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Preface to the First Edition

Buy this book if you are a healthcare professional and you want some guidance in understanding the clinical research literature. It is designed to help you with reading research papers, by explaining their structure and the vocabulary they use. These essential first steps will make interpretation of clinical research that much easier for you. For example, the book will help with questions like:

- ‘Who were the authors, what is their standing, and can they be trusted?’
- ‘What question or questions did they want to answer, and what was the clinical importance of doing so?’
- ‘Who were the subjects in the study, how were they chosen, and were the methods used the most suitable?’
- ‘How were the data collected? Was this the best approach?’
- ‘What methods did the authors use to analyse the data, and were the methods employed appropriate?’
- ‘What did they find? Were their conclusions consistent with their results?’
- ‘Were there any shortcomings in the study? Do the authors acknowledge them?’
- ‘What are the clinical implications of their results?’
- ‘Does it all make sense?’

This book is not an introduction to medical statistics, study design, epidemiology, systematic reviews, evidence-based medicine, or critical appraisal, although we inevitably touch on all of these things (and more). Even so, if you are not already well versed in some of these fields, you should know a lot more by the time you get to the end.

We have concentrated on improving our readers’ understanding of quantitative research papers; and while qualitative papers contain several important elements which we have not been able to cover here, there are many other areas, particularly at the beginning and end of papers, which readers of qualitative papers will find relevant to their needs.

Primarily, this book should be of interest to the following individuals:

- Clinicians currently practising. This includes GPs, doctors in hospitals, in the community and in public health, nurses, midwives, health visitors, health educators and promoters, physiotherapists, dietitians, chiropodists, speech therapists, radiographers, pharmacists, and other clinically-related specialists.
- Clinicians of all types engaged in research activities: as part of their training; as a condition of their clinical duties; for postgraduate studies and courses; or for professional qualifications.
- Those involved with the education and training of health professionals in colleges of health, in universities, and in inhouse training and research departments.
- College, undergraduate, and postgraduate students in all medical and clinical disciplines which involve any element of research methods, medical statistics, epidemiology, critical appraisal, clinical effectiveness, evidence-based medicine, and the like.
In addition, this book should appeal to individuals who, although not themselves clinicians, nonetheless find themselves in a clinical setting and need some understanding of what the published clinical research in their area means:

- Clinical auditors and quality sensors.
- Clinical managers.
- Service managers, administrators and planners.
- Those working in health authorities and in local government social and health departments.
- Purchasers of health provision.
- People not actually employed in a clinical arena but who nonetheless have a professional or personal interest in the medical literature – for example, members of self-help and support groups; medical journalists; research-fund providers; the educated, interested, lay public.

We have structured the contents of the book into a series of chapters or units whose sequence mirrors that of papers in most of the better-quality journals. Thus we start with the preliminaries (title, authors, institution, journal type and status, and so on) and end with the epilogue (discussion, conclusions and clinical implications). Throughout the book we have used a wide variety of extracts from recently published papers to illuminate our textual comments. In these we have focussed largely, but not solely, one example of good practice in the hope that this will provide readers with some 'how it should be done' benchmarks. Any errors remain, of course, our own.

David Bowers, Allan House, David Owens

Leeds, 2001
Preface to the Second Edition

We received a great many favourable comments from those who used the first edition of this book—for which, many thanks. Why, then, a second edition? The reason is the usual one in these circumstances—we think we can make the book even better. When we set out to write the first edition, we had a good idea of what we wanted to include, but inevitably there was some jostling for the available space. In the end, some things that we might have included had to be left on the cutting room floor. With this second edition we have now been able to include most of that excluded material. We have also taken the opportunity to respond to some helpful suggestions from readers. In addition to these changes, we have now added a considerable amount of completely new material.

Thus, this second edition includes a new chapter on measurement scales, and new or significantly expanded sections on the following: ethical considerations; abstracts; consent to randomization into trials; pragmatic and explanatory trials; intention-to-treat analysis; elements of probability; data transformation; non-parametric tests; systematic review; among others.

Moreover, there is a lot of new material in the chapters on regression—including more on variable selection and model building, and on Cox regression. A good deal of the material in the middle chapters of the book has been re-arranged and improved to make for a better and more lucid flow (the treatment of dummy variables has been brought forward a chapter, for example).

We have all taken the opportunity to update many of the extracts from clinical papers which we use to illustrate the various ideas and procedures we describe, and also to revise much of the text in the book to improve clarity and understanding. We remain more than willing to receive any constructive comments and suggestions from readers. Otherwise we are confident that this is now an even better book than the original.

SOME NOTES ON STATISTICAL SOFTWARE

There are several statistical packages, of varying levels of sophistication and complexity, which can be used to analyse clinical data. Among the most widely used are the following:

- CIA (Confidence Interval Analysis)
- EPI-Info
- Minitab
- SPSS (the Statistics Package for the Social Sciences)
- STATA
- S-PLUS

In our opinion, Minitab is the simplest and friendliest statistics package for the general user. SPSS is not quite as easy to use but handles cross-tabulation of two variables rather better and has a wider range of the more sophisticated types of analyses. The choice of types of analysis and their outputs are perhaps easier to understand in Minitab than in SPSS. Each application has, of course, its limitations. To the best of our knowledge, Minitab does not do the McNemar test, nor does it have a clinically-based survival analysis program, nor does it allow for a direct calculation of Spearman’s correlation coefficient (the
data need first to be ranked). On the other hand, SPSS does not allow a chi-squared test to be done directly on a contingency table in the columns of the data sheet, nor does it provide confidence intervals for the difference between two proportions, or with the Mann-Whitney or Wilcoxon tests, all of which Minitab does. But as we have said, SPSS has a wider range of applications.

CIA, as its name implies only does confidence interval calculations (but in this respect is very useful). EPI-Info is a combination database and epidemiological tool, which originates from the Center for Disease Control (CDC) in the USA. It has the advantage of being free (it can be downloaded from the Internet along with a user’s manual).

Most professional clinical statisticians will probably use either STATA or S-PLUS; both more powerful and versatile than either Minitab or SPSS (but rather less easy to use).

We would not recommend Excel as a statistics program since it is fundamentally a spreadsheet tool and thus has an extremely limited range of statistical functions – and in any case, these are not set out in a way that is well suited to clinical research.

**WRITING PAPERS FOR CLINICAL JOURNALS**

Those of you who envisage writing up your research and submitting paper to a clinical journal may find the following web site addresses (URLs) useful. They contain detailed advice and instructions to authors on what is required prior to submission: for example, how to contact the journal, what should be in the paper (order and content of sections), information on the required style, editorial policies and guidelines, and so on.

The first URL directs you to a set of instructions to authors for each of over 3500 health and life-sciences journals, worldwide. The second and third URLs relate specifically to the British Medical Journal, but contain a huge amount of detailed and splendidly informative material related to the preparation and submission of clinical papers, and collectively provide a set of desirable standards to which anyone who is contemplating the submission of such a paper to the BMJ or any other journal should aspire:

http://mulford.mco.edu/instr
http://bmj.bmjournals.com/advice
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*School of Medicine, University of Leeds, Autumn, 2005*
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Setting the Scene:
Who Did What, and Why