Reviewer’s report

Title: Application of Protection Motivation Theory to Clinical Trial Enrolment for Pediatric Chronic Conditions

Version: 0 Date: 25 Nov 2019

Reviewer: Victoria A. Miller

Reviewer's report:

Thank you for the opportunity to review this manuscript for BMC Pediatrics. This manuscript reports the results of a qualitative study to explore parental decision making about clinical trial enrollment for advanced therapy medicinal products for chronic but manageable conditions. This is an interesting study with generally sound methodology, but I do have some concerns and questions that limit my enthusiasm for the manuscript, which I detail below.

1) The concluding sentence of the Abstract, which is also the concluding sentence of the manuscript, is odd and does not seem to follow from the study results. This sentence makes it sound as if the quality of parental decision making was in doubt and also that providers are in a superior position to judge (and therefore either trust or mistrust) parental decision making. I suggest rewording and staying more consistent with what the study actually found.

2) Page 4: the description of T1D as requiring insulin delivery by injection or pump is overly simple. The T1D treatment regimen involves much more than this and can be quite burdensome.

3) Page 5: the reference to "sharing open access code" is not clear- what do the authors mean?

4) Page 5: The authors should say more upfront regarding what they mean by "unregulated clinics."

5) There is a lack of clarity regarding the adaptation of PMT to this decision making context, which first came up on page 6 at the end of the Introduction. The authors mention that they adapted the PMT- how was it adapted and what was the rationale for the need for adaptation? When was it adapted? Did the results of the study inform adaptation (which is implied on page 8, at the beginning of the Results), or did the authors adapt it first and then fit the results to the adapted framework (which is implied at the end of the Introduction)?

6) More detail is needed regarding recruitment methods. For example, at patient-focused conferences, were research flyers made available? Was a presentation given? Did the research
team depend on potential participants to actively contact them? How many people received the flyers and how many newsletters were sent? How many parents declined participation once details of the study were given?

7) The headings in the Results section are quite confusing. I suggest taking a look and revising for clarity. One example is that there is a header for "threat and coping appraisals," which contains one sub-header for "fear." Then there are separate headers for "threat appraisals" and "coping appraisal." Several of the sub-headers that fall under "coping appraisal" don't seem like they belong under this header. Also, the header for "protection motivation" (page 15) doesn't make sense, as there was an earlier header for "modified protection motivation theory." Overall, the Results section could be revamped to be more concise.

8) Page 17, first sentence of "treatment tourism" section: Is this sentence missing the word "not" between "would" and "enable"?

9) The Discussion needs more context (with references) for how these results show a distinction in this decision making context versus others. Also, differences between this study and studies of other contexts may have been impacted by the fact that this study explored responses to hypothetical trail enrollment, so the authors should be careful to not overstate their conclusions.

10) Page 19: What do the authors mean by the appraisal of benefits impacting "other health behaviors"? More details are needed for this statement.

11) Page 20: The authors should provide a reference for the statement about this being "contrary to best practice."

12) Page 21: The authors should expand on how the recruitment method via patient advocacy organizations may impact the generalizability of the findings.

13) Page 21: Do the authors mean to say, "We conducted individual interviews with parents…" (not patients)?

14) Table 1 needs revising. The row for "Total" under most categories is odd. Also, why not provide mean child age and SD/range instead of presenting it categorically? Why do numbers add up to more than the sample size for some of the variables?
Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

No

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.

No

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

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