Reviewer's report

Title: Statins and the risk of type 2 diabetes mellitus: cohort study using the UK Clinical Practice Research Datalink

Version: Date: 21 January 2014

Reviewer: Swapnil Rajpathak

Reviewer’s report:

Major Compulsory Revisions

1. The final sample included, users and non-users, is mentioned in the results section. However, it will be useful to show a flow chart that resulted in this final sample size (especially to understand the drop in sample size related to inclusion and exclusion criteria and due to the choice of 1:5 matching)

2. The time period from 1989-2009 is very long and guidelines for use of statins changed during this time. One could argue that given that the average risk of a statin patient for diabetes may be different during different time periods -- did the investigators conduct analysis separately for last 10 years vs. earlier years to see if results are different in the different time periods.

3. In the matching process, can a user at a later time, matched as a non-user for an earlier user? If not, if it is required that non-users should be non-users throughout this time period -- how does impact of validity of the measures of association observed?

4. Would it be possible to conduct an analysis within the users for a dose response (e.g. high vs. low dose)?

5. The mean follow-up time differed significantly between users (5.43 y) vs. non-users (3.89 y). What is the explanation for this? Did the authors conduct an analysis with mortality as the outcome? Does survival bias impact the study results?

6. Table 4. Add reference groups. Almost follow-up time categories don't seem mutually exclusive.

Minor Essential Revisions

Use Type 2 Diabetes and not Type two Diabetes as in the abstract

Discretionary Revisions

None
Quality of written English: Acceptable

Statistical review: Yes, but I do not feel adequately qualified to assess the statistics.

Declaration of competing interests:
I am employee of Merck & Co