Reviewer’s report

Title: Patient Experiences in Retinal Trials: a Cross-sectional Study

Version: 1
Date: 23 February 2015

Reviewer: Rhonda G Kost

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Overall, the authors are to be lauded for undertaking a participant satisfaction survey in an effort to better understand and improve the patient research experience and its impact on health-related decisions for this population. Their findings are very positive and may reflect excellent organization, conduct and service at the retinal clinic site. Additional attention to description of methods and addressing sources of potential bias would strengthen the results.

Recognizing the value of participant satisfaction in improved health-related decision making and treatment adherence, and citing published experiences in other ophthalmology contexts, the authors examined participant satisfaction in the context of retinal clinical trials.

MAJOR COMPULSORY REVISIONS

1. The methods section could be strengthened. There is no reference provided to support the method of reaching the sample size calculation. There is no discussion of the testing or validation of the survey instrument. Even if full validation is beyond the scope of the study, face and content validation could be discussed. The range of questions in survey covers well the scope of the intended research question, however, some questions are constructed with positive bias. For example, the question “How did you benefit from participating in the study?” does not offer a neutral or negative response option, such as “I don’t know” or “I did not benefit”. It is not surprising therefore that a high majority of respondents described the study as beneficial. Other questions appropriately include the full range of response options

REVISIONS: Please provide a reference to support the method of reaching the sample size calculation. Provide a discussion of how the survey questions were tested or refined and whether any face or content validation was conducted before fielding the survey. In the Discussion section, address how the absence of a negative response option in the “benefit” questions might have impacted the results.

2. Results: Eighty consecutive patients were enrolled from 14 trials however the distribution of the patients across the trails is not shown. The study is represented as cross-sectional therefore it is important to know whether enrollment from any one of the trials was overrepresented. The survey completion rate is very high (96%). The authors do not comment on the potential undue influence of being handed the survey by research staff and the expectation to complete it on site. (US hospital patient satisfaction surveys are
not to be completed on-site due to presumption of positive bias in this setting however this latter approach yields much lower response rates.) A notable positive finding is that 95% of respondents felt the staff kept them up to date on study progress. The desire to be appraised of study progress and outcomes is a strong finding across qualitative and quantitative studies of research participants.

REVISIONS Please provide a table or sentence illustrating the distribution of survey respondents across the 14 retinal studies.

MINOR ESSENTIAL REVISION

3. There is one figure, which is clear and credible. REVISION: Figure 1 appears twice in the manuscript, both before and after the Appendix. The duplication should be eliminated.

DISCRETIONARY REVISIONS

4. The research question is defined by the elements of the survey they authors created, seeking to understand motivation to participate, issues related to informed consent, the nature of the participation experience, and its potential impact on future research participation. The authors rely primarily on older patient experience literature and more recent ophthalmology patient satisfaction studies. REVISIONS: The authors might do well to review the literature of the past 5 years concerning the participant experience studies more broadly in the context of translational research, and in the development of validated instruments.

5. REVISIONS: The finding that 14% of participants did not understand that they could withdraw requires additional discussion beyond the comment that it is important to stress participants’ rights. The conduct of verbal consent, and the conduct of the survey on site for the current study, as well as the signing of the consent for retinal studies in less than one day, may all be unintentional subtle sources of undue influence to be examined.

6. Does the manuscript adhere to the relevant standards for reporting and data deposition? Yes

7. Are the discussion and conclusions well balanced and adequately supported by the data? Yes, except as above.

8. Are limitations of the work clearly stated? – Yes, except as above

9. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished? The references the authors use are classic, and rather old. There is a more recent literature of both the patient experience and research participant experience that they might find useful to review.

10. Do the title and abstract accurately convey what has been found? Yes

11. Is the writing acceptable? - yes
Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

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

Declaration of competing interests:
I declare that I have no competing interests