Author’s response to reviews

Title: Retrospective assessment of the quality of diabetes care in a rural diabetes clinic in western Kenya

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Author’s response to reviews:

Please find the attached document which includes responses and illustrations in response to the comments.

Here is the text version of those comment (it misses one of the figures which is included in the attached version)

Editor Comments:

1. Please read and address the comments provided by the reviewers (given below).

2. Please provide a list of all the abbreviations used in the manuscript. This list should be placed just before the Declarations section. All abbreviations should still be defined in the text at first use.

The abbreviations section has been added as requested.
3. In your “ethical approval and consent to participate” section, please confirm whether informed consent, written or verbal, was obtained from all participants and clearly state this in your manuscript. If verbal, please state the reason and whether the ethics committee approved this procedure. If the need for consent was waived by an IRB or is deemed unnecessary according to national regulations, please clearly state this, including the name of the IRB or a reference to the relevant legislation.

The following statement has been added to both of the relevant sections.

A waiver of informed consent was obtained from both of the institutions as all data being assessed was collected through routine clinical care and was de-identified before being retrospectively assessed.

BMC Endocrine Disorders operates a policy of open peer review, which means that you will be able to see the names of the reviewers who provided the reports via the online peer review system. We encourage you to also view the reports there, via the action links on the left-hand side of the page, to see the names of the reviewers.

Reviewer reports:

Reviewer 2 (Reviewer 3): PEER REVIEWER ASSESSMENTS:

OBJECTIVE - Full research articles: is there a clear objective that addresses a testable research question(s) (brief or other article types: is there a clear objective)?

Yes - there is a clear objective

DESIGN - Is the current approach (including controls and analysis protocols) appropriate for the objective?

No - there are minor issues
EXECUTION - Are the experiments and analyses performed with technical rigor to allow confidence in the results?

N/A - no experiments or analyses

Statistics - Is the use of statistics in the manuscript appropriate?
Yes - appropriate statistical analyses have been used in the study

INTERPRETATION - Is the current interpretation/discussion of the results reasonable and not overstated?
Yes - the author's interpretation is reasonable

OVERALL MANUSCRIPT POTENTIAL - Is the current version of this work technically sound? If not, can revisions be made to make the work technically sound?
Probably - with minor revisions

PEER REVIEWER COMMENTS:

GENERAL COMMENTS: Very important paper that seeks to determine the quality of diabetes care by describing relevant clinical, process, and structural outcomes in a rural diabetes clinic in SSA.

REQUESTED REVISIONS:
Here are a few comments to consider:

Introduction
In line 76, probably better to say 'leading cause' instead of leading factor.
Thank you for this comment, we have made this change.
Otherwise the introduction is well-written and articulates the key gaps

Methods

Line 132, what qualifications do physician assistants hold?

I’ve added the following statement within parentheses in the document to provide more clarity (diploma level providers equivalent to physician assistants in other settings)

For more information you can see a longer description here - https://en.wikipedia.org/wiki/Clinical_officer

Line 138, suggest rephrasing to 'patient's clinical need' –

Thank you for this, we have changed to improve clarity

How did participants consent? Was this by virtue of just coming to the clinic?

For this evaluation, we looked only at routinely collected clinical data that was retrospectively assessed after being de-identified. We had received a waiver of informed consent through both of the IRBs. We have added a statement indicating this as requested by editor.

A waiver of informed consent was obtained from both of the institutions as all data being assessed was collected through routine clinical care and was de-identified before being retrospectively assessed.

What was the inclusion/exclusion criteria?

Basically it was everybody who had their data stored in the database which means everybody who received care. Here is the statement from the paper explaining this:

We included data from all patients with type 1 or type 2 diabetes who received care in the WDH diabetes clinic between July 2009 and September 2011. Data was abstracted from the clinic’s electronic database using a predesigned data collection tool by a trained data manager who also checked the information for completeness and discrepancies by periodically comparing the information to the paper-based records.
Often a paired t-test such as in this instance is used in tandem with some form of a regression analysis to identify factors that maybe associated with outcomes. Did the authors consider this?

Great suggestion. We had actually considered this but this analysis seemed a bit out of place with the scope and focus of the paper on assessing the quality of care. The paper was already quite long as it is and adding this additional analysis would make it longer and not suitable for publication. We partially tackle this issue within the paper by highlighting that participation in home glucose monitoring was one of the biggest predictors for improvement in outcomes. We also did not want to replicate the analysis we did in another paper which focused specifically on identifying factors which are associated with positive outcomes amongst patients involved in the self monitored blood glucose program. Those results can be found below and was much more relevant for that paper since most patients started with similar, much higher HbA1cs. (Pastakia SD, Cheng SY, Kirui NK, Kamano JH. Dynamics, Impact, and Feasibility of Self-Monitoring of Blood Glucose in the Rural, Resource-Constrained Setting of Western Kenya. Clin Diabetes. 2015;33(3):136-43.).

The other complication with doing the analysis you propose here is that the patients started with very different HbA1c’s. Picking an outcome that we could correlate to potential factors presented a challenge because of the variability in the initial HbA1c and difficulty in reasonably tracking changes across a large population.

The authors should explain how they calculated the sample size for this study.

Thank you for raising this concern. This study was done retrospectively and evaluated and described all patients with data in the database which limited the need for a sample size since we evaluated the whole population.

Results

How many patients were approached?

All patients with data in the database were included in the analysis.

Was there any difference between those who participated and those who did not?

Line 200, please state the IQR

This has been added.
Line 202, please provide the SD
This has been added.

Were there any reasons associated with loss to follow up e.g transfer of care and deaths?

Great question, unfortunately, we were not able to collect this information but our subsequent care efforts have specifically tracked this vital information.

What are the clinical and research implications of this study?

Thank you for this comment and feel we need to add We have added the following statement to the conclusion

This comprehensive analysis highlights many unique attributes found in a rural diabetes clinic in western Kenya. With the projected increases in diabetes prevalence across SSA, it is essential that lessons are learned from this analysis and responsive, contextualized infrastructure is created to continue expanding access to high quality diabetes services across the region. The many gaps in care and unique attributes found amongst this patient population create a rich platform for future research efforts geared towards addressing the many pressing challenges patients with diabetes in SSA face. A combined approach which simultaneously focuses on the creation of much needed clinical infrastructure for comprehensive diabetes care with contextualized research will help stave off the many anticipated health and economic consequences associated with diabetes in SSA.

Whilst the authors have highlighted the limitations of this study, there is also scope to highlight the key strengths of the study.

Thank you for this, we have tried to address with the addition in the discussion

Despite these limitations, our comprehensive analysis provides an in-depth assessment of the unique aspects of providing care in rural resource-limited settings in SSA. The improvements in the glucose control of the population, highlights how barriers to care can be overcome through collaborative partnerships including local providers, international funders, and academic institutions. This analysis has also provided our overarching diabetes clinic operations team with considerable guidance on how to promote continuous quality improvement within our service delivery. In order to address the domains in which the WDH clinic failed to meet the recommended IDF criteria standards for quality care, we have specifically addressed many of the limitations of the clinic by including programs which have studied the ideal methods for assessing gestational diabetes [29], assessed the reliability of point of care lipid testing [30], incorporated point of care testing for creatinine and potassium, tested various screening
approaches [31], incorporated additional medications such as statins within the clinic pharmacy [13, 32, 33], implemented community based diabetes care delivery alongside microfinance services [34], and included a mobile point of care electronic medical record system eliminating the need for duplicative data entry [35-37].

Note: This reviewer report can be downloaded - see attached pdf file.

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