Reviewer’s report

Title: Supplementing claims data with outpatient laboratory test results to improve confounding adjustment in effectiveness studies of lipid-lowering treatments

Version: 2 Date: 13 August 2012

Reviewer: Judith K K. Jones

Reviewer’s report:

1. Is the question posed by the authors well defined? Comment: The authors actually address a relatively simple question, e.g., whether laboratory data adjunct to claims data can material contribute to interpretation of data in comparative effectiveness research (CER). However, as described below, the answers are very complex.

2. Are the methods appropriate and well described? Comment: Yes, both in the body of the paper and using effective diagrams, the authors explain the methods relatively thoroughly.

3. Are the data sound? Comment: The data are quite sound, with some modeling of prior periods to identify optimal observation times for confounders and exposure.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition? Comment: Yes.

5. Are the discussion and conclusions well balanced and adequately supported by the data? Comment: The discussion and conclusions are well-balanced and explore many possibilities and explanations for the findings and reasons for missing data, and begin to explore some possible areas are useful interpretation despite marked occurrence of missing data.

6. Are limitations of the work clearly stated? Comment: Yes, the authors do explain this in some detail.

7. Do the authors clearly acknowledge any work upon which they are building, both published and unpublished? Comment: Yes

8. Do the title and abstract accurately convey what has been found? Comment: The title explains more the objectives and what was found, but the abstract does convey some sense of the complexity of the effort and the findings.

9. Is the writing acceptable? Comment: The writing is quite acceptable, and of very high quality.

General Comments.

No form for evaluating this paper was found, so these are high level comments on it to supplement the answers to the above questions.

In general, this is a very interesting and useful paper that addresses the
hypothesis that laboratory data can enhance the quality and quantity of information to demonstrate effectiveness of therapeutic interventions in large scale medical claims (and, in fact) electronic medical record data studies used to do comparative effectiveness research and other pharmacoepidemiological studies. It carefully explores the many avenues that lead to considerable uncertainty over the reasons and causes of missing laboratory data; further, the authors do hypothesize and demonstrate the reasons for some the findings.

This methodological exploration should provide a very useful reference for further studies hoping to address laboratory data as a covariate, or outcome in various studies in these databases.

I recommend approval for publication.