Author's response to reviews

Title: The Use of Clinical Guidelines Highlights Ongoing Educational Gaps in Physicians' Knowledge and Decision Making Related to Diabetes

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Version: 4
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Author's response to reviews: see over
August 7, 2014

Dear Dr. Marques:

Thank you for the opportunity to submit a revision of our manuscript titled, “The Use of Clinical Guidelines Highlights Ongoing Educational Gaps in Physician’ Knowledge and Decision Making Related to Diabetes”, for consideration by *BMC Medical Education*. We believe that the revised manuscript has been strengthened by suggestions from our reviewers. While the attached responses outline point-by-point how we have addressed the issues raised by our reviewers, the following are major changes to the revised manuscript:

- We have included further details regarding survey methodology and the questions included, as well as response rate, and clarified that no financial or other incentive was offered to participants.
- We have added further description regarding the categorization of covariates in our analyses.
- We have added additional details regarding percent survey completion and missing information among participants.
- We have included a discussion regarding the inclusion of endocrinologists and primary care physicians in the sample.
- We have included potential selection bias as a limitation of our study.
- We have added a description of team care approaches for diabetes care and that future studies are needed among other team members such as nurse practitioners and physician assistants.
- We have included newer references in our manuscript as suggested.

Thank you for your consideration and we look forward to your decision.

Sincerely,

Rita Kalyani, MD, MHS
We thank all the reviewers for their helpful comments. We have endeavored to address all concerns and feel that the manuscript has been strengthened as a result. We have carefully revised the text in response to these concerns, particularly with further details regarding analytic methodology in response to reviewers’ comments. Specific revisions are detailed below and indicated in boldface text in the manuscript.

Reviewer #1

Reviewer’s report
Title: The Use of Clinical Guidelines Highlights Ongoing Educational Gaps in Physicians’ Knowledge and Decision Making Related to Diabetes
Version: 3 Date: 1 July 2014
Reviewer: Arlene Smaldone

Reviewer’s report:
This is clearly an important topic. Use of clinical guidelines has the potential to improve care outcomes for adult patients with diabetes and to decrease variations in practice patterns. However, this manuscript as written presents several areas of concern.

Major Compulsory Revisions:

1. I do have concerns regarding reporting the findings of a survey that has not been validated.

We appreciate this point from the reviewer and agree this is a limitation. Future studies need to be performed to further validate the survey and the results reported in the present study. However, since the goal of our study was exploratory and included results not previously reported in the literature, these findings remain of important scientific interest. In response to the reviewers’ concerns, we have added the following limitation to the discussion on page 17, last paragraph:

"The survey tool we utilized has not yet been validated but should be more critically examined in studies specifically designed for this purpose."

In addition, we have added the following sentence on page 17, last paragraph:

"However, our study nonetheless provides exploratory findings that can be further investigated in representative populations of diabetes providers in the future. Given the absence of other literature regarding current gaps in diabetes-related knowledge among practicing physicians or the relationship of diabetes clinical guideline use to providers’ familiarity with diabetes therapies and clinical decision making, our study remains informative and provides findings that have not been previously reported."
2. Provide more detail about the survey. Was it restricted to use of guidelines for adults with type 2 diabetes? How many questions in total? How long did the survey take to complete? The authors provide 2 appendices but it is unclear if this was part of the survey or the entire survey.

We thank the reviewer for this comment. The survey included questions about national consensus guidelines for diabetes including those from the American Association of Clinical Endocrinologists and the American Diabetes Association/European Association for the Study of Diabetes. These guidelines are comprehensive and include sections for both type 1 and type 2 diabetes. However, the specific knowledge and clinical-decision making questions in our survey focused primarily on type 2 diabetes since the majority of patients with diabetes have type 2 diabetes (>95%).

The appendices provide the complete 5 knowledge and 4 decision-making survey questions that were analyzed in the present study. There were also questions related to participants' specialty, profession, patient volume, familiarity with clinical guidelines, etc. that are further described in the methods section. In total, there were 24 questions in the survey sent by email invitation. There were 3 questions for which guidelines from different societies may be conflicting such as those regarding initial management of diabetes (lifestyle ± metformin), optimal sequencing of therapies in diabetes, and the role of tight glycemic control in reduction of macrovascular complications. Newer guidelines from the ADA and other consensus societies have focused on individualized therapy regarding the selection of agents beyond metformin and the goals of care depending on patient factors (Reference #13). Thus, these questions were not included in our study. Also, we did not include 2 questions related to prediabetes since this was not the focus of our study and consensus guidelines may also differ. There were 3 questions related to suggested topics for CME development that were not relevant to clinical management and also not included in our study.

As a result, there 16 survey questions included in the present study. For clarification, we have only included the knowledge and clinical decision-making questions analyzed in this study in the appendices. It is difficult to ascertain how long the study took to complete as participants were not asked to report this but our estimate would be no more than 5-10 minutes based on authors’ completion rate of the survey. In response to the reviewer we have clarified these details in the manuscript as follows on page 8, first paragraph:

“While the consensus guidelines referenced in the survey include sections for the management all types of diabetes, the focus of our study was on type 2 diabetes given that this represents the majority (>95%) of cases (1). Thus, the survey questions included in our study focused primarily on the management of type 2 diabetes in adults although some of the diabetes-related knowledge questions may be common to other types. The appendices provide the full knowledge and clinical decision-making questions that were included in this study which is in addition to the other questions described below regarding participant specialty, patient volume, etc. Other survey questions related to management of prediabetes, suggested topics for future continuing medical education, or for which there were no clear consensus guidelines were not analyzed in our study. In total, the responses to 16 survey questions served as the basis for the results of our study.”
3. Reporting of survey methodology is also very limited. Survey response rate is not reported although it was “low overall response rate.” What methods were employed to attempt to improve response rate. Were subjects incentivized to complete the survey? Without this information, the reader cannot be assured that a rigorous process was conducted and may find it difficult to trust the study findings.

This is a good point. We agree that response rate is a limitation of our study. However, not all the registrants in the database were physicians. Also, not all registrants cared for patients with diabetes; as a result, the survey was not relevant to their practice. As a result, recruitment for our study had to be broad. Approximately 80,000 users are currently registered in the database. An email invitation was sent to all these users, however, we had no available method to confirm if the users were: 1) physicians and 2) cared for patients with diabetes in their practice (both inclusion criteria for our study), or if the emails were successfully received by users. Of the emails sent to participants, 1,279 accessed the survey and 655 fully completed the survey. Once participants opened the email and accessed the survey link, we were then able to track responses. To improve response rate, reminder emails were sent to users of the database to complete the survey. There was no monetary or other incentive offered to complete the survey. We agree that a formal and rigorous process would be important to include in future confirmatory studies of our findings. The results of our study should be considered exploratory but given that such findings have not previously been reported, remain of important scientific interest. What appeared to be a low response rate was in fact necessary to recruit an adequate number of participants for our study. Of note, the sample size of our study is larger compared to those of similar studies in this topic area. In response to the reviewer, we have added the following sentences in the manuscript in the methods section starting on page 6, last paragraph:

"Invitations were sent to all registered users in the database (~80,000 users) without a priori knowledge of which of these registrants actually treated patients with diabetes in their practice and which registrants were physicians. In addition, we could not confirm that invitation emails were successfully received by users. Thus, to improve response rate, reminder emails were sent periodically to all users of the database. A total of 1,279 persons visited the survey website. Of these individuals, 655 participants fully completed the questionnaire and 238 participants partially completed and reported treating patients with diabetes in their practice. Of those who fully completed and submitted the questionnaire, 270 were other providers (nurses, podiatrists, dieticians, pharmacists, and other) and excluded. In the following study, we focused on the remaining physician respondents given that we were interested in exploring therapeutic decision-making by providers, as well. The database of registrants includes health care providers who manage multiple chronic diseases; diabetes is only one of these diseases. Also, other allied health professionals in addition to physicians were in the database. This partially accounts for what appeared to be a low overall response rate; nonetheless, the relatively large number of invitations was necessary to effectively recruit physicians that manage patients with diabetes for our study. Yet, the number of physician participants recruited for our study was still relatively large compared other studies exploring clinical guideline use (15, 16). Among physician respondents that submitted the questionnaire, 2 participants had missing information for the question regarding the use of clinical guidelines, resulting in 383 participants for our study."
And, also in the methods section, we have added a sentence to clarify that no financial or other incentive was offered to complete the survey on page 6, first paragraph of methods section:

"There was no financial or other incentive for participants to complete the study questionnaire."

We have also included the following sentences in the limitation section of our discussion on page 17, first paragraph:

"The database of registrants includes other providers in addition to physicians who manage multiple chronic diseases; diabetes is only one of these diseases. This partially accounts for what appeared to be a low overall response rate; yet, the relatively large number of invitations was imperative in order to recruit an adequate number of physicians that care for patients with diabetes which was comparatively larger than other studies (15, 16)."

Further, we have included the following sentence regarding our study’s comparatively larger sample size on page 15, last paragraph:

"The strengths of our study include the relatively large number of participants examined . . . in comparison to other studies on clinical guideline use (15, 16)."

We later summarized in the discussion section that our findings are exploratory on page 17, last paragraph:

"However, our study nonetheless provides exploratory findings that can be further investigated in representative populations of diabetes providers in the future. Given the absence of other literature regarding current gaps in diabetes-related knowledge among practicing physicians and the relationship of diabetes clinical guideline use to providers’ familiarity with diabetes therapies and clinical decision making, our study remains informative and provides findings that have not been previously reported."

4. Statistical analysis: The authors propose use of the student’s t test for continuous outcomes. There do not appear to be any variables that meet this criterion. Please revise to make specific for this analysis.

We appreciate this point from the reviewer. In response, we have corrected the methods section and removed description of the student’s t test as this was not performed for any of the variables in Table 1. However, differences in knowledge score (continuous variable) were compared using the student’s t-test and we have clarified this in the text as follows on page 10, last paragraph:

"Clinical characteristics of guideline versus non-guideline users were compared using chi-squared test for binary outcomes. In addition, mean diabetes-related knowledge scores were compared using student’s t test for continuous outcomes."

5. Figure 1: It’s questionable whether this figure is needed as the figure is descriptive only. However, if it is retained, my suggestion is to compare the proportion of physicians rather than the raw number at each knowledge
assessment score. Also, the X axis should be labeled by content of the question rather than 1, 2, 3, etc. to make it more informative for the reader. Where are the areas of knowledge deficit?

We agree with the reviewer that the figure is descriptive and the results of the figure are already described in the text. As suggested by the reviewer, we have removed the figure from the manuscript. We have also added a description of the specific questions of knowledge deficit as follows on page 11, last paragraph:

“Overall, the mean diabetes knowledge score was higher among GU versus NGU (3.37 vs. 2.76, p<0.001, n=364). Among individual questions, only the question about risk factors for diabetic foot ulcers had a similar proportion of correct responses among GU versus NGU. Otherwise, GU had a significantly higher proportion of correct responses to all of the knowledge questions compared to NGU. Specifically, three-quarters of GU correctly identified that the UKPDS demonstrated a decrease in microvascular complications while only half of NGU could correctly answer this question (p<0.001). Further, 34.3% of GU compared to 24.1% of NGU correctly identified a target glucose goal range of 140-180 mg/dl among critically ill patients (p=0.03). Also, GU were more likely than NGU to answer correctly that early diagnosis and treatment of diabetes can help prevent complications (GU 78.4% vs. 66.8%, p=0.01) and that prediabetes is commonly present for a few years (> 24 months) before it progresses to diabetes (GU 54.6% vs. NGU 44.4%, p=0.046)."

6. Page 10 – last sentence. There were no differences in prescription of early insulin treatment between GU versus NGU. The sentence should be removed as it is misleading.

We thank the reviewer for this comment and agree this sentence is misleading. Given that information regarding proportion of diabetes providers that prescribe early insulin treatment has not been previously reported in the literature, we have clarified as follows on page 12, third paragraph:

"A similar proportion of GU versus NGU reported frequently prescribing early insulin treatment (i.e., more than 20% of the time) in patients on 1-2 oral agents with a hemoglobin A1c (HbA1c) >8% (GU 36.5% vs. NGU 28.2%, p=0.09)."

Minor Essential Revisions

1. Several references are quite old and should be replaced by newer references. The references in question are numbers 1, 13, 14, 15 and 16.

We thank the reviewer for this comment. In response to the reviewer, we have added several more recent references. Given the paucity of studies specifically exploring educational interventions for physicians that manage patients with diabetes, in some cases newer references were not available, and as a result we have retained some of the original references in order to be able to provide a comprehensive and informative discussion in our manuscript. The new references added to the manuscript are indicated below (new references #1, 2, 18, 19, 25):


Discretionary Revisions:

1. Table 2 – remove the asterisk at the end of the title and remove the legend associated with the legend. The title is reasonably clear without it.

As suggested by the reviewer, we have removed both the asterisk and the legend associated with the title from Table 2.

Reviewer #2

Reviewer's report
Title:The Use of Clinical Guidelines Highlights Ongoing Educational Gaps in Physicians' Knowledge and Decision Making Related to Diabetes
Version:3Date:17 July 2014
Reviewer:Sharon Hewner

Reviewer's report:

This paper reports on the results of a survey sent to new practicing physicians regarding knowledge of diabetes care and the use of diabetes guidelines. This is an important topic given the increasing prevalence of diabetes and the evidence that guideline adherence can improve long term health outcomes for persons with diabetes.
Overall all the paper is well written and the title and abstract are appropriate to the content. The authors acknowledge their own previous work and current related work in the field. The question is well defined.

1) Methodologically there are some weaknesses. The sampling strategy relied on subscribers to a guideline service which may have created some bias.

We thank the reviewer for this comment and acknowledge this is a limitation of our study. In response to the reviewer, we have added the following sentence to the discussion on page 17, first paragraph:

"The source of our study sample may also represent a limitation. All subscribers to an online clinical decision-making program were invited to participate without a priori knowledge of which registrants of the database routinely manage patients with diabetes. There was no financial or other incentive for participants to complete the study questionnaire... Consequently; selection bias may limit generalizability of our findings."

2) The response rate is not reported in the methods section and on page 6 it is difficult to discern if only fully completed survey were used and if all the respondents cared for diabetes patients in their practice.

This is a good point. This was a similar concern shared by reviewer # 1. In response, we have added the following text to the methods section on page 6, last paragraph:

"Invitations were sent to all registered users in the database (~80,000 users) without a priori knowledge of which of these registrants actually treated patients with diabetes in their practice and which registrants were physicians. In addition, we could not confirm that invitation emails were successfully received by users. Thus, to improve response rate, reminder emails were sent periodically to all users of the database. A total of 1,279 persons visited the survey website. Of these individuals, 655 participants fully completed the questionnaire and 238 participants partially completed and reported treating patients with diabetes in their practice. Of those who fully completed and submitted the questionnaire, 270 were other providers (nurses, podiatrists, dieticians, pharmacists, and other) and excluded. In the following study, we focused on the remaining physician respondents given that we were interested in exploring therapeutic decision-making by providers, as well. The database of registrants includes health care providers who manage multiple chronic diseases; diabetes is only one of these diseases. Also, other allied health professionals in addition to physicians were in the database. This partially accounts for what appeared to be a low overall response rate; nonetheless, the relatively large number of invitations was necessary to effectively recruit physicians that manage patients with diabetes for our study. Yet, the number of physician participants recruited for our study was still relatively large compared other studies exploring clinical guideline use (15, 16)."

All participants cared for new or established patients with diabetes in their practice to some degree. Only 2 participants reported “rarely if ever” for both making a new diagnosis of diabetes and seeing an established patient with diabetes in their practice but completed remaining
questions in the survey regarding their management of patients with diabetes. We have added the following sentences to the manuscript on page 7, end of first paragraph:

“All the respondents cared for patients with diabetes in their practice”.

We have added further information regarding missing information on clinical guideline use among physician participants and corrected the sample size to 383 throughout the manuscript which was a typographical error. We have added the following sentence to the methods section on page 7, first paragraph:

"Among physician respondents that submitted the questionnaire, 2 participants had missing information for the question regarding the use of clinical guidelines, resulting in 383 participants for our study."

For the knowledge score and each of the questions reported in Table 2, very few (≤5%) of respondents had missing information. The abstract includes the exact odds ratios and CI that were reported in Table 2 and in the manuscript text. We have added the exact n for participants who had a complete knowledge score available (n=364) in the text of the manuscript. We have also added the n for those who responded to questions about: prescribing early insulin treatment (n=367); their understanding of currently available diabetes medications (n=362); and their unfamiliarity/experience with pharmacologic options as a reason for not adopting an intensive multifactorial approach (n=371) in the manuscript. These n have been added to the relevant sentences in the results section on pages 11-13.

3) There was no discussion of the inclusion of endocrinologists as well as primary care physicians in the sample, but this may impact the results.

We appreciate this comment from the reviewer. It is possible that endocrinologists may have greater familiarity with clinical guidelines and see patients with diabetes more often. However, when we adjusted for participants’ specialty and frequency of treating patients with new or established diabetes, our results remained significant in Table 2. Also, in sensitivity analyses of primary care physicians only, results were similar. In response to the reviewer, we have included the following sentences to the discussion on page 15, second paragraph:

“Specialists (i.e., endocrinologists) may be more likely to adhere to guidelines published by their professional societies than primary care physicians (11). Physicians that see more patients with diabetes may become more adept at caring for such patients and/or have a stronger need to be up-to-date with clinical guidelines for this disease. However, we found that associations of clinical guideline use with better diabetes-related knowledge and decision making persisted even after accounting for physician specialty and clinical practice characteristics.”

In response to the reviewer, we have also added the following sentences later in the discussion on page 17, first paragraph:

“The inclusion of endocrinologists as well as primary care physicians may have resulted in a more heterogeneous study population and limited power; however, we still detected significant associations and found that results were similar when restricted to only
primary care physicians in sensitivity analyses suggesting consistency of associations within each specialty.”

4) Many survey responses were converted from ordinal variables into dichotomous variables. This is a concern in the size of practice question and the three frequency of diabetes care questions which were converted to a high low category. It seems that these details would be very important to understand the results. Furthermore, the familiarity with guidelines went from a 5-point to a 2-point scale, but especially in the NGU group the responses were very different.

This is a good point. In response to the reviewer, we have now included the specific options selected by participants that were used to classify them in these groups in the manuscript as follows for practice volume on page 9, last paragraph:

“High” volume practices were defined as physicians who reported > 250 patients each month (i.e. the participant selected one of the following options: 251-500, 501-750, or more than 750 patients) while “Low” volume practices were defined as physicians who reported <250 patients each month (i.e. options selected were either less than 100 or 100-250 patients)."

For the question on frequency of new diagnoses of diabetes, further details have been added starting on page 9, last paragraph:

A “high” frequency of making new diabetes diagnoses was defined as physicians who reported one or more new diagnosis a week (i.e. 1-3 times per week or more than 3 times per week). A “low” frequency of making new diabetes diagnosis was defined as physicians who reported less than one new diagnosis a week (i.e. less than once a week, less than once a month, or rarely if ever)."

For the question on frequency of treating established diabetes, there was a typographical error and this should have read as ≥ 5 diabetes patients a week for the high frequency group in the manuscript text; also the numbers in the tables for % indicating high and low had been inadvertently switched. We have corrected both these instances in the revised manuscript. Further details have been added to page 10, first paragraph:

"A “high” frequency of treating established diabetes patients was defined as physicians who reported ≥ 5 diabetes patients a week (i.e. 5-10 times per week, 11-20 times per week, or more than 20 times per week). A “low” frequency of treating established diabetes patients labeled physicians seeing < 5 diabetes patients a week (i.e. less than 5 times per week or rarely if ever)."

And for the question on treatment of hospitalized patients, further details were added to page 10, first paragraph:

"The providers were dichotomized as “high” if they chose “often” or “very often” for treating hospitalized diabetes patients or “low” if they chose “never” or “seldom” for treating hospitalized diabetes patients."
We chose dichotomous variables for the size of practice and frequency of treating diabetes questions in our analysis given that there were fewer participants with responses in the extreme categories and in order for meaningful comparisons to be made in adjusted analyses. The use of dichotomous variables also facilitated a more straightforward interpretation of the results. These were also not our primary variables of interest but potential confounders that we explored and found did not significantly impact the relationship between guideline use and the outcomes of our study. In response to the reviewer, we have clarified that the ordinal variables were classified as dichotomous variables as follows on page 10, last paragraph:

“For purposes of analyses, and because there were fewer responses in the extreme categories, ordinal variables were categorized into dichotomous variables for the size of practice and frequency of diabetes care questions.”

The familiarity with guidelines questions went to a 2-point scale with only those that actually reported using clinical guidelines included in the “guideline user” category. We acknowledge that it is possible that those in the NGU category may have been familiar with the guidelines though they reported not using them in the survey, however, this would have overestimated the knowledge score in this group and made it more difficult to detect differences by group. In response to the reviewer, we have added the following text to the discussion on page 16, second paragraph:

“We dichotomized participants as guideline users versus non-guideline users based on their responses; only those that reported using clinical guidelines in their practice were included in the guideline user category. It is possible that some unrecognized familiarity of guidelines was also present in the NGUs but this would have overestimated knowledge scores of this group and limited our ability to detect associations.”

5) The discussion and conclusion are balanced and supported by the data, but seem to ignore some key concepts such as team care approaches in redesigned practices where care of diabetes cases is often managed by nurse practitioners and physician assistants who use the guidelines to direct care and incorporation of new roles such as practice facilitators or medical assistants to address guideline issues.

This is a good point. Team care approaches are important to acknowledge, especially the role of nurse practitioners and physician assistants in the management of patients with diabetes who may also refer to guidelines. In response, we have added the following sentence in the manuscript on page 18, last paragraph:

“The clinical care of patients with diabetes often uses a team care approach involving not only the physician but also nurse practitioners, physician assistants, practice facilitators, and medical assistants who may also refer to consensus guidelines. Future studies should explore potential knowledge gaps in these other specialties.”

6) What was most striking to me was the low level of knowledge among both GU and NGU groups. Clearly use of the guideline still leaves knowledge gaps about very basic care.
We agree that the low level of knowledge in both GU and NGU was a striking finding in our study. In response, we have added the following sentence on page 14, first paragraph:

“Strikingly, there existed a low level of diabetes-related knowledge among both guideline and non-guideline users.”