Reviewer's report

Title: Proton Pump Inhibitors and the risk of pneumonia: a comparison of cohort and self-controlled case series designs

Version: 3 Date: 14 January 2013

Reviewer: Xiaofeng Zhou

Reviewer’s report:

It is clear that the authors have worked hard to address the comments from the original submission, and the 2nd draft of the manuscript provides more important details that help the readers to understand the method and limitations of the research.

I have a couple of minor suggestions that would help with the clarity of the details being presented:

As this is a methodological study, and using SCCS design to examine an drug safety issue offers practical value, I would encourage the authors to include more details in an appendix or an electronic supplemental documents that could be made available online. For example, such more detailed information may include the explicit description on how to handle repeated exposure and multiple outcomes in the SCCS analysis, the distribution of additional covariates included in both study designs; the results of the sensitivity analyses in SCCS. Also, it would be useful for sharing the SAS codes handing time-varying variables for SCCS (i.e. conditional Poisson regression) as such codes are not readily available in the SAS software and could be valuable for those who are considering to apply SCCS in a pharmaco-epidemiological study.

Minor Essential Revisions

1. In the Discussion section (page 13), the authors stated that “The ability of the self-controlled case series method to control for confounding both measured and unmeasured and it’s decreased computational time means it will be of particular practical value in pharmacoepidemiology”. Since this study did not assess the technical performance of the SCCS method (i.e. computational time), can you clarify this sentence? If you have a reference for the technical performance of SCCS, please cite the reference.

2. In the Results session (page 10), there is a typo – listing “Table 2”, which should be “(Table 3)” instead.

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.

**Declaration of competing interests:**

I am an employee of Pfizer Inc.