Reviewer's report

Title: The stepped wedge trial design: literature review

Version: 3 Date: 11 October 2006

Reviewer: Rebecca Turner

Reviewer's report:

General

The paper reviews the use of a particular type of trial design – the stepped wedge design. The topic is relevant and the review is well-written. The review would benefit from some critical discussion of the methodological quality of the studies identified and discussion of the potential disadvantages of the stepped wedge design itself.

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

(1) In the Background section (paragraph 3), the authors describe situations which justify the use of a stepped wedge design: where it is unethical to withhold the intervention from a proportion of the participants, and where there are constraints which prevent the intervention from being implemented simultaneously across all intervention participants. I think a standard cross-over design would be adequate in the situations as described, so perhaps this needs some rewording. An argument for the stepped wedge design which I have seen elsewhere is that it would be unethical or impractical to withdraw the intervention once implemented. It would be useful also to point out the disadvantage that using a stepped wedge design increases the length of the trial.

(2) The Results section would benefit from a report of the methodological quality of the studies included. In particular, when reviewing the methods of data analysis (p10/11), could the authors provide some critical discussion of the methods used or, where there is insufficient information on the methods, provide critical discussion of the clarity of reporting. For example, did the 8 cluster studies make appropriate allowance for the clustering in their sample? The complexity of the methods required and lack of clarity in reporting may form an argument against use of this design (see comment 3), so it would be interesting to hear about the methodological quality of the existing stepped wedge studies. It would be useful to reference the very recent paper by Hussey and Hughes [1], who discuss methods for analysis of stepped wedge cluster randomised trials.

(3) Currently, the Conclusions section presents only the advantages of the stepped wedge design. An important disadvantage of this design is that the statistical analysis can be complex and thus difficult to communicate, particularly when clusters rather than individuals are randomised [1]. The studies included in the review may demonstrate this. Given the increased complexity, it seems that researchers would need strong reasons to justify choosing the stepped wedge design over a simpler cross-over design. I think the Conclusions section should include some discussion of this point, in addition to the concluding paragraph which advocates use of the stepped wedge design.

References


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

(4) In Table 1c, please clarify what is meant by the column headings “Intervention” and “Control”. In the context of the stepped wedge design, it’s not clear whether these present the total numbers ever receiving intervention and control, or the numbers receiving these treatments in the first step.
In Figure 1, it would be helpful to note that the design presented has 5 steps

Discretionary Revisions (which the author can choose to ignore)

**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:** Acceptable

**Statistical review:** No

**Declaration of competing interests:**

I declare that I have no competing interests