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(DOI: 10.1002/sim.2920)

2. APPLIED LONGITUDINAL ANALYSIS. Garrett M. Fitzmaurice, Nan M. Laird, James H. Ware, Wiley-Interscience, Hoboken, NJ, 2004. No. of pages: xix + 506. Price: \$105.00. ISBN 0-471-21487-6

The powerful impression that this book leaves is of meticulous care in stating, exemplifying, and translating statistical language and thinking, in the context of analysis and modeling for longitudinal analysis. The book proceeds as a calm, unhurried conversation with the reader.

The authors have taken great pains to make their ideas accessible to a wide audience. I was struck by the number of times the authors used the phrase ‘That is,’ signaling a plain-spoken translation of the statistical concept immediately preceding. I was equally struck by the number of times the authors used the phrase ‘For example,’ signaling a straightforward example that directly related to the previous sentence. Fitzmaurice was kind enough to count those two phrases at my request: 404 and 301 occurrences, respectively. This is no small matter; too many authors just ignore the substantial gap between whom they claim the book is intended for and those who can actually read it in finite time.

An example of the attention to detail is the inclusion of a full section on the interpretation of regression parameters in generalized linear mixed models, including a simple worked example. The authors discuss at length the difference between the population-averaged and the subject-specific models in the context of generalized linear mixed-effects models, why those models will differ, and why one might choose to use one over the other. A similar example is the care with which they introduce, discuss, and compare several different strategies for dealing with a baseline response. Another example of the flavor is their inclusion of useful although *ad hoc* advice e.g. use

$\alpha = 0.10$  instead of 0.05 for testing boundary hypotheses with the likelihood ratio test. A final example: the authors include a detailed description of relevant and important hypotheses, including the structure of a rational testing program, rather than a sequence of unrelated tests. The issues are less about the statistics than the deployment of the outcome in substantial real-world problems. These are the pragmatic problems of modeling longitudinal data. This book would have saved me a lot of head scratching a year ago.

The authors tackle slightly more advanced topics as well, including a lovely description of REML and the problems associated with choosing a reference distribution for the likelihood ratio test when the parameter of interest is on a boundary. These topics are useful beyond the direct remit of the book; I have recommended it to graduate students in classes about mixed-effects models, so clear is its coverage.

The infrastructure of the book makes it ideal for self-teaching or use in an upper-level undergraduate or graduate level class in statistics or biostatistics. The data sets for the examples are available online, along with suitable codes. Detailed case studies recur throughout the book, and are coded in SAS. Useful problems conclude the important chapters. There is a painstaking development of notation, and gradual, detailed, and rational build up of models. The authors sensibly and explicitly omit derivations, although targeted further reading would be welcome. Chapters contain generous connecting text and useful signposts for technical depth.

One note seemed peculiar. In introducing early models, the authors focused on the independence of observations rather than residuals, or conditional independence of observations. Likewise, the authors mentioned normality, or symmetry, of observations, rather than residuals. I think that this

is potentially misleading because it may leave the analyst with the impression that, for example, their data ought to be normally distributed for these models to work. Clearly the authors know the difference, as their writing elsewhere in the book indicates. Also, I would have liked to have seen more references supplied for the sensibly omitted details, e.g. on the normal quantile plots of empirical blups and the properties of transformed longitudinal residuals.

I very warmly recommend this book for teaching, as noted above, as well as for biostatisticians

and statisticians who analyze and communicate longitudinal data. I expect it to be very well suited to the readership of this journal. I also recommend it to anyone who wishes to write a technical book for a wide audience. I consider it a first-rate representative of the craft.

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(DOI: 10.1002/sim.2924)

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3. STATISTICAL EVIDENCE IN MEDICAL TRIALS: WHAT DO THE DATA REALLY TELL US? Stephen D. Simon, Oxford University Press, Oxford, 2006. No. of pages: xvii + 197. Price: £65.00, \$114.50 hardcover; £25.00, \$44.50 paperback. ISBN 0-19-856760-X (hardcover), ISBN 0-19-856761-8 (paperback)

Reading the vast peer-reviewed medical literature these days is a challenge for research practitioners, let alone health professionals. There is a plethora of study designs, studies of varying degrees of quality, and a mixed bag of analytical techniques. After almost two decades as a statistician in observational epidemiology, I moved into the world of clinical trials about 12 years ago, a world that has undergone dramatic changes in design methodology, and has become heavily regulated. The field of biostatistics is also maturing; traditional training in statistical methodology is now being supplemented with exposure to epidemiological concepts and design issues. One should never attempt an analysis of research data without first understanding the study design. However, good reference books, specifically on interpreting medical trials, aimed at biostatisticians and health professionals, are few. That has started to change. An example is Stephen Simon's recent book entitled *Statistical Evidence in Medical Trials. What do the data really tell us?*

This 174-page book (chapters only), based on notes from an informal course offering and a companion website [www.childrens-mercy.org/stats/journal.asp](http://www.childrens-mercy.org/stats/journal.asp), is aimed at health-care professionals who are reading the medical literature and attempting to make sense of the results. Simon covers a wide range of topics in seven chapters with catchy interrogative headings.

In Chapter 1 (*Apples and oranges?*), he discusses covariate imbalance, patient selection, randomization, concealment, minimization, matching, statistical adjustment, and non-randomized study designs. In Chapter 2 (*Who was left out?*), he covers inclusion, exclusion, refusals (i.e. generalizability), drop-outs, cross-overs, missing data, and the intention-to-treat principle. Chapter 3 (*Mountain or molehill?*) includes topics on selecting and measuring outcomes, blinding, clinical importance, and briefly, negative trials, equivalence, non-inferiority. Chapter 4 (*What do the other witnesses say?*) is devoted entirely to the criteria for causation, conflict of interest, and fraud, although the chapter title is misleading. In Chapter 5 (*Do the pieces fit together?*), Simon reserves the largest chapter (36 pages) for systematic reviews and statistical metaanalysis. In Chapter 6 (*What do all these numbers mean?*), he covers the basic statistical aspects of research such as type I and II errors, *p*-values, confidence intervals, a few summary risk measures, correlation, survival, and prevalence *versus* incidence. Finally, Chapter 7 (*Where is the evidence?*) deals with electronic searching *via* PubMed and the internet, and the useful PICO format.

Each chapter follows a similar format; an introduction, a discussion of the key elements, a brief 'Counterpoint' section that attempts to address controversy in the form of '[element] is overrated,' a summary section, and finally a section called 'On your own' where Simon has summarized various studies with issues related to the topics covered in the chapter. Along with the study details, he has also included the reference and in most cases, a link to the article on the internet. This section is probably the book's greatest asset. In total, he provides 32 examples, although only six are randomized clinical trials.