INAHTA Briefs

Issue 2010/037

Title **Contamination in Trials of Educational Interventions**

Agency **NETSCC, HTA, NIHR Evaluation and Trials Coordinating Centre**
Alpha House, University of Southampton Science Park, Southampton, SO16 7NS, United Kingdom;
Tel: +44 2380 595 586, Fax: +44 2380 595 639; hta@soton.ac.uk, www.hta.ac.uk

Reference Volume 11.43. ISSN 1366-5278. www.hta.ac.uk/project/1570.asp

Aim

To consider the effects of contamination on the magnitude and statistical significance (or precision) of the estimated effect of an educational intervention; to investigate the mechanisms of contamination; and to consider how contamination can be avoided.

Conclusions and results

The probability, nature, and process of contamination should be considered when designing and analyzing controlled trials of educational interventions in health. Cluster randomization may or may not be appropriate and should not be uncritically assumed to be a solution. Complier Average Causal Effect models are an appropriate way to adjust for contamination, if it can be measured. When conducting such trials, it is a priority to report the extent, nature, and effects of contamination.

Although few relevant studies quantified contamination, experts largely agreed on where contamination was more or less likely. Simulation of contamination processes showed that with various combinations of timing, intensity, and baseline dependence of contamination, cluster randomized trials might produce biases greater than, or similar to, those of individually randomized trials. Complier Average Causal Effect analyses produced results that were less biased than intention-to-treat or per-protocol analyses. They also showed that individually randomized trials would, in most situations, be more powerful than cluster randomized trials despite contamination.

Recommendations

Since few studies reported on whether contamination occurred, the literature search uncovered little evidence that contamination is actually a problem in trials of educational interventions in health. However, there is consensus on the types of situations where contamination is more or less likely. If it is likely, then cluster randomization may reduce contamination unless entire clusters are contaminated. CACE analysis may reduce bias if contamination is measured. A priority in future trials of educational interventions in health would be to report the extent, nature, and effects of contamination.

Methods

An exploratory search for literature published up to May 2005 was conducted via major electronic databases. The results of trials included in previous relevant systematic reviews were then analyzed to see whether studies that avoided contamination resulted in larger effect estimates than those that did not. Expert opinions were elicited about factors more or less likely to lead to contamination. We simulated contamination processes to compare contamination biases between cluster and individually randomized trials. Statistical adjustment was made for contamination using Complier Average Causal Effect analytic methods, using published and simulated data. The bias and power of cluster and individually randomized trials were compared, as were Complier Average Causal Effect, intention-to-treat, and per-protocol methods of analysis.

Further research/reviews required

See Executive Summary link at www.hta.ac.uk/project/1570.asp.

Written by Professor Max Bachmann, NETSCC, United Kingdom

ISSN 1654-501X