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:** 9 June 2006

**Reviewer:** Rafael Perera

**Reviewer's report:**

General
1. Is the question posed by the authors new and well defined?
The objectives are not specified in the paper, however it appears to me that the aim is to determine if poor glycaemic control in pregnant women with type I and type II diabetes is a risk factor associated with miscarriage, congenital malformations, and perinatal mortality.

2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?
The authors have applied the QUORUM statement which deals with reporting systematic reviews of randomized controlled trials of interventions. However their question is one of prognosis, not treatment. Therefore they need to approach this as a systematic review of prognostic studies. A discussion of the potential problems with dealing with this type of systematic reviews can be found in:

3. Are the data sound and well controlled?
The data obtained is relevant to answering the question. A justification might be required for the use of different study designs within a meta-analysis. As with systematic reviews of diagnostic studies, issues about different cut-off thresholds complicate the interpretation of the findings.

4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
It does, however as it deals with prognostic studies a more extensive discussion about the quality of each study is required. It would be useful to define a stringent inclusion/exclusion criterion for the trials. High quality is particularly important when dealing with observational data.

5. Are the discussion and conclusions well balanced and adequately supported by the data?
They are in general. One part that is not adequate is their discussion about publication bias. The funnel plot shows clear indication of asymmetry and at least one of the formal tests presented in the paper shows that this is likely.

6. Do the title and abstract accurately convey what has been found?
No

7. Is the writing acceptable?
Needs some editing, but it is generally adequate.

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**Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)**

***The systematic review should follow the steps for the evaluation of prognostic studies, not of therapy.***

*An adequate discussion about the likelihood of Publication bias in the review.*

*Specify a method for assessing heterogeneity in case a Meta-analysis is carried out.*

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**Minor Essential Revisions (such as missing labels on figures, or the wrong use of a term, which the author can be trusted to correct)**

*The results subsection of the Abstract needs to be clearer.*

*Please state the version of Statistical packages used.*

*State the objectives of the Review after the Background.*

*In Table 1 Specify the number of women with optimal and Poor glycaemic control by trial (some trials might
have much more in one group than others) as well as the number of events.

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'