Reviewer's report

Title: Opportunities and Challenges for the Inclusion of Patient Preferences in the Medical Product Life Cycle: A Systematic Review

Version: 0 Date: 19 Oct 2018

Reviewer: Stephanie Christopher

Reviewer's report:

The review aimed to understand the potential roles, expectations, concerns and requirements associated with the use of patient preferences in industry, benefit-risk assessment, and reimbursement decision-making. This is an important area of research as FDA and other regulators seek to understand the potential use and value of patient preference information, but also need to be assured of the quality and validity of the patient preference data.

The description of the selection criteria and data analysis was appropriate and well-suited for the type of study described.

The authors stated that they want to understand the desires, expectations, concerns and requirements regarding the use of patient preference information across the medical product development life cycle. However, it seems the majority of text on the results focuses on concerns regarding the use of patient preference information in industry, BRA/MA decision-making, and HTA/reimbursement. This is valuable content, but additional context as to the expectations of this information would be helpful. Why are these groups seeking patient preference information? What do they hope to get out of it? That context will help the reader understand the concerns and recommendations as presented. The authors may consider adding appropriate examples from the literature where each of these groups used patient preference information in a decision-making context. If such examples exist, they would help the reader understand the use of this information.

I appreciate the discussion about requirements to move the field forward and hope that researchers take on the identified topics for future research.
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

Does the work include the necessary controls?
If not, please specify which controls are required in your comments to the authors.

Yes

Are the conclusions drawn adequately supported by the data shown?
If not, please explain in your comments to the authors.

Yes

Are you able to assess any statistics in the manuscript or would you recommend an additional statistical review?
If an additional statistical review is recommended, please specify what aspects require further assessment in your comments to the editors.

Not relevant to this manuscript

Quality of written English
Please indicate the quality of language in the manuscript:

Acceptable

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