Reviewer’s report

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

Version: 1 Date: 21 Apr 2018

Reviewer: Natalia Loskutova

Reviewer’s report:

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.

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. 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? What was the target for the number of providers? 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?

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. 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:

1. The amount of time (FTE or otherwise) the RN navigators designated to navigation, their employment arrangements, their location - please include in methods.
2. 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?

3. 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?

4. 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.

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

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

2. 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.

4. 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.

Additionally, suggest:

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

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

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

**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.

No

**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

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Needs some language corrections before being published

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