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Book Reviews

An Introduction to Randomized Controlled Clinical Trials. J. N. S. Matthews. London: Arnold, 2000. xiv+189pp. Price £19.99 (paperback). ISBN 0-340-76143-1.

This small guide to the essentials of the statistics of randomized controlled trials (RCTs) will be invaluable as a handy (and inexpensive) reminder of the basics for the experienced statistician. Junior statisticians who have absorbed its contents will be ready to start provision of competent technical support for clinical trials, whether within the pharmaceutical industry or in academic environments. Moreover, its clear style, and direct approach to the main statistical issues arising in RCTs, mean that it deserves to be used much more widely than this: as a text for epidemiology students and clinical researchers. In tropical health, RCTs are often planned and carried out as a secondary activity of clinicians and scientists with many other responsibilities and in such contexts this book provides just the type of introduction to the topic that is needed.

The book was written though to fulfil a more limited role, as a primer for final-year undergraduate or post-graduate statistics students at British universities, and, in a few minor respects, the tailoring of the book to this audience has made it a little less appropriate for other users. Because of the timing of teaching about clinical trials in the statistics curriculum, Professor Matthews has laid the emphasis on the analysis of continuous responses, although clinical trials typically have binary outcomes. One might also have wished that the example programs were written in more widely used software than Minitab or GLIM. On the other hand, while the approach is unashamedly mathematical, there is no complicated matrix algebra and scientists with relatively little background in mathematics should not be afraid of it. Even if your only other statistics book is an elementary text written for the numerically challenged, you might consider getting this one.

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Design and Analysis of Cluster Randomization Trials in Health Research. A. Donner & N. Klar. London: Arnold, 2000. x+178pp. Price £35.00 (paperback). ISBN 0-340-69153-0.

Nowadays, few clinicians or researchers doubt the need for well-designed randomized trials to test new drugs and vaccines. Not everyone though would know how to evaluate programmes for social marketing of condoms or bednets, mass-treatment of parasites in schoolchildren, or new initiatives in training health staff. Such programmes are likely to affect whole villages, hospitals, or even districts at the same time, since the intervention must necessarily be introduced over a wide area simultaneously. Health care interventions often do not lend themselves to individual randomization.

In poor countries, the costs of evaluation of such an intervention can be substantial in relation to those of the intervention's introduction and it is absolutely crucial to get the evaluation right. Most of us recognize the need for a comparison group comprising people who do not get the intervention. But this alone is not good enough—a sound test of an intervention requires both *replication* (more than one school, hospital, district, or more generally cluster) in both the intervention and control arms, and *random* assignment. One-against-one comparisons should be consigned to the history books.

Trials where a number of clusters are randomized are not used as much as they should be, and are analysed correctly even less often. One reason for this is that they raise statistical issues that do not arise in individually randomized trials, for example how to weigh up the advantages of many small clusters as against a smaller number of larger ones; how to analyse the results when cluster sizes vary. Sound answers to these questions are not easy to find, and without these answers it is all too likely that inappropriate designs will be used.

Cluster randomization may appear to be a minor component of the whole field of clinical trials, but it raises enough practical issues to fill a whole book. Donner and Klar have now written that book. While it is not quite correct to claim, as does the cover, that this is the first book to present a systematic and unified treatment of the topic, the clarity of presentation and the orientation towards practical issues may well make it the first one to be widely used. If you are already involved in designing or analysing cluster randomized trials you should certainly consider getting a copy. If you are trying to evaluate the impact of clustered health care interventions using some other methodology then you need this book desperately.

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