Reviewer's report

Title: The stepped wedge trial design: literature review

Version: 2 Date: 13 September 2006

Reviewer: Jim P Hughes

Reviewer's report:

General

This is a well-written and straightforward review of an unusual type of clinical trial design - the stepped wedge. The authors point out the strengths and advantages of the design and do a nice job of finding the few examples of the use of the design that are in the literature. They argue for greater use of the stepped wedge design and, indeed, I believe that use of this concept is growing - so I think this paper is very timely. I look forward to the future paper the authors are preparing on the modelling and analysis of this design.

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

none

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

none

Discretionary Revisions (which the author can choose to ignore)

I would point out one further advantage of the stepped wedge design that was not mentioned in the manuscript, namely, the possibility of conducting the trial in fewer communities than would be required for a standard parallel design. Also, I would point out disadvantages to using the stepped wedge design. Typically, the stepped wedge will have a longer trial duration relative to a comparable parallel design. Also, the analysis is most straightforward if variations in the outcome over time are equal at all sites. Otherwise, underlying time trends in the communities can be confounded with time trends in the intervention effect. This last point may be too subtle to go into in this review paper, however.

What next?: Accept after discretionary 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