Reviewer's report

Title: Alternation as a Form of Allocation for Quality Improvement Studies in Primary Health Care Settings: the on-off study design

Version: 4 Date: 1 April 2015

Reviewer: Andrew Vickers

Reviewer's report:

Major revisions

Just to review, my overall comment was “why alternate once? Why have this decided by the clinician rather than at random?” The authors response, which was generally a good one, was “yes, you can have multiple crossover and decide the order at random”. Well terrific, except now what you have is a cluster, crossover trial, something that has been described in methodologic papers http://www.ncbi.nlm.nih.gov/pubmed/25278228 and some examples http://www.ncbi.nlm.nih.gov/pubmed/19896184 and http://www.ncbi.nlm.nih.gov/pubmed/23363666. But the authors don’t make any reference to this design or cite any papers. I would also comment that the authors’ terminology is unhelpful. First off, having duplicate terminology confuses things. Others have reported a crossover cluster design; why rename this as “alternation”. Secondly, alternation has overtones of studies when individual patients were alternated (first patient gets drug, second gets placebo, third gets drug etc. etc.). This is a highly problematic and criticized approach.

Level of interest: An article whose findings are important to those with closely related research interests

Quality of written English: Acceptable

Statistical review: Yes, and I have assessed the statistics in my report.

Declaration of competing interests:

none