

been adjusted to allow for the similarity between individuals.²

Individual level analyses allow for the similarity between individuals within the same cluster, by incorporating the design effect into conventional standard error formulas that are used for hypothesis testing and estimating confidence intervals.^{2,21} For adjusted individual level analyses the intraclass correlation coefficient can be estimated from the study data in order to calculate the design effect. About 20-25 clusters are required to estimate the intraclass correlation coefficient with a reasonable level of precision and a cluster level analysis is to be preferred when there are fewer clusters than this.

(9) Allow for confounding at both individual and cluster levels

When confounding variables need to be controlled for at individual level or the cluster level, regression methods for clustered data should be used. The method of generalised estimating of equations treats the dependence between individual observations as a nuisance factor and provides estimates that are corrected for clustering. Random effects models (multilevel models) explicitly model the association between subjects in the same cluster. These methods may be used to estimate intervention effects, controlling for both individual level and cluster level characteristics.^{22,23} Regression methods for clustered data require a fairly large number of clusters but may be used with clusters that vary in size.

(10) Include estimates of intraclass correlation and components of variance in published reports

To aid the planning of future studies, researchers should publish estimates of the intraclass correlation for key outcomes of interest, for different types of subjects, and for different levels of geographical and organisational clustering.¹²⁻¹⁴

Recommendations

Investigators will need to consider the circumstances of their own evaluation and use discretion in applying these guidelines to specific circumstances. Conducting cluster based evaluations may present unusual difficulties. The issue of informed consent needs careful consideration.²⁴ Interventions and data management within clusters should be standardised, and the delivery of the intervention should usually be monitored through the collection of both qualitative and quantitative information, which may help to interpret the outcome of the study.

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1 Murray DM. *Design and analysis of group randomised trials*. New York: Oxford University Press, 1998.

2 Donner A, Klar N. Cluster randomisation trials in epidemiology: theory and application. *J Stat Planning Inference* 1994;42:37-56.

- 3 Donner A, Brown KS, Brasher P. A methodological review of non-therapeutic intervention trials employing cluster randomisation, 1979-1989. *Int J Epidemiol* 1990;19:795-800.
- 4 McKinlay JB. More appropriate evaluation methods for community-level health interventions. *Evaluation Review* 1996;20:237-43.
- 5 Whiting-O'Keefe QE, Henke C, Simborg DW. Choosing the correct unit of analysis in medical care experiments. *Med Care* 1984;22:1101-14.
- 6 Grosskurth H, Mosha F, Todd J, Mwijarubi E, Klokke E, Seikoto K, et al. Improved treatment of sexually transmitted diseases on HIV infection in rural Tanzania: randomised controlled trial. *Lancet* 1995;346:530-6.
- 7 Black N. Why we need observational studies to evaluate the effectiveness of health care. *BMJ* 1996;312:1215-8.
- 8 Cook TD, Campbell DT. *Quasi-experimentation. Design and analysis issues for field settings*. Chicago: Rand McNally, 1979.
- 9 Donner A, Birkett N, Buck C. Randomisation by cluster. Sample size requirements and analysis. *Am J Epidemiol* 1981;114:906-14.
- 10 Donner A. Sample size requirements for cluster randomisation designs. *Stat Med* 1992;11:743-50.
- 11 Hsieh FY. Sample size formulae for intervention studies with the cluster as unit of randomisation. *Stat Med* 1988;7:1195-201.
- 12 Hannan PJ, Murray DM, Jacobs DR Jr, McGovern PG. Parameters to aid in the design and analysis of community trials: intraclass correlations from the Minnesota Heart Health Programme. *Epidemiology* 1994;5:88-95.
- 13 Ukoumunne OC, Gulliford MC, Chinn S, Sterne JAC, Burney PGJ. Methods for evaluating area-wide and organisation-based interventions in health and health care. *Health Technol Assess* 1999;3(5).
- 14 Gulliford MC, Ukoumunne OC, Chinn S. Components of variance and intraclass correlations for the design of community-based surveys and intervention studies: data from the health survey for England 1994. *Am J Epidemiol* 1999;149:876-83.
- 15 Thompson SG, Pyke SDM, Hardy RJ. The design and analysis of paired cluster randomised trials: an application of meta-analysis techniques. *Stat Med* 1997;16:2063-79.
- 16 Klar N, Donner A. The merits of matching: a cautionary tale. *Stat Med* 1997;16:1753-6.
- 17 Martin DC, Diehr P, Perrin EB, Koepsell TD. The effect of matching on the power of randomised community intervention studies. *Stat Med* 1993;12:123-31.
- 18 Diehr P, Martin DC, Koepsell T, Cheadle A. Breaking the matches in a paired t-test for community interventions when the number of pairs is small. *Stat Med* 1995;14:1491-504.
- 19 Feldman HA, McKinlay SM. Cohort versus cross-sectional design in large field trials: precision, sample size and a unifying model. *Stat Med* 1994;13:61-78.
- 20 Diehr P, Martin DC, Koepsell T, Cheadle A, Psaty BM, Wagner EH. Optimal survey design for community intervention evaluations: cohort or cross-sectional? *J Clin Epidemiol* 1995;48:1461-72.
- 21 Donner A, Klar N. Confidence interval construction for effect measures arising from cluster randomisation trials. *J Clin Epidemiol* 1993;46:123-31.
- 22 Rice N, Leyland A. Multi-level models application to health data. *J Health Serv Res Policy* 1996;1:154-64.
- 23 Duncan C, Jones K, Moon G. Context, composition and heterogeneity: using multi-level models in health research. *Soc Sci Med* 1998;46:97-117.
- 24 Edwards SJL, Lilford RJ, Braunholtz DA, Jackson JC, Hewison J, Thornton J. Ethics of randomised trials. In: Black N, Brazier J, Fitzpatrick R, Reeves B, eds. *Health services research methods. A guide to best practice*. London: BMJ Books, 1998:98-107.



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Corrections and clarifications

Risk factors for human hantavirus infection: Franco-Belgian collaborative case-control study during 1995-6 epidemic

In this paper by N S Crowcroft and colleagues (26 June, p 1737-8) the names of two authors were transposed in the list of addresses. J-C Desencos is head of the infectious diseases unit at the Réseau National de Santé Publique, Saint-Maurice, France; and F Van Loock is an epidemiologist at the Scientific Institute of Public Health (Louis Pasteur) in Brussels, Belgium.

Annual general meeting of the BMA

In this letter by David Gullick (3 July, p 59) the second sentence of the first paragraph was misleading. It should have started: "It will be proposed that our 4000-odd overseas members (except those in the armed forces)..."

Obituaries

Dr Gordon Cunningham Taylor (19 June, p 1702) was incorrectly described as a lieutenant general in the Royal Army Medical Corps. He was a lieutenant colonel.

In the obituary of Dr Kevin Anthony Valiant (24 July, p 262), Dr Valiant's surname was incorrectly spelt.