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.

DIANA ELBOURNE
Radcliffe Infirmary
Oxford

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.

ANN JACOBY
Centre for Health Services Research
University of Newcastle upon Tyne

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