Author's response to reviews

Title: The most effective strategy for recruiting a pregnancy cohort: A tale of two cities

Authors:

Donna P Manca (dpmanca@ualberta.ca)
O’Beirne Maeve (OBeirne@ucalgary.ca)
Teresa Lightbody (teresal@ualberta.ca)
Johnston David (davidw.johnston@albertahealthservices.ca)
Dayna-Lynn Dymianiw (daynallynn@shaw.ca)
Katarzyna Nastalska (knastalska@shaw.ca)
Lubna Anis (lubna.anis@albertahealthservices.ca)
Sarah Loehr (sloehr@ualberta.ca)
Anne Gilbert (Anne.Gilbert@ales.ualberta.ca)
Bonnie Kaplan (bonnie.kaplan@albertahealthservices.ca)

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Author's response to reviews: see over
Dear BMC Editors,

Re: Research manuscript on recruitment of a pregnancy cohort titled:
“The most effective strategy for recruiting a pregnancy cohort: A tale of two cities”

We appreciate your consideration of this paper for publication in the BMC Pregnancy and Childbirth and have addressed the reviewers concerns as follows:

**Referee 1:**
**Minor Essential Revisions:**
1. Please add a short description of the overall goals of the APrON study, as well as the study protocol outlined in Figure 1. As stated in the paper, different aspects of the protocol (e.g. non-essential blood collections, whether participants will have access to personal results, etc) will influence participants’ willingness to participate in the study. At the moment, these details are not immediate clear to the reader.
   • **RESPONSE:** More details have been provided in the introduction, including number of visits and estimated time commitment for participants. A reference has been added to another paper that provides detailed information (see lines 73-80 and reference 15).
2. Please add a caption for Figure 1.
   • **RESPONSE:** We removed Figure 1 since the details are included in reference 15.
3. Methods, Recruitment strategies section: Please add a sentence explaining whether midwifery clinics were also targeted as another clinical setting in which to enroll women in early pregnancy (and see comment 7 below).
   • **RESPONSE:** The midwives were invited to participate and this is outlined under methods #6 however we did not target their clinics as described in #1 and did not see a need to explicitly highlight the low number of deliveries that they attend. The midwives did not see the volume of patients that would warrant the cost of recruiting on site. [For example -in 2008 in Calgary —midwives attended 163 hospital births while family physicians attended 6,834 and obstetricians 11,028.]
4. Please describe the social media aspects of the recruitment campaign in more detail. This is a relatively new method of participant recruitment, and other researchers / ethics board members would benefit from hearing about your experience. Did your ethics board have any concerns about patient confidentiality using social media recruitment methods?
   • **RESPONSE:** We have provided more details in methods- ‘internet’: “Participants were not recruited directly from Facebook or Twitter to avoid issues with exposing participants’ confidential information. The social medial pages posted information on APrON, including where and how to participate in the study.” We have also included links to the Facebook and Twitter pages. Our Ethics Board did not have concerns with the manner in which we advertised the project using social media since we did not collect confidential information using the social media. (See lines 173-175, and 181-186)
5. Methods, 2nd paragraph: How was the <27 week gestational age (GA) at enrollment defined (e.g. ultrasound dating, last menstrual period, etc)?
• RESPONSE: Information collected included EDC, gestation at the time of the visits and included the researchers obtaining access to health records such as prenatal and delivery records. The information in the methods has been updated to describe these details (see lines 107-109). All women underwent a second trimester ultrasound. Some of the women had a first trimester ultrasound for either dating or genetic screening. The earliest ultrasound (after 6 weeks gestation) was used to date the pregnancy. If the expected date of confinement (EDC) as determined by the last menstrual period did not agree with the EDC as determined by the ultrasound (taking into account the error of the ultrasound), the EDC was changed.

6. Methods, Media section (and elsewhere). Please add links (or a supplementary file) to your posters, press release, TV ad for Access Network, and when possible, to examples of some of the “earned media” used to promote the study. These examples would help other researchers undertaking similar recruitment campaigns. Another sentence about how you promoted the study to capture attention from “earned media” would also be helpful.
• RESPONSE: We added a sentence describing how the media we targeted including a link to detailed information on the mass media articles. (see lines 148-149 and 174-175)

7. Methods, section 6: Other. You state that study staff contacted the Doula Association, naturopath clinics, midwives, etc. Was there much uptake / interest from these groups? If not, what may have been the barriers to recruitment in these settings?
• RESPONSE: These groups were supportive however they were not able to assist substantially with recruitment numbers since they did not attend to the volume of pregnant women that the family physicians or obstetricians did (see explanation in #3 above). Table 1 identified 14 patients recruited from midwives in Calgary. We did not think more detail on this group was warranted.

8. Methods, section 6: Other, 2nd paragraph. Please revise the 1st two sentences in this paragraph. The current explanation is not clear. Who are the community supporters? Was the monthly draw run by the Apron Study? Were the coupons and brochures from the APrON study?
• RESPONSE: The sentence is revised to clarify the community supporters, the monthly draw and where the coupons and brochures came from. (see lines 196-200).

9. Discussion, 6th paragraph: your wording implies that approximately 45% of the Calgary and Edmonton populations (aged 25-34 yrs) have less than high school education. Is this true, or is the wording misleading? Lower down in the same paragraph you state that 18% and 22% of people in Calgary & Edmonton do not have certificates of diplomas. Please clarify this section.
• RESPONSE: The numbers are correct and do not include all the various types of education in the Census. We understand how the wording can be misinterpreted and have decided to use a better comparison group from the census: that is, the women aged 25-35 that have no certificate, diploma or degree. We have revised this section accordingly. (see lines 363-366).
10. Table 1: Clarify in footnote if women were only allowed to report 1 recruitment method. The text suggests that women had often heard about the study several times before being officially recruited into the study.
   - RESPONSE: This has been clarified.
11. Table 1: Change % values to 1 decimal (not 2)
   - RESPONSE: Done
12. Table 1: In “Other for Calgary section”, add % calculations.
   - RESPONSE: Done
13. Table 1: In “Other for Calgary section”, define PSA. Some people may not be familiar with this acronym.
   - RESPONSE: Done – spelled out Media Public Service Announcement at bottom of the table.
14. Table 3: Please add comparison data for the background target population, where possible. Then discuss potential volunteer bias in your recruited population, if relevant. If present, this recruitment bias will affect the external validity of the study, and needs to be discussed as a limitation.
   - RESPONSE: This is titled as Table 2 in the revised paper. We did not add comparison data to table 2 since the census data was collected in 2005 and did not collect data using the same definitions and categories used in our project. Instead, we discuss potential volunteer bias in the discussion (6th paragraph – 359-360) including a better description of the higher education levels of participants (though the data is from 2005 we believe that there could be a bias of higher educated participants in our sample (This bias/limitation is also found in other pregnancy cohort studies as described in the discussion.).

Discretionary Revisions:
1) Background, last paragraph: Consider changing wording to “women with obstetrician-attended births”, rather than “women delivered by obstetricians.”
   - RESPONSE: Done - Excellent suggestion! (see lines 103-106)
2) Discussion, 6th paragraph, 3rd last sentence: suggest removing the phrase “and pregnant women who participate in research studies appear to be of higher SES”. This point has been made above.
   - RESPONSE: Done

Referee 2:
The conclusion that face-to-face approaches by staff that receive a small honorarium for their efforts is not surprising. But the issue of generalizability is important. It is likely that similar strategies will be successful but it seems likely that the approach will depend very much on the subject of the study and the degree of invasiveness of the study and the degree of effort required of the subjects. This issue was not addressed.
This study should be read and referenced and described
   - RESPONSE: The paper suggested to be referenced is a cross-sectional survey of clinicians (obstetricians, family physicians (who provide antenatal vs intrapartum...
care), and others (e.g. midwives). The survey assessed clinicians attitudes towards the use of technology demonstrating that family physicians providing antenatal care only had similar scores to obstetricians favoring technology, and those family physicians providing intrapartum care had intermediate scores. The methods of recruitment targeted clinicians through memberships in national organizations, etc. The audience was not pregnant women. The response rate was 68.7% of the obstetricians and only 27.2% of the family physicians. While this is a key paper in the discipline and known to the authors, we decided not to include it as a reference since it is a different topic and does not relate to the recruitment of a pregnancy cohort.

- We believe that our finding that recruitment should focus on high volume clinics that attend to women in early pregnancy is a novel and important finding that can be generalized.

**Referee 3:**

**Major compulsory revisions**

- This reviewer is not aware that the published literature has actually addressed volume of presenting patients as a critically important factor in meeting recruitment targets; if so, this article reports a novel finding which should be stressed.
  - **RESPONSE:** We have emphasized this in the abstract and conclusion by adding “a new critically important finding” (see lines 38, 399-400)

1. **Background**… under Results, this reviewer got lost in the detail provided in the Background lines 71-85 about who was providing care. It is recommended this paragraph be reworked to highlight the real distinguishing feature – the volume of pregnant patients seen in the FP offices in Edmonton vs the “high volume” FP-maternity practices in Calgary.
  - **RESPONSE:** We have reworked the background to highlight the volume of pregnant patients seen in Edmonton vs Calgary as the distinguishing difference between the two cities. (see lines 86-96)

2. **Methods** - Despite the heading “Recruitment strategies common to both cities”, there are several differences in the recruitment methods in the clinical settings which have been noted to be an influence in other reports on this subject, and one is left wondering whether these were also a factor. For example, in descriptions of Edmonton, it seems the research assistant was the one who made the contact. The authors then describe another method whereby clinic staff discussed the study with patients and then made a referral to the research assistant; and another method whereby the family doctor first introduced the study.

Are the authors able to provide any more detail about the denominators in these different scenarios such as the “getting to yes rate”, the number of women asked vs the number who agreed to participate? Does their data suggest that an approach to learn about the research study led to a higher level of recruitment if there was a prior relationship with the patient (clinic staff or physician) vs research assistant? Or can they say that there appeared to be no difference in the recruitment rates of these modestly different approaches, and conclude that the major difference was just the sheer volume of access to women in early pregnancy?
RESPONSE: This is an excellent point. Detailing the denominators in the various scenarios would have been ideal and would have provided information that could have been used for comparisons at that level. Regrettably, due to feasibility we were not able to capture this information to be able to compare groups. For example – in many scenarios we relied on the good will of physicians and their staff to provide information to their patients about the projects and were not able to request that they also capture information on the patients that they approached. Hence our paper is focused on the information we were able to capture and we are not able to comment on the potential impact of these other variables.

3. Results - Since study recruitment is a huge expense, and if targets are not met, the study fails, it would be good for the authors to provide some detail on the relative cost of each of their recruitment strategies. This would allow comparison with other studies of this nature where one can see the “participant recruitment cost” for media vs staff etc. This information could be included in Table 1 for ease of comparison. This is actually quite important information, as it can be used to justify budgets for cohort studies which most agencies balk at.

RESPONSE: While this would be useful information a cost analysis goes beyond the scope of this paper and could result in a separate paper on costs.

4. While the authors do describe the differences in prenatal care between Edmonton and Calgary, somehow the real distinguishing difference gets lost in all the detail about FP vs obstetrician. For example, it seems in 1 family practice selected in Edmonton, over 1/3 of women approached were excluded because they were already beyond 27w gestation. This finding doesn’t mesh with points made in the discussion lines 251-3 that early care is provided by FP; and lines 260-1 about more prenatal care being provided by obstetricians making it difficult to recruit women <27w gestation. When it is stated that after 2 weeks the majority of pregnant women in the Edmonton family practice had been approached by the research assistant, it becomes clear that the real issue was the lack of volume of newly pregnant women.

In this regard, it would be good to provide some more info about the features of the Edmonton family practices that were accessed, compared to the “high volume family medicine maternity clinics” in Calgary: define “high volume”, number of practitioners?, is there a predilection for maternity care in the Calgary practices or are they just overall high volume?, clarify if women are referred from their regular FP to the family physician-led maternity clinics in Calgary, or have they already an established relationship with these physicians.

RESPONSE: The issue with our project was, as the referee identified, a need to access a high volume of women in their early pregnancy. In Edmonton we could not access these women in either family physicians or obstetricians offices (since neither saw a high volume of early pregnancies). In 2007 there were two main family physician groups who provided prenatal care and delivery. One, the GNFMC Mom Care group delivered 150 women per year, the other MOM care group was estimated at delivering 300 women per year. In Calgary the family physician run maternity clinics had a higher volume and saw women earlier in their pregnancy. Women attending these clinics were
both self-referred or referred by their family physician. Examples of high volume maternity clinics in Calgary were the Low Risk Maternity Clinic, Grace Maternal Child Clinic and the North West Maternity Clinic. These were three dedicated maternity clinics that attained 2100 deliveries a year in 2007. They were located in one location with most women admitted at 10-14 weeks gestation. We have added the information about the Edmonton and Calgary family physicians accessed (see methods, recruitment strategies common to both cities, -1. Physicians’ offices –first paragraph. Lines 120-126).

5. Please clarify that the 821 (Calgary) and 159 (Edmonton) participants on whom mode of recruitment was determined, derive from the total recruitment figures given of 1028 and 172, respectively.
   • RESPONSE: Yes, the numerators and denominators have been added to Table 1.

6. The information about WCHRI is very interesting but it might suffice to say that this was not effective with majority unable to be contacted or declining. Table 2 with details of failed WCHRI recruitment is unnecessary. It is important to leave this strategy in the methods as, to awareness of this reviewer, this is the only reported occasion upon which a research institute set out to systematically support the recruitment of participants to multiple research studies.
   • RESPONSE: Agreed & done. (see lines 232-233 which describe what was in Table 2)

7. The data in Table 3 should be subjected to statistical analysis, and ideally then summarized with a statement “no statistical differences in the SES between the cities” which might obviate the need for this table.
   • RESPONSE: Table 3 is now Table 2 in the revised manuscript. We subjected Table 2 to statistical analysis and though we did not find significant statistical differences in the table using Fisher's exact test and Chi-square (see lines 276-281), we decided to keep the table since it adds descriptive details used in describing similarities and differences with the census data.

8. Figure 1 is nice, but perhaps not necessary. Reference could be provided to previous publications on this cohort study for those that might want that detail, and the important points about longitudinal follow-up for 3 years with 7 physical assessments and 8 questionnaires, briefly noted.
   • RESPONSE: Agreed & done – Figure 1 is removed and more details and reference provided (see lines 73-80 and reference 15)

9. This reviewer hesitates to ask, however, many reports of this nature also include some documentation of subject retention. It is acknowledged that sufficient time has not lapsed such that all participants will have completed the study. However, if known, it would add weight to this report to show that the overall trend was that ‘once recruited; retained’; or whether there was a greater drop-out rate in one of the cities compared to the other.
   • RESPONSE: A detailed retention strategy was utilized by APrON to maintain good follow-up and avoid dropouts. The present paper is focused on recruitment of a pregnancy cohort. Data on retention is not yet complete since we are following this cohort for 3 years. Also, adding the details and
approach to retention would make this recruitment paper excessive long and blur the original intent. We do intend to publish on retention in another future paper.

General comment
Since this article will have an international audience, a brief description of the universal nature of Canadian health care system and adequacy of maternity care is warranted (the authors could reference the PHAC Canadian Maternity Experience report if they think this is still accurate information).

- RESPONSE: We have added the following paragraph in the background fourth paragraph: Health care in Canada is provided through a publically funded system (see lines 82-85). Medical services are governed by the Canada Health Act but are delivered provincially. The Canadian population does not pay for individual visits for medically necessary treatments. Maternity care is fully covered under the system.

Sincerely,

Donna Manca MD, MCISc, FCFP

Director of Research
Associate Professor
Department of Family Medicine
University of Alberta
901 College Plaza
Edmonton, Alberta T6G 2C8
Telephone: 780 492-8102
Fax: 780 492-2593
Contribution of Authors

Donna Manca, MD, MCISc, (dpmanca@ualberta.ca) – involved in development of the recruitment strategy and follow-up, conceived and designed the paper, involved with conducting the initial literature review, wrote the first draft manuscript, revised the manuscript and gave final approval.

Maeve O’Beirne, PhD, MD, (OBeirne@ucalgary.ca) – involved in development of the recruitment strategy and follow-up, conceived and designed the paper, reviewed the initial literature review, involved in the drafts and revising the manuscript, and gave final approval.

Teresa Lightbody, MSW, RSW, (teresal@ualberta.ca) - involved in development of the recruitment strategy and follow-up, conceived and designed the paper, involved with conducting the initial literature review, wrote the first draft manuscript, revised the manuscript and gave final approval.

David Johnston, MA, (davidw.johnston@albertahealthservices.ca) - involved in development of the recruitment strategy and follow-up, helped to conceive and design the paper, involved with reviewing the initial literature review, assisted with the drafts, revised the manuscript and gave final approval.

Dayna-Lynn Dymianiw, BSc, (daynalynn@shaw.ca) - involved in development of the recruitment strategy and follow-up, contributed to the conception, composition, and revision of the article, and approved the final version to be published.

Katarzyna Nastalska, BSc, (knastalska@shaw.ca) - involved in implementation of the recruitment strategy and follow-up, contributed to the conception, composition, and revision of the article, and approved the final version to be published.

Lubna Anis, MBBS, (lubna.anis@albertahealthservices.ca) -- involved in development of the recruitment strategy and follow-up, contributed to the conception, composition, and revision of the article, and approved the final version to be published.

Sarah Loehr, BSc, (sloehr@ualberta.ca) - contributed to the conception, composition, and revision of the article, and approved the final version to be published.

Anne Gilbert, BSc, RD, (Anne.Gilbert@ales.ualberta.ca) - contributed to the conception, composition, and revision of the article, and approved the final version to be published.

Bonnie Kaplan, PhD (bonnie.kaplan@albertahealthservices.ca) – principal investigator, involved in development of the recruitment strategy and follow-up, conceived and designed the paper, reviewed the initial literature review, involved in the drafts and revising the manuscript, and gave final approval.
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