Reviewer's report

Title: Implementing a guideline for the treatment of type 2 diabetics: results of a Cluster-Randomized Controlled Trial (C-RCT) among general practitioners (GPs) of Lazio region, Italy

Version: 1 Date: 1 October 2006

Reviewer: Sumit Majumdar

Reviewer's report:

General

Perria et al conducted a rigorous and fairly valid cluster-randomized trial of 2 different strategies for implementing guidelines for type-2 diabetes. Both interventions (guidelines disseminated passively and dissemination plus small-group CME) were fairly low intensity, and the investigators found that neither approach was better than usual care. This is a robustly negative study, but I think both interesting and worthy of publication – if it can be better described and a number of details clarified.

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

1. Abstract. This is the weakest part of the manuscript and especially the Methods and the Results need to be overhauled.

2. Intervention description (page 5). I would use common descriptors. Arm 2 is traditional passive guideline dissemination. Arm 1 is the addition of a 2-day CME workshop based on the principles small-group learning. Arm 3 is usual care. Instead of referring to Arm 1, 2, 3, I would instead refer to “active implementation” or “active strategy” versus “passive dissemination” versus usual care or control.

3. Outcomes (page 5 to 7). I think these are confusing as described, and need to come up with better labels for each (which should be explicitly defined in the Abstract, see #3). I think the primary outcome was measurement of A1c, not actual glycemic control as stated. I think the primary outcomes should be labeled something like “assessment of glycemic control; assessment of macrovascular complications; assessment of microvascular complications.” For the drug indicators, given that there is no evidence of safety or clinical efficacy for use of “long life sulfonylureas in the elderly” I wonder why this was included? Last, would delete the section on economic evaluations, since they did not do it...

4. Outcomes (2). Again, it needs to be clarified, but I think the authors looked at their process indicators after the intervention, and compared the 3 arms. If this is what was done, it needs to be stated. But do they not have BASELINE data? I would prefer to see what baseline rates of assessment of glycemic control were (“pre-intervention”), what they were after intervention (“post-intervention”), and the change over time (delta percent) for each of the 3 arms. I think they are only presenting the “delta” but alone this is not enough information – see points below.

5. Analysis (page 8). Again, this needs to be better clarified. I think (because they tell us they used GEE) that in fact the patient is the unit of analysis, with confidence intervals and p-values adjusted for the ICC and clustering within GPs (the unit of allocation). But they make it sound like they have averaged the values for each GP, and used the GP as the unit of analysis which I do not believe is the case. Regardless, it should not be this hard for me to figure out.

6. Results (page 9). Need to tell us what baseline rates of measurement of glycemic control, macrovascular, microvascular risk were before the intervention. This is profoundly important, and a major limitation of the study if they cannot provide this data.

7. Results (2). The actual trial results are very very very difficult to interpret the way they are presented. I would suggested a paragraph with a subheading (Active implementation versus usual care) and then another paragraph with (Passive implementation versus usual care).

8. Discussion (page 10). I think the authors are being overly nihilistic about their results. Is not one of the alternate explanations a “ceiling effect.” Specifically, they were looking for 10% (absolute) improvements in
A1c measurement. But what if the baseline rates were already 60 or 70%? I bring this up because rates of actual acceptable/optimal glycemic control across arms at baseline were about 75% - which is very good, and better than most previous reports.

9. Discussion (page 11). Because of the way the authors enrolled GPs, one of their limitations is that they likely enrolled “the better performing” docs, who may have had less room for improvement, while the lesser 75% of docs did not even participate. All of the limitations should be collected together in one paragraph—in particular, the very high non-attendance rate for the teaching sessions.

10. Table 3. This is the main results, and is the second weakest part of the paper. It needs to be expanded, (if available) baseline measures, post intervention measures, and deltas need to be presented, and the individual components (not just the aggregate “metabolic control” etc) need to be presented.

11. Figure 1. I can’t understand what the “followup” and the “analysis” rows mean, and they are not consistent with text.

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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)

1. Discussion (page 11). Think the authors should use the more recent and very rigorous and comprehensive systematic review by Shojania et al (JAMA, July 2006) as a discussion reference and framework than the much older Renders review (Diabetes Care, 2001, their ref #25).

2. Appendix. I would like to see what the adapted guideline looks like – perhaps as an appendix? How good was this guideline, e.g., according to AGREE instrument?

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Discretionary Revisions (which the author can choose to ignore)

1. Grammar and language. There are many minor spelling, language, and grammar errors throughout – I’ll assume a good copy-editor can take care of these, but will not otherwise detail them here.

2. Title. I would suggest something like “Comparing different strategies for implementing practice guidelines for type 2 diabetes in Italy: a cluster-randomized controlled trial” The specific region of Italy and that GPs were involved doesn’t’ need to be in the title.

3. Discussion (page 11). The authors refer only to reviews, but to contextualize their findings, they should at the least refer to other guideline/CME dissemination studies done in type 2 diabetes. For example, Harris SB, et al. Teleconferenced educational detailing…J Cont Education Health Professionals. 2005; 25: 87-97 and Gerstein HC, et al. A controlled evaluation of a national continuing education programme designed to improve family physicians…Diabetic Med. 1999;16:964.

4. Discussion (page 12). I would like to know what the authors think would “work” in their context? Disease management? Financial incentives? Academic detailing? Etc – clearly, more rather than less needs to be done.

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: Not suitable for publication unless extensively edited

Statistical review: No

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