

optimistic. Questionnaires can be and are produced that, for practical purposes, produce equivalent responses. Further research will resolve lingering reservations. To some extent the positive and practical tone of the work described is determined not just by its commercial origins but also by the fact that most work has been conducted in relatively compliant and homogeneous sections of European and North American societies. There are a few intellectual doubts reported in the volume. Naughton and Wiklund report evidence that the widely used Centers for Epidemiologic Studies – Depression (CES-D) scale does not produce patterns of depressive symptoms in some Asian American groups consistent with other cultural groups. Guyatt briefly suggests that the field reflects the “cultural hegemony” of middle-class American concerns before going on to suggest pragmatic research solutions. On the whole, similarities between cultures are far more apparent in this book than differences. It offers a powerful challenge to moral relativists, although the message is implicit, this not being the intention of the contributors.

While such work is confined to examining non-specific effects of drugs in the context of international randomised controlled trials, the cross-cultural thrust of much HRQOL may remain relatively uncontroversial. The current volume clearly, and in a most scholarly way, demonstrates the scientific caution and care of this new approach. If like the QALY, international assessments of HRQOL become involved in issues of choice about human life and resource allocation, we can expect a wider and more heated debate.

RAY FITZPATRICK  
*Nuffield College,  
Oxford*

## Good Clinical Practice and Ethics in European Drug Research

Edited by Peter Bennett, Bath, Bath University Press, 1994, 159 pages, £30.

This edited collection arose out of a symposium, held in 1993, that looked at the impact of European

Community guidelines on good clinical practice (EC GCP) in European drug research. The EC GCP sets out a uniform standard for the ethical conduct of clinical trials. The collection examines the effect of applying this uniform standard and details the complexities that exist in the review process due to the large number of ethics committees that have been formed in the member states.

The proliferation of ethics committees is a pressing problem for multi-centred trials and some fascinating case studies are presented that graphically highlight both the time-consuming complexity of multi-centred applications and the often inadequate scientific and ethical evaluation of the intended trial. One team stated that even after their application was considered by 68 ethics committees in 12 European countries “certain basic questions and points concerning the ethics of the trial were not covered by any of the ethics committees” (page 64). The ethics committees also omitted to consider many of the points that are explicitly referred to in the EC GCP guidelines. Notably, information that an investigator was in a position to undertake the study was neither sent nor requested by any of the ethics committees and many of the committees not familiar with the drugs involved in the trial did not request further information, even though the existence of this information was referred to in the protocol. The team concluded: “It is difficult to understand on what basis these ethics committees were able to judge the relative benefits of ... [the] therapy” (page 58). This raises the issue of the effectiveness of any European GCP guidelines if there is no structure in place to ensure that committees rigorously apply these guidelines.

Some of the problems created by multi-centred trials could be addressed by a cross-Europe ethics committee that works in tandem with the local ethics committees. To provide this function the European Ethical Review Committee was set up in the late 1970s and draws its membership from different countries in Europe to give a supranational ethics review. The work and role of this committee is considered in the book.

The contributions are largely from medics and one concern of the book is to give an account of the ethical review process in a number of countries (Denmark, the Nordic countries, Eastern Europe and the USA). This

general overview provides a valuable insight into international differences. The collection also includes essays addressing: general issues in the ethical consideration of informed consent in clinical drug trials, ethical issues of adverse effects, and the problems created by special groups such as psychiatric and cancer patients. Furthermore, there is a discussion of how important it is that the membership of ethics committees fully understand the scientific issues raised by research protocols. This discussion concludes with a useful consideration of what kind of education should be provided for the membership to enhance their understanding of both the scientific and ethical aspects of research protocols.

As an appendix to the book the GCP for clinical trials on medicinal products in the European community is included in full (a useful reference for practitioners). The guidelines begin by stating that “the Declaration of Helsinki is the accepted basis for clinical trial ethics” (page 141). This gives an indication of the overall spirit of the guidelines but, as pointed out by one of the contributors, Oliver Guilloid, this can give rise to a certain amount of ambiguity. There are points where the two guidelines conflict, for instance the Helsinki Declaration allows for conduct of clinical research without informed consent (principle I.II) whereas the EC GCP does not. It is submitted that only one set of guidelines should be kept and this should be the EC GCP as, in Guilloid’s opinion, it is far better than the Helsinki Declaration.

This collection is a useful guide to how the ethical review process works in practice and provides an illuminating insight into regional differences. The consideration of the ethical dimensions of clinical research in a working context is an invaluable exercise, as often the abstract reiteration of ethical principles does not reflect the complexity of practical decision-making.

LUCY FRITH  
*Department of Primary Care,  
University of Liverpool*

## Chronic Illness: From Experience to Policy

Edited by S K Toombs, D Barnard and R A Carson, Bloomington and Indianapolis, Indiana University Press, 1995, 221 pages, £23.50.

In recent years there has been an expanding literature devoted to the case stories of those who are ill, but this collection of articles is unusual in that it starts with this approach in part one, and then considers the ethical, social, cultural and political responses to them, attempting to provide a link with policy issues, in part two. This is an ambitious and important development which deserves far more attention than it has received so far.

The individual contributions to the volume are generally of a high standard, and rather than attempt the briefest sketch of each of them, I will highlight certain issues which I found of particular interest. In the first chapter of part one Kay Toombs's description of her personal experiences – "Sufficient unto the day: a life with multiple sclerosis" – was both insightful and compelling. Two telling quotations speak for themselves. First that "...there is nothing intrinsically good about chronic, progressive multiple sclerosis. Nothing. This is not, however, to deny that my life has been profoundly affected in ways that are enriching" (page 20). Second: "Perhaps the greatest challenge of all for the multiple sclerosis patient is to learn to live with ongoing and permanent uncertainty" (page 20).

In another chapter in part one, "Whose story is it anyway?", Sue Estroff analyses the ethical issues raised in doing narrative research on chronic illness. Estroff's own work has been with the long-term mentally ill and her sensitive and honest account exposes the impossibility of deriving ethical research practices from theoretical considerations alone. In particular she demonstrates the problem of applying ethical codes primarily developed for quantitative research on those with acute physical illness, to qualitative and especially narrative research with those with chronic mental illness. The central issue here is that narrative research requires that the researcher empathise and collaborate with the subjects of the study, whilst also being sufficiently distant from them to maintain a degree of objectivity. One ambiguity that arises from this is that in attempting to adopt a neutral stance the researcher may be seen by the research subject as the most caring person he or she has contact with. Estroff concludes that "the lines between friend and investigator blur over time, producing almost as many difficulties as positive contributions to the quality of the research" (page 91).

In the second part of the book, which focuses on policy, John Douard's chapter "Disability and the persistence of the normal", is concerned with the distinction that arose in the nineteenth century between the normal and the abnormal, both medically and socially and the way it can lead to two responses to disability which tend to sustain conformity and discipline within society rather than solving problems of how to live together. These are, first, giving special rights to distinct minority groups, so institutionalising labelling; and, second, requiring people to behave in such a way as to "qualify" as normal, so that they are held responsible for their own status. These observations are important and demonstrate the relevance of social and historical analysis to ethical issues, a theme which Arthur Kleinman takes up in his chapter on "The social course of chronic illness": "I maintain that there is a role for anthropology, social history, and other social sciences in shifting the object of inquiry to include the social processes of everyday local worlds which shape suffering in ways quite distinct from the usual individual psychological orientation of clinical and ethical approaches taken to this most human of conditions [that of suffering]" (page 185).

The difficulty though is how to put this process into operation and make it relevant to social policy; the structure of the book is itself an indication of where the problem lies. The first part concentrates on the individual experience of suffering, and the second on how to harness that experience in fostering better approaches to policy-making. However, the two parts are largely unrelated to each other. Only Estroff connects the direct accounts of her own narrative research with ambiguities in its nature and so points to ethical dilemmas relating to research policy; and there is no attempt to form a bridge between the other chapters in the two parts of the book.

This then is not just a collection of interesting articles, because it raises the question of how to bring together illness narrative research with more traditional historical, sociological and anthropological approaches in such a way as to enrich the overall analysis and more fruitfully inform social policy. Although the book is limited in how far it has taken this project forward, the distinction of many of the contributions is in having shown

the importance of this area for the future.

DAVID GREAVES

*Centre for Philosophy and Health Care,  
University of Wales,  
Swansea*

## Justice and Health Care: Comparative Perspectives

Edited by Andrew Grubb and Maxwell J Mehlman, John Wiley, Chichester, 1995, 350 pages, £35.00.

Limited resources and rationing are "buzz words" today in health care across the globe. The development of modern medical technology with its ability to prolong life has at the same time raised the dilemma of just who should get the treatment? *Justice and Health Care: Comparative Perspectives*, a collection of essays which, as the title suggests, discusses particular problems relating to health care allocation in the light of experiences drawn from a number of jurisdictions is thus a timely publication.

A number of essays concentrate on broad questions of policy in resource allocation. For instance, Alan Maynard, an economist, examines rationing – currently one of the most hotly debated issues within the National Health Service (NHS). Maynard argues for the establishment of criteria for resource allocation within the NHS, drawing upon experiences in Oregon and elsewhere. While overt resource allocation decisions may prove a difficult and uncomfortable task, some may see this as preferable to the somewhat covert allocation process undertaken in the past. Physicians on both sides of the Atlantic have taken into account a patient's lifestyle in deciding whether to undertake treatment. Robert Schwartz questions this in his essay "Life style, health status and distributive justice". For example, decisions regarding lifestyle may not be truly voluntary – the fact that an individual becomes an alcoholic may relate to a whole series of factors beyond whether or not an individual chooses to have a drink. In addition, he doubts whether restriction of resources on lifestyle criteria is justifiable on the basis of punishment or of deterrence.

Many of the essays in this collection address the role of the law in