Reviewer's report

Title: Minimally Important Difference of the Treatment Satisfaction with Medicines Questionnaire (SATMED-Q).

Version: 1 Date: 7 March 2011

Reviewer: Diana Rofail

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- Major Compulsory Revisions

1. There are statements in the introduction that should be referenced. The authors should read through the introduction and ensure that key statements are supported by relevant references. For example, in the 2nd para of the introduction, the authors state: ‘There would seem to be a relationship between satisfaction with medication and medical treatment and patient adherence or compliance with treatment.’ This statement could be supported by the following references:
   b. Rofail et al 2010. Assessing treatment satisfaction during a product’s lifecycle to facilitate market access: definitions, frameworks and measurement. ISPOR Connections.

2. The ISPOR connections reference should also support the statement: ‘In addition, knowledge of the degree of satisfaction with treatment may make it easier to predict treatment compliance and help clinicians make health decisions.’

3. In the first para of the introduction, the authors state: ‘When treatments administered do not modify survival rates, when there is not a significant difference between one and another, and when the treatments and other medical interventions cause serious side effects for months or even years, the need arises to evaluate effectiveness in other terms.’ It is recommended to change the term and to or, since assessing outcomes such as treatment satisfaction could be useful in any one of these instances.

4. The authors should consider rewording the last sentence in the first para of the introduction which states ‘Health Outcomes research, a relatively new discipline, among other things, focuses on the measurement of disease and treatment impact upon patient-perceived health, and provides an answer to these new requirements of modern medicine.’ The latter part of the sentence is controversial and could be considered an overstatement.

5. It is recommended to change the last sentence in the 2nd para of the introduction which states ‘Consequently, this parameter is one of the health
outcomes which must be measured in both daily clinical practice and biomedical research’ to ‘Therefore, this parameter may be a useful indicator to measure in daily practice and biomedical research’.

6. The authors are good to differentiate treatment satisfaction from satisfaction with healthcare, and to cite the work of Cleary and Shikiar. However, the paper does not appear to acknowledge that whilst treatment satisfaction as a concept may be similar between various conditions and treatments, research suggests that there may be some critical differences. Also, some mention of the difference between generic and disease/treatment specific instruments and their pros and cons would be beneficial. These issues are addressed in part in the following paper which should be cited: Rofail et al 2010. Assessing treatment satisfaction during a product’s lifecycle to facilitate market access: definitions, frameworks and measurement. ISPOR Connections.

7. The 1st sentence of the last para in the introduction describes the SATMED-Q. It would be useful to know how many items the instrument comprises. Also, the names of the dimensions. The authors mention that it was developed using the classical test theory. But statistics alone are not adequate. Its recommended to describe (prior to mentioning its developed by classical test theory) whether the items of the SATMED-Q were developed based on patient interviews and if so how many. This would provide further support regarding the statement about the validity of the measure. Also, the statement, ‘...with good metric properties of reliability and validity’ should be more specific to state in what kind of sample/populations.

8. In the methods section, the authors state that ethical approval was provided by The University of Madrid. It is good practice to include the reference number/approval number. I would also suggest that the authors consider the order in which the design of the study and sample are described. For example, it makes sense to state the design but then ethical approval prior to describing that informed consent was obtained from patients.

9. In this first para of the methods, the authors state that the sample is comprised of patients ‘...suffering from different diseases...’. It is politically preferable to state for example, patients with type II diabetes... – rather than labelling patients as sufferers.

10. For the last para in the ‘Design of the study and sample’ section, the authors should reconsider the language used. For example, the term ‘over-dimensioned’ is ambiguous.

11. Also, the statement, ‘Thus we decided to select a minimum of 50 patients...’. This does beg the question why 50 patients and how exactly were the patients selected? It’s important to be transparent to demonstrate that no bias was incurred.

12. Table 1 is interesting and provides descriptive information about the sample. However, it’s not clear why the number of patients by disease is split out by males and females. If this differentiation is important then it should be clear in the text of the manuscript, and also to consider splitting out other parameters by
gender such as age, BMI etc. If splitting out by gender is not important then, the authors should consider pooling the information as necessary. It would also be useful to see a total column for number of patients by disease.

13. Also, what was the rationale for including patients with these conditions and not others? This should be specified in the methods.

14. Under the section scales, the authors should pre-specify what the exact wording of item 14 of the TSQM is OR clearly explain the concept it measures. First option is preferable to avoid potential misinterpretation.

15. In the same section, the authors explain the total amount of variance explained by the domains of the Spanish version of the TSQM but they don't do the same for the SATMED-Q. There should be consistency throughout.

16. It would be useful to know the recall periods of both the SATMED-Q and the TSQM. Also, the range of scores for items, domains and total scores so that it's easier to interpret the findings and know what a high score or a low score represents.

17. Under the section ‘Calculation of the MID and statistical procedures’, the last sentence of the first para states ‘Differences between neutral and satisfied/dissatisfied was considered to be the MID...’. It would be useful if the authors explained the rationale for this compared to other possible methods.

18. This section is generally well written. I think it would be good for the authors to explain how they intended to interpret the ES. Usually this is done using Cohen's rule of thumb. In any case, it should ideally have been pre-specified a priori and therefore useful to mention in this section in the methods. They should also reference Cohen (OR whoever) when referring to moderate/large ES in other sections such as the discussion.

19. Also, the authors have used various methods to establish MID. Hopefully they pre-specified a priori which one would be the main indication vs. which were obtained for informative purposes and there should be rationale for this.

20. In the discussion, the authors state they were not able to use the traditional methods typically used to establish MID. The authors should be explicit why they were unable to.

21. It would be good to have more discussion about anchor vs distribution based methods of establishing MID and the importance of being sensitive to the intended purpose. This is briefly discussed in the ISPOR connections paper and should be cited.

22. In the discussion the authors state that the sample size was considered large enough to proceed with the MID determination. According to what standards? Ideally there should be a reference to cite to explain that typically this would be an adequate enough sample size and if the authors cannot locate one, they should cite other papers that have used similar sample sizes for the same kind of purpose and who have discussed the implications of sample size related to these kind of analyses.

23. At the end of the conclusion, it would be good to have a sentence
emphasising why the results are important / implications?

- Discretionary Revisions

1. The authors could consider including a conceptual framework of the SATMED-Q to show how items of the questionnaire are associated with domains and total scores.

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

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** Yes, but I do not feel adequately qualified to assess the statistics.

**Declaration of competing interests:**

I AM COPYRIGHT OWNER OF THE SATISFACTION WITH ANTIPSYCHOTIC MEDICATION (SWAM) SCALE AND FROM TIME TO TIME I RECEIVE ROYALTIES FOR ITS USAGE IN COMMERCIAL SETTINGS.

- Do you have any other financial competing interests? SEE ABOVE
- Do you have any non-financial competing interests in relation to this paper? YES I’M A TREATMENT SATISFACTION EXPERT AND I HAVE A SERIES OF PUBLICATIONS ONGOING – HOWEVER, NONE RELATED TO THE SATMED-Q