Systematic Review of Mixed Studies: Protocol

Cannabis User and Healthcare Provider perspectives on the use of cannabis during pregnancy and lactation.

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We are conducting two paired systematic reviews of mixed methods research, using a convergent integrated approach to synthesis and integration and following the Joanna Briggs Institute guidance for conducting and reporting this type of review.[1, 2]

1)A systematic review of primary empirical studies that describe the perspectives of pregnant and lactating people who have experience with cannabis use on their experiences, beliefs, and information needs related to cannabis use during pregnancy and while breastfeeding.

2) A systematic review of primary empirical studies that describe the perspectives of prenatal care providers on counselling and screening for cannabis use during pregnancy and lactation.

Rationale: This review of the literature will act as a starting place to understand the range of experiences, beliefs, and social contexts of women who consider using cannabis during pregnancy and breastfeeding. We will also examine the perspectives of prenatal health care providers asked to counsel about this issue. Findings from this study will contribute valuable information towards the scoping and design of data collection for future primary studies and will help situate the findings from these studies within the socio-historical context of legalized recreational cannabis. Our clinical experiences demonstrate that the experiences and beliefs of women who use cannabis during pregnancy and breastfeeding are very diverse. We are particularly interested in understanding the experiences of poly-substance users, who may choose to use cannabis to reduce or cease use of other substances. Accordingly, our review will include studies of women who use multiple substances, not only those who use cannabis in isolation. This is in contrast to a recent review of literature in this area.[3]

Research Questions for Systematic Review 1 (Pregnant People & Partners):
1. **What are the experiences, beliefs, and opinions of pregnant people and their partners who consider using cannabis during pregnancy and lactation?**
2. **What role do pregnant people and their partners desire their prenatal care provider to have in the decision-making process about the use of cannabis during pregnancy and lactation?**

Analysis will be sensitive to people's experiences <u>discussing</u> cannabis use during pregnancy with health care providers, elicit women's <u>self-identified information needs</u>, and <u>motivations to use</u> or cease using cannabis during pregnancy.

Research Questions for Systematic Review 2 (Prenatal Health Care Providers):
1. **What are the perspectives (experiences, beliefs, opinions) of prenatal care providers about cannabis use during pregnancy and lactation?**
2. **How do prenatal care providers understand their role regarding screening for and counselling about cannabis use during pregnancy and lactation?**

Analysis will be sensitive to HCP's experiences of <u>discussing</u> cannabis use during pregnancy and breastfeeding with their patients, and <u>any identification of needs from the HCP perspective</u>, as

well as their <u>perceptions of people's motivations to use</u> or cease using cannabis during pregnancy and breastfeeding.

Methods and Methodology:
This integrative review will not impose eligibility limits on study approach or methodology, time, country, or confluence with other substance use. Eligible articles will be peer-reviewed publications and theses in English that use any design to investigate the perspectives of pregnant people and their partners about cannabis use in pregnancy or during breastfeeding OR healthcare professional perspectives regarding counselling pregnant and breastfeeding people about cannabis use. We will consider pregnancy and breastfeeding to be two distinct periods of time. We will not limit the search by year or by country. We will use constant comparative analysis to examine the differences between results from studies conducted in jurisdictions where cannabis use is legal or depenalized for recreational or medical purposes, and places where it is illegal.[4] We will also use this technique to consider the change in the nature of cannabis overtime, with the understanding that contemporary consideration of cannabis includes the availability of many different types of products, and that THC concentrations may be higher in cannabis now than in the past.

Search Strategy: In partnership with an information scientist (Caroline Higgins), we designed a systematic search strategy guided by the aforementioned research questions. This search strategy was peer reviewed according to the PRESS guideline.[5] It is included as Appendix 1 to this protocol.

A search for published literature was performed by a medical librarian on April 01-02, 2020 using the following databases: MEDLINE (via Ovid), APA PsycINFO (via Ovid), Cumulative Index to Nursing and Allied Health Literature (CINAHL, via EBSCOhost), Social Science Citation Index (SSCI, via Web of Science) Social Work Abstracts (via EBSCOhost), ProQuest Sociology Collection (including Sociological Abstracts).

The search strategy comprised both controlled vocabulary (e.g., Medical Subject Headings), and keywords and was peer-reviewed according to the PRESS checklist (Peer Review of Electronic Search Strategies)[1]. The search was limited to English language publications; however, no date limits and no study design filters were applied. For more details on the search strategies used, please see appendix. The search retrieved 3,569 papers after duplicates were removed.

Further to the systematic search, we conducted a handsearch of the following relevant journals, from their most recent issue to their first published issue: *Journal of Human Lactation, Breastfeeding Medicine, Journal of Obstetrics and Gynecology of Canada, Cannabis and Cannabinoids Research, Journal of Cannabis Research, Medical Cannabis & Cannabinoids, Journal of Cannabis Therapeutics, Neuropsychopharmacology, and Pharmacology & Therapeutics.*

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[1] McGowan J, Sampson M, Salzwedel DM, Cogo E, Foerster V, Lefebvre C. PRESS peer review of electronic search strategies: 2015 guideline statement. J Clin Epidemiol. 2016;75:40-6.

After identifying eligible articles, we will search through the reference lists of those articles to identify other included articles. Using Google Scholar, we will search to see who has cited each of our included articles and seek to identify additional included articles this way.

After determining our final list of included articles, we will engage 2 topic experts to review the list and suggest additional publications they are aware of which we may have missed.

Grey literature search will be confined to theses, searched through the ProQuest Dissertation Abstracts database.

Screening and selecting studies for inclusion: Two reviewers will independently screen the titles and abstracts of all citations retrieved from the literature search based on the eligibility criteria. Full text will be reviewed when necessary. Discrepancies between the two reviewers will be resolved through discussion with a third reviewer until consensus is reached.

General Category	Specific Category for This Project
Disease or Condition	Pregnancy, lactation
Sub-Category of Disease Population	N/A
Relevant Perspectives	Pregnant or lactating people, their partners; prenatal health care professionals
Age	No limit
Gender	Pregnant people will have a biological sex of female, but we are not limiting by gender identity. Partners and health care professionals may be of any gender.
Country	No limits
Language	English
Publication status	Peer-Reviewed publications or successfully defended theses.
Dates	No limits

Critical Appraisal
We will conduct critical appraisal using the MMAT, a mixed-methods appraisal tool for systematic mixed studies reviews.[6] Each study will be appraised by two reviewers who will determine a final score for each article by consensus. The final score is derived by dividing the number of criteria met by the total number of criteria for the methodology used by that study. All eligible studies will be included, as long as they present data in evidence of their conclusions.[7, 8] Per integrative review methodology, the appraisal score will be considered in the data analysis stage, and reports of low rigour and relevant will contribute less to the analytic process.[9]

Data collection and extraction: Data collection will involve extracting two types of data from each included study: 1) study characteristics and 2) study results relevant to the research question.

1) Study Characteristics

a) From each eligible article about pregnant people's perspectives, descriptive data about features of the study will be extracted into a standardized electronic form. This will include information about study objectives, participant characteristics, study design and methodology, date of publication, funding for study (if applicable), nation in which the study was conducted and legality of medical and recreational cannabis in the nation. Specific information about participant characteristics collected will include: experience with pregnancy (e.g. currently pregnant) and substances studied (e.g. cannabis, alcohol, tobacco, etc.). We will also record demographic information when the author identifies the participants as belonging to a socially marginalized group (e.g., by virtue of race or ethnicity, income level, immigration status, rural or remote location).

b) For each eligible article about prenatal care provider perspectives, descriptive data about features of the study will be extracted into a standardized electronic form. This will include information about study objectives, participant characteristics, study design and methodology, date of publication, funding for study (if applicable), nation in which the study was conducted and legality of medical and recreational cannabis in the nation. Specific information about participant characteristics collected will include: type of prenatal care provider (e.g. nurse, gynecologists, midwife, other) and substances being commented on (e.g. alcohol, cannabis, tobacco).

2) Study results of the study relevant to the research question will be extracted by one reviewer and verified by a second. As described by Sandelowski and colleagues, the "extraction of findings in mixed-methods research synthesis studies is a highly interpretive process where reviewers must define what information in a report will constitute a finding and resolve issues related to content (what a finding says), context (what information in a report is most relevant to understanding a finding) and form (how a finding-in-context is to be expressed." (p. 1429).[10]

In the case of qualitative studies or the qualitative portion of mixed methods studies, findings are the main source of information for our analysis. Qualitative findings are "data-driven and integrated discoveries, judgments, and/or pronouncements researchers offer about the phenomena, events, or cases under investigation."[11] This data will be managed with N-Vivo 12. In the case of quantitative studies or the quantitative portion of mixed methods studies, findings are "data-based outcomes of the various descriptive and inferential statistical tests applied in answer to research questions and/or to support or refute hypotheses".[10] For the purposes of this review, quantitative data will be "qualitized" following the procedures described by Sandelowski and colleagues.[2]

Sandelowski's method of "qualitizing" quantitative data involves identifying and extracting findings and transforming each finding into a portable declarative sentence that are understandable on their own. These declarative sentences are constructed in a way that integrates findings with information about the study deemed most relevant to characterizing those findings. To do this, methods talk that might interfere with reader comprehension is removed.

Example (from Sandelowski): Instead of the statement that CES-D scores were significantly negatively correlated with FACES scores, a re-statement might read: Among mothers of children with cystic fibrosis, there was a statistically significant negative correlation between maternal depression and family functioning, such that the more depressed the mother the less adaptable and cohesive the family. Instead of the statement that there were three themes that emerged in the data, a restatement might read: Mothers' initial reactions to their child's diagnosis of cystic fibrosis included shock followed closely by fear and/or relief.

These declarative sentences are recorded on a data extraction sheet for the individual study, so they may be analysed with reference to the methodological context of the report.

Data Analysis: A descriptive analysis of study characteristics will be conducted and reported in tabular form. Typically, this includes the number and type of participants, information about study design and methodology and distribution of studies by national context. The purpose of this analysis is to describe the set of included studies and understand the range of study designs and methods that will inform the resultant synthesis.

As described by Whittemore and Knafl, strategies for data analysis are one of the least developed aspects of the process, potentially because they must be attuned to the particular range of data available in each individual review.[9] To overcome this challenge, we have adopted methods from qualitative meta-synthesis for the synthesis of the declarative statements generated from each study. The Joanna Briggs Institute refers to this process as "qualitizing" data; or extracting data and translating it into a textual description to allow integration with qualitative data.[2] Findings from all studies will be analysed concurrently, following the convergent integrated approach in Hong's (2017) typology. [1]

Qualitative research will be analyzed using techniques of integrative qualitative meta-synthesis,[7, 12, 13] also known as qualitative research integration. The objective of qualitative meta-synthesis is twofold: first, the aggregate of a result reflects the range of findings across studies while retaining the original meaning; second, by comparing and contrasting findings across studies, a new integrative interpretation is produced. The goal of qualitative meta-synthesis is to produce a report which produces succinct findings that accurately reflect both the aggregated results but also the interpretive depth of the component studies, providing the reader a sense of the complexity and richness of the original work.[7] Analysts will use a staged comparative coding strategy adapted from Grounded Theory.[14] This approach involves the comparison of research findings across primary included studies, categories, and co-investigators' interpretations of the studies. In this comparative analysis we will pay particular attention to the identified experience with cannabis (e.g. medical user, poly-substance user, initiated use to control nausea and vomiting). All analytic interpretations are negotiated during regular meetings with the whole research team.

Appendix 1:

Database Literature Search Overview

Dates of search: April 01-02, 2020

Databases searched: MEDLINE (1946 to March 31, 2020) via Ovid

APA PsycINFO (1806 to March Week 4 2020) via Ovid

CINAHL (1981 – April 01, 2020) via EBSCOhost

Social Science Citation Index ((1976 – April 02, 2020) via Web of Science

Social Work Abstracts (1965 - April 02, 2020) via EBSCOhost

ProQuest Sociology Collection:

- Applied Social Science Index & Abstracts (ASSIA, 1987-present)
- Social Services Abstracts (1979 – present)
- Sociological Abstracts (1952 – present)
- Sociology Database (1985 -present)

Limits: English language publications.

Database Search Strategies

Databases: APA PsycInfo <1806 to March Week 4 2020>, Ovid MEDLINE(R) and Epub Ahead of Print, In-Process & Other Non-Indexed Citations, Daily and Versions(R) <1946 to March 31, 2020>

1   Pregnant Women/ (8045)

2   exp Pregnancy/ (926143)

3   exp Prenatal Care/ (29146)

4   exp Perinatal Care/ (9884)

5   exp Pregnancy Complications/ (421074)

6   (pregnant* or pregnanc* or prenatal* or perinatal* or antenatal* or periconcept* or interconcept* or peripart* or antepart* or expect* mother*).ti,ab,kf. (690274)

7   Postpartum Period/ (25055)

8   (postpartum* or postnatal* or puerperium*).ti,ab,kf. (193701)

9   Lactation/ (43271)

10   exp Breast Feeding/ (40650)

11   Bottle Feeding/ (4029)

12   Milk, Human/ (19002)

13   (breastfeed* or ((breast or bottle) adj2 feed*) or lactati* or ((human or breast or maternal) adj2 milk)).ti,ab,kf. (109973)

14   or/1-13 (1317245)

15   Cannabis/ (14392)

16   exp "Marijuana Use"/ (5363)

17   Marijuana Abuse/ (6195)

18   Medical Marijuana/ (1135)

19   exp Cannabinoids/ (19232)

20   (THC or tetrahydrocannabi* or cannabi* or CBD or marijuana* or hash or hashish* or hemp or weed or marihuana or dagga or ganja or edibles).ti,ab,kf. (85448)

21   or/15-20 (89540)

22   14 and 21 (3450)

23   22 use ppezv (2472)

24   exp Animals/ not Humans/ (5032056)

25   23 not 24 (1971)

26   limit 25 to english language (1862)

27   exp pregnancy/ (926143)

28   prenatal care/ (28922)

29   perinatal period/ (2762)

30   antepartum period/ (171)

31   intrapartum period/ (8)

32   (pregnant* or pregnanc* or prenatal* or perinatal* or antenatal* or periconcept* or interconcept* or peripart* or antepart* or expect* mother*).ti,ab,id. (672539)

33   postnatal period/ (4534)

34   (postpartum* or postnatal* or puerperium*).ti,ab,id. (191562)

35   Lactation/ (43271)

36   breast feeding/ (40517)

37   (breastfeed* or ((breast or bottle) adj2 feed*) or lactati* or ((human or breast or maternal) adj2 milk)).ti,ab,id. (108229)

38   or/27-37 (1290796)

39   exp cannabis/ (17180)

40   "cannabis use disorder"/ (423)

41   marijuana usage/ (2828)

42   exp cannabinoids/ (19232)

43   (THC or tetrahydrocannabi* or cannabi* or CBD or marijuana* or hash or hashish* or hemp or weed or marihuana or dagga or ganja or edibles).ti,ab,id. (85022)

44   or/39-43 (88285)

45   38 and 44 (3359)

46   45 use psyh (997)

47   (animal not human).po. (358440)

48   46 not 47 (746)

49   limit 48 to english language (704)

50   26 or 49 (2566)

51   remove duplicates from 50 (2076)

Database: CINAHL

S1   (MH "Expectant Mothers") (8034)

S2   (MH "Pregnancy+") (217126)

S3   (MH "Prenatal Care") (17398)

S4   (MH "Intrapartum Care+") (8133)

S5   (MH "Perinatal Care") (4442)

S6   (MH "Pregnancy Complications+") (4442)

S7	(pregnant* or pregnanc* or prenatal* or perinatal* or antenatal* or periconcept* or interconcept* or peripart* or antepart* or expect* mother*) (272688)
S8	(MH "Postnatal Period") (9682)
S9	(MH "Puerperium") (557)
S10	(postpartum* or postnatal* or puerperium*) (51378)
S11	(MH "Lactation") (4095)
S12	(MH "Breast Feeding+") (24483)
S13	(MH "Bottle Feeding") (1857)
S14	(MH "Milk, Human") (6303)
S15	(breastfeed* or ((breast or bottle) N2 feed*) or lactati* or ((human or breast or maternal) N2 milk)) (47201)
S16	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 (333055)
S17	(MH "Cannabis") (9490)
S18	(MH "Medical Marijuana") (1526)
S19	(THC or tetrahydrocannabi* or cannabi* or CBD or marijuana* or hash or hashish* or hemp or weed or marihuana or dagga or ganja or edibles) (25087)

S20   S17 OR S18 OR S19 (25087)

S21   S16 AND S20 (1099)

S22   (MH "Animals+") OR (MH "Animal Studies") OR TI animal model* (217916)

S23   (MH "Human") (2385599)

S24   s22 not s23 (190641)

S25   s21 not s24 (1062)

S26   Narrow by Language: - english (1055)

Database: Social Science Citation Index (SSCI)

S1   TOPIC: ((pregnant* or pregnanc* or prenatal* or perinatal* or antenatal* or periconcept* or interconcept* or peripart* or antepart* or expect* mother*)) (87660)

S2   TOPIC: ((postpartum* or postnatal* or puerperium*)) (24486)

S3   TOPIC: ((breastfeed* or ((breast or bottle) NEAR/2 feed*) or lactati* or ((human or breast or maternal) NEAR/2 milk))) (12130)

S4   S4: #1 or #2 or #3 (98961)

S5   TOPIC: ((THC or tetrahydrocannabi* or cannabi* or CBD or marijuana* or hash or hashish* or hemp or weed or marihuana or dagga or ganja or edibles)) (26189)

S6   #4 and #5 (1078)

Database: Social Work Abstracts

S1	SU pregnancy (435)
S2	SU pregnant women (0)
S3	SU pregnant (0)
S4	SU pregnant women or pregnancy or expectant mothers (913)
S5	SU prenatal care or pre-natal care or perinatal care (77)
S6	SU intrapartum care (4)
S7	SU Perinatal Care (13)
S8	SU pregnancy complications (0)
S9	TX (pregnant* or pregnanc* or prenatal* or perinatal* or antenatal* or periconcept* or interconcept* or peripart* or antepart* or expect* mother*) (1195)
S10	SU Postnatal Period (1)
S11	SU Puerperium (0)
S12	TX (postpartum* or postnatal* or puerperium*) (166)
S13	SU lactation (0)
S14	SU (human milk or breast milk or breastfeeding) (8)

S15	(breastfeed* or ((breast or bottle) N2 feed*) or lactati* or ((human or breast or maternal) N2 milk)) (39)
S16	S1 OR S2 OR S3 OR S4 OR S5 OR S6 OR S7 OR S8 OR S9 OR S10 OR S11 OR S12 OR S13 OR S14 OR S15 (1294)
S17	SU cannabis (1)
S18	SU marijuana (77)
S19	SU marijuana use (6)
S20	SU marijuana abuse (5)
S21	SU marijuana smoking (1)
S22	SU medical marijuana (0)
S23	SU tetrahydrocannabinol (0)
S24	SU cannabinoid (0)
S25	TX (THC or tetrahydrocannabi* or cannabi* or CBD or marijuana* or hash or hashish* or hemp or weed or marihuana or dagga or ganja or edibles) (335)
S26	S17 OR S18 OR S19 OR S20 OR S21 OR S22 OR S23 OR S24 OR S25 (335)

S
2   S16 AND S26 (4)
7

S
2   marijuana use during pregnancy (247)
8

S
2   (S27 OR S28) (251)
9

Databases: ProQuest Sociology Collection: ASSIA (1987 – present), Social Services Abstracts (1979 – present), Sociological Abstracts (1952 – present), Sociology Database (1985 – present)

S1   mainsubject.Exact("pregnancy trimester, first" OR "pregnancy in adolescence" OR "pregnancy trimester, third" OR "pregnancy trimesters" OR "pregnancy trimester, second" OR "pregnancy" OR "pregnancy/pregnancies/pregnant" OR "pregnancy complications" OR "adolescent pregnancy") (17827)

S2   mainsubject.Exact("pregnant women") (4431)

S3   mainsubject.Exact("prenatal care") (2047)

S4   mainsubject.Exact("perinatal care") (426)

S5   TI,AB(pregnant* or pregnanc* or prenatal* or perinatal* or antenatal* or periconcept* or interconcept* or peripart* or antepart* or expect* mother*) (43939)

S6   mainsubject.Exact("postnatal care") (237)

S7   TI,AB(postpartum* or postnatal* or puerperium*) (8238)

S8   mainsubject.Exact("breastfeeding & lactation" OR "lactation" OR "breastfeeding") (3076)

S9   mainsubject.Exact("milk, human") (14)

S10   TI,AB(breastfeed* or ((breast or bottle) N/2 feed*) or lactati* or ((human or breast or maternal) N/2 milk)) (5315)

S11   s1 or s2 or s3 or s4 or s5 or s6 or s7 or s8 or s9 or s10 (53850)

S12   mainsubject.Exact("marijuana smoking" OR "cannabis" OR "marijuana" OR "marijuana abuse" or "cannabis") (7267)

S13   mainsubject.Exact("tetrahydrocannabinol" OR "hashish") (68)

S14   TI,AB(THC or tetrahydrocannabi* or cannabi* or CBD or marijuana* or hash or hashish* or hemp or weed or marihuana or dagga or ganja or edibles) (12948)

S15   s12 or s13 or s14 (13160)

S16   (s11 and s15) (327)

S17   (s11 and s15) AND la.exact("ENG") (326)

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