Author's response to reviews

Title: Measuring the quality of patients' goals and action plans: development and validation of a novel tool

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Author's response to reviews: see over
Re: MS 1710812447735728
Dear BMC Medical Informatics and Decision Making Editor,

Thank you for considering the attached manuscript, “Measuring the quality of patients' goals and action plans: development and validation of a novel tool” for BMC Medical Informatics and Decision-Making. Evidence-based management of diabetes includes training patients to perform self-management, including goal setting. However, evaluating efforts to train patients to set goals and action plans that will result in completion of self-management tasks have been limited by a paucity of reliable measurement instruments. We believe that the paper begins to bridge this gap by offering a measurement tool for goal-setting quality. We were pleased that the reviewers found the paper well-written and our methods generally sound. However, the reviewers also offered a number of insightful and provocative remarks that we have addressed, and believe that these revisions strengthen the presentation of the work. In the letter that follows, we begin with each reviewer’s major compulsory revisions and our attempts to address these concerns; we hope you and the reviewers will find these adequate. Then we address minor and discretionary revisions, including our edits and specific responses. We appreciate the opportunity to address these concerns. All edits in the revised paper are captured in “bold” font.

We will also upload a copy of the published manuscript in Archives of Internal Medicine described the parent study and participant sample in greater detail given that a number of reviewer comments related to this prior work.

MAJOR COMPULSORY REVISIONS

Reviewer #1:

1) “Methods: ‘To identify criteria that defined high-quality goals and action plans, and establish content validity, we undertook a review of articles specifically related to goal-setting in the context of diabetes.’ How were the articles identified, and which articles specifically were reviewed?”

2) “Methods: ‘The review resulted in ten criteria overall...’ What process was used to identify the 10 criteria?”
Our response: Upon re-reading, we realized that our original manuscript lacked details about our review process, which were curtailed in our efforts to reduce the amount of text in the manuscript. In the revised manuscript, we have added text to this section to describe our process. This detailed process included a review of key theories to identify goal and action plan attributes and then a specific review of scientific articles to determine how to operationalize these attributes as GET-D criteria.

We have described our process more clearly in the Methods sub-section labeled “GET-D Criteria Identification and Scoring,” which we believe will adequately answer both these questions raised by Reviewer #1.

Reviewer #2:

3) “There is a great belief in goal setting and action planning. However, while there are many opinions about these, there is very little evidence to support which parts or combination of parts are useful in achieving the desired outcomes, i.e. lower A1c. Until we know this, the use of a scale to measure goal setting and action planning is not very useful. In fact it may be detrimental to the field as it may discourage exploration into this important issue. For example the quality of goal setting/action planning will be determined by how well it meets the scale criteria rather than how well it predicts outcomes. The authors have chosen their components based on the recommendations and opinions of well known researchers but have not presented evidence that any of these components are really important.”

Our response: The literature review presented in response to reviewer 1, comments 1-2 describes several empirically-based studies that established the validity of goal-setting theory in a number of non-health care settings over many years. We wholeheartedly agree with the reviewer that the clinical outcome evidence about the effectiveness of goal setting and action planning in health care (in contrast) is mixed and not always compelling. We developed the current study precisely to address this research gap—because most health care studies using goal-setting are atheoretical and have not reliably measured the process of goal-setting itself. These prior studies did not use reliable and valid measures of goal-setting as a mediator of the relationship between self-management education and clinical outcomes. We agree with the reviewer that clinical endpoints are ultimately the most important outcome of interest. However, empiric clinical studies that are not based on theoretical models are limited in their capacity for replication and generalizability. We developed the GET-D instrument and conducted this measurement validation study to address the exact concerns of the reviewer. The next logical study after establishing measurement validity and reliability is to determine the relationship between change in the measure and the clinical outcome of interest using a different participant sample.

We have revised the introduction ad methods and discussion sections to more clearly state these points.
4) “It appears that the authors have both measures of the components of goal setting and action planning and have outcomes from an ongoing study. It is very surprising that the associations of these data were not presented.”

Our response: We appreciate the reviewer’s interest in the outcomes of the larger EPIC study. The outcomes of that study (showing significant differences in HbA1c between the intervention and control groups) are published elsewhere: Naik AD, Palmer N, Petersen NJ et al. Comparative effectiveness of goal-setting in diabetes group clinics: Randomized clinical trial. Archives Intern Med. 2011;171:453-459).

In the current manuscript, we have described significant differences between intervention and control groups in goal-setting quality as a form of “known groups” validation. Studies confirming an instrument’s measurement reliability (i.e., development validity) and its predictive validity should be done with two distinct samples (or a population with a much larger sample size to allow for non-duplicative sampling of development and validation cohorts). Our sample size and the characteristics of the parent study limit our ability to conduct both an instrument development and predictive validation analyses in this one manuscript.

5) “How does the quality of goal setting and action planning as a whole and the component parts, contribute to outcomes? Until we know this the scale is of limited or no usefulness. Is goal setting really important or just action planning (the scale does not differentiate the two and this is very important)? What components of action planning predict or are associated with better outcomes? Maybe we do not need all the components.”

Our response: Reviewer #2 may be right. As such, we included in the Results Table (Table 3) a breakout of the full GET-D score, Action Plan score and Goal Score, and our data certainly suggest that the quality of action planning is driving the results we observed. However, because our data had significant floor effects (which we described in both Results and Discussions) on a variety of items in both Goal Quality and Action Plan quality, we felt we could not adequately discern the relative contribution of goal criteria quality versus action plan quality. As such, we did not address this in the original version, leaving it to the reader to determine based on the data quality.

In the revised manuscript, we have added a brief sentence to the Discussion section to reflect our thinking about this and the limitations section does discuss the limitation arising from measurement floor effects.

6) “Is a set time for completion important if so how much time? AA uses one day, many programs use a week, a month or between visits. If time is important we need to know how much time.”

Our response: Our review of the literature, which we describe more thoroughly as requested by Reviewer #1, suggests that the amount of time is less critical than having a set time for goal
completion (i.e., deadline for goal completion). While some do suggest that having both a short-term and long-term goal is helpful to patients (see Bodenheimer et al, 2009, for example). Goal criteria 2b and Action Plan criteria 4b get at these two distinct facets of time (deadline for a goal and frequency of an action).

7) “There are no data presented on success or failure of action plans and the influence of these on outcomes. In fact there is nothing in the scale that looks at completion or non-completion. This is an important factor in the literature that was cited but is not discussed.”

Our response: We agree with the reviewer that goal attainment is an important issue. The literature focuses heavily on goal attainment scaling to assess goal success. However, this literature is beyond the scope of our described study (the validation of a tool to assess quality) and as such, we did not address it. Further, in the larger EPIC study, we did not conduct goal attainment scaling and did not have data to report on this facet. We are not denying the importance of this point; however, as goal attainment scaling has its own large instrument development and validation literature. The goal-setting measurement literature is sparse by comparison.

We have added text in the discussion section about next steps evaluation the relationship of goal-setting to goal-attainment.

8) “This is not a patient centered study. In fact the patient appears to have no part in the study except to supply data. Then raters, make determination on such factors as are the goals, related to diabetes self-management. In fact the relationship of a goal to diabetes self-management may not be apparent to the professional rater while it is directly relevant to the patient. Also we do not know if the goal/action plan was shaped by a professional or was really that of the patient. In shared decision making the word shared is key and in this study little sharing was apparent. Patients were not included in the rating and there is no rating of the quality of sharing.”

Our response: We agree wholeheartedly with the reviewer that patient-centered interventions are critical (and in fact, the EPIC intervention was guided by patient-centered principles, see Naik AD, Palmer N, Petersen NJ et al. Comparative effectiveness of goal-setting in diabetes group clinics: Randomized clinical trial. Archives Intern Med. 2011;171:453-459).

Given the more narrow objectives of the current study (to examine the validity of a tool to assess quality of a patient-written goals and action plan), we did not delve heavily into the EPIC study design in the current manuscript. However, we agree with the reviewer that a diabetic patient should be able to set the goal that is most relevant to their diabetes self-management. As such, we deliberately made very inclusive instructions to raters about what to include (see instructions in Appendix), which include a wide variety of potential goals.
In the revised manuscript, we have added text to clarify and emphasize that the goals and action plans were selected and written by patients, without shaping by professionals, and reflect patient-centered goals. We have also added additional text about the parent study to avoid confusion about the nature of the goal-setting.

9) “The assumption (not stated) is that the purpose of goal setting and action planning is to change diabetes specific behaviors. An equally important purpose may be to give individuals, especially those with depression and or low activation, success experiences which lead to more success experiences and less depression and or more activation. (note that as mentioned above this was not measured). One of the key components of enhancing self-efficacy is skills mastery (i.e. making an action plan and completing it). These in turn may lead to improved outcomes. The authors cite references that make both of these assumptions but do not acknowledge or discuss this.”

Our response: We agree with the reviewer that improving activation and self-efficacy are key attributes of a successful intervention goal-setting intervention. The parent EPIC study monitored these outcomes of the goal-setting intervention. However, the scope of the current manuscript was not an assessment of the goal-setting intervention. The objective of the current study is the development and measurement-validation of a novel tool to assess the quality of a patient-written goal and action plan. We did form validation hypotheses about activation and self-efficacy and an inverse relation with depressive symptoms, based upon the literature, as well as report data about these constructs and their correlation with goal-setting scores.

We are careful not to make all the claims suggest in reviewer comment 9 because these outcomes are beyond the scope of this study and the available data. The purpose of this study was to develop an instrument to measure goal-setting and action planning in a reliable and theoretically-grounded manner. We completely agree with the reviewer about next steps: correlation of goal-setting/action planning quality with goal attainment and self-management performance and a subsequent path analysis model that links goal-setting to goal attainment to improved clinical outcomes. We have added text to the discussion section to describe these next steps in the research process.

Reviewer #3: No Major Compulsory Revisions noted.

MINOR ESSENTIAL REVISIONS

Reviewer #1:

1) Methods: ‘This study was approved by an Institutional Review Board.’ Identify the Institutional Review Board.

Our response: We have changed this text to “the Baylor College of Medicine Institutional Review Board as requested.

2) ‘Effective goals for diabetes care required that four criteria…’ This should be three?”
Our response: The reviewer is correct. We have modified this text accordingly.

Reviewer #2:

3) “Note that references 7 and 12 are the same.”
   Our response: The reviewer is correct. We have modified the text and citation list to correct our error.

Reviewer #3:

4) “Methods: There is a very good description of the development of the GET-D, including the relevant existing knowledge regarding action plans and the initial pilot testing and modifications to the instrument. However, the description of the methods for testing the psychometrics of the GET-D need to be greatly expanded. Who are the participants in this part of the study? How were they recruited? How were they randomized? It sounds like this was part of a larger study? If so, please say something about that larger study.”
   Our response: We have provided additional details regarding the parent EPIC study and its participants in the Methods and Results. We have not included specific recruitment details (which are described in the cited manuscript) but have provided more information about participant recruitment, randomization design, and characteristics. We have attempted to address the reviewer’s primary need – to immediately know a bit more about the study – without adding considerable text that has been published elsewhere.

5) “Introduction, 1st paragraph, last sentence: please qualify by adding “possibly” after ‘this mixed performance’.”
   Our response: We have made this change.

6) “Methods, 3rd paragraph: The authors state that there are seven additional criteria, but upon reading the rest of the paragraph it appears there are 3 criteria (one with 5 different parts). The final “criteria” isn’t stated as if it were required, but merely a judgement of quality (i.e., should read “the action plan must be feasible for the patient to carry out”).”
   Our response: All 7 criteria were required and we have modified text to make this clearer.

7) “Methods, 5th paragraph 1st sentence: please change “usability” to “usefulness” – avoid jargon when possible.”
   Our response: We have made the suggested change.

8) “Methods, 5th paragraph, 2nd sentence: How were the raters paired to assess inter-rater reliability (was each rater always paired with the same person, or were they rotated so that each rater was paired with different raters?)”
   Our response: We have added text to clarify our rotated rating scheme.

9) “Methods, 9th paragraph, 4th sentence: “We recruited and trained two physician-fellows to use the GET-D to rate each goal and action plan.” Why did you use physicians? Is this level of expertise necessary to use the GET-D?”
Our response: We are grateful to the reviewer for raising this point, because the GET-D definitely does not require expertise to use, only training. We have added a brief discussion of this in our discussion section to address.

DISCRETIONARY REVISIONS

Reviewer #1

1) “Results, For clarity, recommend changing ‘On average, the 85 participants were…’ to ‘Overall, the 85 participants were…’ ”

Our response: We have made the suggested change

Reviewer #2: No discretionary revisions noted.

Reviewer #3

2) “Results, 1st paragraph: The information provided on participants seems rather scanty. Would be nice to have more information about the participants such as, did they all have type 2 diabetes, some indication of the extent to which their diabetes is controlled or not (i.e., HbA1c), how long have they lived with diabetes, BMI, diet, physical activity, smoking status.”

Our response: We have added some of the requested information in Table 1. We have also clarified that the subject were drawn from the parent study and the citation that provided detailed information.

3) “Discussion, the last sentence in the first paragraph: I think that saying this instrument provides the “missing link between patient education intervention and patient outcomes” is a bit strong – although it certainly adds more information to the picture by shedding light on the fact that what people DO with the tools they are given as part of a education intervention matter. This information could be used to inform intervention strategies, ensuring that information is delivered in ways that brings about the most effective action plans. The authors need to more clearly distinguish the instrument that the patient completes in goal setting and developing their action plan from the evaluation tool used to evaluate those action plans. It seems these two pieces become quite muddled in the discussion section.”

Our response: We believe the reviewer makes an important point. We hope that changes in the methods section and more substantial ones in the discussion section will better clarify our meaning.
We believe that the revisions we have made considerably strengthen the manuscript, and we are indebted to the reviewers for raising these important issues. To help facilitate understanding of our revisions, we have placed all text that was moved, substantially rewritten or added in **bold**.

Thank you again for your consideration of our work. Please let me know if you need any further information.

Best Regards,

[Signature]

Cayla R. Teal, Ph.D.
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And

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