Reviewer's report

Title: Use of the bootstrap in analysing cost data from cluster randomised trials: some simulation results

Version: 1 Date: 24 August 2004

Reviewer: gillian raab

Reviewer's report:

General

This is a useful practical paper that will be helpful to those who are designing cluster RCTs with skewed outcome measures. It adds to other evidence as to the unsuitability of bootstrap methods for small samples in these situations, and provides useful guidance as to their performance in moderate sized samples.

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

There has been some discussion in the health economic literature on the suitability of bootstrap methods for individually randomised trials with skewed outcome measures. To give one example, (O'Hagan, A. and Stevens, J. W. (2003). Assessing and comparing costs: how robust are the bootstrap and methods based on asymptotic normality? Health Economics 12, 33-49) argue against the bootstrap and in favour of bayesian methods. I would have expected that the authors would have cited this paper in the context of their comments on the needs of methods for small numbers of clusters. Has a full literature search of the Health economic literature been carried out? If so I would like the authors to justify not having cited it. they may well have good reasons for this.

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

Quite a few split infinitives eg page 6 line 2, page 7 line -2
I found tables 1 to 3 hard to read without codes for the methods in the table and having to pick out one from 3 numbers to compare. Would 3 smaller tables with each one just giving results for one method perhaps be clearer?

Discretionary Revisions (which the author can choose to ignore)

Page 4 line -6 Negative lower limits don't necessarily imply poor coverage, but they do suggest a failure of assumptions.

What next?: Accept after discretionary revisions

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

**Quality of written English:** Acceptable

**Statistical review:** No

**Declaration of competing interests:**

none