# Elements of Clinical Research in Psychiatry

by James E. Mitchell, M.D.; Ross D. Crosby, Ph.D.; Stephen A. Wonderlich, Ph.D.; and David E. Adson, M.D. American Psychiatric Press, Washington, D.C., 2000, 207 pages, \$34.50.

This book meets its goal to provide the basic guidelines needed by those planning or already conducting clinical psychiatric research. Moreover, the authors have successfully met the hopes stated modestly in their introduction. They have "communicated a sense of genuine enthusiasm for clinical research and a sense of enjoyment in what we do... because we believe it is important, and we hope that we can contribute to the welfare of psychiatric patients" (p. ix).

This short presentation of the elements of clinical research is remarkably comprehensive. Its 12 chapters, each of which is only 10 to 15 pages, are logically arranged and cover a remarkable number of topics. They begin with a brief discussion, "Careers in Clinical Mental Health Research," and then present basic material about clinical research in 3 succinct, clearly written chapters—"Research Design," "Measurement," and "Assessment"—that are followed by 2 outstanding chapters on statistics, one, "Descriptive Statistics," and the other, "Inferential Statistics," which even includes a short explanatory section on principles of hypothesis testing. Just those 5 chapters, beginning with "Research Design" and ending with "Inferential Statistics," are short, explicit presentations of many of the essentials of clinical research that are well worth the modest price of this book and the time devoted to reading them. They are sufficiently elementary to be of practical assistance to beginning researchers and also are so well presented that they are an interesting review for the more experienced.

This book also includes the chapters "Research Support" and "Use of Human Subjects in Research," with words of wisdom about working with and learning from institutional review boards. The chapter "Ethics and Misconduct" discusses practical ethical concerns, illustrated by ethical scenarios, and also lists a spectrum of ethical offenses that range from the more minor, such as fragmentation or dividing the data into "least publishable units" in the hope that a number of articles about it can be published, to the very serious, if not malignant, offenses such as plagiarism and even fabrication.

The last 3 chapters will be especially helpful to beginning investigators. They are: "Writing Journal Articles," "Reviewing Journal Articles," and "Scientific Presentations." Also, the 7 appendices deserve special attention. They include the important "Nuremberg Code," "The World Medical Association Declaration of Helsinki," listings of frequently used research questionnaires and scales, and a great deal of useful information about the National Institutes of Health (NIH), research applications, the grant review process, and, as an added bonus, the telephone numbers of NIH offices from which researchers can obtain meaningful advice and assistance about a grant application for proposed research.

As can be seen, I regard Dr. Mitchell and his colleagues' book as more than meeting the aims stated explicitly in its introduction and implicitly by its title. It is an excellent "must buy" for those embarking on clinical research and a refreshing review for experienced researchers, even for those of us who have been doing research for 4 decades or more. Highly recommended!

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# Medicolegal Issues in Clinical Practice: A Primer for the Legally Challenged

by Deborah J. Wear-Finkle, M.D., M.P.A. Rapid Psychler Press, Port Huron, Mich., 2000, 244 pages, \$32.95.

The increase in the number of medical malpractice cases and arrival of managed care have placed many physicians in the position of needing to learn more about the law as it applies to medical practice. For a substantial number of physicians, this is an uncomfortable position that can only be remedied by reading about material that they generally find distasteful and anxiety provoking, often written by either lawyers or forensic psychiatrists. As a result, these texts tend to go into overwhelming detail and specificity, often concentrating on areas that are of limited utility to the average clinician. Few authors have attempted to present primers that provide the basics for all physicians. It is precisely this niche that Dr. Wear-Finkle aims to fill.

The author calls upon her experience as an internist turned psychiatrist turned administrator to put together a usable primer. While one may or may not appreciate her sense of humor or penchant for abbreviations, she writes clearly, delivering practical messages in an accessible manner that is punctuated by comic illustrations and a casual font. The book is surprisingly easy to read considering the subject matter and is also fairly well packed with useful information. The table of contents is particularly useful for locating various legal concepts without appearing dizzyingly encyclopedic. The book is well referenced and contains a useful glossary and listing of resources.

The author opens by reviewing data on the increase in lawsuits since the 1960s and explores some of the causes and highrisk areas. She then gives a brief overview on legal basics, such as the sources of law and elements of medical malpractice litigation. An excellent discussion of risk management follows, leading into clinical issues and the doctor-patient relationship as well as discussions of informed consent, patient rights, confidentiality and privilege, and boundary issues.

The author then provides strategies for limiting liability and dealing with managed care, difficult patients, and regulatory agencies. She somehow manages to breathe a little life into the latter topic, which has historically been one of the more tedious

for most physicians. Next, she explores the operational organization of medical care facilities and provides a carefully conceived but succinct review of key issues in the risk management of various medical specialties.

In the end, Dr. Wear-Finkle succeeds in producing a readable introductory text on key legal issues in clinical practice. As promised, she has authored a book that is both a useful review for those with advanced knowledge bases and an understandable primer for physicians yet to be exposed to these issues. This book is thus useful to all practitioners at various stages of knowledge and training and belongs on the clinician's office bookshelf. I would particularly recommend this text be utilized for courses in medical school and residency training; I doubt few if any physicians will ever outgrow it, as is so often the case with other introductory texts.

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#### Textbook of Pain, 4th ed.

edited by Patrick D. Wall, F.R.S., D.M., F.R.C.P., and Ronald Melzack, O.C., F.R.S.C., Ph.D. Churchill Livingstone, Edinburgh, Scotland, 1999, reprinted 2000, 1588 pages, \$265.00.

In the previous (3rd) edition of the *Textbook of Pain*, published in 1994, Patrick Wall wrote an "Introduction to the Edition After This One," in which he took psychiatrists to task for their "silence," or lack of interest in patients with pain. He was absolutely right then, but, hopefully, times are changing. By now, we all believe in the biopsychosocial model, and few conditions put together all facets of medicine and psychology so manifestly as chronic pain. In increasing numbers, psychiatric patients have comorbid pain problems, and pain patients have confounding psychological or behavioral issues. Indeed, pain management recently became an official subspecialty of psychiatry, with certification offered by the American Board of Psychiatry and Neurology.

Although the price may deter most psychiatrists from owning a personal copy, the *Textbook of Pain*, edited by noted algologists Patrick Wall and Ronald Melzack, is an excellent reference source when the psychiatrist needs to learn about the many complex areas of pain. Do you want to know about the effectiveness of antidepressants or other adjunctive medications in chronic pain? This literature is cogently reviewed in chapter 50. Do you wonder whether epidural injections may be the answer for your chronic back pain patient, or will these just support his contention that he is disabled? In chapter 52 you will discover that of 13 patients receiving such epidurals, only 1 is likely to obtain long-term relief.

The *Textbook of Pain* is not only updated from the previous edition, but also improved in several respects. The cover is far more appealing, the quality of the paper much better, and the enhanced visual presentation of the text makes it much more readable. The frequent use of headings and subheadings throughout all the chapters contributes to coherence throughout, making it easy to navigate within and between chapters. The tables and figures are comprehendible and quite useful. References are numerous, pertinent, and up to date for most chapters.

The book has 68 chapters divided into 3 sections: "Basic Aspects," "Clinical States," and "Therapeutic Aspects." Each section is divided into several subsections. The first section includes several superb chapters on the physiology and anatomy

of pain pathways. It also includes extensive reviews of measurement issues, particularly useful for the researcher. Two chapters review the psychology of pain. In Section 2, most of the 29 chapters on various clinical conditions include pertinent psychiatric issues, at least briefly, with varying degrees of sophistication. Chapter 40 is an excellent review of psychooncology. The last section includes 3 chapters under the heading "Psychotherapy." Two of these discuss cognitive and behavioral strategies. The third, which does not really involve psychotherapy directly, is an extremely valuable chapter titled "The Placebo and the Placebo Response" by Patrick Wall. He skillfully reviews the literature and presents a cogent theory that avoids mind-body dualism and is relevant to the response of patients to treatments of any type.

In a multiauthored text, chapters may be conflicting or even contradictory. Dr. Wall notes the presence of this conflict in his introduction and indicates that no attempt was made to unify the concepts, giving the reader the opportunity to select from among various views—a wise choice since pain involves many controversial issues, and the conflicting opinions reflect the state of the field.

Some areas of importance to the psychiatrist are not well covered in the book. These include the diagnosis and treatment of somatoform pain disorders, the impact of compensation and litigation, working with families of pain patients, and working in a multidisciplinary setting. Another missing area is the psychology of giving and receiving medication, including issues of detoxification when managing the chronic pain patient for whom opioids and sedatives create more problems than they solve.

Overall, this is a rich volume that fulfills the promise of its title.

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# Handbook of Headache

by Randolph W. Evans, M.D., and Ninan T. Mathew, M.D. Lippincott Williams & Wilkins, Philadelphia, Pa., 2000, 352 pages, \$36.95 (paper).

Most dictionaries define a "handbook" as a manual or reference book that is usually small enough to be carried in the hand and gives concise information about a particular subject or place. This handbook achieves just that. It is a very comprehensive text intended for primary care physicians but will be of interest to neurologists and, indeed, anyone dealing with headache patients. It is well organized and informative and is divided into 16 chapters packed with practical knowledge.

The book opens with a general approach to the diagnosis of headache. It then discusses different categories such as migraine, tension-type, chronic daily, cluster, first or worst, and posttraumatic headaches. Chapters follow on different groups affected by headaches, including children, adolescents, women, and those over 50 years of age. Secondary headaches, shortlasting pains, and rarer disorders such as hypnic headache are also reviewed. The last 3 chapters provide a nice finishing touch: chapter 14, "What's My Headache," contains 39 interactive cases with answers; chapter 15 has "The Headache Quiz"; and chapter 16 contains information on patient resources, educational materials, and alternative treatments.

There are few errors and omissions worth mentioning. In optic neuritis, eye pain is more common than stated; 92% of

patients in the Optic Neuritis Treatment Trial had ocular or periocular pain, most (87%) during eye movement.<sup>1</sup> Pituitary apoplexy is abrupt by definition; how can it be chronic? There are more causes of a painful white eye than listed in Table 12-6, e.g., Adie's myotonic pupil, ciliary spasm, some corneal disorders, frontal lobe hemorrhage, greater occipital neuralgia, hemicrania continua and pre- or non-eruptive herpes zoster ophthalmicus, and so on.

The publication of the *Handbook of Headache* is opportune because, as the authors state in the preface, this is an exciting time for physicians and headache sufferers as new diagnostic approaches and treatments are becoming available.

I found this a very useful and enlightening text and strongly recommend it to residents, primary care physicians, internists, and neurologists, indeed all dealing with headache sufferers.

#### REFERENCE

 Optic Neuritis Study Group. The clinical profile of optic neuritis: experience of the Optic Neuritis Treatment Trial. Arch Ophthalmol 1991;109:1673–1678

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# Ethics, Culture, and Society: International Perspectives

edited by Ahmed Okasha, M.D., F.R.C.P.; Julio Arboleda-Flórez; and Norman Sartorius, M.D., Ph.D American Psychiatric Press, Washington, D.C., 2000, 227 pages, \$29.95 (paper).

This book is a response to the Declaration of Madrid, a set of international guidelines about ethical behavior in the practice of psychiatry worldwide. The Declaration was passed by the World Psychiatric Association (WPA) in August 1996. One of the questions raised by the authors is whether such guidelines can be considered absolute across the world or whether they will be valid only to the extent that they are consistent with the cultures in which they are applied.

The book consists of a thoughtful introductory chapter on issues related to international psychiatric ethics and the Declaration by Norman Sartorius, M.D., well known as a leader in international psychiatry at both the World Health Organization and the WPA. Nine essays follow, which are written by experts invited to contribute by the editors. In addition, 3 essays on overarching issues are included. These address research on incompetent patients, informed consent, and an international perspective on mental health law reform.

The Declaration of Madrid is included as a useful appendix. It addresses 7 basic issues: quality treatment, maintaining scientific psychiatric knowledge, accepting patients as partners and allowing them to make free and informed decisions, protecting the rights and dignity of incompetent patients, informing patients about the pros and cons of treatment, confidentiality, and ethical standards in research. Notations are also made on 5 special situations: euthanasia, torture, the death penalty, sex selection, and organ transplantation. Interestingly, the issue of personal relationships with patients, particularly sexual liaisons, is not addressed by the Declaration or the book.

The Sartorius chapter is an excellent introduction to the basic questions involved in the efforts to create and implement an international set of ethical principles in psychiatry. Two ques-

tions are posed: Can there be one set of ethical rules, and if so, what should be done to assure that psychiatrists will contribute to good versus evil? Implementation of guidelines is considered to be critical, and at least 2 decades are required for a strategy "to become a self-evident way of proceeding."

The invited chapters on ethics and psychiatric practice in different countries vary greatly in their breadth and depth and in the degree to which they address ethical issues in psychiatry. However, taken as a whole, they raise many interesting and potentially conflicting views of the world and psychiatric ethics: the impact of religion and culture vs. psychiatric medicine, family/social rights vs. individual autonomy, subjective/ personal ethics vs. social standards, traditional healers vs. psychiatric physicians, treatment as a favor vs. a right, availability of complete ranges of psychiatric service vs. limited largely hospital-based care, full disclosure vs. keeping negative information from patients, psychiatrists' use of authority vs. partnership, external vs. internal causes of illness, and culturally unique illnesses and stigma. Although some of the essays are more descriptive of mental health systems and cultural mental illnesses than psychiatric ethics, the discussions provide substantial food for thought as to how a universal code of psychiatric ethics could work in countries with strong cultural traditions related to mental illness and mental health care.

The chapter "Culture and Ethics of Managed Care in the United States" by Renato D. Alarcon, M.D., M.P.H., is an excellent overview. It points out the challenge of balancing the needs of managed care organizations and patients, and effectively discusses the roles of the media, DSM-IV, and advocates in the psychiatric managed care world. It outlines clearly the ethical challenges of double agentry, fidelity to principles, confidentiality, informed consent, honesty, and vulnerability of services.

The essays on the overarching issues are useful discussions of research on incompetent mental patients and informed consent from the German mental health system perspective. The discussion of law reform is broadly based and addresses universal issues of past abuses of patients through involuntary hospitalization and current issues such as dangerousness, patient autonomy vs. need for care, and closures of psychiatric hospitals when little care is available in the community.

A summary chapter would have been useful, given the disparate information that is presented, but this is a book that will be food for thought as international ethics in psychiatric practice is debated in the future.

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### The Science of Marijuana

by Leslie L. Iversen, Ph.D. Oxford University Press, New York, N.Y., 2000, 304 pages, \$29.95.

Since research is relatively sparse on the pharmacology of marijuana compared with other psychotropic drugs, books about marijuana often present opinions rather than data. Dr. Leslie L. Iversen, one of the world's leading neuropsychopharmacologists, has now written a superb, scientific summary on marijuana, with the stated goal to describe "what is known about how marijuana acts in the brain, and to compare the profile of marijuana with other drugs that are used because of their euphoriant or psychostimulant effects—cocaine, amphetamines, heroin, alcohol, and nicotine." I would like to report

that Dr. Iversen succeeds admirably. *The Science of Marijuana* is a brilliant, clearly written, comprehensive neuroscience volume focused on available research data regarding the effects of marijuana on the brain. One chapter is devoted to the pharmacology of tetrahydrocannabinol (THC; the active ingredient in marijuana), another to the effects of marijuana on the central nervous system, and a third to the potential toxicity of marijuana.

Many readers will be particularly interested in the chapter that reviews the potential medical uses of marijuana. Citing the many anecdotal reports in other volumes written about the potential medical uses of marijuana, Dr. Iversen, in a manner typical of a careful scientist, writes conservatively, comprehensively, but provocatively as well. He notes that almost all reports of the medical usefulness of marijuana are anecdotal and not derived from controlled studies. Those that are the result of scientific scrutiny, however, receive careful attention and positive comments such as the use of marijuana for glaucoma and multiple sclerosis. He is less enthusiastic about the reports of its efficacy for chronic pain or bronchial asthma. In conclusion, Dr. Iversen agrees with the Institute of Medicine report<sup>1</sup> that further study of the medical use of marijuana is important to pursue.

As one might expect from a book written by Dr. Iversen, the pharmacology of marijuana and its active compound THC is the most useful part of this excellent volume. Updated information is provided about the effect of THC as a partial agonist on neurotransmitters, which is likely the most specific pharmacologic effect of THC, as opposed to a less specific effect on nerve cell membranes. In addition, cannabinoids inhibit cyclic adenosine monophosphate, the cannabis receptor that has been identified and mapped in the central nervous system of rats and has been shown to have at least 2 distinct subtypes. A naturally occurring cannabinoid named anandamide is present in the brains of all mammals including man and may have pharmacologic and behavioral properties similar to those of THC. Iversen reviews the physiologic effects of THC and anandamide on cardiovascular and immune system function, sex hormones and reproduction, and pain sensitivity. For readers interested in the neurobiology and pharmacology of these compounds, this chapter alone is worth the price of admission.

Since marijuana is not presently used in clinical practice, this book will be of interest primarily to researchers, academicians, and those who have a special interest in the future medical uses of marijuana. For these readers, *The Science of Marijuana* will provide an exhaustive bibliography and numerous tables and graphs illuminating marijuana's pharmacologic and pharmacodynamic effects on the central nervous system, which are presented clearly and authoritatively. For those who are interested, this volume must be on your shelf.

#### REFERENCE

 Joy JE, Watson SJ, Benson JA Jr, eds, for the Institute of Medicine. Marijuana and Medicine: Assessing the Science Base. Washington, DC: National Academy Press; 1999

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## Psychiatric Services in Jails and Prisons: A Task Force Report of the American Psychiatric Association, 2nd ed.

American Psychiatric Association, Washington, D.C., 2000, 77 pages, \$19.00 (paper).

This is a very short book that should be read by both mental health personnel and general medical staff who work in jails and prisons, psychiatry residents and forensic psychiatry fellows who serve this population, nursing personnel who work in these facilities, mental health and medical administrators, and the sheriffs and wardens who have ultimate responsibility for the psychiatric care in their institutions. This book presents the most basic information, the do's and don'ts, that practitioners should think about in evaluating and treating inmates. It is the second edition of these guidelines, which were first published by the American Psychiatric Association in 1989. The chairman of the task force to revise the guidelines was Henry C. Weinstein, M.D.

The authors list and discuss the most important principles governing the delivery of psychiatric services in jails and prisons, including the issues of access to mental health care and treatment, cultural awareness, informed consent, confidentiality, and suicide prevention. For instance, they discuss the psychiatric aspects of the use of segregation units, which is a euphemism for solitary confinement or "the hole." Inmates are placed in segregation units because of disruptive behaviors, so the authors point out that this recourse should not be used solely because the inmate exhibits the symptoms of a mental illness. Once in segregation housing, the inmate should still have access to regular rounds by a qualified mental health clinician. Regarding ethical issues, the authors emphasize the importance of being clear about the roles of the professionals involved, that ordinarily the same psychiatrist should not both treat inmates and also conduct forensic or administrative evaluations. This book brings together the ethical standards that have been published by the National Commission on Correctional Health Care, the American Psychiatric Association, the American Academy of Psychiatry and the Law, and the American Correctional Health Services Association.

This book is particularly useful in clarifying the various components of psychiatric services in jails and prisons. For instance, the "receiving mental health screening and referral" is a brief screening that takes place immediately upon the detainee's arrival at the facility. The "intake mental health screening and referral" is a more comprehensive examination performed on each newly admitted detainee within 14 days of arrival at the institution. The "brief mental health assessment" is an individualized assessment that is conducted by a mental health professional. A "comprehensive mental health evaluation" is a more complete assessment conducted by a psychiatrist or psychologist. In addition to the general principles and guidelines, the authors address specific situations and populations, such as substance use disorders, HIV and AIDS, female inmates, youth who are in adult correctional facilities, geriatric inmates, and individuals with mental retardation. This book provides concisely what mental health professionals need to know when they work in jails and prisons.

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