PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Improving access to primary health care for vulnerable populations in Australia and Canada: Protocol for a Mixed-Method Evaluation of six complex interventions
AUTHORS	Russell, Grant; Kunin, Marina; Harris, Mark; Levesque, Jean-Frederic; Descoteaux, Sarah; Scott, Catherine; Lewis, Virginia; Dionne, Emilie; Advocat, Jenny; Dahrouge, Simone; Stocks, Nigel; Spooner, Catherine; Haggerty, Jeannie

VERSION 1 – REVIEW

REVIEWER	Colleen Varcoe University of British Columbia
REVIEW RETURNED	13-Feb-2019

GENERAL COMMENTS	This is a well written paper that tackles a very complex set of projects. I greatly appreciate the challenge of capturing such complexity. The diversity among the projects is evident, and the authors have shown this effectively. What is less clear is the commonality across the projects. Other than targeting (very diverse) marginalized (or in the authors words', vulnerable) populations, and attention to PHC access, how were the projects unified? Was there an overarching research question? Or just the individual project questions? Where there any guiding principles? Theoretical framework? Methodological commonalities? Common definitions? This might be facilitated by positioning Table 1 after a discussion of commonalities and what holds these diverse projects together. The diversity offered by situating projects from Australia and Canada within one overarching project is clear. However, what is not clear is the 'value added'. Other than a statement that in both countries PHC reforms prioritise access to effective and high-quality health services, with equity being at the heart of that system, but that inequities persist, there is no comparison of contexts. Australia and Canada are great comparison partners, given our similar geography, colonial history etc, but how is the potential being harnessed here? Further, what is the potential value added of the diversity of settings and interventions? The fact that there are six different interventions in six settings is clear, and Figure 1 suggests that all 4 projects were conducted at all six sites. Is this the case? The 4 projects are not described (just named), but Box 1 suggests that this paper is describing Project 4. Is that the case? It might be useful to move some of the text from Box 1 to provide a brief overview of the IMPACT program in text in the background.

	In concert with my comments above, it seems as though there was effort to have some commonality and site-specific tailoring. That is, it appears that the survey questions may have been common across sites with tailoring as to sequencing; qualitative guides were aligned with a framework but then allowed to reflect features of the local intervention, and so on. How was standardization determined and insured? What was the balance between standardization and tailoring? To what extent and on what variables will comparisons be possible? Under data analysis, a common coding and variable naming convention is identified, but the extent of this is not clear. Finally, other than stating that ethical approval was obtained, there is no discussion of the key ethical issues, yet this is likely a very rich opportunity for considering ethics related to such interventions. On a more minor note: • Under Strengths and Limitations following abstract, a statement of limitations would be useful. • I see no evidence that this study was registered. • The title might reflect that the projects aimed at primary health care access. • There is some unevenness in the descriptions across the projects. For example, Table 1 reports (under recruitment) for the Australian LIPs what data are planned to be collected, but this is missing for the Canadian LIPs, and the term practices and practitioners seem to be used interchangeably. Why were observations only conducted in the Canadian sites? And are the "non-participant observations in PHC settings" the same as the "non-participant observations" described later? • Throughout, could more precision be offered? For example, "in some LIPs…" (2,4,5?) and why in 'some' and not others? • How was it determined that sample size was sufficient to assess predictors of change? • What is meant by "structural coding techniques"?

REVIEWER	Professor Tim Stokes University of Otago, NZ
REVIEW RETURNED	13-Mar-2019

GENERAL COMMENTS	This BMJ Open Protocol paper reports the approach for the evaluation of a large-scale, multi-site complex intervention to improve access to primary health care for vulnerable groups in Australia and Canada. Overall this is an important and timely mixed method complex intervention study of an area of high health policy importance whose overall design deserves publication as a methodology / protocol paper. The challenge I have as a reviewer is that, as currently written, the paper does not appear to well fit the criteria set out by BMJ Open for reporting of protocol papers. I consider this can be addressed and set out proposals as to how the authors can address these in the requested revisions section below. In addition I have a small number of minor comments that would improve the clarity of the paper. Major requested revisions

	1. BMJ Open guidance is that "protocol papers should report planned or ongoing studies. The dates of the study should be included in the manuscript … if data collection is complete, we will not consider the manuscript". As currently drafted it is confusing to the reader as to whether this paper reports the methods of a completed study; or is a protocol for a planned and/or ongoing study. Thus throughout the paper, including the abstract, different substudies are referred to in the past tense, and others in the present or future tenses. It would be usual in a protocol paper to use the present or future tense when reporting an ongoing study. There therefore needs to be the correct use of tense throughout. 2. As a follow up to the above, the chief reason why tense is confusing is that the authors have not clearly set out the timeframes for the study, including specific timeframes for each substudy, so it is unclear to the reader which substudies are completed, which are ongoing, and which are to be initiated. As I note this is a requirement for a BMJ Open protocol paper (to be clear on timeline), I suggest this can be addressed by a table / box / figure clearly setting out the time points of each of the substudies. 3. The methods section lacks a study aims and objectives section, which is usual in protocol papers. It would be helpful for the reader if this can be developed and the research questions, currently sitting in the data analysis section, moved forward into this section. Minor discretionary revisions 4. Title (p. 2, LL5-6). Improving access to what? I suggest this is expanded to "Improving access to primary health care for vulnerable …." 5. Discussion (p. 18, LL45): "over the next twelve months". Revise this wording in line with comment 2 above.

VERSION 1 – AUTHOR RESPONSE

General Comments

Comment 1:

Reviewer 1 Overall this is an important and timely mixed method complex intervention study of an area of high health policy importance whose overall design deserves publication as a methodology / protocol paper. Reviewer 2 This is a well written paper that tackles a very complex set of projects. I greatly appreciate the challenge of capturing such complexity. The diversity among the projects is evident, and the authors have shown this effectively.

Response: Both reviewers have commented positively on our attempts to address the complexity of the diverse interventions and their evaluation. We acknowledge their suggestions for improving the paper and have arranged our responses in sections corresponding to the key areas of concern.

Paper title

Comment 2: The title might reflect that the projects aimed at primary health care access. (reviewer 1)

Response: Both reviewers have made insightful suggestions to the title of the study. We have revised the title to read "Improving access *to primary health care* for vulnerable populations in Australia and Canada: Protocol for a Mixed-Method Evaluation of six complex interventions"

Tense and timing of the study

Comment 2: Reviewer 2 BMJ Open guidance is that "protocol papers should report planned or ongoing studies. The dates of the study should be included in the manuscript … if data collection is complete, we will not consider the manuscript". As currently drafted it is confusing to the reader as to whether this paper reports the methods of a completed study; or is a protocol for a planned and/or ongoing study. Thus throughout the paper, including the abstract, different substudies are referred to in the past tense, and others in the present or future tenses. It would be usual in a protocol paper to use the present or future tense when reporting an ongoing study. There therefore needs to be the correct use of tense throughout. (Reviewer 2)

Response: IMPACT is an ongoing study. We thank Reviewer 2 for his suggestion that we include the dates of the study to inform the reader that we have adhered to the journal's imperative that "protocol papers should report planned or ongoing studies." Data were still being gathered to inform components of the evaluation at the time of submission in November 2018, and, in some of the sites, continue to be collected. Hence, while our lengthy period of data collection was still continuing prior to the submission of the paper, for clarity we have oriented data collection to the past tense.

We have included the following sentences that highlight our approach to the use of tense in the study and have modified the tense in the document to have the interventions and the data collection described in the past tense and analysis in the future tense (noted in red in the text).

If necessary, this is simple to modify to fit with the journal's requirements.

[Background p6] *Interventions were implemented between June 2016 and June 2018. At the time of submission, data are still being gathered to inform components of the evaluation.*

This paper describes the approach that will be used to evaluate the effectiveness and further scalability of the interventions generated by the IMPACT program.

[Design p7] *This paper describes the strategy that will be employed to evaluate the collected data.*

Comment 3: As a follow up to the above, the chief reason why tense is confusing is that the authors have not clearly set out the timeframes for the study, including specific timeframes for each sub-study, so it is unclear to the reader which sub-studies are completed, which are ongoing, and which are to be initiated. As I note this is a requirement for a BMJ Open protocol paper (to be clear on timeline), I suggest this can be addressed by a table / box / figure clearly setting out the time points of each of the sub-studies.

Response: We acknowledge the importance of clarifying the timeline used within the study. We have added a diagram (*Figure 2. Timeline of IMPACT activities*) showing the timeline of the intervention that highlights the fact that this protocol relates to the evaluation of a series of interlinked regionally based interventions.

Comment 4: (Reviewer 1): Was there an overarching research question? Or just the individual project questions?
Comment 5 (Reviewer 2): The methods section lacks a study aims and objectives section, which is usual in protocol papers. It would be helpful for the reader if this can be developed and the research questions, currently sitting in the data analysis section, moved forward into this section.

Response: Both reviewers have asked for clarification of the research question – Reviewer 1 in asking for clarification of the research question and Reviewer 2 in asking for the methods section to include a study aims and objectives section. We have added a study aims and objectives section to the methods section.

We have included the objectives of the overarching project works with a clarifying comment (p6):

The objectives of the overarching IMPACT project are as follows:

1) *To develop a network of partnerships between decision makers, researchers and community members to support the improvement of access to PHC for vulnerable populations;*
2) *To identify organisational, system level CBPHC innovations designed to improve access to appropriate care for vulnerable populations, and establish the effectiveness and scalability of the most promising innovations;*
3) *To support the selection, adaptation and implementation of innovations that align with our regional partners local populations' needs and priorities; and*
4) *To evaluate the effectiveness and efficiency and further scalability of these innovations.*

This paper describes the approach to address the fourth objective.

In addition we have moved up the broad areas relating to the evaluation aims to the STUDY AIMS AND OBJECTIVES section at the beginning of the METHODS section (p7).

- *The research program's support for the intervention.*
- *The implementation of the intervention*
- *The impact of the intervention on patients, providers, practices and on health care utilisation.*

These are complemented by additional detail in the data analysis section and documentation of the comprehensive evaluation questions (APPENDIX 1). We feel that this helps the reader's ability to interpret the evaluation plan.

Comment 6: (Reviewer 1) Under Strengths and Limitations following abstract, a statement of limitations would be useful.

Response: We have added the following text to the Strengths and Limitations list (p4):

The study evaluation is limited by it being confined to six jurisdictions within in two affluent Western nations. No rural communities were involved. Instruments were only available in English, French (in Canada) and Arabic (in New South Wales). The Victorian team worked with an accessible language service to develop Easy English versions of consent documents ad questions within the patient survey.

Comment 7 reviewer 1: Where there any guiding principles? Theoretical framework? Methodological commonalities? Common definitions?

Response: The research team adopted a series of guiding principles to negotiate its work, however the overall program was informed by Levesque et al's model of access to health care. For the purposes of the study this was operationalised into a program logic model. The access model has been included as APPENDIX 2. The program logic model is listed as APPENDIX 3. Both had already been mentioned in the Design section.

Comment 8 Reviewer 1: The diversity offered by situating projects from Australia and Canada within one overarching project is clear. However, what is not clear is the 'value added'. Other than a statement that in both countries PHC reforms prioritise access to effective and high-quality health services, with equity being at the heart of that system, but that inequities persist, there is no comparison of contexts.
Australia and Canada are great comparison partners, given our similar geography, colonial history etc, but how is the potential being harnessed here? Further, what is the potential value added of the diversity of settings and interventions?

Response: This is an important point. We refer the reviewer to a piece in the conclusion that highlights the value add of the program of work and its evaluation. We have added to this section to further highlight the importance of context in the diversity of the study (p22-23):

For the broader PHC community, the results of evaluations of the evolution of the partnerships and the impact of the interventions will provide a better understanding of the influence of context in the implementation of community focussed access interventions and significant new data on mechanisms supporting the implementation of community-academic partnerships. The evaluation will provide unique insights into how innovations work in different contexts and both their direct, indirect and unanticipated impacts. Resorting to a clear logic conceptualisation of PHC systems will enable us to identify relevant organisational levers and contextual influences that can be harnessed to create sustainable and scalable changes in CBPHC to favour access for the vulnerable.

The work should generate a deeper understanding of the ways in which system-level organisational innovations can improve access to PHC for vulnerable populations and new knowledge concerning improvements in primary health care delivery in health service utilization.

Comment 9: Reviewer 1 What is less clear is the commonality across the projects. Other than targeting (very diverse) marginalized (or in the authors words', vulnerable) populations, and attention to PHC access, how were the projects unified?

Response: Reviewer 1 has asked us to highlight how the projects (interventions) were unified. We have made minor modifications to reflect this in the background (under work of the Local Innovation Partnerships)

The regional interventions were all set in vulnerable communities where partnerships could be developed between principal investigators and clinicians, policy makers and community members.

Each region used a common approach to assessing access related need and prioritising the need. The approach was informed by common definitions.

Then teams in each region were charged with arranging resources to enable one of the priority needs to be addressed by an intervention. The development of the partnerships and the implementation of the interventions were informed by two documents, developed by members of the study team.

Evaluation used a common set of tools (described under DATA ANALYSIS); however, local and national additions to the core methodology have been encouraged.

Comment 10: Reviewer 1 The fact that there are six different interventions in six settings is clear, and Figure 1 suggests that all 4 projects were conducted at all six sites. Is this the case? The 4 projects are not described (just named), but Box 1 suggests that this paper is describing Project 4. Is that the case? It might be useful to move some of the text from Box 1 to provide a brief overview of the IMPACT program in text in the background.

Response: To clarify, projects 1 and 3 were conducted independent of the sites – the knowledge generated from both was designed to inform the work conducted within the Local Innovation Partnerships. Project 2, while coordinated centrally, involved settings in realist reviews of the interventions.

We have taken Reviewer 1's suggestion to move some of the text from Box 1 to provide a brief overview of the IMPACT program in text in the background. We have also expanded on the descriptions of the projects 1-3 (in text explaining Figure 1 on P 27).

Comment 11: Reviewer 1 How was standardization determined and insured? What was the balance between standardization and tailoring? To what extent and on what variables will comparisons be possible? Under data analysis, a common coding and variable naming convention is identified, but the extent of this is not clear.

Response: Reviewer 1 went on to ask about standardisation between methods and how this was achieved. This was managed by having overarching qualitative and quantitative committees focussing on the design and focus of the data collection instruments and have been exploring the quality of the data as it evolves. These have been emphasised in the data management section (p 18). We have needed to make decisions in terms of limiting finer details of the cross site evaluation believing that the resulting complexity would be beyond the remit of this paper.

Comment 12: Reviewer 1 There is some unevenness in the descriptions across the projects. For example, Table 1 reports (under recruitment) for the Australian LIPs what data are planned to be collected, but this is missing for the Canadian LIPs, and the term practices and practitioners seem to be used interchangeably.

Response: We have reviewed the content of table 1 and tried to standardise the descriptions of the interventions. The term "practitioner" has been changed to "provider" except where it describes a specific profession. A row has been added to Table 1 listing modifications to data collected for all LIPs.

Comment 13: Reviewer 1 Throughout, could more precision be offered? For example, “in some LIPs…” (2,4,5?) and why in ‘some’ and not others?

Response: We appreciate the reviewer’s request to add more detail to our overarching description. The challenge is in increasing the complexity of the paper. As mentioned above we have modified and expanded the description of the interventions in table 1 and added a row to table 1 that shows the major modifications to the planned evaluation in each jurisdiction.

Comment 14: Reviewer 1 Finally, other than stating that ethical approval was obtained, there is no discussion of the key ethical issues, yet this is likely a very rich opportunity for considering ethics related to such interventions.

Response: Other papers generated from the project will focus in more detail on the ethical challenges of this complex venture. We have added a sentence that alludes to the challenges of ethics in the ETHICS AND DISSEMINATION section (p21):

Ethics applications were tailored to the needs of the vulnerable populations included in the study and to the sometimes complex requirements of health services implementing components of the study. At times this required additional tailoring of the survey tools, in particular the patient questionnaires.

Comment 15: Reviewer 1 I see no evidence that this study was registered.

Response: Concerning trial registration, we should clarify that the IMPACT study was not a clinical trial. Rather, it was an exploratory evaluation of six health service innovations using a mixed methods approach and a before/after design. Each of the interventions represented heath service innovations that were developed in a collaborative manner and then evaluated using a common methodological approach. Regarding registration, we were informed by the ICMJE definition of clinical trials at www.icmje.org and the statement: "Purely observational studies (those in which the assignment of the medical intervention is not at the discretion of the investigator) will not require registration. (http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/).” None of the interventions gave any discretion for the investigator to determine participation. However, the Ottawa intervention secured funding to subsequently incorporate a subsequent clinical trial that has been registered.

We have included the following text under REGISTRATION (p26):

Given that the IMPACT study was an exploratory evaluation of six health service innovations using a mixed methods approach and a before-after design and that the assignment of the medical intervention was not at the discretion of the investigators, we followed the guidelines of the International Committee of Medical Journal Editors (http://www.icmje.org/about-icmje/faqs/clinical-trials-registration/) in not registering the overall study. The Ottawa intervention secured funding to subsequently incorporate a clinical trial. This study (recently described in JMIR Research Protocols available at https://www.researchprotocols.org/2019/1/e11022/) has a trial registration number at ClinicalTrials.gov of NCT03105635 (https://clinicaltrials.gov/ct2/show/NCT03105635/).

Comment 16 Reviewer 1: How was it determined that sample size was sufficient to assess predictors of change?

Response: We have included the following comment on sample size in the DATA ANALYSIS section (p21):

Sample size varied across interventions. In terms of patient level data we require interventions being included in the quantitative components of the final evaluation to have at least 25 patients with data available for analysis.

Comment 18: Reviewer 1 What is meant by "structural coding techniques"?

Response: Structural coding is a form of elemental, first level coding that is a useful initial approach to organising large qualitative data sets. It is well described in Saldaňa, J. (2013). The coding manual for qualitative researchers (2nd ed.). Thousand Oaks, CA: Sage. This reference has been added to the text.

Comment 19: Reviewer 1 Are the "non-participant observations in PHC settings" the same as the "non-participant observations" described later?

Response: The two descriptions of non participant observations relate to the same process.

Comment 20: Why were observations only conducted in the Canadian sites?

Response: Resources, health service interest and researcher capability varied between sites and nations. As mentioned above we have reviewed the contents of table 1. We have made changes in Table 1 to reflect key differences in evaluation.

Comment 21: Reviewer 2 Discussion (p. 18, LL45): "over the next twelve months". Revise this wording in line with comment 2 above.

Response: We have revised the tense throughout.

VERSION 2 – REVIEW

REVIEWER	Prof Tim Stokes University of Otago, NZ
REVIEW RETURNED	04-May-2019

GENERAL COMMENTS	The authors have fully addressed reviewer 1 & reviewer 2's concerns in their detailed rebuttal and revisions to the paper.