Correspondence
From Max Bachmann


We wish to correct some statistics reported in our paper that arose from calculation errors. In the Results, the 95% confidence limits for no inter-cluster variation in outcomes should be 3.1 and 16.9% (not 8.3 and 11.7%). The $\chi^2$ value for moderate inter-cluster variation should be 2.84 (not 1.64) with $P > 0.05$ (not $p > 0.1$). The $\chi^2$ value for large inter-cluster variation should be 0.75 (not 0.43). All other reported $\chi^2$ values, $P$ values and confidence limits are correct, the implications of the statistics are unchanged, and there is no need to change the text in any way. We are grateful to Pat Yudkin for spotting our mistakes.

From Patricia Yudkin

The thought-provoking paper by Butler and Bachmann illustrates the difference made by cluster effects to the design and analysis of a randomised trial. Butler and Bachmann used Cornfield’s method to estimate the necessary increase in sample size, and the method of Donner and Klar to adjust chi-squared values and confidence intervals.

It may not be generally realised that both methods are essentially the same. Clusters (e.g. general practices) present a problem to the extent that individuals within clusters are more similar than individuals in general; this leads to an unusual degree of variation between different clusters. The cluster effect can therefore be estimated either by considering the intra-cluster correlation coefficient—a measure of the similarity of subjects within clusters—or, equivalently, by considering the increased variability between clusters. Cornfield’s inflation factor uses the latter approach; that of Donner et al. uses the former. The two methods may produce slightly different answers, mainly because the Cornfield formula assumes clusters of equal size while that of Donner et al. takes account of unequal cluster sizes.

In designing a cluster-randomised trial, equal cluster sizes will usually be assumed, in the absence of other information. For estimating sample size, Butler and Bachmann used the Cornfield method, based on their hypothetical data. The data in Table 2 produced an inflation factor of 2.88, whereas the method of Donner et al. would have given a value of 2.76.

At the end of a trial, the inflation factor can be estimated from the trial results. In principle, confidence intervals and significance tests can be calculated as though the trial were individually randomised, and the results adjusted using the inflation factor to take account of the cluster effect. Thus the ordinary chi-squared value (7.84 in the Butler and Bachmann paper) would be divided by the inflation factor (2.76) to give the adjusted value (2.84). The width of the confidence interval (3.1 to 16.9 = 13.8) would be increased by the square root of the inflation factor (1.66)—since confidence intervals are based on the square root of the variance—to give the adjusted width (±1.5 to 21.5 = 23.0). Although this approach is suitable if there is a large number of clusters in each group, if this is not the case, the inflation factor is poorly estimated, and alternative methods of analysis are advocated.

References


