Reviews of Books and Other Media. Note to publishers: Send review copies of books, films, tapes, and software to RESPIRATORY CARE, 600 Ninth Avenue, Suite 702, Seattle WA 98104.

Books, Films, Tapes, & Software

Clinical Evaluation of Medical Devices: Principles and Case Studies, 2nd edition. Karen M Becker PhD and John J Whyte MD MPH, editors. Totowa, New Jersey: Humana Press. 2006. Hard cover, illustrated, 346 pages, $145.

In our day-to-day working lives we are in contact with medical devices constantly. What might you do if you had an idea for a new or remodeled device that could improve care, cost, or outcomes for patients? How can you develop the idea? The 2nd edition of **Clinical Evaluation of Medical Devices: Principles and Case Studies** is likely to be of value to therapists, technicians, physicians, and nurses who are curious and inventive. The book is divided into 2 parts: the first part is on principles, and the second part gives case studies to highlight selected topics. You will want this book if you have ideas at present or want to understand the process. At least remember this reference for when that lightning-bolt of creativity strikes. Those preparing for or working on the development or clinical evaluation of a device will certainly find this book of value.

It is estimated that 20–25 million people in the United States have an implanted medical device. This book is based primarily on experiences with cardiac devices. None of the cases studies or examples are in the field of respiratory care or lung devices, but the principles apply to respiratory devices. The stated audience is clinical professionals and regulatory specialists in medical-device development and marketing. The book achieves that goal and more. The authors bring experience from academic, industry, legal, and consulting perspectives. This combination plays well to the complexities of device regulations, clinical trials, intellectual property, and biostatistics.

The first chapter is a good overview of clinical trial design and monitoring; it includes informative comparisons between device and drug regulations and development. Device development faces unique challenges, including the influence "by the skill and discretion of the user, who is typically a health-care professional but may be the patient." In contrast to new drugs, most new devices are developed by small rather than large companies, and devices undergo frequent incremental changes that drugs do not. This chapter could have more information and guidance on adverse events and how investigators and adjudication committees should rate severity and relationship to procedures or devices.

The second chapter describes the laws and regulations that govern clinical studies. I was initially distracted by a few typographical errors, but the chapter is comprehensive and valuable for both its content and the 194 references included. Anyone starting in this field should review this chapter, which covers the differences between significant and nonsignificant risk devices. The chapter would benefit from a section on humanitarian device exemptions; the only mention of humanitarian-use device status is on page 164, as part of combination products.

The third chapter is new to this edition and speaks to the importance of reimbursement, especially by Medicare, to the success of a new device. Regional Medicare coverage is also highlighted in Chapter 15, which is loaded with acronyms (eg, LCD is not a TV) and jargon, but very informative. The largest hurdle for a new device used to be obtaining safety and effectiveness data for the Food and Drug Administration, but that hurdle is now overshadowed by the need to show necessity and benefit for Medicare beneficiaries. A Medicare noncoverage decision dooms a device, since most other insurance carriers follow Medicare's lead. Adding to the challenge of showing necessity and benefit is uncertainty about what those terms mean. "It has been more than 15 years since the Centers for Medicare and Medicaid Services first attempted to publish their criteria for making coverage decisions," and they have gone beyond the statutory language in applying cost considerations to coverage decisions. Chapter 3 includes information on payment and coding systems and includes 113 references. Reimbursement is also addressed in a case study in Chapter 16 about a bone-healing device and the lessons learned on the path to reimbursement.

Chapter 4 and the case studies in Chapter 17 address the post-market requirements for surveillance. Some devices are mandated to be tracked and reported on after market approval. The case examples are interesting and make the wisdom of surveillance apparent. The examples are about new types of device failure that were not known or anticipated. One example is that clavicles crushed pacemaker leads against the first rib when subclavian venous access began.

Chapters 5 and 14 relate to Bayesian methods for device trials and imputing missing data. This is a new topic for this 2nd edition and reflects the growth of this methodology. These chapters are great for those who like mathematics and formulas, but everyone involved in the design, execution, and evaluation of results of clinical trials will need some understanding of these methods.

Chapter 6 is very important for considering a new idea and whether it can be patented. Patents are part of intellectual property law and a key factor for success of a start-up company with a new device. This chapter can help avoid missteps along this path. The chapter includes guidance on foreign patents.

Chapter 7 is about compliance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA).

Chapter 8, "Overview of Medicare Coverage of Clinical Trials," is short, because President Clinton issued an executive order in June 2000 that authorized Medicare coverage for clinical trial participants. However, the Centers for Medicare and Medicaid Services still "intends to implement a process. . . although a process has not been formalized." The author nicely summarizes important information for planning trials.

Chapter 9 is very timely and important; it concerns drug-and-device combinations. The experience from the development of drug-eluting coronary stents is opening avenues for many new approaches. The first concluding sentence is forward-looking; it states that combination products "will bring therapeutic solutions to many unmet medical needs."

Chapter 10 (which is the last before the case studies) was my favorite to read. It offers a Wall Street perspective. I learned about moats, disruptive technology, and the Babe Ruth effect. The product life cycle and other ways investors view medical devices are explained in a fun-to-read style.

Chapters 11 and 12 are important if you are involved in study design. Chapter 11 uses the experience with the left-ventricular-assist device to provide detail on studies without a concurrent control and sham procedure. They also describe their use of a gatekeeper for reviewing eligibility in their trial. Chapter 12 addresses the ethics of sham procedures, "when the benefits derived from the study outweigh the risks from exposure to the sham procedure."

In Chapter 18 an eminent pathologist enlightens us on the detailed examinations possible for devices. His research work is on heart valves and how the study of failed artificial valves benefited understanding of valve design. I suggest that future editions include some guidance on how this experience can be generalized to other devices and fields.

I enjoyed reading this book and I learned new information. Many pulmonary devices are in development or clinical evaluation, and this book will help respirologists learn from other fields. Coronary devices created the field of interventional cardiology several decades ago, and bronchial devices may give interventional pulmonology similar growth in the coming years.

Steven C Springmeyer MD
Spiration Inc
Redmond, Washington
and
Department of Medicine
University of Washington
Seattle, Washington

Spiration Inc is developing a bronchial device. The author of this review reports no other conflicts of interest.

Study Design and Statistical Analysis: A Practical Guide for Clinicians. Mitchell H Katz. Cambridge United Kingdom: Cambridge University Press. 2006. Soft cover, illustrated, 188 pages, $39.99.

As a developing medical writer, I spent considerable time learning what I wanted to know about biostatistics—without drowning in what I didn't want to know. Years later, as one who now teaches how to interpret and report statistics, I know my frustration is shared by more than a few students and health-care professionals. The sad truth is that most people are leery of studying statistics, and those who teach the topic are not always skilled in doing so, especially to those who do not aspire to be statisticians. Thus, it was a pleasure to read Mitchell Katz's **Study Design and Statistical Analysis: A Practical Guide for Clinicians**. The author has a keen sense of audience, which by itself is an endorsement of the book. In addition, he presents an excellent overview of a difficult topic, by organizing the material in a familiar way and by explaining the concepts in familiar terms. As a result, I recommend this book highly to those looking for an introduction to clinical research and statistical analysis.

The author is well qualified to write this book. He is a Clinical Professor of Medicine, Epidemiology, and Biostatistics at the University of California, San Francisco, and the Director of the San Francisco Department of Public Health, as well as an attending physician at San Francisco General Hospital. He is clearly knowledgeable about the topic from personal experience and obviously comfortable with writing about it.

Although the book's subtitle indicates that the target audience is clinicians, this book should be valuable for anyone who wants an introduction to clinical research. In particular, the book will be appreciated by university students and professionals in the fields of health and clinical medicine, especially those who need to understand the medical literature or who are considering careers in some aspect of clinical research.

The book is primarily an overview of research, but it might also be used as a guide to planning research. Although the author does not explicitly recommend that new investigators consult with a statistician before beginning their research (an almost universal recommendation among seasoned researchers), I believe he did not intend this book to be their only guide to research. In fact, the book should help new investigators ask the right questions of statisticians and help them put the statistician's responses into perspective. Also, despite being relatively short (180 pages), the book will serve as a reference for some time to come; the underlying principles of clinical research and statistical analysis are not likely to change markedly in the next several years.

The book's 12 chapters are organized chronologically, around the steps in planning, conducting, interpreting, and publishing clinical research. Most of the chapters are 13 or 14 pages long, though the chapters on research designs (Chapter 2) and bivariate analysis (Chapter 5) are understandably longer, at 30 and 54 pages, respectively. The longer chapters do not detract from the flow of the book, however, despite addressing broader topics.

The Introduction (Chapter 1) establishes the value of statistics, with both the standard coin-toss examples and examples from clinical medicine. In fact, the clinical examples throughout the book are well-chosen and keep the discussion focused on practical applications.

Chapter 2, on choosing a research question and a study design, does a nice job of explaining the characteristics of a good research question and the need to address the question with an appropriate research design. The major observational and experimental designs are nicely described and are discussed in the context of the need to control for error, confounding, and bias—concepts nicely summarized in this chapter.

Often unaddressed in introductory books on statistics is the art and science of data management. Chapter 3 offers sound advice on this important aspect of research and reflects the author's hands-on expertise in conducting research.

Chapters 4, 5, and 6 contain most of the information on statistical analyses. With the intimidating titles of "Univariate Statistics," "Bivariate Statistics," and "Multivariable Statistics," these chapters are organized in the conventional way—that is, from the perspective of the field of statistics, rather than from that of an audience unfamiliar with the field. My only criticism of the book is this conventional approach, which is nearly universal in the field. One could argue that readers need to see the terminology and concepts of the field if they are to learn them, but my experience is that too much too soon is *the* major problem in teaching statistics. Headings such as "How do I test an association between a dichotomous variable with an interval variable?" will empty a lecture hall in record time. That said, readers who push through their fear will find these chapters readily understandable, and, I think, will be able to appreciate the underlying elegance of statistics.

These chapters, then, describe how to summarize data sets (a topic called descriptive statistics, Chapter 4); how to test for associations and differences between 2 variables (Chapter 5), and how to predict the value of a response variable from the values of 2 or more explanatory variables (multiple linear, multiple logistic, and Cox proportional hazards regression analyses, Chapter 6). Through simple, worked examples, readers are taken through the calculation of

The purpose of Clinical Evaluation of Medical Devices: Principles and Case Studies, Second Edition is to provide an updated and expanded presentation of the scientific methods and regulatory requirements applied to the study of new significant risk medical devices. The text now includes (1) new information on the requirements and process for gaining reimbursement of new products from Medicare and private insurers, with case studies of research specifically designed for this p- pose as well as health care technology assessment methods; (2) infor- tion on new statistical methodologies applied to