SCI, 2) during pregnancy and 3) during breastfeeding. Data was collected from August to September of 2018. The email provided an external internet hyperlink to a secure website host that complies with the British Columbia (BC) Freedom of Information and Protection of Privacy Act (FOIPPA).²¹ The informed consent form was on a separate page, allowing women to express their wish to participate or exit

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80 the survey. Further information on the survey administration was provided in accordance with the 81 Checklist for Reporting Results of Internet E-Surveys (CHERRIES) (Appendix B). Basic 82 frequency descriptive statistics for each question comprised the planned statistical analyses, 83 including range as a measure of variability.

Part 2 included a ten-item hardcopy survey for physicians, which was also developed by our research team (Appendix C-D). Physicians working at a SCI rehabilitation centre in BC, were contacted by telephone calls and in-person recruitment. Survey distribution and collection occurred from September to October 2018. Primary outcome measures of the physician's survey included knowledge on therapeutic and adverse drug reactions of synthetic and recreational cannabis. Moreover, we also enquired about physicians' years of experience, volume of patients, comfort prescribing cannabis, and physicians' perceptions of reasons for use and areas requiring more research as secondary outcomes. Statistical analyses included frequency descriptive statistics, including range, as well as Spearman's rank-order correlations between total number of years of practice, total daily patients and total number of patients with SCI seen daily, and comfort prescribing medical cannabis, knowledge of cannabis benefits and knowledge of cannabis side effects.

Results

98 Part 1: Women with SCI cannabis use

Among the 59 women with SCI emailed for part 1, 21 women visited the link, and 20 completed the survey (one woman did not continue to the survey). Among the 20 women with SCI that started the survey, only seven completed the survey since 13 never used cannabis (Table 1). Notably, two women used cannabis, i.e. one during pregnancy, one during breastfeeding, and one during both.

Most current users reported using cannabis for both medicinal and recreational purposes (n=4), while some used cannabis only for either medicinal (n=2) or recreational (n=1) purpose. The most common route of cannabis administration included edible products (i.e. baked goods infused with cannabis) (n=5) followed by inhalation/smoke (n=4), oral use of oils (n=2), topical use of oils (n=1) and other unspecified means (n=1).

The most commonly reported benefits of cannabis use following SCI included a reduction of tone and spasticity, pain, and depression/anxiety, improved sleep, and decreased morning sickness (Table 2). The same results were also observed among the two women who used cannabis during pregnancy, and likewise with women during breastfeeding, excluding sleep aid. Perceived negative impacts included inconsistency of effects, the legality of obtaining cannabis, fatigue, and issues with mobility.

Part 2: Physician perceptions and knowledge of cannabis

Fifteen physicians were recruited for part 2. At the time of survey completion, this group had practiced for a mean of 14 years, with all but one physician having seen patients with SCI in their practice (Table 3). Most physicians strongly agreed that they felt comfortable prescribing synthetic cannabinoids (Figure 1) and rated their knowledge of its therapeutic and side effects as excellent (Figure 2). Physicians considered pain relief as the most common reason for medical cannabis use, followed by spasticity relief and appetite stimulation. The majority of physicians reported their knowledge across five recreational cannabis products as being "none, very little or poor", as shown in the distribution of physician knowledge of recreational cannabis products (Figure 3).

No significant Spearman's rank-order correlations were found between the number of total years of practice, total daily patients or total patients with SCI, and comfort or knowledge with

medicinal synthetic cannabinoid therapeutic benefits or side effects (Table 4). Physicians then indicated priority areas to address, that would help guide their practice regarding cannabis use. Physicians were able to indicate more than one topic due to the open-text entry format of the question. Priority areas indicated were: further research on compound composition (n=6), product quality (n=4), a comprehensive database of available products (n=3), side effect profiles (n=2), evidence of efficacy (n=1) and impaired driving (n=1) (multiple reasons permitted).

33 Discussion

This study provides preliminary insight on cannabis use in women with SCI from the perspective of patients and knowledge of recreational cannabis and synthetic cannabinoids among physicians. Of the 20 women originally surveyed, seven (35%) were using cannabis and two (10%) women with SCI used cannabis during both pregnancy and breastfeeding. Spasticity and pain management were the most common reasons for use. The most frequent challenges were inconsistent effects and issues acquiring cannabis legally, since retrospective responses likely reflected a prelegalization period. Physicians reported a high level of knowledge and comfort prescribing synthetic cannabinoids and the contrary for recreational cannabis products.

Demont-Heinrich *et al.* reported a more frequent use of cannabis use in the general population during pregnancy and breastfeeding in current cannabis users (i.e. 36% during their most recent pregnancy and 14% used while breastfeeding) compared to past users (5% during pregnancy and <1% while breastfeeding).¹⁴ With respect to the former study, our cohort of women with SCI had a percentage of cannabis use during pregnancy and breastfeeding somewhere in between. Consistent with the literature, women with SCI in our study reported perceived benefits of cannabis use such as management of pain, spasticity^{22,23}, depression and anxiety. These findings

follow a recent study suggesting higher rates of postpartum depression and anxiety in mothers with SCI compared to the general maternal population.²⁴ Our study also reported cannabis useassociated fatigue which potentially could have a negative effect on cognitive function. This is especially concerning as SCI can significantly impair various cognitive domains including; executive function, memory, attention, language and visuospatial domains.^{4,25-27}

Women with SCI most commonly consumed edibles, contrary to two studies examining routes of administration across the general SCI population.^{28,29} Notably, edible products were consumed by all three individuals who used cannabis during pregnancy and/or breastfeeding. It is possible that edibles were utilized intentionally to avoid harms of smoking cannabis, such as carcinogen exposure and increased risk of cancers.^{30,31} However, we did not examine participant attitudes on different routes of administration or perceived impact on their infants. The high prevalence of edibles may account for the reported inconsistent effects; both retail and homemade edibles are poorly regulated and vary widely in cannabinoid concentrations.³² Ingestion of edibles can have a delayed onset of both initial (30-90 minutes) and peak subjective effects (2-4 hours), which complicates appropriate dosing.³³

Our sample of physicians reported a substantially greater level of knowledge of medicinal synthetic cannabinoids than similar surveys, potentially due to their focus on SCI care.³⁴⁻³⁶ However, up to 87% of physicians self-reported their knowledge of recreational cannabis products as limited. As individuals with SCI continue to explore alternative treatments to manage secondary conditions, the state of clinician knowledge on these now legal compounds seems alarmingly inadequate. This paucity of physician knowledge regarding recreational cannabis may be due to the myriad of such products available, the rapidly evolving nature of product development, the lack of transparency and regulation regarding composition, and the absence of a central recreational cannabis database. Clarity on THC:CBD ratios and compositional details in
recreational cannabis products were identified as a clear area of need.

There are several limitations to our work which should be considered including the small sample size of this pilot study, from which definitive conclusions regarding patterns of cannabis use cannot be drawn. It has to be noted that women with SCI represent only about 20% of all individuals with SCI³⁷, so information is limited related to their health and wellness. Furthermore, the relatively high number of non-responders (i.e. almost two-thirds of women with SCI did not respond to the invitation), which could be due to stigmatization of cannabis use, especially during pregnancy and breastfeeding. Moreover, at the time when we invited women to answer the survey, there were still laws that criminalized cannabis use which could have been a reason to not fully disclose cannabis use (i.e. frequency, dose, and occasion). Furthermore, the study design (i.e. cross-sectional and internet-based) does not allow to understand the pattern of cannabis use or confirm cannabis blood levels (i.e. the influence of maternal side-effects and infant physiology). Moreover, participants were limited to Vancouver, which may yield greater rates of cannabis use than rural settings, due to varying attitudes or access.³⁸ Similarly, physicians who work in a major city may be more knowledgeable and comfortable with cannabinoid prescriptions due to greater exposure to patients using cannabis. The self-reported nature of survey data may furthermore affect the representation of knowledge among physicians on cannabis products.

190 Considering the aforementioned limitations of this study, future research may want to 191 consider utilizing an international, multi-center, qualitative study design in order to gain a greater 192 depth of knowledge into the population of interest, which is relatively small. Moreover, it would 193 be beneficial to conduct longitudinal studies on the impact of maternal cannabis use on pre- and 194 post-natal development with an emphasis on neurocognitive function. Emerging evidence has

shown that cannabinoid exposure in utero or via lactation induces perturbations of brain circuitry that cause long-term disruption of cognition and increased psychiatric vulnerability.³⁹ Furthermore, infants of women with SCI are often born preterm⁴⁰⁻⁴², with low gestational length⁴² and birth weight.^{42,43} As cannabis use has been documented to exert similar effects, cannabis exposure during early development may exacerbate these issues in neonates.^{19,44} Different routes of administration, including edibles, should also be evaluated to better represent the effects of everyday cannabis use.

This study demonstrated for the first time that cannabis use occurs during pregnancy and breastfeeding among women with SCI, potentially at a greater frequency than the general population.¹⁴ Moreover, it revealed a need for more information on recreational cannabis products to guide patient care. It is advisable for physicians of patients with chronic conditions such as SCI to closely monitor for cannabis use during the reproductive period. We advocate for further education of clinicians and additional research regarding safety and efficacy of cannabis use in women with SCI and their impacts on offspring, to improve long-term intergenerational health outcomes.

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We have removed all information to avoid identification. However, all information has been provided to the editorial office in a separate file, hence it will be displayed in the final version in

16 case this manuscript will be accepted for publication.

217 Declaration of author(s)' competing interests

18 The authors do not report any conflict of interest.

219 Author contributions

All authors contributed to conception, study design, and surveys. Authors 1, 2, 3, and 5 analysed

the data. All authors interpreted the data. Authors 1 and 2 drafted the manuscript. Authors 3, 4, 5,

and 6 revised the manuscript. Authors 1 and 2 contributed equally (i.e. shared first author) and

authors 5 and 6 contributed equally (i.e. shared senior author).

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FIGURE LEGENDS

Figure 1 – Comfort prescribing synthetic cannabinoids among physicians.

Physicians generally reported comfort in prescribing synthetic cannabinoids to patients with SCI.

Figure 2 – Knowledge of synthetic cannabinoids among physicians.

Physicians self-reported having fair to excellent knowledge of synthetic cannabinoids within the

context of therapeutic cannabinoid use by patients with SCI.

Figure 3 – Physician knowledge of recreational cannabis products.

Between 47-87% of physicians reported their knowledge across five recreational cannabis products as being "none, very little or poor". Between 13-53% of physicians reported "fair, good or excellent" knowledge. No physician reported "excellent" knowledge for any listed product.

TABLES

Table 1

Frequency statistics of cannabis use

Cannabis use	Frequency rep	Frequency reported		
	Yes (n)	No (n)		
Lifetime use among women with SCI	7	13		
Pre-SCI use among users	4	3		
Current post-SCI use among users	7	0		
Use during pregnancy	2	5		
Use during breastfeeding	2	5		

SCI = spinal cord injury.

Table 2

2 3

5 6

8

Perceived impact	ts	Frequency reported (n)
Benefits		
	Tone and spasticity	5
	Pain management	3
	Depression/anxiety	2
	Sleep aid	2
	Morning sickness	1
Negative impacts		
	Inconsistent effects	5
	Illegal to obtain	4
	Fatigue	2
	Mobility	1

Perceived benefits and negative impacts of using cannabis after SCI

breastfeeding. Negative impacts specifically experienced during pregnancy and breastfeeding were not inquired.

Table 3

253 Characterization of physician experience and practice

Mean ± SD	Range
14 ± 12	2 - 40
9 ± 4	4 - 20
5 ± 4	0 - 12
	14 ± 12 9 ± 4

SCI = spinal cord injury, SD = standard deviation.

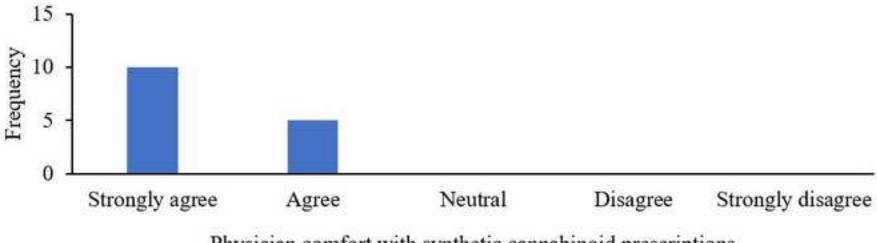
Table 4

Spearman's rank-order correlations between characteristics of physician practice and

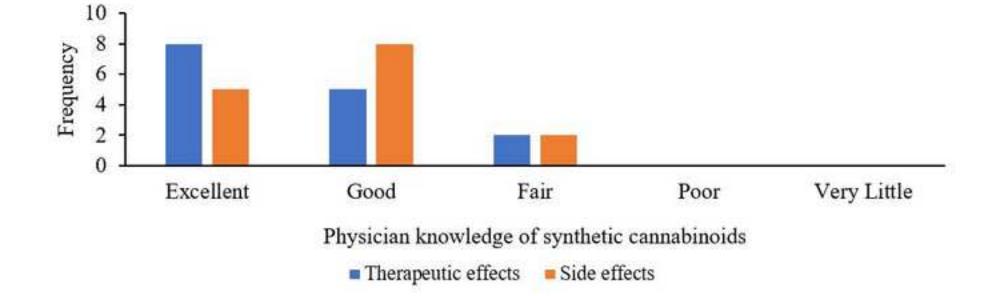
comfort and knowledge of synthetic cannabinoids

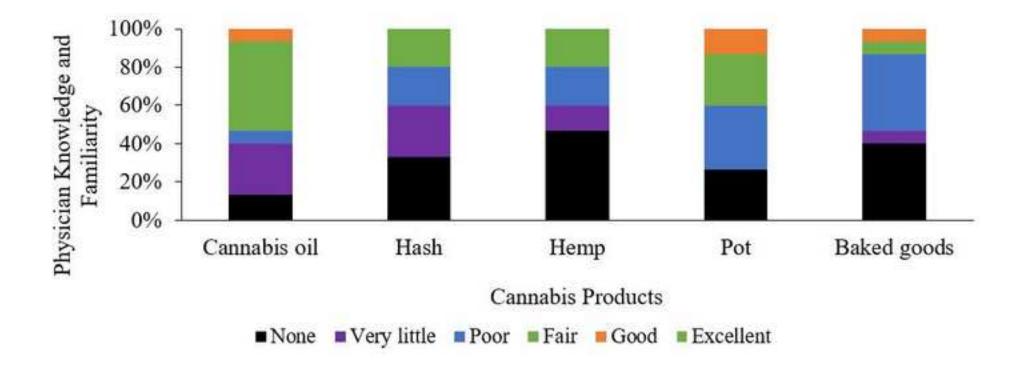
Physician characteristics	Comfort	Knowledge of SC	Knowledge of SC
	prescribing SC	therapeutic effects	side effects
Total years practiced	$R_s = 0.1, P = 0.7$	$R_s = 0.5, P = 0.09$	$R_s = 0.5, P = 0.1$
Daily patients	$R_s = 0.2, P = 0.5$	$R_s = -0.1, P = 0.6$	$R_s = 0.001, P = 1.0$
Total SCI patients	$R_s = 0.5, P = 0.07$	$R_s = -0.5, P = 0.09$	$R_s = -0.3, P = 0.3$

SC = synthetic cannabinoids, SCI = spinal cord injury.



Physician comfort with synthetic cannabinoid prescriptions





call re Ethics and QI study ..

Valente, Maria <maria.valente@ors.ubc.ca> To: "Krassioukov, Andrei (vch.ca)" <Andrei.Krassioukov@vch.ca> Cc: "amandalee92@gmail.com" <amandalee92@gmail.com> Wed, Jun 16, 2021 at 12:29 PM

Hi Dr. Krassioukov,

It was nice speaking to you today. Below is the information I promised I would send. Please let me know if you have any questions.

According to the Tri Council Policy Statement (TCPS2, Article 2.5), the overarching Canadian framework for research ethics, "Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review." This is because a clear distinction is made between such activities and research, which is defined by the TCPS2 as: "an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation".

Therefore, it is the intent of the activity that determines whether it meets the definition of research requiring review rather than its nature (in other words conducting an interview, for example, doesn't mean that institutional ethics approval is automatically required - it depends on why the interview is being conducted). For this reason, at UBC the potential publication of findings is not the litmus test for whether institutional ethics review is required - it is the intent of the activity, not its outcomes, that is the deciding factor.

For further information, please see the following link to our program evaluation/QA/QI vs. research checklist: https://ethics.research.ubc.ca/sites/ore.ubc.ca/files/documents/BREB_ChecklistForResearchRequiringE thicsReview.pdf

Importantly, if your activity involves none of the listed elements, it is very important that you do not frame it as 'research' to participants in the program or when you report on the outcomes of your evaluation as this sets up expectations about institutional ethics review. Lastly, if publication should come out of a QA/QI project and a journal asks whether or not you received institutional research ethics review, you would answer "no" to that question and in the comments box state that "According to Article 2.5 of TCPS2, Canadian policy framework governing research ethics, QA/QI activities do not require institutional research ethics review." It is your responsibility to be comfortable with the TCPS2 article and explaining it to anyone who asks why your project did not get institutional review.

Thanks, Maria

Maria Valente, M.A. Research Ethics Review Coordinator-Behavioural UBC Office of Research Ethics The University of British Columbia | Vancouver Campus | Musqueam Traditional Territory 102-6190 Agronomy Road | Vancouver BC | V6T 1Z3 Canada Phone 604 827 5112 Email maria.valente@ors.ubc.ca https://ethics.research.ubc.ca/ List and description of supplementary files [mandatory when a paper includes supplementary material]

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