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

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Version: 2 Date: 14 May 2018

Author’s response to reviews:

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

Reviewer reports:

Nancy Schoenberg (Reviewer 2): The authors have been extremely responsive to reviewers' critiques and the manuscript is stronger. There are very few remaining issues to be addressed. The few are as follows:

1. P. 14: The level of detail on which counties in Appalachian Ohio and the percentages of people with diabetes is unnecessary. An overall snapshot would suffice.

   We thank the reviewer for this comment and have shortened the section describing our region.

2. Given the preeminence of the Diabetes Endocrine Center in which this navigation project took place, can the authors comment on whether and how such a program might be able to exist in a less well-resourced environment? That is, what are the chances of dissemination of this approach to other, less well-endowed centers or communities?

   The reviewer raises an excellent point. The Diabetes Endocrine Center is a comprehensive facility in large part due to the association with the medical school and the Diabetes Institute. We have added several statements addressing this in the Limitations in the Discussion section. We
have provided suggestions for centers and communities with fewer resources to pursue programs such as this one.

3. Page 34, lines 39-40, consider rephrasing: …the social determinant need". The authors have done a good job revising their use of this term, but in this line, they seem to go back to substituting "social determinant" for "risk factor."

We thank the reviewer for catching this mistake. We have corrected the phrase to read “patient barriers.”

Natalia Loskutova (Reviewer 3): This is a resubmission of the manuscript that presents results of a qualitative study that evaluates a patent navigation (PN) program. The program is delivered by 5 registered nurses (RN) who serve patients with diabetes of the Diabetes Center but not collocated and not employed by the Center.

In response to previous reviewer comments, the authors provided some details about the program that was missing. While somewhat helpful the information provided is still not sufficient to fully assess feasibility or fidelity of implementation of the program.

1. Including evaluation questions in the report is very helpful however the insufficient data provided to support question#1 "was the diabetes navigation program implemented as design?" limit the ability to assess whether it was. As reported, the answer to this question is "no" or "unknow" at best.

In the Results, we included a Design section of the study to better explain how the program was implemented. The study was implemented as designed; however, we encountered numerous challenges along the way (many of which you have identified in your review and several we have identified in our evaluation). The purpose of this evaluation was to identify these issues so that we can correct them in the future for a randomized control trial. We thank you for your help in identifying ways to improve the study design.

2. For example, enrollment and patient participation targets were not clear and perhaps were not reached, not sure if there were any provider participation targets (only 5 participated, how many work at the Diabetes Center?)

There are five diabetes providers at the Diabetes Endocrine Center and all five providers participated in the Diabetes Navigation Program. In addition, all five providers were interviewed for the study. This is a small specialty practice located in southeastern Ohio so there are only five providers (three physicians, one nurse practitioner, and one certified diabetes educator). We have added this information to the methods section under Program Recruitment in paragraph 1 and 2.

3. What was the target for the number of providers?
There were five providers at the Diabetes Endocrine Center. The navigation leadership team met with all five providers and all five providers made referrals to the navigation program. We have included this information in the manuscript. We added two sentences in the Methods under Program Recruitment in paragraph 1 and 2.

4. The number of referrals? The number of eligible patient out of 2124 served that year?); what was planned for the referral mechanism and data exchange between providers and navigators? Did EHR and fax use issues emerge during implementation and were not a part of the initial implementation plan/protocol/workflow?

At the beginning of the program, we planned to use the fax as the main referral mechanism and transition to the EHR. However, with the merger of a large health care system into the region, we were unable to gain access to the EHR. Therefore, we stayed with the fax system. This likely contributed to our ongoing issues with the referral system. Forty-nine patients were referred (this is presented in the Fidelity of Implementation paragraph) and 10 of these patients declined to participate in the navigation program. We encouraged providers to slowly begin referring to the program so that we could manage problems along the way; this is why the center only referred 49 patients during Year 1. The planned data exchange was a letter documenting the navigation visit with updates about the patient’s progress to be submitted within two weeks; however, this was not listed in the Work Plan.

5. Essentially, the evaluation will need to compare what actually happened to what was planned and assess fidelity and well as adaptations. As is, it is not clear what was planned and what was discovered in the process. It would be helpful to provide more specifics about how the program WAS designed.

We added a section on the design of the study. The design was implemented as planned (as stated above); however, we identified many flaws to our design that we plan to correct in the future.

The workplan for the initiative Objective 1 is helpful but still insufficient as it does not provide any specifics on the planned design of the navigation service.

In terms of program implementation, it would be helpful to address the following:

7. The amount of time (FTE or otherwise) the RN navigators designated to navigation, their employment arrangements, their location - please include in methods.

We agree that this information is important and we have included it in the Methods section under Program Leadership. The diabetes nurse navigator hired for the Diabetes Navigation Program and funded by the external grant was a 1.0 FTE. The navigation nurse manager was funded 0.1 FTE by the grant. The three other nurse navigators were not funded by the grant for the Diabetes Navigation Program; however, they did consult and work collaboratively with six patients
(which is why we included all of the navigators for the process evaluation). All of the navigators shared an office suite in the Community Clinic at the University’s medical school building.

8. Did the RN navigators also have clinical responsibilities? If so, was it an essential part of their responsibilities? What kinds of parameters were used to distinguish the navigator's responsibilities from their clinical responsibilities as RNs? The scope of responsibilities of a navigator as opposed to other health care team members remains a topic of debate in the field and it is important to address the responsibilities and boundaries. What was outside the scope of the patient navigators in this program and when these needs arose that fell outside of the PN responsibilities how they handled these?

We thank the reviewer for raising this important issue. The nurse navigators did not provide any clinical care. The nurse navigators provided strictly navigation services. We included a sentence in the first paragraph in the Methods section, Context, last sentence.

9. What was a necessary skill set specific to navigation responsibilities? How the navigators were trained? What kind of training they received (content, who developed, duration of training etc.)? How the competency was assessed? It appears that 5 navigators were sub-specialized providing navigation to pediatric or gestational diabetes etc, it is not clear how this specialization was supported or implemented in the program. Do the authors see value in such specialization, what about assessment of feasibility of this approach? What if anything was different in the scope or uptake by PN sub-specialty?

The reviewer raises several important points about the navigation training and sub-specialization. In the original submission and revision, we did not do a good job explaining the different navigator positions and their roles in relation to the program. In brief, the Diabetes Navigation Program was funded by an external grant. The external grant funded one full time nurse navigator and a small portion of the navigation nurse manager (FTE 0.1). The University already employed two nurse navigators (FTE 1.0) specializing in high risk pregnancies, and a part-time diabetes navigator (FTE 0.5) specializing in children and type 1 diabetes. These three nurse navigators consulted on six patient cases, which is why we included them in the interviews for the process evaluation. The specialization of the nurse navigators is unrelated to the Diabetes Navigation Program presented in this manuscript. We addressed these issues in the Methods section under Program Leadership and Sample. We did not assess competency or skill set of the new navigator; this is a weakness of our design and we addressed it in the limitations.

10. What was planned for the navigator-patient workflow? Was there a set min/max number of touch points? How the patients exited the program, for example, decisions related to program completion/meeting goals as well as termination of services by the PN? How the goals of navigation were set and met for each individual? What was included in the initial assessment? A generic list of assessments is listed in the manuscript but not clear what specifically was collected and how this information was used by the navigators? Was clinical and psychosocial wellbeing assessment in the required scope of the patient navigators? Specifically, what skills
were necessary to conduct such assessments, how much time they took? (this is mentioned in the discussion but not described in methods or presented in results and as such this relevant discussion point is not supported by the data provided). The authors emphasize the unrecognized barriers uncovered and addressed by the navigators but provide no data on what these barriers were (number/frequency and type) for the patients included in the study and how they were addressed.

The reviewer raises excellent questions, some of which are beyond the scope of this process evaluation and the overall Program. The Diabetes Navigation Program was a feasibility study designed to implement the Program and determine whether or not it was appropriate for further testing (i.e., randomized controlled trial). In this study, we included a broad array of assessments in order to decide which assessments to use in a future trial. We included additional details about the assessment, including the names of specific assessments with citations. The baseline intake was similar to a complete health history that register nurses are trained to conduct. On average the intake took 2 hours. We did not have a formal termination of services protocol for the program; we planned to develop a protocol during the grant period. We chose to develop a termination of services protocol while simultaneously conducting the program in order to tailor it to patient preferences. Finally, we included the barriers identified by the navigators for the patients during Year 1 of the program. All of these revisions were provided in the Methods under Project Recruitment.

In relation to evaluation approach and results, I have flowing concerns:

11. It seems that the interview questions were slightly positively biased and not neutral, perhaps skewing the responses.

The interview questions were written to address both the successes and challenges after the first year of implementation. We asked the participants about what went well in the first year and what did not go well. For every question that we asked how the program was doing well, we included a question about how the program was not doing well. We included a balance of positive and negative questions. Following content and thematic analysis, the data included a sizable amount of critical feedback and negative experiences with the program.

12. It is not clear if the saturation was reached 3. It is stated that the navigators did not document all encounters (e-mails, texts etc. were not documented), it not clear how the "visit" was defined and how this approach many affect feasibility of the program (and its economic/cost evaluation) in relation to the full set of interactions and time/resources it required.

We added more to theme 3 to demonstrate that this theme is fully saturated. Previously, we had cut these quotations before due to length of the manuscript and word count. We have added them back in the manuscript.

Visits were documented as in-person meetings and phone calls with the patient. You are correct, that the diabetes navigator did not document the exchange of emails and texts with patients. This
is a major weakness of the program because it impacts the cost evaluation. This is information that we learned from conducting this feasibility study through a programmatic external grant. We now know that we need to document all interactions with patients as these count as personnel/time resources. We reviewed all 39 charts and added the included the mean number of visits along with the standard deviation in the Program Recruitment paragraph.

13. While the authors present the early results of the program as early successes, and there are certainly some, the concerns that the patient enrollment targets were not reached, the implementation encountered substantial barriers in every key aspect: referral process, obtaining necessary patient data to support navigation services, reporting back to the referring provider and an overall estimation of a workload of 39 patients per 5 navigators (less than 8 patients per a navigator per year served) which is substantially lower compared to the workload reported by other initiatives (see Horny et al, 2017 for example), and the significant patient attrition rates, all dampen my enthusiasm for the feasibility and potential cost-effectiveness, reproducibility and uptake of this program.

We agree with the reviewer that there were a number of concerns with the program after Year 1 of implementation. The diabetes navigator saw all 39 patients in Year 1; the specialty navigators consulted with six of the patients. Thus, the workload of the navigator is much higher. However, we agree that the high rate of patient attrition and the barriers with the referral process may limit the reproducibility and sustainability of this program in the future. We have edited our language in the Discussion and Conclusion to reflect these points.

Additionally, suggest:

14. excluding any references to improved glycemic control as premature and seemingly outside of the scope of this paper.

We included one sentence with preliminary data on improved glycemic control to support the participants’ comments regarding improved glycemic control association with the Diabetes Navigation Program. We have edited the language in Theme 2 to more clearly reflect that improved glycemic control represented participants’ perceptions and quantitative research is needed to confirm this finding.

15. in Ongoing Challenges- first sentence "systematic barriers": "systemic" perhaps?

We thank the reviewer for noting the typographical error.

16. use improved "glycemic control" instead of "glycemia" when refer to outcomes

We have changed glycemia to glycemic control when referring to outcomes in the manuscript.