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BOOK REVIEW

Biostatistics Books for Clinical Researchers: Reviewed and Contrasted

[1] Multilevel Modeling of Health Statistics, by A. H. Leyland and H. Goldstein, 2001, John Wiley & Sons, Ltd Publication, ISBN: 0-471-99890-7, pp. 217 + xvii. $ 105

[2] Dictionary of Clinical Trials, by Simon Day, 2002, John Wiley Publication, ISBN: 0-471-98596-1, pp. 217 + xiii, $ 43.50

[3] Recurrent Events Data Analysis for Product Repairs, Disease Recurrences, and other Applications, by Wayne B. Nelson, 2003, SIAM ASA-SIAM Publication, ISBN: 0-89871-522-9, pp. 151 + xi, $ 85

[4] Medical Biostatistics, by A. Indrayan, S. B. Sarmukaddam, 2001, Marcel Dekker, Inc. Press, ISBN: 0-8247-0426-6, pp. 643 + xxv, $ 195

[5] Sample Size Calculations in Clinical Research, edited by S-C. Chow, J. Shao, and H. Wang, 2003, Marcel Dekker, Inc. Press, ISBN: 0-8247-0970-5, pp. 358 + ix, $ 165

[6] Testing Statistical Hypotheses of Equivalence, by Stefan Wellek, 2003, Chapman & Hall/CRC Press, Boca Raton, Florida, ISBN: 1-58488-160-7, pp. 284 + xv, $ 79.95

[7] Statistical Methods for Survival Data Analysis, by Elisa T. Lee and John W. Wang, 2003, John Wiley & Sons Publication, ISBN: 0-471-36997-7, pp. 513 + xii, $ 94.95

[8] Randomization in Clinical Trials, by William F. Rosenberger and John M. Lachin, 2002, John Wiley Publication, ISBN: 0-471-23626-8, pp. 259 + xvii, $ 83.95

[9] Modeling in Medical Decision Making: A Bayesian Approach, by G. Parmigiani, 2002, John Wiley & Sons Publication, ISBN: 0-471-98608-9, pp. 266 + xi, $ 95.00

[10] Modelling Survival Data in Medical Research, by David Collett, 2003, Chapman & Hall/CRC Press, ISBN: 1-58488-325-1, pp. 391, $ 59.95

[11] Applied Mixed Models in Medicine, by Helen Brown and Robin Prescott, 2001, John Wiley & Sons Ltd., ISBN: 0-471-96554-5, pp. 408 + xx, $ 110

[12] Analysis of Longitudinal Data, by P. J. Diggle, P. Heagerty, K-Y. Liang, and S. L. Zeger, 2002, Oxford University Press, ISBN: 0-19-852484-6, pp. 379 + xv, $ 85

[13] Survival Analysis: Techniques for Censored and Truncated Data, by John P. Klein and M. L. Moeschberger, 2003, Springer-Verlag Publication, ISBN 0-387-95399-X, pp. 536 + xv, $ 89.95

This review is about biostatistics books that might help clinical researchers in their planning, execution, and analysis of medical studies aimed at discovering new drugs. This application area has benefited significantly from statistical thoughts and tools over the years.

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The book [1] edited by Leyland and Goldstein contains 13 well written chapters by experts covering topics: *variance components and random coefficient models for multilevel data with an application to children's sleep patterns, autocorrelation and growth models for multivariate repeated measurements data with an example in bone age and adult height, binomial regression with healthcare and geographic applications, Poisson regression for cancer mortality and food poisoning, multivariate linear regression for blood pressure in low birth weight babies, outlier and robustness ideas to detect discrepant data, modeling nonhierarchical data structures with an example in artificial insemination, multinomial regression for hazards in smoking and its cessation, sampling methodologies and optimal sample sizes, meta analysis for combining several data sets, and software SAS, BMDP, MLwiN, and HLM* among others. Elementary knowledge of statistics is necessary. The references are recent and useful. It can be used as a textbook in graduate level modeling course.

The book [2] by Day is extremely useful as a pocket reference guide to clinical researcher to refer about a terminology now and then. Definitions and regulatory guidelines without jargons of about 2700 commonly used words in clinical trials are alphabetically arranged in this wonderful book. No previous knowledge of calculus, probability, or statistics is necessary to understand any item in this dictionary.

The book [3] by Nelson is useful to clinical researchers to capture a cost-effectiveness of disease episodes in patients. The book also surveys software to calculate and plot mean cumulative function, renewal process, nonparametric methods, homogeneous and nonhomogeneous models. Other relevant topics in the book that might be useful to clinical researchers are *recurrent event data analysis, confidence interval estimation of mean cumulative function, point and group comparisons of mean cumulative function.* Calculus and mathematical statistics background are necessary to read and comprehend this book. The problems in each chapter are of a challenging type. It can be a textbook for a graduate level course on repeated events data modeling.

Biostatistical concepts and techniques are becoming important tools in clinical trials. This book [4] by Indrayan and Sarmukaddam contains state-of-the-art statistical methods with examples and references to planning of medical data collection, analyzing and interpreting the data. Emphasis on concepts and interpretations rather than the theory is focused. Some well illustrated topics in this book are *medical uncertainties, how sampling versus experimental principles help to control uncertainties, methods to represent variations, charts and graphs, survival analysis, hypothesis testing, categorized data analysis, relationship versus agreements, statistical quality control techniques in clinical trials,* and *statistical fallacies.* A weakness of this book is that software packages SAS, SPSS, SYSTAT, S-Plus, NCSS, SIGMAPLOT, TABLECURVE 3-D, SIGMASTAT, EQUIVTEST, n-QUERY ADVISER, SOLAS, STATXACT, and STATA that can be used in clinical trials are just mentioned but not illustrated.

At almost every stage of clinical trials to ensure validity, reliability, and reproducibility, one of the most important questions to be answered is how many observations should be considered. This well composed book [5] edited by Chow *et al*. contain sample size formulas and examples. Current *regulatory requirements in clinical trials, hypothesis testing of equivalence, superiority, and inferiority, interim analysis, proportionality, time to event data analysis* are exemplary features in this book. The case study of vaccine trials is very interesting. This is a good reference book for researchers in clinical trials.

Equivalence testing is more of verifying rather than rejecting null hypothesis and has become a very popular technique in clinical trials. The book [6] by Wellek describes basic and advanced topics in equivalence testing. Several computer programs are at http://www.zi-mannheim.de/wktsheq. Among several topics, this book has explained well with examples and case studies the topics *definition and limitation of equivalence, how it*

helps in clinical trials, classical and Bayesian approaches to equivalence, noninferiority concepts, McNemar tests for paired data, equivalence tests for binomial and Gaussian data, multisampling test for equivalence, collapsibility, testing for equivalence, and a list of special computer programs. Researchers will find this book thought provoking. A basic level of statistical theory is necessary to comprehend the material in this book. The reference section contains recent articles.

The book [7] by Lee and Wang contains thorough descriptions and illustrations of several useful nonparametric and parametric statistical methods to analyze survival data. Needless to say, survival data are often encountered in clinical trials. The references are current. A basic level of statistical theory is necessary to follow this book. Examples are interesting and motivating. The noteworthy illustrations occur in the topics: *nonparametric methods for survival rates, Mantel–Haenszel tests, parametric methods for exponential, Weibull, lognormal, gamma, and log-logistic data, probability and hazard plotting, prognostic factors in model building, Hollander–Proschan's tests,* and *regression methods.* There are challenging exercise problems in each chapter. This is suitable for a textbook in a graduate level survival analysis course.

The book [8] by Rosenberger and Lachin is excellent for learning on how to use randomization ideas. Randomization is an integral part of clinical trials. Both theory and applications of randomization are equally emphasized. Well described topics are *causation versus association, importance and ethics of randomization, sources of bias in clinical trials, adjustment for noncompliance of randomization, Efron's versus Wei's method of balancing treatment assignments, Zelen's versus Pocock–Simon's procedure of balancing known covariates, effects of unobserved covariates, selection bias, permutation tests, stratified-blocked-covariate-adjusted analyses, response adaptive randomizations, use of Martingale theory in randomization,* and *delayed response.* Readers will enjoy case studies about optic neuritis treatment, heart failure, diabetes, and cancer chemotherapy. There are challenging exercise problems in each chapter. It is suited to be a textbook for a graduate level randomization course.

The book [9] by Parmigiani provides Bayesian methodologies and Monte Carlo simulation techniques with medical and health applications. A basic knowledge of statistical theory is necessary to comprehend the material in the book. Among other chapters, well illustrated topics are: *sensitivity, specificity, predictive value, Bayes factor with nomogram, genetic counseling, chronic disease modeling, utility theory and loss functions for decision making, elicitation of expert's opinion, strategies for simulation, illustration of meta analysis using migraine headache data, decision trees,* and *chronic disease modeling.* This book is full of case studies and applied minded readers will like it. No exercise problem is given in the chapters.

The book [10] by Collett is a well written practical guide with a demonstration of SAS software to perform survival analysis. This book illustrates with examples topics: *hazard function, survivor function, non-parametric tests, modeling, checking model assumptions, identifying influential observations, Gompertz proportional model, accelerated failure time model, modeling time-dependent variable, survival analysis of interval censored data, sample size calculation, frailty model,* and *modeling of cure probability* among others. I liked the presentation style. A good amount of statistical theory background is necessary to read and comprehend this book. It can be used as a textbook in a graduate level survival analysis course provided the instructor can supplement exercise problems. The reference contains a good amount of recent articles.

The book [11] by Brown and Prescott is useful to researchers in pharmaceutical industry who are eager to learn or practice mixed linear models for analyzing, comprehending, and interpreting data. Well described topics in the book are: *mixed model concepts, baseline covariate model with an example using hypertension data, covariance pattern versus random*

coefficients models in repeated measures data, estimation of random, fixed, and mixed effects in normal data, specification of prior knowledge, negative variance components, generalized linear mixed models, mixed models for ordered and unordered categorical data, meta analysis for integrating multi-centre clinical trials, sample size for normal and non-normal cases, covariance pattern model (for count and normal data), cross over trials, complete and incomplete designs, mixed model for matched and control studies, mixed model for cluster sample, and *software SAS and GLIMMIX for practicing mixed model* among others. Readers should have statistical theory background to read and comprehend this book. This is a suitable textbook for a graduate level course.

The book [12] by Diggle *et al*. contains methodologies for analyzing repeated or longitudinal data. The topics that are well illustrated are *designs for clinical trials, exploratory techniques, generalized linear models for count and continuous data, missing value analysis, graphical techniques, weighted least square and other estimation methods, covariance models, time-by-time ANOVA, transition Markov model with Indonesian Children's respiratory infection, log-linear model, generalized estimating equations, sample size calculation, logistic regression, Bayesian methods for categorized data of Madras schizophrenia, time dependent covariate analysis, methods for missing values, modeling drop out process, nonlinear regressions,* and *modeling drug therapies* among others. The software that is used in the illustration are *S-Plus, MLn, SAS, Mplus,* and GENSTAT. Another useful software but in public domain is R software (see www.r-project.org). The data that are used in the book are in www.maths.lancs.ac.uk/∼diggle or in http://faculty.washington.edu/heagerty/.

Applied statisticians and researchers in medicine will find this book [13] by Klein and Moeschberger very useful. A basic level of statistical theory is necessary to understand the material of this well written book. The topics that are well illustrated are *clinical trials for acute leukemia, for kidney dialysis, for breast cancer, for burning, for cancer, for allogeneic bone marrow, for sexually transmitted diseases,* and *for psychiatric studies.* Statistical methodologies that are described well are *mean residual life function, competing risks, censoring versus truncation, counting processes, cumulative hazard functions, Bayesian nonparametric methods, semi parametric proportional hazard regression with fixed and time dependent covariates, additive hazards, parametric regression models for data from Weibull and binomial population,* and *multivariate survival analysis.* In every chapter, there are challenging and easy problems. It is suited for a graduate level course in survival analysis. The statistical tables and reference contain recent material.

I enjoyed reading all these books and strongly recommend them to clinical researchers and statisticians. They will find these books useful.

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