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Reviews of books and studies

Rozovsky F.A. Consent to Treatment, A practical guide, second edition, 814 pp. Little, Brown and Company, Boston, Toronto, London.

The doctrine of informed consent has developed, particularly in the United States, from a simple concept to an extremely complex body of law. A few writers may still regard the process of informed consent as a glorious fiction, but the courts have become increasingly clear as to the circumstances and the manner in which consent must be sought and given in health care.

This book, the second edition of which is expanded with chapters on the elderly and on AIDS as well as with much additional case law, is nominally intended as a guide to practitioners. Lawyers will thrive on it; whether it does actually reach the individual doctor seems doubtful, but it should at least be available in every hospital and health centre for reference, for it is an ideal example of how a complex legal topic can be rendered accessible to the non-lawyer. That is partly because of its lucid writing, partly its structure and its very good index. The four main sections deal successively with the concept of consent, the criteria for valid consent, the need for adequate disclosure and the elements of negligent consent litigation. Each of these is structured so logically that merely by scanning the list of contents one can find the point at which the answer to one's question is likely to be sited. The range of topics extends to consent for research as well as treatment, brain death, organ donation, and conscientious objections to treatment (as in the case of the Jehovah's Witnesses). The case material is almost exclusively American, though there is a little English and Canadian Law. The law and ethics of consent do differ a little from country to country, but they are so much more accessible in the United States than elsewhere that Ms Rozovsky's book can be warmly recommended to an international readership, in the disciplines both of medicine and of law.

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Tempelaar A.F., Veiligheid en risico in de gezondheidszorg, Epidemiologische aspecten van iatrogene schade, 115 pp. Styx Publications, Groningen, 1991.

It is a pity that Tempelaar's literature study, an examination of the epidemiology of iatrogenic injury, is so far available only in Dutch. Data on the pattern and extent of the harm done in health care are so scarce that when they are collected and intelligently analyzed the results deserve to be widely known, particularly when the work is so excellently documented both internationally and historically; your reviewer, at least, was not earlier aware of the ancient Roman law on medical injury (*Damnum Injuria Datum per Medicum*).

Tempelaar is cautious with his figures, but he does not hesitate to draw conclusions sufficiently concrete to justify action. Taking, for example, as one measure of medical injury the number of deaths attributable to the acts and omissions of doctors, he concludes that between 4700 and 7900 people die annually in hospitals in The Netherlands as a consequence of "iatrogenic" injury and estimates that half of these are avoidable. To those figures must be added the less drastic consequences of medical injury and the largely undocumented problems arising outside the hospital.

Like other professions, argues Tempelaar, physicians will benefit from a study of their own errors. Those errors comprise not only choosing the wrong therapy or administering it incorrectly but also undertaking the 30% of surgical operations in the U.S.A. which are estimated to be unnecessary and the 15–40% of all X-ray examinations which are believed to be superfluous. Women, it seems clear, run particular risks; Tempelaar's own expression of concern on this score is curiously based on some uncertain estimates as to the over-treatment of mild hypertension in women, but one could add to it the well-established case of benzodiazepine drugging as well as the oestrogen story documented by Ingar Palmlund in this issue of the *Journal*. Drugs are naturally a chapter apart; most of the evidence of drug-induced injury which Tempelaar has gathered is readily accessible elsewhere, but it complements his material on other problems.

This book documents the issue of medical injury better than most, but it only touches on the solutions, e.g. the risk management approach; what one would like to see is a full follow-up account of what has been done worldwide to reduce medical injury, and the extent to which it has been successful. Perhaps Tempelaar, an experienced general practitioner with all the right motives, can be prevailed upon to undertake it.

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Mori W. and Homma S. (Eds) Medical science and health care in the coming century; a report from Japan. Elsevier, Amsterdam, New York and Oxford, 1987.

The English edition of this report on a major interdisciplinary complex of studies funded by the Japanese Ministry of Education, Science and Culture, has for some reason only recently reached reviewers. Its considerable interest for the non-Japanese reader lies in the manner in which it opens a window onto a world which is still poorly understood in the West, namely that of the relationship between physicians, patients and treatment in Japan. However westernized some aspects of medical practice have become, Japan is commonly reputed to have particular problems as regards over-treatment, the dictatorial approach of physicians, and the emergence of some epidemic medically-induced problems virtually unknown elsewhere, such as subacute myelo-optico-neuropathy.

It would be unfair to this book to suggest that it deals only with such problems, but they are necessarily the point of interest in this present review. The authors provide repeated surprises. Some 91% of Japanese medical students, for example, considered as undesirable "the patient requesting only medicine" (p. 104) while 71% of patients declared that they liked "the doctor explaining the patient's disease in detail and giving little medicine to the patient" (ibid). The more nonsensical type of health food, propagated in the west as an oriental wonder, found little following; only 2% of patients interviewed used ginseng. Medical malpractice litigation in Japan is lively and has developed some trends similar to

those in the west, e.g. as regards the standard of care, and while some courts have preferred to found the physician's obligation to the patient in contract rather than in tort, the burden of proof for the patient will usually be as in cases of tort. Interestingly, the Supreme Court has drawn a clear distinction between the standard of proof of injury which natural science would demand and the lower standard of proof ("where a reasonable lay person can feel confident of the truth") which will suffice in civil law.

Essentially, however, the authors of these studies are looking forwards, and they are optimistic. The book concludes that in recent decades patients have become increasingly aware of medical knowledge and human rights, and that health care is not something to be rendered one-sidedly by a doctor but to be carried out cooperatively by both the doctor and patient. That is the trend which it seeks to carry into the future.

One misses exact references in this book for the mass of data and the many references which it provides, but that is an inevitable consequence of the language problem; fortunately the study itself is sufficiently detailed to serve as a primary source of reference. It can be recommended.

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Walker S.R. (Ed.) Creating the right environment for drug discovery, C.M.R. Workshop series. Proceedings of a Workshop held at the Ciba Foundation, Quay Publishing, Lancaster, 1991.

Dinkel R., Horisberger B., Tolo K.W. (Eds) Improved drug safety: a joint responsibility, 338pp, Springer Verlag, Berlin, Heidelberg etc., 1991.

The Centre for Medicines Research is an arm of the Association of the British Pharmaceutical Industry; that can be both a recommendation of its publications, which are always well prepared, and a reason to caution the reader. The caution obviously reflects the unilateral interest of the sponsor; he is hardly likely to tackle a question if the answers which emerge are not expected to be in industry's interests. Sometimes those interests run entirely parallel with those of society as a whole; that was the case with the excellent studies published by CMR to illustrate the limited predictive value of animal safety research in drug discovery. "Creating the right environment for drug discovery" is rather a different story; it is a collection of all the over-familiar dogmas relating to the value of industrial drug research and its formulas for success (unsurprisingly formulated as "strength, stamina, skill, suppleness and stimulation"). There is not a word about the serious weaknesses of the current industrial research process - the vast number of me-too products which still emerge, the high percentage of failures, the many second-rate drugs which (fortunately) have their careers arrested by regulatory agencies. One is left with a memory of large type on glossy paper, spiced by clichés and without a single reference. It reads like an advertising brochure, and that is what it is. It is not one of C.M.R.'s best efforts.

Dinkel et al. have edited a book which is also fully inspired by the pharmaceutical industry but it is simply much, much better. Essentially it is an edited report of an international meeting at Wolfsberg, Switzerland, in April 1990 to advance the cause of drug safety. The strong point of the volume is its painstaking effort to represent every honest point of view and tackle every significant problem, and the presence of an occasional

propagandistic item does not get in the way of that central theme. The book is too extensive to be described simply; essentially it is an excellent tool for the reader who wants to form a view on how drug risks in society can be put into perspective, and how they can be realistically contained through processes ranging from industrial research through the application of medical ethics and regulatory systems through to the proper education and involvement of the patient. The Wolfsberg Meeting is one of the bases on which the international RAD-AR initiative ("Risk/Benefit Assessment of Drugs, Analysis and Response") is being built. It augurs well for the programme's future.

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Sale G.E. (Ed). The pathology of organ transplantation. Butterworths, 327 pp. Boston, London etc., 1990.

Clinical transplantation, as the author of this multi-author volume puts it, is a major new discipline which crosses conventional interdisciplinary boundaries within the basic and clinical sciences. Not only have surgeons, internists and immunologists teamed up to develop and improve techniques, there is also a laudable trend, manifest in this volume, towards cross-contacts between those working in the various fields of transplantation, whether well-established (as in the case of renal and marrow transplants) or adolescent (as with heart, heart-lung, liver and pancreatic transplants). The fact that some of these techniques are already cost-effective means that they are bound to grow rapidly; rendering them progressively safer is now a matter of urgency, and one to which this broad collaboration will contribute. Alongside the basic need to develop the best operative techniques, the major challenges – those of rejection and infection – are after all common to all transplants. Suppression of immune reactivity is a helpful approach to the former problem, but it remains a stopgap approach with its own risks; the ultimate aim, as Wolfgang Muller-Ruchholtz puts it in this book, must be to reprogramme the reactivity repertoire of a graft recipient, and evidence from animal work suggests that this will be attainable in the long run. Drastically reducing the risk of acute infection seems more attainable in the short term; despite the fact that some 38% of cardiac transplant recipients do die from such infections, the essential instruments to solve the problem (i.e., improved technique and antibiotic coverage) are available. The same applies to problems such as that of thrombosis with infarction after pancreatic transplantation.

This is a finely written, illustrated and referenced book. While it is primarily for the specialist in the transplant field, any physician with a patient who is a hesitant candidate for a transplant would do well to browse in it, to obtain a clear idea of the problems and the prospects.

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