Reviewer’s report

Title: The Improved Delivery of Cardiovascular Care (IDOCC) through Outreach Facilitation: study protocol and implementation details

Version: 2 Date: 4 May 2011

Reviewer: Mary Ann O’Brien

Reviewer’s report:

Thank you for asking me to review this manuscript. It describes the design of a pragmatic stepped wedge design randomized controlled trial of Practice Outreach Facilitators in primary care to improve the care of patients at high risk of cardiovascular disease.

The study addresses an important problem in primary care through an innovative research design and the use of a comprehensive complex intervention. The authors have carefully outlined their research questions and methods. My comments are, for the most part, minor in nature. I hope that by addressing these comments, the authors will strengthen their manuscript.

Minor Essential Revisions

1. One of the strengths and challenges of the intervention design is that it is based in part, on the Chronic Care Model (Wagner et al. 2001). While the components of this model have been broadly described in the literature, it would be helpful if the authors could provide a justification for their choice of the specific model components that they used in the design of their intervention.

2. Abstract Page 3. Methods/Design. Description of the intervention. It would be clearer if the authors could describe (in the abstract and elsewhere e.g. page 6 para 4 and page 7 section b) the target audiences for each intervention component. For instance, the linkages to community support and self-management support tools appear to be for patients while the decision support and delivery system redesign appear to be directed to health professionals and those responsible for the organization of the practice, respectively.

3. Abstract Discussion (also in last para of Background section and Implication for Practice section). The intervention is complex and likely expensive. Yet, in the concluding sentences of both the abstract and the manuscript, the authors state that they anticipate that the program will be effective, practical and sustainable. The authors are encouraged to describe how this intensive intervention is likely to be practical and sustainable. This information is important for many types of readers including physicians and policymakers and other researchers.

4. Background. Page 4.Para 3. Last sentence. The authors provide references for their assertion that the intervention should be “based on elements of the chronic care model” (refs 18-22). Yet, only one of these references (19) actually
refers to this model in a substantive way. I suggest that the authors simply reword this sentence with the appropriate references.

5. Methods Page 5 (and Table 1). The authors describe their research design succinctly. Yet it is a quite complex design with ‘divisions’, geographical regions, and ‘Steps’. I suggest replacing Figure 2 with another Figure that would provide a visual aid to help the reader to understand the design including randomization and control units (see next comment).

6. Methods Page 6. The authors state that “Each of three divisions per stratum was randomly assigned to one of three Steps”. Do I understand correctly that each division was a region? Is a region considered the unit of randomization? Could the authors clarify the comparability of the divisions with respect to practices and patients?

7. Components of the ICOCC project, Pages 6-8. The authors are encouraged to provide more details. To whom and how will the Practice Outreach Facilitators (OFs) give the feedback? For the interactive meetings, please clarify how these meetings are truly interactive. This information will be helpful to other researchers interested in applying these interventions.

8. Community Resources: The authors state the Champlain Cardiovascular Disease Prevention and Management Guideline includes a community resources section and that this information is updated annually. The OFs will give information to the practices based on stated needs. Yet this approach appears to be fairly ‘passive’. How will this potentially valuable information get to the health care providers (HCPs) and then to the patients at the right time?

9. Self-management Support Tools: Similarly, while an inventory is important, how will the HCPs get this information in a timely manner for the right patient in a busy practice?

10. Delivery System Redesign: Can the authors clarify that the OFs would really have the necessary skills and time to undertake what would appear to be a large undertaking (redesign of aspects of the practice organization) given all their other responsibilities in multiple practices?

11. Data Collection Page 8. What are the differences in the data collected in the baseline period and that collected retrospectively post intervention?

12. Data Collection Page 9. Narrative Reports. How is the quality of the narrative reports assessed?

13. Page 10. The authors state that they are linking to administrative databases for clinical outcomes. What data are being collected in this process and how will data quality be assured?

14. Analysis. Page 11. The analysis is well described and pre specified comparisons are outlined clearly. It appears appropriate but I should note that I am not an expert in the stepped wedge design. I note that in the abstract, the authors state that the primary outcome is a composite improvement score at the level of the practice. The intervention is also at the level of the practice. Could the authors clarify why the unit of analysis is the patient rather than the practice?
15. Analysis Page 11. Qualitative analysis. NVivo 8 is really for data management. The analysis needs to be done by the researcher(s). The authors should provide information about how the data will be coded and analyzed. How will the quality of the coding and analysis be assessed? The authors state that “narratives from each OF will be analyzed as a separate case”. The definition of a ‘case’ needs to be clearer. Will the ‘case’ be all narratives from all practices for a given OF? Are these narratives nested within practices? How will between-OF variation be examined for communication differences?

16. The limitations section is well-written and balanced.

17. The tables and figures (except Figure2- see earlier comment) are clear and informative.

18. Could the authors clarify whether they need both Table 1 and Figure 2? I don’t think Figure 2 adds very much to the information contained in Table 1.

19. There are few small typos here and there e.g. abstract, Methods/Design “over a one-two year period” (needs an a). Also see page 5 Methods/Design, para 2, “every 6-12 weeks” (needs an s). The manuscript would benefit from a copy edit to fix these and other small errors.


21. Reference #58 needs to be updated.

Reference

**Level of interest:** An article of outstanding merit and interest in its field

**Quality of written English:** Acceptable

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I declare that I have no competing interests.