Author’s response to reviews

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

Authors:

Elizabeth Beverly (beverle1@ohio.edu)

Jane Hamel-Lambert (jane.hamel-lambert@nationwidechildrens.org)

Laura Jensen (jensenl@ohio.edu)

Sue Meeks (meeks@ohio.edu)

Anne Rubin (ar445116@ohio.edu)

Version: 1 Date: 02 Apr 2018

Author’s response to reviews:

We thank the reviewers for their thoughtful critiques. Below we outline our responses to the issues raised by each reviewer. Edits in the document are made via track changes.

In addition, we have updated the manuscript with new references and statistics for diabetes in the region of southeastern Ohio in the United States.

Reviewer reports:

Enza Gucciardi (Reviewer 1):

1. Page 8 of the PDF, line 51 - more details on explaining the various roles of navigators - For instance, do the navigators direct patients or provide patients with diabetes education?

We thank the reviewer for this comment. We have expanded this section to clarify the role of navigators. In addition, we added a section in our Methods to explain the role of the diabetes navigator in our program (Context).

2. Sound background and model to support the navigation concept that has been used in cancer care with promising results; however, to strengthen this section provide the text about internationally, navigation programs and its impact in the introduction rather than at the end of the discussion.
We agree with the reviewer and we have moved this paragraph to the Introduction. In addition, we have updated our literature review and added more articles to this section. A couple of articles were published since we submitted our paper in July 2017 so we added those citations to the Introduction.

3. Perhaps in the discussion section describe the gaps even with the multidisiplinary teams. Does the literature describe any gaps that potentially navigators may fill?

We have added more content to our Discussion section (paragraph 2) on how diabetes navigation fills clinical gaps. We identified another research study that supported our findings and added it to the Discussion.

4. Fidelity of the implementation wasn't really assessed. Fidelity means to assess if the intervention was implemented as intended most often compared to a procedural manual. However, this was a qualitative process evaluation of the implementation of an intervention. There was no checklist or process that described how fidelity was measured. Perhaps the term fidelity should not be used?

We thank the reviewer for making this point. We did not properly assess fidelity of implementation in our original submission. We have revised this section substantially to follow traditional evaluations of fidelity. We included our Work Plan from our grant submission to the Health Resources and Services Administration (HRSA). The Work Plan details all of the activities we proposed to accomplish in Year 1 of the grant. We described our progress with each of these activities. In addition, we added content to the Methods section to describe the Diabetes Navigation Program, Program Recruitment, and Program Leadership to enhance integrity of the program.

Nancy Schoenberg (Reviewer 2): This manuscript explores perspectives of a patient navigation program for diabetes as assessed by the navigators themselves, health care administrators, and office staff. The project took place in Appalachian Ohio, where residents experience high burdens of diabetes. The manuscript is very clearly written, the research methods well described, and the findings reasonable and enlightening. There are several recommendations, as follows:

1. "Social determinants of health" (p. 1 line 51) (SDH) should be defined. Some readers may lack familiarity with the term.

We thank the reviewer for making this comment as well as the one below. We have revised this sentence to state "health disparities" to avoid confusion.

2. Also, the way that this term is used on page 4 (line 19) is a bit challenging—"one or more social determinants of health" seems to connote that SDH are negative when, in fact, they are like any other determinant of health—neutral. I believe a more precise term might be
"risk factor". For example, low SES is not a social determinant of health; SES is the SDH and having low SES is a risk factor for poor health outcomes.

We agree with the reviewer. We used the term SDH incorrectly. We have revised this term throughout the manuscript to avoid incorrect use and confusion. We used the term sources of health disparities.

3. It is unclear what the statement on page 4, line 48 means: "to address the complexities of diabetes and its management in the context of Appalachian culture." I did not see any cultural tailoring or culturally specific programming described, so some clarification of how the contextual background was addressed would be helpful.

We removed this section from the manuscript due to substantial revisions. We agree that this sentence was not needed. We hired nurse navigators from Appalachian Ohio so that they would have a medical background in diabetes as well as a cultural background in Appalachia. However, we did not tailor any programing or education to the patients.

4. Please describe what the nurse navigators actually do, particularly in addressing social components of health care. Do they actually arrange to "fill the holes" (p. 8), addressing housing issues, food insecurity, etc.? How? Do they arrange for a refrigerator (p. 9)? Is this more a referral to another agency or direct service? How does this intersect with the standard diabetes care?

We have added a section that lists the services the navigators provided in the program (Context). The navigators in our program actively addressed the patients’ barriers. Referrals were made to a lawyer at a civil legal aid firm and mental health and specialty care providers; otherwise the navigators provided direct services. We believe that this list demonstrates that the navigators do fill in holes. Yes, that navigator did arrange to have a refrigerator delivered to a patient’s trailer. This intersects with diabetes care because the navigators are able to remove barriers that stand in the way of patients being able to take care of their diabetes.

5. I'd suggest staying away from "outcomes" data like that presented on page 11, line 29—where participants indicated improvements in self-care and glycemia. This discussion goes beyond the data and is not verifiable.

We thank the reviewer for this comment. We agree and have added preliminary findings from the patients’ outcome data. We ran a Wilcoxon Signed-Rank Test with the 17 patients who returned for 6-month follow-up. We found a significant improvement in A1C from baseline to 6 months (mean change: -0.79% or -1.3 mmol/l, Z= -2.131, p=0.033).

6. Similarly, in the discussion, there are a lot of positive assessments provided, which is understandable because the navigators have done a great deal of work and their clients
likely are very pleased by their help. But it is important to refrain from comments like that on page 17 referenced early successes, improvements in glycemia, and even navigators providing a consistent point of connection until the evaluation data come in.

We removed the sentence about a consistent point of connection from the Discussion. We will save this for our manuscript on the long-term outcomes data. We kept the positive assessments based on the preliminary findings from the 17 patients with A1C data; however, we noted that we need to confirm these findings with more patients.

7. Please share with readers the limitation of involving a nurse as a navigator may be for the population targeted. Specifically, in a low resource environment, why is reliance on health care professionals a potential limitation?

This is an excellent observation. We have added this to the limitation section. Here is what we added: “Finally, we utilized nurse navigators in our program to address the medical complexities of diabetes and its complications. However, the salary of a registered nurse is substantially higher than a community health worker or peer. Thus, the sustainability of nurse-led navigation program may be difficult. In addition, resource limited areas tend to be health professional shortage areas and staffing a navigation program with nurses may not be feasible.”

8. Some of the material in the beginning of the discussion seems like it belongs in the introduction. It either is somewhat repetitive of the introduction (like prevalence rates) so does not need to be repeated in the manuscript or is more akin to a literature review so does not need to be in this section.

We agree with the reviewer and have removed this from the Discussion section.

Natalia Loskutova (Reviewer 3):

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.

1. 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".

We thank the reviewer for these comments. We have added several sections to the Methods and Results to address these issues. Specifically, we added a section to the Methods to describe the Program (“Context – A detailed description of the Diabetes Navigation Program”). We also added our research questions to the Methods section under “Process Evaluation” as well as our interview guide questions to Table 1. Also, we recognize that we did not do a thorough evaluation of the fidelity of implementation. We have revised this section substantially and included our Work Plan from the Health Resources and Services Administration (HRSA) grant and described our progress on each of the activities listed.

2. 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.

We employed registered nurses given the medical complexities of diabetes and its related complications. We cannot glean any advantages of using nurses as navigators from the qualitative data. We will have to wait until we analyze the quantitative data (A1C, depression, diabetes distress, emergency department use, hospital admissions and readmissions) to make any statements about the value of nurse navigators, if any.

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

Abstract:

* Review whether capitalization is really necessary in presenting the themes.

We removed the capitalization.

* Suggest using "unrecognized" instead of "new" barriers

We like this suggestion and put unrecognized in the abstract.
* 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).

We updated the Introduction section to include a review of existing diabetes navigation programs. In addition, we cut two sentences describing the goals of the process evaluation in the last paragraph.

* 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.

We removed the content on cancer, and replaced it with content on diabetes navigation programs. Also, we added a description of our Diabetes Navigation Program in the Methods per your suggestion.

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?

We thank the reviewer for the comment. We used total population sampling, a type of purposive sampling, for this study. We interviewed all of the providers, administrators, staff, and navigators who had direct or indirect contact with the program. This sampling frame included the entire population so it was very representative of our population.

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

We added our research questions to the Methods section under the subheading “Process Evaluation.” We also added our interview guide in Table 1.

* 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).

We added the number of patients seen by navigators in Year 1 along with their demographic information. Our navigators did not document every communication with the patient (e.g., phone calls, texts) so we do not have the exact number of contacts. We also included A1C data for the
17 patients who showed up for their 6-month follow-up appointment. We emphasized in the Discussion that these data need to be interpreted with caution given the high rate of attrition and that more data is needed to determine the clinical effectiveness as well as to assess the value of a nurse-led navigation program.

* 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.

We have added the date when the program started as well as a description of the program. We added a section about Program Leadership which included how the navigators were recruited and trained by the nurse manager, a navigator herself. We described all of the navigator services in the Methods under the Context section. We made major revisions to the Fidelity of implementation and included our Work Plan (this included the number of patients to be seen at the end of Year 1 – we did not specify a number of touch points as it would vary widely by individual patient). We included our revised referral form and documentation form to demonstrate how the process evaluation improved our communication and operational processes.

* 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.

We included the interview guide in Table 1. We believe that by revising the Fidelity of Implementation section, we have clarified the thematic analysis. We kept the length of the quotations to maintain the rigor of the qualitative data.

* 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.

We have removed the redundant sections in the discussion or moved it to the Introduction. We have revised our discussion about the fidelity in light of our major revisions.