

## Reviewer's report

**Title:** Implementing Electronic Clinical Reminders for Lipid Management in Patients with Ischemic Heart Disease in the Veterans Health Administration

**Version:** 1 **Date:** 8 April 2007

**Reviewer:** Martin Lee

### Reviewer's report:

General

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

I have serious concerns about the design of the study and the statistical approaches used. I would like to see responses to these points before consideration of the acceptance of the paper.

1)pg.5: I am not clear as to why the authors chose not to use cluster randomization (possibly stratified by the size of the institution). Instead they arbitrarily assigned the institutions to the two study arms based on the whether they were in the eastern or western side of the Network. With only 6 institutions, the need for randomization to help in some small way in eliminating or reducing bias is essential. This, however, raises a very fundamental issue with the study. I could not find any indication of a sample size calculation. This points to the concern with the 6 clusters (institutions) and how the authors came up with this number and, in turn, the number of subjects per cluster. What intracluster correlation needed to be assumed to demonstrate the effect size they were interested in should be elucidated. All of this is fundamental to supporting the study design.

2)pg.7: I do not understand the last sentence at the bottom of the page. What is the significance of "...no specific implementation efforts were undertaken"? Please elucidate.

3)pg.9: Why were the number of reminders only collected during the last half of the intervention period? What happened during the first part? Was this an arbitrary delineation to begin collecting data? In this description of data collection, there is no mention of how non-response was handled in order to control for the possible bias that non-response can introduce.

4)pg.10: In the second paragraph, the authors refer to testing "statistical inference". I believe they meant statistical significance. They then go on to state that "only those IHD patients who were present in all time periods during the study period" were included for analysis. This is almost certainly going to introduce bias into the analysis. An intent-to-treat paradigm needs to be incorporated into their analyses. Also on this page, the authors mention the use of cluster correlation. They need to state how they incorporated this into the analysis, i.e. what methodology was used to adjust the standard errors of their logistic models.

5)pg.11: The evaluation of the trends in figure 1 are overinterpreted. The fact that the change in guideline compliance is positive and negative over time could simply be random fluctuations. They need to do a time-dependent analysis to determine whether this is or is not the case.

6)pg.12: In the first paragraph, p-values are needed throughout or at least some assessment of the significance of the comparisons given in that paragraph (confidence intervals, perhaps). The second paragraph discusses the modelling done for each site, or so it appears. I cannot understand why the authors do not do a global analysis comparing the two study arms. Furthermore, ORs are presented, but no confidence intervals. Also, p-values are given as "<0.05". P-values should always be presented as their exact value (to two decimal places).

Basically, I had a hard time trying to decide what was demonstrated here statistically and, therefore, clinically. Their adjustment model appeared to change things, but I am not sure why. I would strongly suggest that the authors revamp their statistical analyses in order for this study to be considered for publication.

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Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)

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Discretionary Revisions (which the author can choose to ignore)

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

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

**Quality of written English:** Acceptable

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