Article details: 2020-0304
Title: Contraceptive counselling in three Canadian bariatric surgery clinics: a multicenter qualitative investigation of patients' and healthcare professionals' experiences
Authors: Brigid Dineley MD MSc, Sarah Munro PhD, Wendy V. Norman MD MHSc, Boris Zevin MD PhD, Dennis Hong MD MSc, Babak Katiraee MD, Brian Fitzsimmons MD, Regina Renner MD MSc

Reviewer 1: Ilona Hale
Institution: Kimberley Medical Clinic

General comments (author response in bold)
Main comments:
1) The authors were able to effectively explore the experiences of health care practitioners and patients in line with the stated objectives. From my reading, the key findings of the study seem to be primarily that 1) from the patient perspective, the recommended content is not being delivered consistently or adequately and patients had some useful suggestions for how this might be done and 2) HCPs aren't providing it for a variety of reasons including some incorrect assumptions.
Thank you!

In the results, interpretation, conclusion and abstract however, the authors describe the "main findings" of the study as the identification of the priority topics for contraceptive counselling ("We identified three distinct topics that our participants felt contraceptive counselling in bariatric surgery clinics should encompass: information explaining the reasons for and duration of the need for contraception post- operatively, education on which contraceptive methods are safe and available, and a discussion surrounding changes to gynecologic health, including increasing fertility after bariatric surgery.")
Thank you for this comment. We agree, and believe that our response has improved our manuscript to address this concern. This is addressed above under the editor's comment section with respect to the results and in the manuscript on pages 8-14 and the interpretation section on pages 14-16 and the conclusion on page 17.

As stated in the introduction, the recommended content of contraceptive counselling in the context of bariatric surgery has already been established – the study does not appear to have been designed to establish the content of the counselling but rather the objective was to describe the experiences of participants and HCPs related to this counselling (which it did). Rather than "defining" or "identifying", the study confirmed that these topics were important.
Thank you, that was our intention. We have modified our language to reflect this observation in the interpretation and conclusion sections of the paper.

The authors could look again at the objectives and the themes they identified and carry these through into the interpretation section and conclusions. The results, interpretation, conclusion and abstract should be revised to more clearly reflect the stated objectives of the study and the themes identified.
Thank you for this feedback. We have revised our paper to better organize the themes that came out of our data analysis. There is no guidance available in Canada on what should be included in contraceptive counselling in bariatric surgery clinics beyond avoiding pregnancy for 18 months. We feel that the three

educational topics identified provide important, novel patient and provider insights on what could be covered to improve experiences.

2) The qualitative analysis is described as thematic analysis using an inductive approach followed by latent interpretation however it appears that the approach used was more descriptive than interpretive.

As is common in clinical research, the findings of this study did not require significant interpretation or analysis to provide meaningful information. Rather than developing new themes based on participant responses, the “themes” identified aligned fairly directly with the pre-determined concepts described in the introduction section and the objectives, based on previous research and using an interview guide based on a similar study. This type of qualitative analysis is more in line with interpretive description (Thorne) or qualitative description (Sandelowski). It would be helpful to see the interview guide and perhaps the codebook to better understand the authors' process.
We have added the interview guide and coding tree to provide more detail on our process. We hope that the reviewer agrees, upon reading them, that we extended our analysis from simple description to interpreting gaps in contraceptive counselling in bariatric surgery clinics. Additionally, we point out scope of practice and inter-professional roles that contribute to lack of counselling. Professional scope and roles were not identified through participant description, but rather through our interpretation of patterns across the transcripts. Interview guides and codebooks have been included.

3) COREQ Checklist
Although item 9 on the COREQ table was checked, I was unable to clearly identify a methodologic orientation or theory used to guide the research in this manuscript or the referenced papers. It might also be helpful for authors to clearly state why the other items not checked on the COREQ checklist were felt to be “not applicable”.
We see our work as reflexive thematic analysis approach informed by feminist traditions. This focuses on researcher subjectivity and knowledge as constructed, situated, and contextual. We were not seeking a single truth but rather multiple perspectives. The methodology has been expanded in page 7 lines 164-172
As per the CORE Q instructions, if the information was not included in the manuscript we indicated that with NA. We used NA for sections 4,23,28 and 32. For section 4 we have added in the gender of the PI. For sections 23 & 28: We did not return the transcripts for review to participants for member checking, but we did have them provide feedback on findings by participating in the review and creation of a contraception counselling tool specifically created for Canadian Bariatric surgery clinics. This counselling tool development process was outside the scope of this paper. We have provided more information on the methodology in the paper. We have woven discussion of minor themes and diverse cases throughout our qualitative results, and have included them in our coding tree.

4) Recruitment by HCPs
Although it is stated that efforts were made to minimize sampling bias, and the practice is quite common, recruitment by HCPs could be considered a potential limitation with some associated ethical concerns. Since the HCPs were aware of the ongoing study, it might have have influenced their counselling practices.
Additionally, there may be some power-over concerns about recruiting vulnerable participants who have likely been on a surgical waitlist for many years.

Finally, when the interviews were done post-operatively, there may have been some reporting bias from patients unwilling to speak negatively about the team that has provided this much-desired and long-awaited procedure (halo effect) although it seems from the data that many participants were happy to share their views (in many cases negative views).
We were advised by a reviewer on our local ethics board that they prefer that participants are made aware of studies by a member of the care team. In this study, the participants were made aware of the opportunity by their HCP, but learned more details about the study and had a consent discussion with a research assistant that was outside of their circle of care. The decision to participate or not was not disclosed to their care team. This recruitment practice limits concerns re power imbalance. We acknowledge that it could have influenced counselling practices, however based on our results, individuals reported they were having limited counselling. The interviews were done post operatively to try and limit concerns that by speaking negatively about the care team could trickle back and affect care provided. As you have pointed out, participants were happy to speak openly about their experiences.

Minor comments:
1. Line 109 – recruitment was done at final pre-op "to ensure all counselling was complete" but interviews weren't done until 4-6 weeks post op – slightly confusing why it was important for all counselling to be done prior to recruitment and if there no counselling done after the surgery.
We did not want patients to decline to participate because they were recovering post-operatively. We were concerned that suggesting interview times too close to the surgical date would be stressful given the life-altering nature of the surgical procedure.

2. Line 151 – For clarity, the first section of results could be identified using a sub-heading such as "Demographics, patient reproductive histories and baseline provider knowledge" and data presented more clearly in these categories rather than mixed together. Data presented in tables need not be repeated.
This has been revised on page 8 lines 170-176 and table 1&2 have been combined.

3. Line 199 – This section on assumptions seems like it should be a separate theme rather than part of the "information exchange" section.
Thank you – we agree. The results section has been substantially altered based on the peer review feedback and "making assumptions" has been identified as its own theme on page 12.

4. Table 1 & 2 – it seems the baseline demographic data is presented but the other baseline information (reproductive history and provider baseline knowledge) is not and it is not clear why – this might be of interest to the reader.
Thank you, table 1&2 have been combined and show only baseline demographic data. In the results section on page 8 lines 170-176, we have included some baseline information including sexual activity, contraception use etc. We have not included all reproductive history as we felt that the focus of the results was on the qualitative data. We also did not wish to provide too many demographic details outside the scope of our paper to mitigate the potential of participants being identified.

5. Table 2 – it would be helpful to add “Canada” to each of the geographical areas i.e.- Eastern Canada for clarity.
This has been revised, table 2 is now also combined with table 1.

Reviewer 2: Tamara Williamson
Institution:

General comments (author response in bold)
The main findings that both patients and HCPs perceive gaps in the consistency and quality of contraceptive counselling received pre-surgery is important and should be used to inform efforts to improve counselling and reduce unintended pregnancy in these women.
Thank you for this most encouraging reflection.

ABSTRACT
1. Please define ‘contraceptive counselling’
This has been added to page 1 line 44. “Evidence suggests an increase in fertility and unintended pregnancy following bariatric surgery; contraceptive counselling, traditionally defined as a discussion of contraception options, is therefore an important facet of surgical planning.”

2. The time frame (dates) of the interviews could be included here
This has been added to page 1 line 51. “publicly funded Canadian bariatric surgery clinics from May 2018-Feb 2019.”

3. Please define HCPs here (i.e., nurses? Physicians?)
This is clarified in the inclusion criteria page 1 line 56 “HCPs included any individual delivering care in a Canadian, publicly funded, hospital-affiliated bariatric surgery clinic” as well on page 5 line 109-113 “Given the lack of clear Canadian guidelines on who should perform contraceptive counselling and the lack of published studies available on this topic, we invited interested HCP from all disciplines (e.g. physician, surgeon, nursing, counsellor) who worked in a Canadian, publicly funded, hospital-affiliated bariatric surgery clinics”

INTRODUCTION
1. Although the rationale for the study is conveyed clearly, the introduction is overly brief and the statistics cited are vague. This section would be strengthened by quantifying the statements made in support of your rationale, and adding more detail/specificity (described below).
Thank you, the introduction has been reformatted to reflect your comments below and we believe it is stronger.

2. Please include the gender breakdown (i.e., what % of surgeries are performed on women?). Specify which recommendations suggest avoiding pregnancy (American, Canadian, both?). This data should be easy to obtain from the literature cited.
This has been updated on page 4 line 75 “In Canada, most (80%), bariatric surgery is performed on women.” and lines 81-86 “The Canadian Adult Obesity Clinical Practice Guidelines state that “Adequate contraception should be offered to women of reproductive age who undergo bariatric surgery”, but does not provide

details on content or on who should perform this counselling" The Canadian figure comes from the most recent CIHI review of bariatric surgery (2014).

3. Fertility typically improves following bariatric surgery in women of childbearing age. Please add a statistic and citations to this effect in the introduction, as you refer to this later in the manuscript.
This has been updated on page 4, lines 75-79 "Obesity can affect the hypothalamic pituitary axis, cause Polycystic Ovarian Syndrome, and affect endometrial and oocyte quality, all of which can reduce fertility. By inducing weight loss, bariatric surgery can improve these factors and therefore increase fertility."

4. Please quantify the increase in risk of unintended pregnancy that occurs post-surgery. The current statement is vague.
We have not been able to find a statistic providing the exact rate of unintended pregnancy overall in individuals who have bariatric surgery, since a study of pregnancy intendedness in individuals who had bariatric surgery in Canada has not been done. We have quoted the Society of Obstetricians and Gynecologists of Canada reaffirmed clinical practice guideline on obesity in pregnancy and have included another study that reports a rate of 33%, however this study is only in a small group of individuals. This has been done on page 4 lines 88-89. "Despite recommendations, research suggests that those with recent bariatric surgery are at increased risk for unintended pregnancy, with one study reporting 33% of pregnancies were unintended" The reference for this study is reference "Knowledge, attitudes, and behaviors of women during pregnancy after bariatric surgery." Goldenshluger A, Elazary R, Ben Porat T, Farhat HG, Levin G, Rottenstreich A. Surg Obes Relat Dis. 2020 Jul;16(7):925-930

5. "Contraceptive counselling" needs to be defined in the introduction. Who typically provides the contraceptive counselling in bariatric clinics? Further, please elaborate on the "significant knowledge gaps" that HCPs report in past studies (page 4 line 88).
We now provide a definition of contraceptive counseling in the introduction. On page 4 lines 81-83, we discuss the following, "Canadian Adult Obesity Clinical Practice Guidelines state that "Adequate contraception should be offered to women of reproductive age who undergo bariatric surgery", but does not provide details on content or on who should perform this counselling". Regarding who provides contraceptive counselling, this is what our study sought to understand. There are no guidelines on contraception counselling in clinics beyond the Canadian Adult Obesity CPG and the American Metabolic surgery guidelines. They include no further details or instructions on who should perform it and how, beyond that counselling should be included in pre-operative counselling. Knowledge gaps identified in studies have been included on page 4 lines 90-94. "International studies indicate that healthcare professionals (HCPs) working in bariatric surgery have significant knowledge gaps including what types of contraception are safe in individuals with obesity (9,10) and patients report they are not routinely counselled"

METHODS
The methods section requires additional detail and explanation, particularly in the recruitment section:

Please see our specific responses below.

1. Recruitment
a. This section is a bit unclear – I am not sure how patients got from their last pre-surgery appointment to their contact with a researcher. Did the physician direct interested patients to the RA, who then scheduled the interview? Please clarify.
This has been clarified on page 5-6 116-124.

b. Was recruitment of HCPs and patients done concurrently? Please
Yes, this has been clarified on page 6 line 120.

c. Please specify the professions of HCPs who were eligible for the study (physician? Surgeon? RN? RD? etc).
This has been added under the participant section on page 5 lines 107-113

d. It is unclear from the manuscript whether the HCPs who were interviewed would reasonably be expected to engage in contraceptive counselling with their patients. Presumably, there are defined roles from clinic to clinic regarding who provides contraceptive counselling. Could you clarify what role the interviewees had in their clinics?
We did not know who was performing counselling before the study was undertaken. Table 1 (previously table 2) identifies the types of HCP we interviewed. Our results indicate it was unclear to the HCPs themselves who was expected to provide contraceptive counselling.

2. Data Collection
a. Please specify gender identity and any additional relevant characteristics of the interviewers, as per the COREQ guidelines.
This has been added to the data collection section page 6 line 127
b. Can you provide a copy of the interview guide for transparency with supplementary materials?
Interview guides are attached

3. Data Analysis
a. Please include a brief explanation of thematic analysis for readers who are not familiar with this methodology.
This has been revised in the data analysis section on page 7 lines 145-156.

RESULTS
1. In general, this section would benefit from a revised layout (i.e., headings and subheadings that clearly delineate patient results from HCP results, and themes from subthemes). In fact, I was unclear throughout the results section regarding what the main themes in the results were. Adding a table or figure that describes themes by patient/HCP/both, with representative quotes, may help improve readability in this section.
Thank you, this section has been significantly revised. Three main themes have been identified and each them is explored from a patient and HCP view separately, and then a comparison of responses is undertaken. A table (table 2) has been included with the major themes and sub themes. This is included on pages 8- 14.

Table 2: Summary of Themes

Theme Subtheme/Summary
Missing Information Avoiding conception
Choosing contraception
Changing gynecologic health
Making Assumptions Who to counsel
Who does counselling
I don't need counselling
Improving Experiences Content
Repetition
Format

2. The statement "patient participant interviews were completed 2-4 weeks following surgery" should be moved to the recruitment section of the paper. On this note, why were interviews conducted post-surgery if patients were recruited pre-surgery? This should be addressed.
We did not want patients to decline to participate because they were recovering post-operatively. We were concerned that suggesting interview times too close to the surgical date would be stressful given the life-altering nature of the surgical procedure. The interviews were done post operatively to try and limit concerns that by speaking negatively about the care team could trickle back and affect care provided.

3. The statement that "Five of the 11 HCPs were not aware that the oral contraceptive pill is not recommended following RYGB" is very surprising – as outlined above, however, it is important to know what roles these HCPs play in the surgical care continuum to understand whether their ignorance of contraceptive information represents a true practice gap, or not. For example, in our local Canadian bariatric surgery clinic, the role of contraceptive counselling typically falls to the patient's nurse case manager. An RD or physician may not be expected to provide counselling on this matter. Further, the authors indicate that physician participants reported "they were not participating in contraceptive counselling" as they understood this to be a nursing duty – why, then, were these physicians interviewed for the study? By interviewing HCPs who are not responsible for contraceptive counselling, your results may be artificially inflating the actual size of the practice gap in this area.
As there are no published guidelines or protocols on contraceptive counselling, we did not know who would be performing the counselling prior to completing the interviews. What we found shows that there are also inter-team assumptions about who should be, and is, performing counselling. Additionally, participants reported being told misinformation by their surgeons regarding birth control. Given the fact that patient participants universally responded that they were not adequately counselled, we do not think that we are artificially inflating the practice gap. We think that if any of these HCPs are providing medical advice, they should be aware of a key contraindication for their patients in using OCP with malabsorptive procedures. Additionally, in our interviews, participants reported that nurses were doing the majority of counselling not counsellors.

4. I recommend having subheadings for "Patient Results" and "HCP Results" or something to that effect to split up this section.
Each theme is now presented with Patient and HCP experiences separated.

5. Patient participants need improved pre-operative contraception counselling
a. Line 171-172 on page 8 is confusing as written. Perhaps write in the active voice:
The results section has been significantly revised

b. Can you specify how many patient participants said that the study was the first time they learned about contraceptive needs? (p. 8 line 186).
This has been revised on page 10 lines 209 "A minority (two) of patient participants reported that the first time they were told about avoiding pregnancy and the need for contraception was when they were approached by the study team."

6. Patient participants' perspectives on information exchange
a. There was a section describing "making assumptions about who needs counselling" (pages 9-10) within subsection 3.2 (information exchange). It is unclear whether this is its own theme, or whether the authors perceive "making assumptions" to be a sub-theme of information exchange. As mentioned in my general critical feedback for the results, the authors may wish to re-examine the themes/sub-themes within the data or re-organize the presentation of themes to make this clear to readers.
b. I found it confusing that you included HCP's results regarding making assumptions within this section that was primarily patient results.
The "making assumptions" theme has been identified as its own theme (pg 11, line 245). Table 2, above, shows the new theme structure. Results have also now been configured to separate HCP and patient experiences.

7. HCP perspectives on contraceptive counselling
a. Again, I suggest an opening sentence to summarize how many themes/subthemes were identified within the HCP interviews, to make it easier to follow.
b. Please define NP on page 11 line 232
NP has been defined on page 10 line 224

8. Patient participants and HCPS wish to improve and empower contraceptive decision-making
a. This section reads as if there are several sub-themes within the higher-order theme of "wishing to improve and empower contraceptive decision making".
b. I am curious whether the authors coded sub-themes and whether they considered presenting the results within these lower-level categories. It would enhance readability in this section. For instance, they write that "timing and format was discussed frequently", and also discuss the idea of "hand outs and resources" and what should be included in these resources.
Thank you, the results section has been revised and we think it is substantially improved. The new theme of improving experiences (page 13 line 282) encompasses these specific suggestions

INTERPRETATION
1. This section was generally well written but may need to be revised after addressing the above comments for consistency.

2. LIMITATIONS
a. The limitations of the study are not adequately outlined in this section. For example, it does not appear that data was collected regarding the ethnicity/race or socioeconomic status of participants. Given that patients with lower financial resources/lower education

level, patients who have experienced stigma and racism in health settings, etc. may experience different barriers to proper contraceptive education relative to high SES/white women. Some discussion of this problem is warranted.
b. The number of HCPs interviewed was small, and did not include the full range of HCPs that the authors attempted to recruit. This makes the reader skeptical that theoretical saturation was truly reached within the HCP interviews. The authors should address this problem.
Thank you for these suggestions. The limitations section has been revised on page 16, lines 358-367. Given our theme of making assumptions, further research that explores intersectionality on access to contraception counselling for individuals seeking bariatric surgery is warranted.
With respect to sample size, as discussed by Vasileiou et al we focused on developing rich data rather than a recruiting a specific, pre-identified number of HCPs. Over the course of our interviews, we feel that we reached saturation of themes. We did not set out to interview HCPs from all possible categories, but rather those that were interested in participating and had perspectives on contraceptive counselling. Our data (both patient and HCP) suggests that nurses are doing the majority of counselling which is reflected in the breakdown of our HCP participants.
Vasileiou, K., Barnett, J., Thorpe, S. et al. Characterising and justifying sample size sufficiency in interview-based studies: systematic analysis of qualitative health research over a 15-year period. BMC Med Res Methodol 18, 148 (2018)

TABLES
1. Please add data regarding the research sites/areas of Canada that the participants originated from

2. Was the gender of the HCPs recorded? This would be useful to know.

3. I suggest that you amalgamate Tables 1 and 2
Table 1 and 2 have been combined. Gender of HCPs was not recorded. The participants come from three bariatric surgery clinics (two in Ontario, one in BC) we did not analyze the data geographically as the same themes emerged in all interviews so did not indicate the origin of the participants. The location of the clinics has been clarified in the Methods section page 5 lines 101-104.