Reviewer’s report

Title: Impact of Communicative and Critical Health Literacy on Knowledge and Self-efficacy in Diabetes Management in Primary Care: a cross-sectional study in Japan

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Reviewer: Angela Brega

Reviewer’s report:

The authors examine the relationship between health literacy and diabetes knowledge and self-efficacy, also examining the association of patient-physician communication with knowledge and self-efficacy (while controlling for health literacy). Generally, the paper is well-written. However, the authors could be clearer about their objectives and how their analyses address the questions they set out to answer.

A. Discretionary Revisions:

1. It has been my understanding that journals -- in the United States, anyway -- prefer that authors refer to “patients with diabetes” rather than “diabetic patients.” The authors might consider following that convention.

2. I would suggest revising the first two sentences of the second paragraph on page 5. In particular, the reference to “the same three levels” is confusing. What three levels?

3. I think it is worth commenting on the fairly marginal correlations between health literacy and clarity. One might suspect that poor health literacy would lead to lower perceived clarity in patient-provider communication. These results suggest that that is not the case.

4. In the first paragraph of the Discussion section, I would suggest omitting the phrase “due to practice settings.” The authors don’t know that there is variability across clinics in communication.

B. Minor Essential Revisions:

1. For readers who are unfamiliar with the Japanese health care system, it would be helpful for the authors to explain the types of clinics involved in the study (e.g., health cooperative clinics) as well as prefectures.

2. I appreciate the author’s attempt to place their work within a theoretical framework, specifically the model developed by Paasche-Orlow et al. For the most part, using that model as a foundation makes sense. However, I found it confusing for the introductory comments related to access to be organized around that model. The authors provide interesting and important information about access to and utilization of diabetes care in Japan, whereas the Paasche-Orlow model argues for a relationship between health literacy and access/utilization. If the authors intended to look at that relationship, using this...
model to support an interest in access would make sense. But, since they are really just describing diabetes care in Japan, independent of health literacy, I would suggest they not tie this part of the introduction to that model, instead just focusing on the patient-provider relationship and self-care components of the model and discussing access without reference to the model.

3. Did physicians really randomly select survey days… literally, they picked dates from a hat rather than based on other criteria (e.g., clinic workload for the day)?

4. Were survey data collected before or after a patient visit? Collecting data before the visit could mean that patients had not seen their doctors for up to 8 weeks or so, possibly leading to less accurate responses to the communication items.

5. The authors should be careful to avoid using language that suggests causal relationships between variables. For example, in the abstract, they indicate that health literacy and patient-provider communication “affected knowledge of diabetes care and self-efficacy.” In the Discussion, they indicate that clarity “was found to influence” other variables. Given that the data are cross-sectional, all the authors can say is that the variables were associated.

6. Can the authors provide information about the original source and prior psychometric testing of the communication items?

7. Authors should include statistics to back up the claim that test-retest reliability was adequate.

8. Near the end of the Results section, the authors mention univariate analyses examining the relationship of clarity with knowledge and self-efficacy. It does not appear to me that these models were mentioned prior to this point in the paper.

9. The authors note that people with limited health literacy might have been unwilling to respond to the survey, but suggest that “very few” such cases were likely. What would lead them to that conclusion?

10. The authors suggest that patient selection may have been biased. Were any data collected that would allow us to assess that statement? If consecutive patients were approached to participate, patients with favorable relationships with their physicians could not have been purposefully selected. Did practices collect data that would help the authors assess whether all consecutive patients were in fact approached or whether patient selection may indeed have been biased? Since the authors do not know the sample to be biased toward patients with favorable relationships with their providers, I think it is an inappropriate leap to suggest these results could be generalized to that type of patient.

11. The authors include some items in their analyses that receive little or no discussion in the Introduction and Methods. Why, for example, are internet use and social support included in the models. These measures are not justified in the text and seem extraneous. Why did they authors chose to covary for the clinical measures they selected (e.g., number of drugs)? A little justification would help support the analytic approach.

12. The authors should exclude discussion of BMI and A1c (in the analysis section), as these measures are not actually included in their models.
13. Additional information about the response rate would be helpful. Is 326 the number of consecutive patients approached about study participation or is this the number who agreed to complete the survey? If the latter, it would be helpful to note the number of participants approached, as well as the number who agreed, and the number who actually completed the survey.

14. The authors indicate that there were “no multicollinearity problems.” Given that two of the health literacy scales were highly correlated, that the total health literacy score is in the model with the three subscales from which it is derived (and is well correlated with two of them), and that the clarity item is correlated with the communicative and total health literacy scores, I think the authors need to more rigorously address the problem of multicollinearity.

15. Why is the total health literacy score included in the models at all when it is never discussed and seemingly does not address the authors’ objectives?

16. I would suggest introducing economic status in Model 2, where other sociodemographic variables are included.

17. I would include all additional covariates in Model 3, adding only clarity in Model 4. Can the authors at least explain why they chose to include certain covariates in Model 3 and others in Model 4?

18. The description of the association between communication items and subsequent selection of the clarity item for inclusion in all remaining analyses should be in the Methods section.

19. The authors fail to mention the results related to the functional health literacy scale, which predicts diabetes knowledge in all models. That is also an important result and should not be excluded from mention in the Results and Discussion sections.

C. Major Compulsory Revisions:

1. Throughout the paper, the authors are inconsistent in describing their objectives and the questions they set out to answer. In the abstract, the authors suggest that patient-provider communication may moderate the relationship between health literacy and diabetes knowledge/self-efficacy (“We also examined how patient-provider communication factors could affect these relationships”). In the last paragraph of the Introduction and the last sentence in the Results section, they suggest a mediating role, that is, that patient-provider communication may explain those relationships. The analyses conducted actually examine whether patient-provider communication is associated with knowledge and self-efficacy, when health literacy is controlled (although a mediator would cause the significant relationship to disappear, that is not the only analysis that would have to be run to demonstrate a mediating relationship). Later reference to knowledge and self-efficacy being “intermediate variables” again suggests there is an interest in a path model here, which is not really fleshed out. Authors should be consistent in describing their research questions and ensuring that their analytic approach answers those questions.

Level of interest: An article whose findings are important to those with closely
related research interests

**Quality of written English:** Not suitable for publication unless extensively edited

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I have no competing interests to report.