Author’s response to reviews

Title: The relationship between health literacy and patient activation among frequent users of healthcare services: a cross-sectional study.

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On behalf of my colleagues and myself, I would like to thank you and the reviewers for the review of our manuscript « The relationship between health literacy and patient activation among frequent users of healthcare services: a cross-sectional study » and for the relevant comments.

Below, you will find a detailed response addressing each reviewer’s comments.

REVIEWER 1

CHRISTY LEDFOR

Comment: Introduction - I would avoid the language that CCM is gaining importance. We have been using it for almost 20 years.
Response: Thank you for bringing this to our attention. We modified the introduction to better link patient activation and health literacy among frequent users of healthcare services and removed the reference to the Chronic Care Model (CCM).

Comment: The transition between CCM and PAM is awkward. Describe better how PAM is situated within the CCM.

Response: We modified the introduction, and removed the reference to the CCM.

Comment: Also, be careful to conceptualize a concept using proprietary language. The second paragraph uses Hibbard's tool's language to describe a broader concept.

Response: We re-examined the literature on the concept of patient activation and most authors referred to the definition of Hibbard et al. (Development of the Patient Activation Measure (PAM): Conceptualizing and Measuring Activation in Patients and Consumers. Health Serv Res. 2004; 39(4 Pt 1):1005-26.). However, we remain open to any others suggestions concerning the definition of patient activation.

Comment: Also the operationalization of health literacy is hotly debated. Need to at least recognize that when it is a primary variable of the study.

Response: In the introduction, we added that the operationalization of health literacy is debated (line 68).
Comment: Method—what is the target behavior change of the intervention? Activation? Health literacy? Engagement?

Response: We added patient activation as one of the primary outcomes of the intervention (line 96).

Comment: Include more information about the recruitment protocols and dropouts prior to variable assessment.

Response: We included more information about the recruitment protocols and dropouts prior to variable assessment (lines 110-120). We also modified the number of participants. This study presents the secondary analysis of data collected among patients recruited for a larger project, V1SAGES, for which 247 participants were randomized (Hudon C, Chouinard MC, Dubois MF, et al. Case management in primary care for frequent users of health care services with chronic disease and complex care needs: a mixed methods study (V1SAGES), in revision). To promote consistency between articles, we decided to keep the 247 participants who were randomized and remove the 10 participants who completed the questionnaires but were lost before randomization. Results were the same with both samples (n=247 or n=257). In the Methods section, we added information on the flow of the patient through the study and made all necessary modifications in the manuscript and in Table 1.

Comment: Discussion: It is bold to say that none of these studies dealt with frequent users - although that wasn't the focus of those studies, they are likely included.

Response: We agree with the reviewer’s comment and removed this sentence.
Comment: What is the implication of the finding? If they are not associated, which is the better target for intervention?

Response: Because we did not find an association, we suggested that the implementation of interventions on the improvement of patient activation as well as health literacy would be more effective than those focussing only on one of these concepts (lines 227-229).

Comment: What are the discriminant measures of validity?

Response: We added the discriminant validity of the NVS (specificity measured by the receiver operating characteristic (ROC) Curve) in the methods section (lines 137-138). No data was published on the discriminant validity of the PAM.

Comment: What do the findings show for the CCM?

Response: We modified the introduction, and removed the reference to the CCM.

Comment: Do patients not need health literacy to be successful in active participation with their team?

Response: Our hypothesis was that people with good health literacy were more activated patients. As we stated in the discussion, some studies demonstrated an association between health literacy and patient activation, but the relationship could be influenced by covariables, such as age, education, or income, or by the population group studied (chronic patients, frequent...
users, etc.). Our study did not demonstrate an association between health literacy and patient activation. We explored this aspect more deeply in the discussion section (lines 187-198)

Comment: Recommend extending your literature search. Specifically include:


Response: Thank you for your suggestions, we expanded and improved our discussion by including these articles (lines 187-198).
Comment: I find this paper very interesting and believe that it can add good knowledge to the topic of patient's empowerment in the health decision making process.

Response: Thanks you for this positive feedback.

Comment: However, in my opinion, there are some specific issues that I think need further attention: First of all, in the study design section, it is not clear why this cross-sectional part is developed separately if it was part of a randomized controlled trial that was already conducted. This sub study could be included in the trial as baseline data.

Response: Indeed, this study could have been included in the trial as baseline data but it was part of my master project because I was interested in the relationship between health literacy and patient activation among frequent users of healthcare services. The V1SAGES project provided an opportunity to explore this association, especially by conducting a secondary analysis of the baseline data. A manuscript on the evaluation of the effect of the V1SAGES project is actually in revision (Hudon C, Chouinard MC, Dubois MF, et al. Case management in primary care for frequent users of health care services with chronic disease and complex care needs: a mixed methods study (V1SAGES).

Comment: Second, the participants' inclusion criteria should be more specific. If physicians identify participants that "they believe would benefit most" or "based in their clinical judgment", and they also "targeted additional patients they considered complex" it is possible to have high variability and, thus, selection bias might occur affecting the results of the study.
Response: We are truly sorry for the confusion. In fact, what we meant is that the family physician identified the patients with complex care needs they believed would benefit from the case management intervention, based on their clinical judgment and considering the inclusion criteria. A study by Freund et al. (Comparison of physician referral and insurance claims data-based risk prediction as approaches to identify patients for care management in primary care: an observational study. BMC Fam Pract. 2013; 14:157) reported that a combined approach of healthcare providers’ judgment and data from a database system appears to be a most promising recommendation to identify frequent users of healthcare services who could benefit from case management intervention. Even though we followed current recommendations for the identification of patients, the involvement of family physicians in the selection process could have introduced a selection bias. However, considering our sample was composed of frequent users, we do not think this had a major impact on our analysis. We added more information in the methods section and reformulated the section on the recruitment of the participants to avoid confusion (lines 104-105; 109-120) and added the possibility of a selection bias in the limits (lines 218-222).

Comment: Third, as the authors mentioned, the Newest Vital Sign focus only in nutritional labels. Therefore, others aspects of health literacy are not covered by it.

Response: We completely agree with this comment and added this in the limits. (lines 213-216).

Comment: Authors should use other indicators (ot test) to see if they obtained the same results before concluding that there is no relationship between the studied variables.

Response: Indeed, we mentioned in the discussion that future studies should use other instruments measuring health literacy to see if they obtain the same results.
Comment: Fourth, through biserial correlation, authors can observe if there is an association of the two variables, but they cannot assure if there is a causal relationship between them.

Response: Our cross-sectional design allowed us to explore an association between the variables, but could not be used to determine a causal relationship.

Comment: The results of this analysis showing no association between health literacy and patient activation can not be taken into account due to the bias in the selection of participants as well as the questionnaire used to asses health literacy.

Response: We discussed these potential biases in the limits (lines 213-216; 218-222).

Comment: My recommendation is that authors improve the participants' selection method, explain more in detail how this study relates with the clinical trial they mention, and include other kinds of measurements of health literacy that take into account the different dimensions of it.

Response: Thank you for the recommendations; we reviewed our manuscript considering your suggestions. However, it was not possible to include other kinds of measurements of health literacy in this study. This suggestion could be addressed in future studies.

We hope this detailed response to the reviewers’ comments addresses all concerns and questions and that you will consider this version of our manuscript suitable for publication.
Kind regards,

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