Book Reviews

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Editor Reports on New Editions, Proceedings, Collections, and Other Books

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Bayesian Adaptive Methods for Clinical Trials, by Scott M. BERRY, Bradley P. CARLIN, J. Jack LEE, and Peter MÜLLER, Boca Raton, FL: Chapman & Hall/CRC, 2010, ISBN 978-1-4398-2548-8, 305 pp., $89.95.

In the pharmaceutical industry adaptive designs are currently the rage because of their many potential advantages due to their flexibility. It allows you to stop early for efficacy or futility. It can do drug dose selection more easily and may have patients on inferior treatment for smaller amounts of time. There have already been four or five books published from the frequentist point of view. This is the first serious text on adaptive designs using the Bayesian approach.

Pharmaceutical companies including Johnson and Johnson, Eli Lilly, Pfizer, Merck, Novartis, Novo Nordisk, Millennium, AMAG, and GlaxoSmithKline have all been successful at running adaptive trials. Merck, for example, has already completed more than 40 adaptive design trials. Such trials can be done in phase II, phase III, or a combining of phases II and III in a single adaptive trial.

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The MD Anderson Medical Center at UT Houston runs hundreds of adaptive trials (all, as far as I know, using the Bayesian methodology). Don Berry runs the biostatistics group at MD Anderson and he and his son Scott own a consulting group that help companies run Bayesian adaptive designs. Eli Lilly has been one of their clients on a drug trial and Biosense Webster, a J&J company, used them for a Bayesian trial on one of their ablation catheters. Scott Berry is one of the authors of this book and a lot of the book is devoted to work of Berry first at Duke and then later at MD Anderson and Berry Consultants.

In 2010 the FDA issued a guidance document on adaptive designs that mostly discussed the frequentist approach. Bayesian methods are clearly acceptable too, if done properly and with multiple testing and inflation of Type I error (frequentist concepts) duly considered. At least a few Bayesian trials conducted by the Berrys have gone through to completion. Examples of Bayesian trials discussed in the book include BATTLE and ISPY-2, which were phase II studies.

The Markov Chain Monte Carlo (MCMC) approach to posterior distribution computation is covered in Chapter 2 and an online reference for R Macro programs is given in the Appendices (Sections 2.6, 3.5, 4.8, 5.9, and 6.5 of Chapters 2, 3, 4, 5, and 6 respectively). The BUGS (Bayesian analysis Using Gibbs Sampling) programming language and the WinBUGS software package to implement the MCMC approach on Bayesian hierarchical models is given Chapter 2, pp. 58–61.

In Chapter 6 of the book the authors cover a number of special topics including incorporating historical data in the prior, multiplicity and false discovery rates, equivalence testing and subgroup analyses.

Adaptive designs have logistic problems but companies have been able to overcome the problems motivated by the overall time and money saving benefits. All types of studies are illustrated from phase I through phase III and the examples are real and practical. Also the combination of phase II and III trials is an approach that advocates of adaptive designs think are promising. The authors call this seamless II–III designs (see page 7), a term not favored by the FDA. These II–III designs are also not encouraged in the FDA guidance document. Even when taking the Bayesian approach, issues about frequentist properties for the designs comes up. Missing data, multiple testing, Type I error and power of the test, both conditional and unconditional are important when the frequentist approach is applied. The authors admit that both frequentist and Bayesian properties for a design are important and can be evaluated through simulation.

Although adaptive designs can be implemented effectively using either the Bayesian or the frequentist approaches, Bayesian trials are a little more natural and simpler. This is the right book to get if you are interested in Bayesian methods for adaptive designs.

Any reader interest in this subject should see the recent *Handbook of Adaptive Designs in Pharmaceutical and Clinical Development* (2011) edited by Pong and Chow. It contains 27 chapters by expert authors covering every aspect of adaptive designs including both frequentist and Bayesian approaches. Peace and Chen (2011) also has coverage of group sequential and adaptive designs in their Chapter 5. Herson (2009) includes adaptive design among the emerging issues in Chapter 8. Chang (2011) includes adaptive designs in Chapters 3, 6, and 7. Earlier texts covering the frequentist approach to adaptive designs are Chow and Chang (2007), Chang (2008a), and Chang (2008b).

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Lectures on Algebraic Statistics. Oberwolfach Seminars, Vol. 39, by Mathias DRTON, Bernd STURMFELS, and Seth SULLIVANT, Berlin: Birkhäuser Verlag, 2008, ISBN 978-3-7643-8904-8, 171 pp., $39.95.

Lectures on Algebraic Statistics arose from the Oberwalfach Seminar organized by the Mathematisches Forschungsinstitut Oberwolfach during the week of May 12–16, 2008 in Black Forest, Germany. The lecture notes have been adjusted to 13 lectures, a chapter for each day with additional exercises in Chapter 6 and Open Problems in Chapter 7.

The chapter on Markov Bases gives statistical tests for contingency table analysis and explains the notion of the model of independence and a special case, the hierarchical model between two variables as well as the well-known Metropolis–Hastings algorithm. A subsequent section introduces the class of hierarchical log-linear models and describes information about their Markov bases. Here the Markov basis is studied in more combinatorial and algebraic detail with the investigation of relationships between Markov bases and other classical bases of an integral lattice, like Gröbner basis or Graver basis.

Chapter 2 is devoted to algebraic aspects of maximum likelihood estimation and likelihood ratio tests. The authors use algebraic statistical models for discrete and normal random variables and explain how to solve the likelihood equations parametrically and implicitly. They also connect model geometry to asymptotics of likelihood ratio statistics. In the case of decomposable models they use a junction tree.

The chapter on Conditional Independence is an algebraic study of conditional independence structures. The authors introduce these generally and then focus on the class of graphical models (conditional independence models defined by graphs), namely three models: undirected graphical models known as Markov random fields, direct graphical models also known as Bayesian networks, and chain graph models. The main results are an algebraic exploration of the Hammersley–Clifford theorem and the recursive factorization theorem, whose graphical presentations were also used, for example, undirected graphs, chain graphs with different number of chain components, and directed acyclic graphs.

The chapter on Hidden Variables describes specific instances of hidden variable models and their geometric structure. The first section is about secant varieties, a special case of hidden variable models. Statistical models presented here are for discrete random variables. In the second section, hidden variables termed factors and the factor analysis are discussed with an example using Gaussian variables. Graphs are presented with each example, for example, directed acyclic graphs for the factor analysis model or the Verma graph, bifurcation three, etc.

The chapter entitled Bayesian Integrals shows the applicability of the algebraic methods in seeking to integrate the likelihood function. This chapter discusses asymptotics of Bayesian integrals for large sample sizes and different information criteria, for example, the Akaike information criterion. The authors use the Newton diagram for graphical presentation. And the subsequent section is about the exact evaluation of integrals for small sample sizes.

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Bias and Causation: Models and Judgment for Valid Comparisons, by Herbert I. WEISBERG, Hoboken: Wiley, 2010, ISBN 978-0-470-28639-5, xi + 348 pp., $99.95.

It is a statistical truism that statistical correlation does not imply causation. Both the author and I agree with this. In fact, it is my opinion that statistical analysis can provide little if any help with causal analysis. In this very interesting and important book, the author shows us what prevents our making causal statements and what we might be able to do about this; note, however, that almost all the things we might be able to do are nontechnical in the sense that they must happen prior to analyzing the data. Note also that this book won the 2010 PROSE award in Mathematics; see *http://www.proseawards.com/* (accessed on 25 March 2011).

There are 11 chapters, a Glossary (very important), a Bibliography and an Index. The first chapter introduces the problem and provides brief summaries of six real-world examples used in the early and late chapters (but unfortunately