Reviewer's report

Title: Factors affecting compliance and non-compliance by physicians in a large-scale randomized clinical trial

Version: 1 Date: 30 May 2006
Reviewer: Thomas Tenhave

Reviewer's report:

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)

1) The analysis is done separately for patients and physicians, but should be combined using hierarchical logistic or linear models. This will adjust for patient and physician factors with compliance as suggested in the Background Section on p. 6, but not implemented.

2) Adjustments for clustering by clinical center also need to be included as they could confound results for physicians and patients. The number and type of clinical centers needs to reported as well.

3) On p. 17, the sensitivity analysis by varying the cut-off for adherence is appreciated. However, the authors need to indicate specifically the maximum change in odds ratios and p-values.

4) As another aspect of the sensitivity analysis, the authors need to move "additional assistance group" into the complier group to see how the results change.

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of limited interest

Quality of written English: Not suitable for publication unless extensively edited

Statistical review: Yes, and I have assessed the statistics in my report.