Author's response to reviews

Title: The stepped wedge trial design: literature review

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Version: 3 Date: 3 October 2006

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We are pleased to enclose our paper “The stepped wedge trial design: literature review” for consideration by BMC Medical Research Methodology. We feel that the stepped wedge design has considerable potential in enabling the rigour of an RCT evaluative methodology in circumstances where a traditional parallel design may not be considered ethical or where the intervention cannot be delivered to all participants simultaneously. In staggering participants’ exposure to the intervention, the stepped wedge design also provides additional opportunities for data analysis in terms of determining the effect of time on the intervention effect. Nevertheless, the stepped wedge design has rarely been used in practice (we review just 12 studies in this paper) and we hope that this paper will raise the profile of the stepped wedge design, as well as providing examples of its use in practice. In a subsequent paper we aim to provide a statistical exposition of the stepped wedge design and outline a model which can be applied to the data collected during such a study.