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:

Thank you for taking the time to carefully review our submission. After making the changes requested through your review, the paper has improved significantly and we look forward to your next subsequent decision. We have included the following documents to assist in your review.

1. Responses to Reviewers

2. Clean version of the revised manuscript with all the changes accepted

3. Version of the revised manuscript with changes tracked
4. International Diabetes Federation (IDF) global guidelines 2005 to be included as a supplementary appendix

5. Email from IDF providing reprint permission

Sincerely,

Sonak Pastakia, PharmD, MPH, PhD
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Editor Comments

The manuscript will benefit from editorial support of the native English speaking medical writer

Response: Thank you for this comment. We have reviewed the manuscript and have revised where appropriate. If there are still questions regarding this, please let us know, perhaps with a few examples.

Reviewer 1

Response: No comments visible. Please let us know if there were any comments from reviewer 1 as we cannot see any.

Isabel Arrieta-Cruz, M.D., Ph.D. (Reviewer 2)

General comments: The authors tried to evaluate the quality of diabetes care provided in the clinic at Webuye District Hospital through the assessment of different domains accepted by the International Diabetes Federation guidelines
Response: Thank you for your review of our manuscript. We have considered your comments and have addressed them in the revised manuscript. Please see below for specific responses.

Introduction

1. The aim of the study should be in this section. The aim is not in the appropriate section.

Response: We have moved the study aim into the introduction (now titled background). Lines 115-117 in the revised text.

Methods

2. The authors should elaborate a flowchart to facilitate the understanding of how were selected the patients, including: total participants at starting, different groups in the follow-up, number of participants quit or loss, etc.

Response: Thank you for this comment. We tried to capture these aspects specifically in Table 1 and Table 2. We agree that a flow chart would be a nice addition, however a flowchart would not have enabled us to present our data with sufficient detail to allow the reader to assess the data and come to their own conclusions. We therefore decided to include the data in greater detail within Tables 1 and 2 so the reader could pick out the data elements they are most interested in and assess beyond our assessment. With the limited number of figures and tables we are allowed in this publication, we decided to prioritize the more detailed tables rather than including a flow chart which would end up repeating most of the information seen in the tables. If the journal is willing to allow an additional flow chart and you feel strongly that it is necessary, we are happy to include a flowchart as requested.

3. It is not clear the inclusion, exclusion and elimination criteria in the selection of the participants. Is must be very clear.

Response: We have edited line 156 (page 7) to explicitly state our inclusion criteria. Every patient who was followed in the clinic was tracked within the electronic medical record and thus all patients were included. None of the patients were excluded during the time frame of analysis. The edited line can be seen below
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.

4. 19 different domains from the IDF Global Guideline for diabetes care should be described in this section.

Response: We have included a more detailed description of this in the Methods section and have also been granted permission from the International Diabetes Federation to include a reprint of their guidelines as a supplementary appendix. We hope the journal will allow us to publish these guidelines online for any readers who are interested in a more detailed understanding of these guidelines. See text below that has been added to the methods section based on your comments.

The International Diabetes Federation (IDF) has provided global guidelines for diabetes care which include a set of minimum standards of care that recognise the dearth of resources available in low resource settings [11]. This guideline provides recommendations for the minimal, basic, and comprehensive standards of care which programs should strive for when developing responsive and effective diabetes care programs. These domains include screening, care delivery, education, psychological care, lifestyle management, glucose control targets, clinical monitoring, glucose control with oral therapy, glucose control with insulin therapy, blood pressure control, cardiovascular risk protection, eye screening, kidney damage, foot care, nerve damage, pregnancy, children, and in-patient care. Additional details can be found in supplementary appendix Figure 1.

5. Include a subtitle "statistical analysis" to point out the description about it.

Response: We have included this as line 189 (Page 8)

Results

6. The management of the patients with type 1 and type 2 diabetes mellitus must be different. For that reason the data should be analyzed into two different groups, one for type 1 and another one for type 2.
Response:

Thank you for this comment. This is an issue we gave very careful consideration to and decided on the approach you see for three specific reasons. We previously commented on this limitation in the discussion and have added additional text to address your very salient point.

1. There were only 14 patients (<3%) who were less than 20 years and fit the typical picture for Type 1 diabetes. As much as a separate description of this population would be useful to describe, the sample size was too small to make many meaningful assessments of their diabetes care. We have also previously described many of these type 1 patients in a paper that was focused on home glucose monitoring which preferentially enrolled pediatric patients. (Pastakia SD, Cheng SY, Kirui, et al. Dynamics, impact, and feasibility of Self-Monitoring of Blood Glucose in the Rural, Resource-Constrained Setting of Western Kenya. Clin Diab 2015:33(3);136-143)

2. We decided to combine the type 1 population into the overarching population because we wanted to look at the quality of care and process measures for the overall diabetes population and wanted that assessment to include these type 1 patients.

3. In our setting, there is considerable grey area in deciding which patients are “type 1” vs “type 2”. We have a significant number of patients who present later in life (>30 years of age) as very lean insulin dependent patients who don’t fit the typical clinical conventions of type 1 vs type 2 diabetes. For this reason, many of our clinicians use the antiquated terminology of classifying patients as insulin dependent or non-insulin dependent. Most of these patients often require insulin for the duration of their management but it isn’t clear how they should be classified using the Type 1 vs Type 2 nomenclature. These dynamics led us to include all patients in the same cohort to avoid these clinical controversies.

   a. We have also changed the presentation of data on age and duration of diabetes to a median with interquartile ranges (instead of means with SD) to try to better capture the distribution of the data and highlight that the vast majority of the population does was older and more recently diagnosed with diabetes.

The revised text which has been included in the limitations portion of the discussion can be seen below.
Another limitation is that patients with type 1 and type 2 diabetes were analysed together in the same cohort. This analysis strategy was utilized to ensure that the process measures analysed in this study reflected the entire population receiving care in the clinic and were representative of the type of patient population typically seen in SSA. This decision to analyse patients in a combined fashion was influenced by several of the limitations we have observed within this population and the limited infrastructure in this setting. Several studies have documented the delayed onset of type 1 diabetes in SSA patients along with the relatively higher presence of atypical variants of diabetes which require unique treatment regimens incorporating intermittent insulin [20, 26-28]. Furthermore, the WDH clinic, like most public sector diabetes clinics in SSA, does not have the capacity to perform C-peptide or antibody testing to help confirm the presence of type 1 diabetes [19]. These factors make it difficult to appropriately categorize patients as having type 1 or type 2 diabetes. While this represents a limitation of this study, it is worth noting that only 3% of the population was <20 years of age at the time of enrollment.

7. The description of the data shown in the tables is not very reflected in the results sections.

Response: We have made some changes to Table 1 (see updated Table 1 on page 9) and the referent text for table 1 (Page 8 and 9) and text changes to tables 3, 5 and 6 in terms of where we reference them in the text to try and address your concern. We have not altered text referring to Table 2 or 4 as we feel it was reflective of those specific tables. Our approach was to use the tables to present more data and only summarising the major findings from each table in the text.

8. The authors must re-write the section for a better understanding of the data shown in the tables.

Response:

We have made considerable changes to the results section to improve clarity and feel this section provides the reader a much better understanding of the data as requested by your comment.

9. Table 2, describe "HGM and non-HGM"

Response: We have edited to write out in full and changed this to SMBG (self-monitored blood glucose) and non-SMBG. See Table 2 on Page 10
10. All tables must be separated of the main document.

Response: We followed the BMC ED rules for tables which state that:

- Tables less than one A4 or Letter page in length can be placed in the appropriate location within the manuscript.

- Tables larger than one A4 or Letter page in length can be placed at the end of the document text file. Please cite and indicate where the table should appear at the relevant location in the text file so that the table can be added in the correct place during production.

11. The authors must clarify each feature about Minimal, Standard and Comprehensive care.

Response: We have included a more detailed description of this in the Methods section and have also requested permission from the International Diabetes Federation to include a reprint of their guidelines as a supplementary appendix. See text below that has been added to the methods section based on your comments.

The International Diabetes Federation (IDF) has provided global guidelines for diabetes care which include a set of minimum standards of care that recognise the dearth of resources available in low resource settings [11]. This guideline provides recommendations for the minimal, basic, and comprehensive standards of care which programs should strive for when developing responsive and effective diabetes care programs. These domains include screening, care delivery, education, psychological care, lifestyle management, glucose control targets, clinical monitoring, glucose control with oral therapy, glucose control with insulin therapy, blood pressure control, cardiovascular risk protection, eye screening, kidney damage, foot care, nerve damage, pregnancy, children, and in-patient care.