Reviewer's report

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

Version: 2 Date: 24 July 2006

Reviewer: Rafael Perera

Reviewer's report:

General
1. Is the question posed by the authors new and well defined?
   It is well defined and clearly stated in the objectives.
2. Are the methods appropriate and well described, and are sufficient details provided to replicate the work?
   They have correctly adapted methods used for reporting systematic reviews of randomized controlled trials of interventions to construct a systematic review of prognostic studies. In particular Tables 1 and 2 provide adequate data on the individual studies and on their quality assessment.
3. Are the data sound and well controlled?
   Yes.
4. Does the manuscript adhere to the relevant standards for reporting and data deposition?
   Yes
5. Are the discussion and conclusions well balanced and adequately supported by the data?
   Yes
6. Do the title and abstract accurately convey what has been found?
   The title could give a better description of the question being answered. Suggestion: “Poor Glycosylated haemoglobin control and adverse pregnancy outcomes in type 1 and type 2 diabetes mellitus.”
7. Is the writing acceptable?
   Yes

Major Compulsory Revisions (that the author must respond to before a decision on publication can be reached)
None

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

Page 5 last paragraph -
Reads: Control data from case-control studies was not used in this review.
Should read: Control data from case-control studies were not used in this review.

Page 9
Reads: Several studies (how many?) only reported major congenital malformations and the pooled estimate was 5.14 (95% CI, 2.94 to 9.01), (Figure 4)

Pages 32 onwards are repeats of information included in pages 19 â€“ 26. Please remove.

Discretionary Revisions (which the author can choose to ignore)

Page 8
“Sample sizes ranged from 83 to 2459 participants in the largest study, with a total of 5480 women.”
This means that the largest study provides half of the data. A sensitivity analysis excluding this one gave similar results? Would help readers if you commented on this.

General question:
Is glycated haemoglobin a synonym for HbA1c? If not, could you include a sentence explaining this?
All other maternal, fetal and neonatal outcomes were only reported in one, two, three, or four of the studies. Note: Please explain which outcomes were reported alongside the number of trials that reported them. According to Table 3 there were 12 studies that reported congenital malformations, 4 studies that reported spontaneous abortions and perinatal mortality, while the rest of the outcomes were only reported once.

However, we believe our process of literature identification was comprehensive and captured all of the published studies on the relation between glycated haemoglobin and outcomes in pregnant women with diabetes. Comment: The possible presence of publication bias is not a criticism to the search done by the authors. It is just a reflection of the types of studies that are more likely to be published. It might affect the results, but do not mean that the review undertaken is methodologically weak or flawed.

Nonetheless, the cut-offs used were appropriate to the method used to measure glycated haemoglobin and relevant to the reference range in use for the individual study populations. Comment: The implication of the above sentence is that the same cut-off might mean different levels in each study. Therefore, would it have been inappropriate to do a subgroup analysis using different cut-off levels as categories? Would help readers if you commented on this.

**What next?:** Accept after minor essential revisions

**Level of interest:** An article of importance in its field

**Quality of written English:** Acceptable

**Statistical review:** No

**Declaration of competing interests:**

I declare that I have no competing interests