BOOK REVIEWS

Data Collection Forms in Clinical Trials. by B Spilker and J Schoenfelder. (Pp 662; \$US112.) New York: Raven Press, 1991. ISBN 0-88167-759-0

My emotions, on receiving this book, having agreed to review it "sight unseen", oscillated from deep depression (it is a VERY LARGE book), to relief at seeing that the actual text for reviewing was relatively quite short, back to depression again that the short text was so verbose and repetitive. Nevertheless, this book does have many strengths.

Most importantly, the authors emphasise the centrality of good data collection forms. As they say: "data are the primary output of a clinical trial [and] the quality of a trial is limited by the quality of the data produced" (page 4). They therefore (rightly) bemoan the fact that such forms are often not given the same care and attention as goes into producing the trial protocol. They offer some guidelines and pointers. Among these is the very sensible suggestion that trialists should not have to "reinvent the wheel" by starting the design of such forms from scratch with each new trial, but see what has already been done and found useful (or useless), and learn the lessons of experience. To this end, the bulk of the book is taken up with good examples of successful forms.

Perhaps one of the most important guidelines is the stress on cooperation and collaboration with the many individuals and groups who may have important insights into the design of forms. These might include clinicians, statisticians, programmers, data processors, and others relevant to a particular trial. Another important emphasis is on the need to pilot such forms before the trial as a whole starts, as it is much more difficult to make changes later.

The first pointer mentioned is "to consider carefully the amount of data to collect" (page 20) in order to protect against both errors of omission (not collecting enough data) and commission (collecting too much). To avoid these errors, the authors suggest categorising data items into those necessary for the statistical analysis addressing the (primary) objectives of the study (which *must* be included on the form); those which are supportive (many of which may be expendable); and those which might potentially be useful depending on the results obtained, ie, the "it would be nice to know" group of questions (which should be excluded). I might want to add to this advice the idea of producing a set of dummy tabulations for the data which should appear in the final report of the trial. This is a wonderful discipline to concentrate the mind on which data items fit into the first category.

Overall, however, the book is disappointing. The text is very repetitive, and many of the most helpful hints are taken (with permission) from the book *Clinical trials: design, conduct and analysis*, by C Meinert and S Tonascia (OUP, 1986). Spilker and Schoenfelder's book seems predominantly aimed at the US audience, and particularly drug company trials.

Some of its strictures are therefore less relevant to those of us involved in large international pragmatic trials of clinical management. However, the library of dataforms is probably unique and should provide a useful reference point for anyone considering designing data collection forms in clinical trials. But the price will deter many from purchasing it.

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Women, Health and Medicine. By Agnes Miles. (Pp 225; £11.99.) Buckingham: Open University Press, 1991. ISBN 0-335-09905-X.

This book provides an extensive review of the literature on women's health and their interactions with health care services. Ms Miles begins with a discussion of the research evidence about possible causes of gender differences in health and illness, and the influences on women's ill health. I would have welcomed more information in this chapter on the role of ethnicity in women's health, but found it otherwise comprehensive. Chapter 2, on concepts of health and illness, provided interesting evidence of the different ways in which men and women define health. In chapter 3, on the experience of sickness, Ms Miles highlights clearly and simply the difficulties of social research in answering questions about, for example, gender differences in illness behaviour, and the methodological problems which beset such concepts as "social support". Her discussion of Talcott-Parson's concept of the sick role and the arguments against it are also clearly presented.

Later chapters in the book look at patterns of interaction between women and health professionals and the medical control of women, in particular in relation to aspects of women's health such as psychiatric problems, reproduction, and child care. There is also a chapter devoted to the research on women as health professionals.

I found the author's discussion, in chapter 4, of stigma and the way it is experienced differently by men and women helpful and enlightening, as was her analysis within this of conditions such as obesity and anorexia. Ms Miles also focused her attention on menstruation, as a condition with stigmatises all women some of the time, rather than some women all of the time. What emerged very clearly for me from reading the book is the way in which firmly held stereotypes about women militate against their health and care. When they are sick, less legitimacy is attached to their illness, either because they consult for female conditions (towards which attitudes are still ambiguous, perhaps because most doctors are still men), or for psychiatric conditions, which are still stigmatising. Women's illnesses are often trivialised or dismissed, and the social, rather than the biological, basis for their ill health ignored. Yet at the same time, women are still seen as the keepers of their family's health, even if neglectful of their own; as the carers, even if not cared for.

Ms Miles has drawn attention to a number of gaps in our knowledge about women's health and the many research questions which remain to be answered. I think this book provides a useful reference point for students, researchers, and health professionals, whether they are women or not.

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Measures of Need and Outcome for Primary Health Care. By David Wilkin, Lesley Hallam, and Marie-Anne Doggett. (Pp 301; £30.) Oxford: OUP, 1991. ISBN 019-261818-0.

The growth of interest in outcome assessment over the last few years has been little short of explosive and therefore well researched guides to the increasingly complex range of measures of need and outcome now on offer are enormously welcome.

This book specifically addresses the problems of outcome measurement in the field of primary health care. As a guide to potential users of measurement instruments it is well structured and clearly set out. Seven of its 11 chapters are devoted to a painstaking appraisal of some 40 established measures selected on the basis of their track record, applicability to primary health care, and ability to demonstrate a range of different approaches to measuring need and outcome.

The measures are grouped under the headings of function, mental illness and mental health, social support, multidimensional measures, disease specific measures, patient satisfaction, and (inevitably) miscellaneous. In each case, the discussion follows an identical format. Firstly the basic purpose of the instrument is described, followed by background information on how it was developed and tested. The structure of the instrument is dealt with next and this includes an illustration of what it actually looks like or, where length or copyright restrictions impose constraints, at the very least a listing of its principal components. Other important attributes discussed include: administration and acceptability; reliability and validity; and appropriate service settings. Finally, the authors conclude with a brief evaluation.

Although they are openly more critical of some instruments than others, the authors explicitly avoid a "best buy" approach, insisting that the final decision to use a particular measure must depend on a wide range of considerations specific to the individual application. Their comments are, however, helpful in making a preliminary selection, as is the detailed list of references supplied for each measure.

The excellent introductory chapters covering basic concepts and methodology should not be overlooked. Although brief, they are packed with useful information. Essential reading for newcomers to the field of outcome measurement, they will also serve as a helpful aide memoire for the more experienced.

In summary, this is an extremely useful and accessible guide for researchers, practitioners, and managers who wish to select

measures of need and outcome for use in a primary health care setting. It is also much more than this. By combining a cogent and well written analysis of a range of established outcome measures with an insistence on a clear conceptual framework it offers an eloquent discourse on the science and purpose of measuring needs and outcomes. I learned a great deal from it.

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Evaluating Health Services' Effectiveness. By A S St Leger, H Schnieden, and J P Walsworth-Bell. (Pp 217; £14.99.) Milton Keynes: Open University Press, 1991. ISBN 0-335-09356-6.

The subject of health services evaluation is curiously lacking a book near to being described as a standard textbook. The interested reader, at all levels, must refer to a range of discipline based texts. The gap in the market is there, but has it been adequately met by Leger and colleagues?

To be fair, the authors do not claim the grandeur of textbook status for their book. It would seem closer to being a "taster" for those involved in decision making (eg, clinicians and managers), commissioning research, and students. The content of the book is extensive, covering a general overview of health services evaluation, routine information sources in the United Kingdom, study design, and methodological issues (mainly statistical and economic), and it has an interesting discussion of the role of health services evaluation in decision making. A serious omission is a reasonably detailed discussion of health status measurement. The material on routine information and quality adjusted life years fail to do this essential subject justice (eg, the Nottingham health profile only gets a mention in the appendix).

A key question is whether this book provides an adequate introduction to the main discipline for health services evaluation and hence at this level avoids reference to other texts. There is very little on the sociological literature. My own discipline of health economics had an entire chapter but has contained unnecessary material on market theory and yet was deficient on the area of prime interest, economic evaluation. I will continue to refer students to journal articles and Drummond's text.

Throughout, the authors succeed in avoiding unnecessary technical language, diagrams, or mathematics. The chapter on methods is especially readable. However, chapters 1 and 2, which introduce health services evaluation, are difficult to read and contain some poor definitions and odd mistakes. As an economist, my sensibilities were upset by the absence of cost in the definition of evaluation and the statement "Cost-effectiveness is the financial cost for a given outcome". (This error was not repeated later, where non-financial costs were acknowledged.) The authors failed to convince me

that the often contrived distinctions between goals, aims, and objectives add anything to Donebedian's framework for health services evaluation.

The authors are clearly committed to evaluation and its growing importance. In overall tone the authors have a sensible and pragmatic view of practical health services evaluation. However, as an introduction to the subject this book is unlikely to replace existing disciplinary texts.

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Ethics and Epidemiology: International Guidelines. Eds Z Bankowski, J H Bryant, and J M Last. (Pp 191; SF 25.) Geneva: WHO, 1991. ISBN 92-9036-048-8.

This book has two components: the proceedings of the conference, and the ethical guidelines revised in July 1991 as a consequence of the views expressed at the conference.

International guidelines for ethical conduct in epidemiological research add some important issues rarely discussed at the purely national level. When research is carried out in developing countries by sponsors from developed countries there is a potential for exploiting individuals and communities which the CIOMS guidelines explicitly recognise. Several conference participants discussed the question of ethical universality versus ethical pluralism and agreed that pluralism cannot be used as an excuse for doing research that may be acceptable in terms of local customs but nevertheless violates fundamental human rights.

A developing country should not be induced to accept epidemiological research that is irrelevant to the country's main health problems. Not only should the research be relevant, but its results should be used to benefit the people of the host country. This point is so important that I believe the guidelines should go further and require that specifications for local dissemination and application of the results of research be an integral part of the protocol that is submitted for ethical review.

The participants recognised that in some epidemiological studies, informed consent at the individual level is impracticable. But they caution against jumping to this conclusion merely because the subjects, especially in a developing country, are poor or uneducated. When consent at the community level can be justified, it is recommended that reliance on a single figure of authority be avoided and that every attempt be made to identify individuals who can speak authentically for the people of the community.

The need to build a capacity for ethical review in developing countries is emphasised. This is important, since the guidelines recommend that in externally sponsored research, ethical reviews be conducted both in the sponsoring country and in the host country.

This book deserves to be carefully read by epidemiologists. It offers an excellent foundation for the further development of ethical guidelines for our discipline.

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Autopsy in Epidemiology and Medical Research. Eds E Riboli and M Delendi. (Pp 277; price not stated.) Lyons: IARC, 1991.

It is rare that one finds the proceedings of a meeting of epidemiologists adorned on the front cover with a picture of a 1632 Rembrandt. The promise of timeless quality and the casting of new light on a familiar topic (as Rembrandt did in so many of his works) beckons one to read on. So it is with *Autopsy in epidemiology and medical research*.

This publication reports the proceedings of a 1989 meeting in Trieste on necropsies sponsored by the International Agency for Research on Cancer. It is not too surprising therefore that of the 29 papers presented, nine are concerned entirely with cancer and most of the remaining 20 include analyses relating to cancer. On the other hand, there is much in this volume of interest to the epidemiologist whose interests are not in the cancer field. For example, there is one section of three wonderful papers (all of them gems) dealing with necropsy in the neonatal period. The need for such attention is summarised by the title of the first paper in the section: "The perinatal autopsy: a neglected source of discovery."

Another aspect of necropsy that is addressed is the need to relate the findings of such work to a population. The necropsy experience of the well known Rochester, Minnesota, population based study is ably reported. Also included is a detailed description of the national necropsy system in Japan. Other population based data relating necropsy to observed disease patterns are provided as well.

Whether one is an epidemiologist or a clinician, one would be hard pressed not to place a high value on necropsy data in an epidemiological context after reading this volume. It is an enlightening compilation. Hopefully, it will assist in reviving the necropsy. My only regret in reading this book was that I was not in Trieste to hear the presentation of the papers—their quality suggests that the discussions must have been high powered indeed!

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Home Care for Older People in Europe. Ed A Jamieson. (Pp 356; £45.) Oxford: OUP, 1991 (CEC Health Series No 7). ISBN 019-2620509.

All over Europe, services for older people face increasing demographic pressure at a time of limited economic growth. This cross national study of home care documents, somewhat