Reviewer’s report

Title: The Impact of Statins on Health Services Utilization and Mortality in Older Adults with Cardiovascular Disease: a cohort study.

Version: 1 Date: 3 March 2009

Reviewer: Pauline Lockhart

Reviewer's report:

MAJOR COMPLAUSORY REVISIONS

Page 4 Paragraph 3

The problem with RCTs not demonstrating effectiveness in usual clinical settings is really due to the design of the trials as opposed to the methodology per se: the design of many, probably most, trials is such that they do not reflect usual care (eg. they have very tight inclusion criteria, or monitor outcomes that are of limited importance to patients and clinicians). In other words, they have poor applicability (or external validity)*. The authors appear to suggest that because RCTs do not reflect usual practice, this is a justification for doing an observational study using secondary data. I have no problem with the authors approach I just don’t think that it can be justified on the grounds that similar work is not possible in an RCT. A well-designed pragmatic trial may also be used. The authors should revisit this paragraph.

*External validity of randomised controlled trials: “To whom do the results of this trial apply?”

Rothwell, P The Lancet (2005) vol. 365 (9453) pp. 82-93 DOI: 10.1016/S0140-6736(04)17670-8

Page 5 Paragraph 3

It is important to clarify for the international readership what membership of the Nova Scotia Pharmacare Program means. For example, does this cover the entire population and, therefore, the study sample can be confidently said to represent the Nova Scotia or Canadian population. Some information about socio-economic, demographic and geographic characteristics would illustrate the generalisability of the study population to the reader. Once this is done, what implication does this (i.e. the Nova Scotia Pharmacare Program population) have for the interpretation of results or their applicability to other populations?

Page 5 Paragraph 3

Further consideration should be given to the recruitment strategy: all patients were recruited from a hospital admission. How might this affect the results seen? Would we expect different results if patients had been recruited from primary care?
Further discussion of the effect of duration of follow up should be included here. It is likely that length of follow up may influence the number of events – was there a significant difference in length of follow up between the two groups?

Page 6 Paragraph 1
It would be very useful to clarify ‘physician services’ further. Is this routine care/chronic disease management program? Or emergency appointments? Is this provided by General practitioners? Is some of it nurse time? Any further information here which is available would further clarify the nature of health service utilisation which is under scrutiny.

Page 6 Paragraph 2
Was any data relating to statin discontinuation available? Compliance is mentioned as an area of current study but this is different to the discontinuation of prescribing by physicians and further information on this would be beneficial. Similarly, in the discussion section, it would be useful to discuss the effects statin discontinuation may have on the data, regardless of whether this was measurable in this study, and discuss whether this should be a future area of work.

Page 7 Paragraph 3
Further clarification of the c-statistic would be helpful: in particular, the cut-off level at which discrimination was set so that later in the paper, when the c-statistic of 0.78 is deemed satisfactory, the reader can judge the strength of this association.

MINOR ESSENTIAL REVISIONS

Title Page
It would be clearer to say in the title that this study looks at the impact of statins prescribed following hospital admission and to state that this is a observational cohort study.

Page 5 Paragraph 3
Consideration is not given to the initial cause for hospitalisation – this may be a confounder for subsequent outcomes – this may have been dealt with using the adjustment for co-morbidity but needs further exploration or explanation.

Page 8 Paragraph 4
These data show that statins are less likely to be prescribed for individuals with more severe disease but there is no clear clinical justification for this ...what is the significance of these differences? What does this mean for the interpretation of the results? Are these patients extremely unwell or are there other factors driving reduced intervention in this group?
Further relation of the findings to clinical care, clarifying what this work adds to the arguments for and against prescribing statins and the implications for practice would clarify the relevance of this work to the reader.

DISCRETIONARY REVISIONS

Another useful piece of work to define the true impact of prescribing statins to this population would be an economic analysis – perhaps this could be considered as future work?

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

Quality of written English: Acceptable

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

Declaration of competing interests:

'I declare that I have no competing interests'