

Author's response to reviews

Title: Tailoring an Intervention to the Context and System Redesign Related to the Intervention: Case Study of Implementing Shared Medical Appointments for Diabetes

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Author's response to reviews:

To the Editor,

We are gratified with the reviews and thank the reviewers for their incisive and challenging reviews. They have helped us think about the subject and the manuscript itself. Our responses to the specific questions from each reviewer and are as follows:

Reviewer 1: Richard Baker

1. The majority of the paper is placed in a section entitled `Methods and Conceptual Framework'. It is easy to get lost in this section, and difficult to find key information. It would be worth attempting switching the structure to the more common Introduction, Methods, Findings, Discussion/conclusion format.

We have added headings to the more common: Introduction, Methods, Results, Discussion and Conclusion for improvement in accessing key information.

2. The methods were unclear. A case-analysis using a systems framework is reported. However, there is no information on the sources of data used by the authors; direct observation, interviews of staff, study of minutes and reports may all have been used but this is not explained. The systems framework method is not referenced. How systematically were data collected and used?

We have provided more detail about the methods including the framework and sources of data. These details are found in the section entitled 'Methods of Evaluation'.

3. Were the researchers working in the clinic or medical center involved, or were they independent?

The researchers were also working in the clinic and this is cited under the heading, 'Methods of Evaluation'.

4. We are told in the abstract that there is evidence that improved clinical outcomes were achieved, and the evidence to indicate this may (it is difficult to be certain from the information given) be due to appear in Quality and Safety in Health Care. The conclusions (page 13) state that clinical outcomes were not sacrificed and may have improved. It would enormously helpful to outline briefly in a box or table what was achieved in terms of clinical outcomes.

Evidence for our clinical outcomes is cited in references and in the paper as a recently published article in Quality and Safety in Health Care (reference 25). In addition we have added our recent analysis of changes in A1c for the 280 patients where we have pre and post-SMA participation data. These results revealed a significant mean change in A1c (%) of -0.9 (+/- 1.7) (Wilcoxon signed rank test, $p < .0001$).

5. A short, simple definition or explanation of shared medical appointments would aid understanding.

We have explained in further detail what constitutes a Shared Medical Appointment or Group Visit in the Background Section.

6. It may be helpful to ask a colleague unfamiliar with the work and field to read the paper through and comment on readability.

This manuscript was read by three of our colleagues and we have incorporated their suggestions to improve the readability.

7. There is no mention of ethics approval by an Institutional Review Board. This may not have been a requirement. However, would it be possible for people referred to in the paper to be identified? For example, the medical director or endocrine nurse practitioner might be identifiable to a few readers since there were only one of each. Should the staff of the clinic be thanked in the acknowledgements?

The study of Shared Medical Appointments is IRB approved. We have added an acknowledgment of the staff of the clinic. Two of the authors have roles in the clinic and SMAs. Their roles are now cited in the text.

8. Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct).

a. Many acronyms are used.

We have eliminated the majority of the acronyms to improve readability.

b. The tables and figure 2 are quite dense. They contain important details but some clarification would help.

The tables and figures have been reviewed and re-labeled to improve access to information. Further description of important aspects of the tables has been added to the manuscript.

Reviewer #2: Peter Wilcock

1. The need for this construct needs a more rigorous justification than is currently provided. In particular they need to describe clearly how it adds value to practice rather than merely another level of conceptual description. It does not feel good enough to simply state that to conceptualize the SMA as another clinical microsystem was not consistent with expanding and integrating other services. Readers familiar with the clinical microsystem (CMS) concept might consider that what they have in fact designed is a high performing CMS as described by Nelson, Batalden and colleagues. However a fuller explanation of the differences between a high performing CMS and the intra-meso concept feels essential if the latter is to be accepted as adding value to current thinking about models of healthcare systems.

A more detailed description and reasoning for the adoption of the term *intra-mesosystem* has been added into the last paragraph under the Background heading as well as the second paragraph under *Planning the Study*. We felt that to conceptualize SMAs as another clinical microsystem was confusing, given the co-presence of the more traditional microsystem and the unique way SMAs expanded and integrated other services and resources of the primary care clinics that was contrary to traditional thinking about care. Moreover, the primary responsibility for the patients seen in the SMA remained with the primary care provider in his/her microsystem. Accordingly, SMAs are identified as an intra-mesosystem component to recognize the linkages among and between other meso components (intra-meso) beyond the microsystem and emphasize the system re-design. Additionally, the SMA with its own iterative improvements and evolution seemed a separate system as opposed to a higher performing system that already existed. This is in contrast to the initial starting system design where there was only the closed microsystem with the components within (intra-micro) the inner clinical microsystem. We have also made reference to the characteristics of high performing Microsystems.

2. Making key elements of the study clearer by using more explicit section headings would make its helpful insights more easily accessible to those struggling to develop new services in old contexts.

We have used more explicit section headings.

3. Table Two provides rich detail and could be supported by stronger reference in the text as about the relative importance of the different elements and especially clarify the nature of the leadership and stronger team working that was necessary for success including crucial human factors.

We agree that further elaboration of details can be helpful and we have added a statement about the factors we thought were most important. However, the

manuscript is already 5000 words and we are concerned about the length. Moreover, we do not want to detract from the importance of have a framework for evaluation.

b. Table Three ¿ mapping of implementation characteristics against Grol and Wensing¿ very helpful framework provides insights which would be strengthened by short descriptions in the text of how they were identified and responded to in practice during the course of implementation.

We have added the following in the Implementation and Evolution heading.

The Grol et al. framework identifies the flexibility and adaptability during implementation as a dimension which can either promote or hinder. We found that this since our SMA had a strong core team, that this was an important aspect to identify and maximize throughout implementation. Once identified, we could use this promoting factor as challenges faced the core team in project implementation. The lack of clear boundaries of what constituted the innovation meant that the team members needed to be allowed options for adapting to local context and needs and that this flexibility had to be maintained throughout the implementation process. As an example, we recognized after initiation of the SMA process that patients wanted to discuss dietary issues in detail and we subsequently added a nutritionist to the team and she has become a core member. Another characteristic is that of complexity of both the innovation (SMA) and its implementation. The SMA was something that was identified initially as a vague unknown type of clinical care which was not easy to explain. Explicit identification of this barrier to successful implementation allowed the core team to consider how best to overcome this, i.e., reduce the uncertainty by pilot testing. We decided to take advantage of a trial period with small numbers of patients to highlight success as well as allow clinic practitioners to sit in on 1-3 SMAs. Through identification of this barrier we were able to strategize and impede its negative impact on SMA success.

4. The ¿iterative¿ nature of implementation is a really important aspect underpinning its success. Readers would benefit from a fuller description of what this looked like and its potential value for becoming a way of life for the clinic team

We have inserted sentences to underscore the iterative nature of implementation for the clinic and the SMA team in the Conclusion section: It is also imperative to recognize the iterative nature of successful implementation that occurred as a part of our evolution. This iterative practice re-evaluation has now become manifest in other SMAs implemented (heart failure and hypertension), thus continuous quality improvement has become ingrained into routine operation in SMAs. This differs from many of the other clinics.

5. The paper is rather short of objective measures of aspects such as processes and outcomes for patients or the claimed ¿high degree of teamness.¿ It would be stronger if some such data was available or if the authors could at least offer ideas for the future. For example what might be measures reflecting the different

purposes of different stakeholders and how each defines success? What might a balanced scorecard measuring the value of SMA clinics to patients, clinicians and other systems levels confronting growing demands and limited resources, look like? What is known about whether the outcomes of this clinic for its patients are reliably better and more encouraging than those of other SMAs referred to?

Although clinical improvements have been sustained for 2 years, it is also important to recognize that outcomes need to be assessed at multiple levels-patients, staff and organization. For staff, this could include satisfaction as well as knowledge and skills. For the organization, it could include cost and efficiency as well as organizational climate and culture. A comprehensive set of measures would constitute the balanced scorecard necessary for overall system optimization.