BOOK REVIEWS

Melanie J. Rantucci, *Pharmacists Talking with Patients: A Guide to Patient Counseling*. Baltimore, MD: Williams & Wilkins, 1997. viii + 262 pp. $28.95 (paperback).

The pharmaceutical care movement is challenging pharmacists to incorporate individualized medication counseling into their daily pharmacy practice. Given the relentless economic and time pressures facing pharmacists today, this is not easily done. *Pharmacists Talking with Patients: A Guide to Patient Counseling* offers a useful resource for pharmacy students and practitioners interested in patient consultation.

The book is organized into nine chapters. The first two chapters provide a context for the rest of the book's discussion of patient consultation. The first offers the benefits of consultation to both the pharmacist and patient, providing statistics on noncompliance, adverse drug reactions, and unneeded hospitalization. The second chapter distinguishes patient counseling from patient education and lays out a theme of the helping process in which the patient is active and at the center of the counseling process. Chapters 3 and 4 help the reader understand patients needs, wishes, and preferences and how these factors can translate into patient noncompliance. Implications for pharmacist interventions are discussed.

A strength of this book is its effort to deal concretely with individualizing the interaction for each patient. Rantucci stresses that the model pharmacist is not a rolling pamphlet covering the same checklist of topics with each patient. Rather, she suggests that the

model pharmacist assesses and adapts consultation to each patient's unique needs. In Chapter 5, a flowchart for patient counseling reinforces the decision-tree nature of the pharmacist's interaction with a patient. Assessment becomes a critical task for effective consultation, and this chapter provides a useful background on medication history-taking. Chapter 6 offers educational methods and counseling aids. While more detail could have been provided, the chapter does include medication charts and reminder cards along with a formula for evaluating the reading level of written patient education materials. Chapter 7 provides more information on communication skills, applied to interprofessional communication, as well as patient consultations. Helpful topics include telephone communication and assertiveness skills.

Chapter 8 identifies factors to be considered in tailoring counseling and provides concrete examples of difficult situations. To underscore the need to tailor interactions, the chapter discusses characteristics of patients, conditions, drugs, and situations and how these influence an interaction. Although the chapter addresses a range of counseling situations such as counseling the elderly, disabled, individuals with poor language comprehension, or those with difficult health conditions, it would have been helpful for more specific, in-depth information on each of these topics. However, the chapter offers tips and underscores the message that pharmacists must tailor their interaction to the patient's unique situation.

One of the most difficult challenges facing pharmacists today is that workflow, delegation of responsibilities among support and professional staff, and the actual pharmacy space of most pharmacy worksites often are not designed to support patient consultation. Chapter 9 makes an important contribution as it attempts to identify and address the most significant barriers to expanded patient consultation by pharmacists. Rantucci suggests changes in pharmacy layouts, outlines the complementary roles of support and professional staff, explains the helping process approach toward consultation, and offers guidance on creating the needed atmosphere, acknowledging just how difficult role expansion is and offering strategies to reduce known barriers.

A strength of this book is its effort to expand readers' resources through three appendices. The first appendix lists resources for

further study of communication and patient counseling as well as resources that pharmacists can provide to patients. The second appendix offers sample dialogues as guidelines of interactions. The last appendix offers a few examples of documentation forms for patient counseling and medication history-taking.

In closing, the book accomplishes its goal of providing an overview of patient counseling to be used in conjunction with more comprehensive training. It moves beyond prior books in this area by focusing so consistently on the need to assess and adapt consultation to a patient's unique needs, with specific examples of how to translate this ideal into actual practice.

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Barry Bleidt and Michael Montagne, eds., *Clinical Research in Pharmaceutical Development* (No. 75 in the Drugs and the Pharmaceutical Sciences Series). New York, Basel, Hong Kong: Marcel Dekker, Inc., 1996. xiv + 360 pp., $135 (hardcover).

Clinical Research in Pharmaceutical Development is a text designed for those interested in the use of drugs in clinical research. The authors of individual chapters have various backgrounds including the pharmaceutical industry, government agencies, clinical medicine, and academia, resulting in considerable topical overlap among some chapters. Rather than being redundant, however, this presentation style offers a view of material from several perspectives and also affords the opportunity to use selected chapters independently.

The text is divided into five parts. Part 1 is introductory and also offers an extensive list of Federal Clinical Research Regulation citations. This wealth of information includes guidelines for such topics as contract research organizations, foreign clinical studies, obligations of sponsors, and IND annual and progress reports. A second table lists 35 guidelines available for clinical evaluation of

drugs. Examples include general considerations for the clinical evaluation of heart failure drugs, gastric secretory depressant drugs, psychoactive drugs in children, and controlled-release products. Also included are manuals which the authors recommend for researchers, relevant addresses and CD-ROM sources of information; no Internet information is included.

The second section of *Clinical Research in Pharmaceutical Development* features a narrative by Albert Hoffman, a prominent figure in the early years of pharmaceutical development. His first-hand account of his many discoveries–including LSD-25–is fascinating reading and especially interesting to the historians among us.

Part 3 begins with a brief history of clinical research in pharmaceutical development from the early 1900s to the present. The authors describe how current clinical research has evolved into a scientifically sound process, offering a societal perspective on the institutionalization of drug development and the political and technical influences which affect it. This is followed by an overview of the preclinical testing process and an explanation of the four phases of clinical trials. The drug approval process is described in depth, with particular emphasis given to protection of human subjects and FDA regulations. Of particular note are thorough discussions of treatment INDs and international consensus statements of good clinical practice, which are essential to foreign collaborative studies.

The fourth section encompasses some specifics of the clinical drug evaluation process. Included is an overview of pharmacokinetics as applied to phase 1 trials. This section highlights major physiologic processes and pharmacokinetics properties of drugs in humans. It also identifies potential sources of data variability or error and describes how to plan and implement a clinical research protocol. The material has been visited previously, but is covered in significantly greater detail here. It provides a blueprint for an entire project and includes such information as how to write a research protocol, how to use case report forms, U.S. codes concerning informed consent of human subjects, and IRBs. Also included are sample case report forms, randomization visit forms, and follow-up visit forms.

Perhaps the finest chapter in the book is William McGhan's discussion of pharmacoeconomics and quality of life: McGhan's introduction to the techniques of measuring costs and benefits and cost-effectiveness is clear and eminently applicable to pharmaceutical development. He discusses quality of life and patient decisions and carefully outlines confounders and sources of error in assessing these factors. He also provides a discerning discussion of the costs of iatrogenic disease attributable to medication use.

The final section of the text addresses the social and legal aspects of drug development. The authors of the chapter on marketing discuss the multifaceted function of pharmaceutical marketing and the substantial role that marketing should play during each step of the drug development and postmarketing periods followed by an in-depth discussion on ethics in clinical drug research. This thoughtfully written contribution describes basic ethical and moral principles as they relate to drug studies. Traditionally sensitive issues are raised, such as the ethics of drug testing in children, women, prisoners, and the mentally incompetent. Other extremely relevant topics include the ethics of funding trials, the use of placebos, and circumstances under which a clinical trial should be abandoned.

This last portion of the book also includes a practical view of the legal aspects of drug development and clinical trials. These are legally demanding processes, and the authors highlight the critical junctures that generally raise difficult legal issues, including types of lawsuits and restrictions on various forms of pharmaceutical advertising. This material is especially well-written and the numerous examples provided add both clarification and interest. The book concludes with a discussion of the impact of patient compliance on clinical trials, intention to treat analysis, and generalization of data in light of compliance issues.

Clinical Research in Pharmaceutical Development will be useful to a wide variety of readers and students. The material is generally introductory in nature and covers a very broad scope of topics. In light of this, it might be useful early in a curriculum. Because some of the material is highly technical in nature, however, the language and concepts involved might exceed the grasp of beginning students. In contrast, the material is not sufficiently detailed to lend

additional utility to advanced students. Some chapters would enhance management and history coursework, and the compiled citations would be useful to anyone beginning a research program. The best curricular fit of all might well be in a Bachelor of Science in Pharmaceutical Science program. Here, the broad base would be appropriate and the level of technicality exactly right.

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