Reviewer's report

Title: Baseline characteristics and patient reported outcome data of patients prescribed etanercept: web-based and telephone evaluation

Version: 2 Date: 19 November 2010

Reviewer: Nan Rothrock

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Major Compulsory Revisions
1. This manuscript would benefit from having a clearer rationale along with a results section that is more aligned with the study purpose. Currently, the authors describe this project as “naturalistic research” that collected “data about [patients] condition, medications and health care experience.” The results provide some descriptive analyses about condition and medications yet provide little information about health-related quality of life measures. It is unclear what instrument is capturing “health care experience”. The manuscript states that substantial information is already recorded in the BSRBR making the rationale for additional data capture unclear. To me, this project is a feasibility study for PROBE. If the introduction could be oriented in this way and additional analyses were conducted addressing several unanswered questions, the manuscript would provide more relevant information that would be of greater interest to journal readers. As it stands, insufficient information is provided to learn about the development of PROBE, its usefulness as a data collection system, instrument differences across data collection modalities, or variability in quality of life across diseases apart from simple descriptive tables. References 9-12 are fabulous at outlining how patients can report adverse drug reactions. The manuscript could outline how PROBE specifically is a tool that can be useful in this emerging field. Knowing information about patients’ experiences with PROBE (e.g., ease of use, satisfaction with online data collection) would help educate the audience about this data collection tool. Additionally, framing this as a feasibility study would address concerns about grouping together patient self-report with caregiver reports as well as grouping diverse modes of administration. Without a clearer goal, this paper reads as an incomplete collection of descriptive information on medication history, diagnosis, and disease severity that was collected for no clear purpose.

2. Follow-up assessments (7 post baseline) were collected but no information about retention, score changes over time, or even descriptive information about these non-baseline timepoints is provided. This is a rich source of interesting data. If the authors choose to only focus on baseline data, it should be clarified that no follow-up data will be presented. It reads as a bit of a tease that there is a wealth of data described in Methods that never reappears in Results. Retention data may still be of interest if this paper is focusing on the utility of PROBE.

Minor Essential Revisions
3. There are several awkward sentences and phrases. For example, on page 10 “However, patients with JIA completed questions regarding age and sex poorly with data not recorded for 5 of the 9 patients.” The manuscript would benefit from additional attention to the clarity of writing.

4. The study included instruments captured in two modes – computer and by phone interview. No information is provided about whether the included instruments have been shown to have equivalence across mode. No information is provided about how instruments, particularly Visual Analog Scales, were adapted to be administered by phone. If data collected by phone is lumped with data collected by self-report via computer, it would be critical to know if this data is comparable. It has been documented that some constructs (e.g., emotional distress, sexual function) produce different results via interview. This poses a problem in contemplating use of PROBE in future research.

5. Participants were allowed to choose mode of administration. Additional information about who choose which mode would be of interest (e.g., older versus younger adults). Did scores on disease severity or health-related quality of life vary by mode? What about by diagnosis? How did rates of missing data compare?

6. On page 6, the assessment is described as “a simple questionnaire.” However, patients reported not knowing answers to some questions as well as providing inaccurate DAS-28 scores. The description of methodology could be improved by removing “simple” as for many patients, there were at least some challenging questions. The manuscript does not report on patients’ evaluations of how difficult the assessment was to complete.

7. On page 12, the differences between the CGI Severity, EQ VAS and EQ-5D are described as small. These differences should be subjected to statistical analyses to help provide meaning to the size of score differences IF the differences between diseases are relevant to the goals of the paper. The measures used for comparisons across disease should be clarified as it currently suggests the health-related quality of life measures were included in evaluating group differences.

8. On page 12 there is a section labeled Correlations which is puzzling as it provides a brief statement with the indication “results not shown”. It would be more helpful to outline earlier in the paper exactly what analyses are planned and omit this section if it is not considered an aim of the analyses.

Discretionary Revisions

9. Please clarify if participants were new users of etanercept.

10. On page 7, the manuscript reads “Efficacy, side effects and compliance data were collected.” Efficacy is not collected – patient symptom reports are collected and changes in symptom scores are calculated to estimate efficacy.

11. It is surprising that no rational for the sample size is provided. The manuscript could be strengthened by adding information such as “In this feasibility study, it was estimated that approximately X participants would be needed to assess participants’ willingness and ability to utilize PROBE” etc.
12. The study protocol used follow-up process to ask additional questions of patients who reported not taking methotrexate. This strikes me as requiring substantial study management staff time and am curious about why these items were not embedded within the PROBE system. If PROBE is to be a useful tool in capturing PRO data, a rationale for why an additional data collection process was needed should be detailed.

**Level of interest:** An article of limited interest

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

**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.