Reviewer's report

**Title:** Prevalence of Lipid Abnormalities Before and After Introduction of Lipid Modifying Therapy among Swedish Patients with Dyslipidemia (PRIMULA)

**Version:** 1  **Date:** 5 August 2010

**Reviewer:** Stella S. Daskalopoulou

**Reviewer's report:**

This study presents the prevalence of lipid abnormalities before and after introduction of lipid modifying therapy among Swedish people with dyslipidemia. The paper is poorly written and its novelty is questionable. Furthermore, there are some major concerns:

Of all patients only 40% were classified as high-risk, with 60% having low to moderate risk. Are the treatment goals the same for high and non-high risk patients in Sweden? This is not the case elsewhere in the world. Different goals apply to different risk groups. In this study this is not addressed and the 60% of moderate to low risk groups are given the same targets. This represents misclassification at baseline and at follow-up and therefore the findings might not be valid.

Also you included data from 1994 to 2007. The guidelines have substantially been changes during this period elsewhere in the world. Was that the case also in Sweden? In that case it is tricky to use the same target for the whole period of time as the guidelines at each time might reflect different practices.

More information on the database should be provided. Is it a GP database? What is the catchment area? Does it include the whole population or a representative sample? What type of information is available in this database? Which age-groups does the database include? 5,424 patients does not seem to be a large number for a period of 13 years. What is the denominator?

In methods, it is mentioned that the baseline period is 15 months prior to lipid modifying therapy (LMT). What is the reason for choosing 15 months as the baseline period and not, for example, 12 months, similar to the follow-up? Why did you use 35 years as the age cut-off and not, for example, 40 years which is the age for screening as some guidelines suggest?

High-risk groups were identified using the ICD diagnostic codes? Are these validated in the Swedish population?

There is no mention on missing data, except something vague at the very end of the discussion. Does this mean that there were no missing data? This would be very surprising in a clinical database. If you only used data from patients without missing data this could have introduced a selection bias. If only patients with complete data were included what is the number of the potentially eligible patients (with dyslipidemia) but without complete data? If there are missing data, the percentage should be mentioned as well as the method that was used to...
handle them.

In Table 1 there is a line about baseline diastolic blood pressure but there are no data presented for this parameter.

Were the lipid values measured in a fasting blood sample (at baseline and follow-up)? This is not mentioned. If a fasting sample was not used the results about triglyceride levels might not be valid. If it is a fasting sample, is it in all participants? On the other hand, if all participants were fasting it is strange how it was managed to have all the patients fasting in a clinical database, except if only patients with fasting profiles were included in your analyses, which again might have introduced a bias. Please clarify.

Page 7, second paragraph it is mentioned that certain variables were included in the final model and refers to Table 3. However, this information is not provided in this table.

Although you have included time on statin in your models we do not know what is the percentage of patients who discontinued their statin treatment? It is possible that a high percentage had discontinued treatment at the 12-month follow-up, which could explain in part the high percentage of treatment failure. As per protocol, treatment gaps are not allowed only in the first 6 weeks post index date. Another possibility is that low doses of statins were used and therefore, the treatment goals were not reached. However, no information about dosage (and dosage titration) is provided and this is a major issue.

In the models for TG and HDL you still used time on statin. Is that appriopriate?

Page 7, last line the upper CI is 0.87 which is lower than the OR (0.93). Is that a typo? OR should be within the range of the 95% CI.

The discussion is poorly written and insufficient.

**Level of interest:** An article of limited interest

**Quality of written English:** Needs some language corrections before being published

**Statistical review:** No, the manuscript does not need to be seen by a statistician.

**Declaration of competing interests:**

I declare that I have no competing interests