Reviewer's report

Title: A cluster randomised controlled trial of a Diabetes REcall And Management system: the DREAM Trial [ISRCTN 32042030].

Version: 1 Date: 4 August 2006

Reviewer: Martin Lee

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General

I will restrict my comments to several statistical issues I have with the paper that I believe need to be addressed before a decision as to publication can be reached.

1) The sample size calculations were based on what appears to be an unadjusted comparison of the rates and means, yet the primary analysis is a regression adjusted comparison. What impact, positive or negative, could this have had on the study? In addition, the authors have assumed very large ICCs in these calculations. Could they provide estimates of the actual values seen? One of the other reviewers commented that this might have had an undue effect on the lack of significance, but this would be the case if the authors had underestimated the degree of clustering. Thus, it would be important to know if this, indeed, is an issue for the study.

2) There is a clear issue of patient non-response here, which is acknowledged in the Data Collection section and actually manifests itself quite significantly in the study with a 51% response rate. Was there any attempt to adjust the analyses for this or, at the very least, evaluate the data for any non-response bias?

3) Some of the regression models are adjusted using "baseline" variables. I could find any indication as to what those variables were and whether they were identified in advance. If they were selected on the basis of statistical significance, then this becomes an "ex post facto" issue subject to Type 1 error.

4) In the same vein as above, the register effect was unexpected and added to the analysis after the fact when "large systematic differences" were found. It would, first of all, be important to state what this statement means and how it was identified. Clearly this was not part of the initial analytical plan. Therefore, it would be very important for the authors to reanalyze the data without this adjustment and, if the results are different, provide a caveat to the reader as to the legitimacy of the adjusted results.

5) Were the baseline comparisons between the control and intervention groups in Table 1 made with a cluster-adjusted analysis? If so, these should be unadjusted. In any event, it should be made clear to the reader. Further, the authors should state what statistical method(s) were used for these analyses.

6) For Table 2, it is very common practice today to present the unadjusted comparisons between the groups so that the reader can see the effect of adjustment on the results. This is particularly important here given the uncertainty as to how the adjustment variables were selected.

7) Comment 6 is also relevant to Tables 3 and 4 with respect to the adjustment for register differences.

8) A measure of variability (probably standard deviation) should be included in Table 3 as it is in Table 4.

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

The comments made above fall into this category.

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

Discretionary Revisions (which the author can choose to ignore)
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, and I have assessed the statistics in my report.