Author's response to reviews

Title: Barriers to self-monitoring of blood glucose among adults with diabetes in an HMO

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Dear Ms. Veitch:

Thank you for the thoughtful and helpful comments on our manuscript. We believe that the revisions and clarifications we made in response to the reviewers’ comments have greatly improved the manuscript. We describe how we have responded to each of the reviewer’s comments below.

Reviewer #1

1. A) Background suggests that DCCT provides proof that self-monitoring is effective

   Response: We agree with the reviewer that the literature does not provide incontrovertible evidence of the efficacy of SMBG. Therefore, the language in the first paragraph was changed to reflect the lack of evidence of the efficacy of self-monitoring. “Since the publication of the Diabetes Control and Complications Trial results demonstrating the efficacy of intense glycemic control using insulin therapy and frequent self-monitoring of blood glucose (SMBG) in improving health outcomes,1 SMBG has become a principal component of diabetes management. While the efficacy of self-monitoring independent of other self-management practices is still uncertain, the practice is recommended for patients using either insulin or oral drug therapy.”

   B) The reviewer expressed concern over the timing of the collection of the data, which occurred prior to the release of the DCCT and wondered how that might impact the interpretation of the results?

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Response: We have included a paragraph in the limitations (Page 12, paragraph 3) regarding the effect of the timing of the study on the interpretation and salience of the results. “The policy to cover the cost of home glucose monitors at this HMO was implemented in anticipation of the DCCT results. In further analyses of the policy, we found that the barriers to SMBG identified in this study did not change over time. Further, the rate of SMBG changed very little pre- and post-release of the DCCT findings and the policy change at HPHC. Lastly, similarities between our results and those from more recent studies of diabetes self-management would lend additional support to our conclusions regarding SMBG.”

C) Prevalence of urine testing as an alternative to SMBG

Response: Only 1.5% of our study population filled prescriptions for urine test strips only during the study period. We have included a sentence on (Page 5, 2nd paragraph under Dependent Variables, last sentence), explaining why we did not include urine test strip use as a measure of self-monitoring in the study. “As only a very small number of patients were using urine test strips to monitor glycemic levels (1.5%), we did not include urine testing as a measure of self-monitoring.”

2. Limited review of SMBG use

Response: We have included additional references uncovered by our literature review of determinants of SMBG in response to the reviewer’s concerns.

3. Page 5, para 1: Does exclusion of patients with more than 45 days disenrollment bias the results?

Response: We recognize that people who disenroll may be different with respect to monitoring. Therefore, our results only provide evidence regarding the predictors of monitoring for a continuously enrolled cohort of diabetes managed care patients. We have included a sentence in the limitations to this effect. Page 13, 2nd paragraph, 2nd sentence: “In particular, we only included patients who were continuously enrolled, thereby limiting the generalizability of our study to continuously enrolled managed care patients with diabetes.”

4. Filling the scripts and using the test strips

Response: We acknowledge that test strips are not a perfect measure of actual use and have included a sentence in the limitations section on page 12, last paragraph, 1st sentence to that effect. “Test strip dispensing are not a perfect measure of actual use, but are likely to be more objective than self-reports.”

5. A) Page 6, para 1 and 3, why were three groups turned into 2 dichotomous variables
Response: We used n-1 dichotomous variables to represent n mutually exclusive groups. This method is preferable to using a single categorical variable because it allows us to interpret the odds ratios for each individual variable relative to the reference group. Inclusion of three dichotomous variables, each to represent one of three categories would result in over identification of the model.3

B) Page 9, multiple comparisons (Table 2)

Response: We performed statistical tests to ascertain whether there were differences among all three groups using one-way ANOVA and chi-square. We recognize that using an arbitrary criterion will tend to inflate the number of significant items. However, since we only used these tests as part of the criteria for determining inclusion in the multivariate models, we chose high thresholds for statistical significance (p<0.20) in order to be more inclusive.

6. A) Page 6, paragraphs 2: test the weightings for the socioeconomic score by analyzing them once on half of the sample and then again on the other half.

Response: We tested the weightings for the socioeconomic score for patients treated with insulin compared to patients using oral medications. Because the results of the two analyses were quite similar, we decided to use one set of weightings for all patient cohorts.

B) How were interaction terms considered?

Response: As stated on page 8, para 1, we used likelihood ratio statistics to test the necessity for interactions terms in the models. However, none of the interactions were of sufficient theoretical or statistical significance to merit inclusion in the final models.

7. Page 6, para 3: how does the CDS discriminate between drugs with multiple uses (e.g., beta blockers)

Response: The CDS does not discriminate between drugs with multiple uses. However, the tests of the CDS have demonstrated its utility in predicting health services utilization and poor outcomes in both children and adults (need references for adults).

8. Page 7, para 3: Do patients attend elsewhere outside the HMO and how comprehensive was the HMOs coverage for diabetic patient costs?

Response: While a small number of patients may have used clinics or pharmacies outside of the HVMA system to purchase test strips and other diabetes services, there was a strong incentive to obtain these services at HVMA due to the relatively low cost per service (e.g., $5 copay for test strips

and all medications). As a result, virtually all patients received their care in the HMO.

9. A) Page 7/8: How were the analyses adjusted for missing data?

Response: We acknowledge the reviewer’s concerns regarding missing data in the limitations section on page 13, 2nd paragraph. To account for the impact of missing data on the multivariate analyses, we added race and BMI at the end of the modeling process and then compared the models with and without these variables. Despite the absence of race and BMI for approximately 30% of the study population, the inclusion of these variables did not affect the significance or magnitude of the included variables.

B) Page 9, How were the differences in neighborhood assessed when ethnicity was often missing?

Response: We intentionally excluded race from our measure of neighborhood SES in order to avoid correlation between it and the left out variable race.

10. Duration of diabetes.

Response: Information on duration of diabetes was unavailable for most patients in our sample. We acknowledge the absence of this variable as a limitation in the discussion section on page 13.

11. Method used for HbA1c calculations

Response: We used a standard conversion algorithm developed by Quest Diagnostics to convert Total Glycosylated Hemoglobin values in the medical record to HbA1c. The method was applied consistently across all patients and was certified by the National Glycohemoglobin Standardization Program.

Reviewer #2

1. Reviewer suggests adding interactions terms or using Bayesian methods to improve model fit.

Response: As stated on page 8, para 1, we used likelihood ratio statistics to test the necessity for interactions terms in the models. None of the interaction terms we tested merited inclusion based on theoretical or statistical significance.

2. Use of statistical significance as a measure of variable importance.

Response: We agree with the reviewer that statistical significance should not be the primary determinant of factor importance. We based our selection of variables to be included for consideration on the theoretical model described under point 3 below and the existing literature. Further, certain variables were
kept in the model regardless of statistical significance (age, gender, CDS, total number of HbA1c tests). However, we did use stepwise variable selection in order to increase the parsimony of the models. Where relevant, we conducted joint tests of variables to account for multiple testing of related variables. We would have preferred to keep race and BMI in the models regardless of statistical significance. However, due to missing values, we entered them at the end of the model building process and included them on the basis of statistical significance.

3. What is the theoretical model on which we base our models.

Response: We based our statistical models on the theoretical model of health behavior described by Kasl and Cobb (ref #13).

4. Buying strips and using them may be different things.

Response: We acknowledge that test strips are not a perfect measure of actual use and have included a sentence in the limitations section on page 12, last paragraph, 1st sentence to that effect. “Test strip dispensing are not a perfect measure of actual use, but are likely to be more objective than self-reports.”

Sincerely,

Alyce S. Adams, PhD
Assistant Professor