Reviewer’s report

Title: A Qualitative Process Evaluation of a Diabetes Navigation Program Embedded in an Endocrine Specialty Center in Rural Appalachian Ohio

Version: 0 Date: 01 Mar 2018

Reviewer: Natalia Loskutova

Reviewer’s report:

The manuscript reports the qualitative results of the process evaluation of a newly established Diabetes Patient Navigation program at the end of its first year. The purpose of this assessment was to evaluate fidelity/implementation of the program and participant experiences by using in-depth interviews with the participants (providers, administrators, office staff, navigators). Identifying effective and practical models for diabetes self-care and reduction of barriers for the patient with diabetes is of importance.

The paper addresses most of the items in the standards for reporting qualitative research (SRQR) and is fairly well organized.

My main criticism of this paper is that it provides inefficient information about the program design and its planned and actual implementation to evaluate fidelity and implementation. Additionally, no evaluation/research questions are presented and it is difficult to assess whether the data as provided addressed the research questions.

While the themes and the quotes are pointing to the perceived value and challenges of the program (participants experiences), it is difficult to see evidence of the assessment of fidelity and implementation of the program. The implementation related findings can perhaps be rather found in the "ongoing challenges".

It would be helpful to clarify what the authors see as the advantage of the stated uniqueness of the program that employed "registered nurses" to "eliminate social determinants of health" (discussion, page 22; lines 19-31) over the programs that used community health workers, lay community members etc.? Based on the limited presentation of the scope of work of the navigators and focus on social determinants of health it does not seem like employing registered nurses added any additional value or eliminated existing/known implementation barriers beyond what has been previously reported. Please clarify what if any was the value added and support by relevant data if available.

Addressing the following specific issues will greatly improve the value of the paper:

Abstract:

* Review whether capitalization is really necessary in presenting the themes.
* Suggest using "unrecognized" instead of "new" barriers

Introduction:

* The introduction can be enhanced and streamlined by including a more thorough review of the existing diabetes navigation programs, elimination of redundancies and condensing the basic content when describing the goals of process evaluation in general (last paragraph for example).

* In the patient navigation model suggest only a brief summary of previous relevant work in cancer. Information related to the program described is very insufficient. Suggest adding a detailed description of the Diabetes Navigation Program in the methods section and indicate how it was similar/different in its design from other comparable diabetes/chronic disease patient navigation programs.

Methods:

* Please describe your sampling strategy: 17 individuals participated in this evaluation: how many participated in the navigation program? How those who participated were selected? How representative of the sampling frame is your study sample?

* Please add research questions or guiding evaluation questions for process evaluation.

* This work ideally would substantially benefit from adding some quantitative techniques to the process evaluation such as reporting on the outputs of the program or measurable program events (the numbers of participants, the numbers of contacts etc.; and not just the description of a very small number of participant experiences with the program and not including patients in the assessment).

* Major omission to be addressed: detailed information about the program that includes at a minimum: when the program started; the navigators’ relevant skill-set and how it was determined; how the navigators were recruited and trained; how the scope of responsibilities was established including what was outside their scope; what services the navigators provided; how the individuals (patients) where selected for a referral; what was a specific referral mechanism and if the referrals forms were used how they were designed and used (if any forms or templates are available include in additional materials if possible); describe how the program was designed to work - the patient flow through the program diagram would be very helpful; the details on the intended program operations and touch points (the set number and the form of patient-navigator interactions) and other relevant details. Without these details it is impossible to gauge the fidelity and implementation of the program and the conclusions drawn by the authors in the discussion "Thus, the Diabetes Navigation Program was implemented as designed" (page 21, lines 21-24) seem to be not substantiated by the methods or the data as presented. Further review of the findings related to fidelity and implementation seem
impossible without sufficient details about the original designs of the program and guiding research/evaluation questions.

Results: In addition to the comments above about limited ability to review the results related to fidelity and program implementation as no detail on the program operations as planned or/and as executed were provided in the methods, the quotes seem to be unnecessarily lengthy and more often than note take attention away from the key points they were supposed to demonstrate.

It would be helpful to review the themes and their linkages to data (quotes) if the interview guides were provided with the manuscript of the questions or prompts were included.

Discussion: It would be helpful if the key points addressed in the discussion were substantiated by the study results. As the methods are results are not fully and adequately reported the discussion points seem somewhat arbitrary. Additionally, some of the information in the discussion is redundant, could be better presented in the introduction and several conclusions related to fidelity or a necessity to develop customized approaches by community (adaptations?) seem unsupported by the data and as such are more speculative in nature.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

No

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

Yes

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

No

**Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?**
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

**Quality of written English**
Please indicate the quality of language in the manuscript:

Acceptable
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Please complete a declaration of competing interests, considering the following questions:

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