Reviewer’s report

Title: Feedback GAP. Cluster-Randomized Trial of Goal-setting and Action-Plans to increase the effectiveness of audit and feedback interventions in primary care. Study protocol.

Version: 2 Date: 9 October 2010

Reviewer: Geert Goderis

Reviewer’s report:

Major compulsotary revisions (remarks)

1. About the tool (the worksheet) and its use: I have some serious concerns / questions / doubts about it.
   a. Is it on paper on electronic?
   b. If on paper, is it ‘ready to use’ (e.g. there is few space to answer the questions).
   c. Since (Family Physicians) FPs work together in larger clinics, wouldn’t it be useful to organize a group approach? E.g. ‘to identify specific patients….’ I suppose that electronic patient registgers will be used to identify patients: I can imagine that each single FP will not act on his own, but that they will ask the secretary to carry out the electronic search? But if a group approach will be organized, what is the use of an individual (family physician orientated) worksheet?
   d. Is there an instruction manual to complete the worksheet?
      i. Some questions seem a bit trivial and large (e.g. if a patient comes to clinic and is not meeting targets, I will…). Not meeting HbA1c target wil mostly induce treatment intensification and in some (or most) cases discussion about lifestyle; not meeting the BMI-target is totally different. And there are about 13 (or more) treatment targets to be met....
      ii. Other questions are not clear because they are extremely large: “for diabetes, I will improve”….: that can mean organizational changes (what possibilities), attitude changes, CME (on insulin therapy, new drugs like GLP-1 analogues,....). Is there any evidence that such a large questions can guide FPs?
   e. Once the sheet completed, will there be some support to ensure (or to try to ensure) that FPs will fulfil their promises?

2. P. 7: ‘the lack of a control group’: this sentence is contradictory to the rest of the manuscript and makes me doubt whether the authors fully agree among each other about the exact design. If it the purpose is to test the effect of the complementary tool (the worksheet) on Family Physicians, like it is stipulated in the study hypothesis, then the control group should compulsatorily receive the ‘usual’ feedback. This is part of the design and a consequence of the study question. So there should not be a control group receiving no feedback at all. So
why this excuse in the sentence “The lack of a control group receiving no feedback at all is both necessary (because participants expected something in return for contributing data) and pragmatic (because most quality improvement interventions include some degree of feedback, making this the ‘usual care’ comparator)?

Minor essential revisions:

1. The authors should specify that their method used is a mixed method, combining qualitative and quantitative research. (p. 7, study design).

2. P.11 allocation and blinding:
   a. please explain the minimization procedure more in detail (e.g. what program used?).
   b. I do not understand that a minimization procedure can be non sequential since minimization is used to (prospectively) reduce imbalance.
   c. If minimization procedure is used, can it be called (cluster)-randomized? According to Altman, “minimisation is based on a different principle from randomisation. The first participant is allocated a treatment at random. For each subsequent participant we determine which treatment would lead to better balance between the groups in the variables of interest.” (BMJ 2005; 330 : 843 doi: 10.1136/bmj.330.7495.843 (Published 7 April 2005)).

3. Introduction (background): P. 4: “A large gap between ideal and actual provided care”: there should be nuancing to this sentence. The gap between theory and practice is not entirely due to the providers’ performance. Patients’ characteristics and system characteristics are also associated with the quality gap.

4. Methods:
   a. Data extraction from EMR: I am not an expert in the evaluation of EMR, but I know it is prone to error, not only for extracting diagnoses, but also for extracting data (laboratory data, clinical data like BP,…).
      i. Please give some details about this procedure prone to bias. There should also be a paragraph in the discussion section because it is a major weakness of the study, not only for generalizibility, but also for internal validity. See also:
      ii. I wonder how EMRALD can define diabetes when the EMR only uses free
text…. There must be a source of bias.

iii. What about the accuracy of laboratory and clinical data extraction from the EMR?

b. P. 8: Please describe the setting compared to the general setting in Ontario. Also in the table, please compare the participating FPs with the general FP population. This is important to have an idea about possible selection bias and to have an idea in what setting the trial was carried out.

c. “However, this concern is partially mitigated by the varied characteristics of physicians in the sample.” Why is this so? Please explain / give some evidence;

5. P.14: 13.7 (=14) clusters ; how many physicians will be involved?

6. What about possible contamination by patient flow? Are patients assigned to one FP/clinic or is there a freedom of choice? If yes, what expected impact on the trial?

7. Discussion:
   a. P.16 To what degree the governments feedback will or will not interfere with trial?

Discretionary revisions
1. P. 7 first sentence: whoms behaviour (physicians I think) ; whoms outcomes (patients’ I suppose)
2. Discussion:
   a. There might be other complementary tools to feedback: e.g. individualized patient feedback sheets that can be used at patients' visits ; electronic pop-up systems ; peer discussion about the feedback. It would be nice to put some perspective on your choice of the used complementary tool with regards to other possibilities
   b. About the generalizability: What about some necessary conditions that must be available to enable some impact. An intervention like feedback can only work when some preliminary conditions are fullfilled. When FPs are unmotivated, burnt-out, overworked,… it will be improbable that neither feedback nor the worksheet have a lot of impact. What do you know about these aspects in the Ontario setting? Does litterature provide some general explanation?

Level of interest: An article of importance in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

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