Author’s response to reviews

Title: Implementation of Mifepristone Medical Abortion in Canada: Pilot and Feasibility Testing of a Survey to Assess Facilitators and Barriers

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Version: 1 Date: 15 Sep 2019

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Response to Reviewer Reports:

PAFS-D-19-00071
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Editor’s comment:

I am pleased to inform you that it is potentially acceptable for publication in Pilot and Feasibility Studies, once you have carried out some essential revisions suggested by our reviewers.

We thank you for the opportunity to make revisions to our manuscript and resubmit to Pilot and Feasibility Studies for consideration for publication.
Reviewer #1

This is an exceptionally well written manuscript that clearly articulates the processes involved in the robust and rigorous design of a survey. It provides useful insights into the implementation of a new service which are transferable, in my opinion, to other new services in other countries and so is of interest internationally. The manuscript also provides a clear and detailed account for novice researchers to follow if they wished to use these methods to evaluate services. Overall an excellent manuscript.

We thank the reviewer for their thoughtful and encouraging remarks and acknowledge that the reviewer has no issues that need to be addressed.

Reviewer #2

1.) This paper describes the development of a survey instrument that will be used to evaluate the implementation of medical abortion in Canada. It is the first part of a multi-stage research program which will examine barriers and facilitators to implementation of the newly approved combination medication for medical abortion. The paper is well written and easy to follow. The design and methodology of this part of the larger project are well described and sound, and the application of theoretical frameworks is impressive.

We thank the reviewer for their thorough read of the manuscript and their suggestions. We have addressed each suggestion below.

2.) In the Background, it would be helpful to provide brief information about the Canadian context for an international audience - does the population who might seek medical abortion access primary care initially or are they able/ would they choose to access OBGYNs? What would their expectations within the Canadian health system be for information, advice and referral/provision of not only medical abortion, but reproductive health care?

We agree that providing Canadian context would be helpful for an international audience. We have added “In Canada, abortion is a publicly funded service. Most women access it either by self-referral to an abortion/reproductive health care facility or through a referral from their family physician to an abortion provider” to the second paragraph in the Background section (page 5 of 31).

3.) Could the number of induced abortions reported in the Background (100,000) be expressed as a rate?

Thank you for this suggestion. Although the Canadian Institutes for Health Information (CIHI) does not publish abortion rates, we have calculated a rate using the Canadian population of females age 15-44 (standard denominator) over most years where we have had excellent capture of abortion numbers. Our rate has been 14-15 per 1000 females age 15-44. We adjusted the second sentence of our Background section to read: “The rate of induced abortion is approximately 14-15/1000 females aged 15-44, annually.” (Page 5 of 31)

Citation Added:
4.) Background, third paragraph - re Australian legislation, while this statement is not incorrect, abortion has been removed from the criminal code in all but one jurisdiction (with various limits and restrictions): this website has a good summary https://www.childrenbychoice.org.au/factsandfigures/australianabortionlawandpractice

Thank you for sharing this current link to Australian abortion legislation. Given that only Queensland and New South Wales still have restrictions, we have changed “several” to “some” in the sentence: “and abortion remains legally restricted or prohibited in some jurisdictions” in the third paragraph of our Background section (page 6 of 31).

5.) Methods page 12 of 29, middle paragraph - ‘…panelists suggested to include questions related to patient satisfaction…’. While questions on this theme were not included, is there scope in the broader study to consider or incorporate consumer perspectives? (Or can this be mentioned in the discussion?) Given the doctor-patient relationship is a dynamic one, one would imagine that implementation of a new technology and service needs to consider the group for whom the new technology is targeting, and physicians would be sensitive to this.

The focus of our funded research was the uptake of a novel clinical service among health care professionals, we interacted in this study with health care professionals to understand health system and policy barriers/facilitators to access mifepristone. We agree the consumer’s perspective is a critical area of study but this was outside the scope of the present research. We are pleased to acknowledge that there are other Canadian researchers who have been funded to study the patient/consumer experience.

6.) Results (page 14 of 29, second line of first paragraph - ?missing word, for clarity ‘…previous abortion *provision* experience’ (?)

We revised this sentence in the first paragraph of our Results section to read more clearly: “previous experience providing abortion services” (page 17 of 31).

7.) Results page 17 of 29 - Physicians dispensing the medication (and Background page 4 of 29). I assume that this regulation is highly irregular and does not apply to any other prescription pharmaceutical product?

The requirement that a physician dispenses a medication rather than the patient being able to buy it in the pharmacy is highly unusual in the Canadian context. To improve the safety and incorporate the best evidence based practices to dispense pharmaceuticals, most jurisdictions in Canada severely restrict physician dispensing. Pharmacists are the acknowledged experts to dispense medications. In the province of Quebec, physician dispensing is actually forbidden. Physician dispensing was perceived to be a potential barrier for those private primary care offices who lacked the infrastructure to dispense medication. To make this clear, we have added to the background and results sections (italics):

Background: “However, the initial approval of mifepristone in Canada stipulated restrictive constraints that did not conform with the clinical guidelines or usual clinical practice” (page 6 of 31).

Results: “The requirement that a physician dispenses a medication in place of the medication being available to purchase at a pharmacy is highly unusual in the Canadian context. This would require physicians interested in prescribing mifepristone, to set up the infrastructure to stock and sell the
medication: …” (page 20 of 31).

Reviewer #3

1.) A well written qualitative research study on the feasibility of a survey to gather information on the implementation of Mifepristone medical abortion. I would like to see more description of the modified DELPHI phase 2 part of the study and for the authors to be a bit more explicit as to why this was a modified DELPHI and how this differs from the normal DELPHI process as this was unclear.

There are many descriptions of the Delphi method in the literature, which can be confusing. We have highlighted why ours is perceived to be a “modified” approach. “A distinct characteristic of the Delphi method is the sequential, staged approach, whereby panelists are involved in subsequent ‘rounds’. We modified this approach by involving Group II in just one round because the goal of our group interviews was to collect important input and not to reach consensus. Our final group interview had the fewest number of participants (n= 3) however we used this as an opportunity to capture more in-depth insights.
Furthermore, between each group interviews we revised the survey instrument to reflect the input provided by the previous group. A final version of the survey instrument was created after all 5 group interviews.” (page 11 of 31).

Reviewer #4

Thanks for the opportunity to read this interesting piece of work. I would ask you to consider the following:

1.) Although this is not a randomised feasibility/pilot trial I would ask the authors to consider the extension to the CONSORT guidelines for randomised polite and feasibility studies. Have the authors used this framework as a guide to reporting of this study? In particular, I am not clear how the aims of this study (which are not well defined in the manuscript) align to a feasibility and/or pilot study? What was being tested for feasibility, what aspect of a larger trial was being piloted? I can see that the work is about the development of a tool using a theoretical background to inform that, I don't see how it fits the definition of a feasibility and/or pilot study. I can see that the final paragraph discusses the piloting of the survey instrument, I would argue this needs to be clearer with stated aims as per the CONSORT statement.

We appreciate the reviewer’s request to include clear and transparent reporting of our methods. We strongly believe that the Standards for Reporting Qualitative Research (SRQR) is the most appropriate reporting guideline for our methodology. While CONSORT would be entirely appropriate for a pilot or feasibility study conducted in preparation for an intervention allocation study such as an RCT, we felt it was not aligned with the aims and approach of our observational study. Briefly again, the aims of our research were:

1. to develop a survey prototype informed by a theoretical framework (Phase 1),
2. validate the survey content using qualitative group interview data (Phase 2) and
3. pilot test the usability and readability of the survey in an online format for feasibility (Phase 3).

Our goal was to understand how policy and practice characteristics relate to access to abortion services throughout Canada.
The aim of our qualitative analysis in Phase 2 was to ensure our questions were relevant, understandable, provided clear answers, and included the range of relevant factors related to physician initiation and ongoing provision of mifepristone medical abortion practice. The purpose of our pilot testing was to ensure the readability and usability was adequate for the online survey instrument.

The reviewer also comments that our manuscript may not fit “the definition of a feasibility and/or pilot study.” We feel our aims and methodological approach align well with the diverse work published in Pilot and Feasibility Studies, which include qualitatively driven research that is best assessed with SRQR or COREQ. Recently published examples from the journal include testing qualitative procedures for a planned grounded theory study (PMID: 29997900) and testing the face validity, feasibility, and utility of a patient health questionnaire (PMID: 28694986).

2.) As per above the definition of specific objectives for the pilot trial need to be clear, is this a pilot trial or are you piloting a questionnaire to examine content and face validity I would argue these things are different.

We agree with the reviewer that piloting our questionnaire is very different from testing procedures for a pilot trial (the latter is not within the scope of our present study). The purpose of this study is to develop (Phase 1), validate (Phase 2) AND pilot (Phase 3) a survey. To address your feedback, we have revised the final sentence of our the Background section to reflect the objectives more clearly: “Our objectives were: to develop a survey prototype informed by a theoretical framework (Phase 1), validate the survey content using qualitative group interview data (Phase 2) and pilot test the usability and readability of the survey in an online format for feasibility (Phase 3).” (page 7 of 31).

We also clarified the purpose of the pilot in our Results of Pilot Testing (Phase 3) section: “In phase 3, one round of surveys was administered via REDCap and distributed for readability and usability testing through an online link that included modifications based on feedback from the larger CART-GRAC network (Group III). The second version of our survey instrument consisted of 9 demographic questions, 52 questions mapped to Greenhalgh’s conceptual model (see Table 1 for an example), the 12-item questionnaire adapted from Légaré’s validated instrument, and 17 open ended questions that provided respondents with the option to elaborate their responses. During phase 3, minor technical changes took place including spelling errors, changing the order of demographic questions, improving the clarity of partner logo images, and moving hyperlinks to resources to the end of the survey. Once each of the technical changes was addressed, we established our final survey instrument.” (page 22 of 31).

3.) Background: Pg 4 line 16, should read support?

We pluralized ‘support’ to capture different forms of supports, including mentorship, ongoing education, and an online community of practice.

4.) Background: Pg 4 para 3 you use the term medication and drug interchangeably here, technically the discussion is about a medication, a combination formulation available within a drug delivery system. The term drug is not appropriate in this instance unless you are discussing a specific and individual chemical entity. There are other examples of this throughout.
We have revised the term “drug” to “medication” throughout the manuscript.

5.) Methods: I do understand the approach you have taken to a modified Delphi process. I would argue that it is subject to bias and string views overruling other, especially given that the focus groups in question here were unusually small, 3-6 participants. How was this managed?

We have made revisions to paragraph 2 under Data Collection to make our modified approach and process more clear. This included changing our language from “focus group” to “group interview”:
“A distinct characteristic of the Delphi method is the sequential, staged approach, whereby panelists are involved in subsequent ‘rounds’(41). We modified this approach by involving Group II in just one round because the goal of our group interviews was to collect important input and not to reach consensus. Our final group interview had the fewest number of participants (n= 3) however we used this as an opportunity for more in-depth insights. Furthermore, between each group interview, we revised the survey instrument to reflect the input provided by the previous group. A final version of the survey instrument was created after all 5 group interview.” (page 11 of 31).

6.) Methods: Pg 11 para 1 line 14 'This included a thorough......' This sentence doesn't make sense to me, please review.

For clarity, we have revised this sentence in our Methods section to read: “This included a thorough review of comments from the group interviews about which survey questions were clear, concise, and comprehensive, and which questions required additional editing” (page 13 of 31).

7.) Results: Again, I am slightly confused here as to what the focus of this paper is. To this point, I would have said it was about the development on an instrument and the assurance of face validity etc. The qualitative section in the results appears to be more about the actual views of practitioners to abortion services rather than a discussion of the instrument itself. I appreciate the qual work has been done well, but this is confused in terms of the aims and objectives of this paper. How do these views align with the instrument design process? I would argue this goes back to my first point above about the aims and objectives of a feasibility and/or pilot study. The statement at the beginning of page 21 does illustrate my point 'Our study process resulted in a more comprehensive survey than any we were able to identify in the international literature to understand barriers to contraceptive and abortion service provision in high-income countries' a survey of what? Views on this issue or on the tool you are developing?

We appreciate the reviewer asking for clarity about our multiple objectives. We sought not only to validate our survey but also gain data on perceptions what access to forthcoming abortion services may look like, and what barriers and facilitators clinicians may face. This contextual data was critical for enriching the survey instrument and including factors that may act as barriers and enablers to implementation.

Briefly, again, the objectives of our study were:

Phase 1: to develop a survey prototype informed by a theoretical framework
Phase 2: validate the survey content using qualitative group interview data; the qualitative data collected in phase 2 enriched the survey instrument by validating the content of the questions and response options.
Phase 3: pilot test the usability and readability of the survey in an online format for feasibility

Our goal was: to understand how policy and practice characteristics relate to access to abortion services throughout Canada. However, to address this suggestion, we have added to a few sections throughout this paper to clarify this:

Abstract: “Additionally, we explored expert, stakeholder and physician perceptions of the impact of facilitators and barriers on abortion services throughout Canada” (page 4 of 31).

Methods: “In phase 2, the panel of physician experts also provided their perceptions of the impact of facilitators and barriers on abortion services throughout Canada which further informed the content we aimed to cover in our survey instrument” (page 8 of 31).

Thematic Analysis of Facilitators and Barriers: “In order to ensure that our survey instrument captured relevant perceived barriers and facilitators to implementation of mifepristone, we also conducted a thematic analysis of group interviews transcripts, informed by critical realist principles – that is, we explored how panelists made meaning of their abortion provision intentions and experiences and the ways that social context informed them, while considering the material reality in which mifepristone would be implemented in Canada (42). The purpose of conducting a thematic analysis of the group interview data was to enhance the development of the survey instrument” (page 15 of 31).

Discussion: “We undertook a rigorous process to develop and pilot test a survey instrument to investigate health policy, health system and health care delivery factors impacting first trimester mifepristone abortion practice in Canada. In phase 1, family planning experts grounded the first version of the survey instrument in established theoretical frameworks. In phase 2, five group interviews leveraged the expertise of reproductive health providers from across the country and determined that Health Canada’s proposed regulations would act as barriers to implementation, particularly in primary care. We collected initial impressions on potential barriers from a sample population of physicians and developed a 65-item baseline survey using three of Greenhalgh’s domains: ‘System Readiness for Change’ (n=19), ‘Outer Context’ (n=21), and ‘System Antecedents for Innovation’ (n=25) to pilot test” (page 23 of 31).

Discussion: “Phase 3 pilot testing only focused on the readability and technical aspects of the online survey instrument. We did not include specific measurements such as Cronbach alpha coefficients to assess internal consistency, test-retest reliability testing, or factor analysis to describe variability among items. However, some of the basic instruments we used to build our survey instrument did report strong psychometric testing” (page 23 of 31).

8.) Conclusion: Where in the study have you tested the tool to be able to make the statement 'We envision that both the approach to developing this survey and the final instrument will be readily adaptable for other jurisdictions'

We have removed the original statement entirely from the conclusion in our Abstract. Our team agrees that it is more accurate to say our survey can constitute a good basis for other jurisdictions which want to study barriers and facilitators to medical abortion given the survey was developed using comprehensive frameworks. We have added to the Conclusion: “The specific questions were developed using frameworks that comprehensively covered barriers and facilitators to provider implementation of
medical abortion practice. As such they constitute a good basis for surveys in other jurisdictions which want to study barriers and facilitators to medical abortion” (page 26 of 31).