Reviewer's report

Title: Glycosylated haemoglobin and adverse pregnancy outcomes in type 1 and type 2 diabetes mellitus: Systematic review of observational studies

Version: 1 Date: 8 May 2006

Reviewer: Stephen Walkinshaw

Reviewer's report:

General
This is a well written and clear paper. The message is not new, as evidence from many of the individual papers systematically reviewed here have been incorporated into practice. However the approach is novel and allows some quantification of the effect. As such it is a useful addition to the literature in the field.

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
Search strategies for these types of papers are difficult and can miss important papers. I was surprised that Mills J NEJM 1988, 318, 671-7 (malformation) and Mills J NEJM 1988, 319, 1617-23 (miscarriage) and the papers of Judith Steel (BMJ and others) did not meet the criteria for inclusion. These were influential papers using both blood glucose levels and glycated haemoglobin to look at outcomes and they did stratify in poor and good control for miscarriage at least.
They are case control studies but the stratification into good and poor control only occurred in the diabetes cohort. Though statistically and from a purist point of view these might be considered not true observational studies, they provide data identical to the various studies included in the final analysis. It may be that other studies (e.g. some of prepregnancy studies analysed by Ray in his systematic review) may contain 'observational' data that could be used.
If the authors feel that this may confound the systematic review to too large an extent, then they will need to discuss the omission of these and other key papers. Workers in this area will regard their omission as odd and this would potentially reduce the impact of the study. It should be clear in the methods that prospective or retrospective series only and that case control studies even where comparable data could be extracted have been excluded.
Given the complexities of this type of analysis, there should be formal statistical review. Methodology is clear and the statistical methods appear satisfactory but this is an 'embryonic' field and should have more formal input at referee stage.

Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)
Though most of the literature refers to glycosylated haemoglobin, the accepted term now is 'glycated'

Discretionary Revisions (which the author can choose to ignore)

What next?: Unable to decide on acceptance or rejection until the authors have responded to the major compulsory revisions

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: Yes

Declaration of competing interests:
I declare that I have no competing interests.