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Book reviews

Philosophical Issues in Nursing

Edited by Steven D Edwards, London, Macmillan, 1998, 205 pages, £14.99.

Steven Edwards's collection provides a welcome addition to the under-explored area of philosophical issues in nursing. It is recommended as a well-founded introduction to this novel area for undergraduate and postgraduate students in nursing and other interested parties.

The work is written by a range of authors with backgrounds in philosophy, nursing, or both, all of whom are involved in nurse education. The volume ambitiously spans enquiry in the areas of ontology and epistemology with one paper engaging in value-enquiry or ethics. A slightly disjointed feel to the various contributions is ameliorated to some degree by the summaries which precede each chapter. These are helpfully written by the editor to guide the reader through the book. Whilst no prior philosophical expertise is assumed the text succeeds in avoiding over-simplification.

The opening section of the collection examines nursing practice and knowledge. A fascinating paper by Joan Liaschenko discusses various types of nursing knowledge, including knowledge of how to get things done, knowledge of patient experience and knowledge of the limits of medicine. Large portions of this knowledge Liaschenko claims are invisible and silenced. Keith Cash's chapter proposes a conception of nursing as a practice. He relates this understanding to the problem of reaching a widely agreed theory of nursing. Cash proposes the merits of some of the traditional virtues that have united nursing. Although the latter suggestion is somewhat preliminary in nature it provides a useful starting point for further work. A well-written contribution by Trevor Hussey examines the concept of change and its application to nursing. Hussey proposes a Lamarckian model of evolutionary change as being of greatest utility when considering, for example, theory development. A conceptual analysis of holism is undertaken by Simon Woods. This well-signposted chapter explodes some of the myths underpinning the rhetoric of holism in nursing. Positivism as a method in nursing research is discussed by the editor, Steven Edwards. Although this chapter centres on debates which will be familiar to nurse researchers the cogency of the paper has much to recommend it. In a dense chapter which utilises some helpful illustrations Edward Lepper discusses the feasibility of arriving at a credible theory of mind, from four differing perspectives: nursing, science, common sense and philosophy. Drawing upon the work of Heidegger and Dreyfus, Stephen Horrocks proposes a radical approach to curricula in nursing in which the practical world would be seen as more fundamental than the theoretical world. Janet Holt provides a powerful exposé of many philosophies in nursing. Despite their popularity the vast majority of these many philosophies do not match up to the rigour necessitated by a critical evaluation of assumptions and arguments. In a wide-ranging chapter Paul Dawson ambitiously, and with a considerable degree of success, addresses the nature of the self. Philip Ross reaches some very different conclusions concerning the nature of the self when he discusses compulsory treatment. Ross's work provides an interesting response to the anti-psychiatry movement.

Philosophical Issues in Nursing illuminates the novel partnership that is emerging between nursing and philosophy. This disparate collection provides a useful point of departure in this burgeoning area of enquiry.

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MRC Guidelines for Good Clinical Practice in Clinical Trials

Medical Research Council, London, Medical Research Council, 1998, 46 pages, free.

The background to the publication of this very helpful, well and clearly written book (one of the Medical Research Council [MRC] series) is the publication of the *European ICH Harmonised Tripartite Guidelines for GCP* in 1996; knowledge of some well publicised (and perhaps some less well known) lapses of ethical probity in clinical trials, the perceived need for public accountability in public corporations, and the fact that the clinical trials supported by the MRC cover fields far wider than the drug product licensing ambit of the European guidelines.

The draft was circulating for comment amongst MRC-supported groups, and has now been published, following revision.

The randomised controlled trial is accepted as the basis for these; human research without controlled trials is to be the subject of another paper under current preparation.

The aims of the guidelines are chiefly the difficult job of balancing concurrently and without loss the elements of the ethical clinical care and safety of trial participants, the

business administration of these studies, their financial management and adherence to a well formulated and construed scientific protocol so as to gain an outcome of high quality. And this has to happen without loss of trust and without a stifling bureaucracy.

The mechanisms which must be added to the normal practice of good clinical trials are monitoring by the MRC, independent scientific advice, a committee with the remit of trial management without loss of "blindness" to the data (the trial steering committee) and another to monitor progress of the trial in relation to ethical probity, adverse events and novel information about matters relevant to the trial. This is done by an independent but "unblinded" group, the data and monitoring and ethics committee. This group is not to substitute for the local research ethics committee, whose review is an essential preliminary to the study. Also the roles and remits of principal investigators, investigators and host institutions are set out clearly. So, the added arrangements which impinge on ethics are the presence of independent scientific advisors, of a committee which reviews data as it accrues without "blindness" but in confidence, and the defined responsibilities of the heads of host institutions to be accountable in part for what goes on with the trials in those institutions.

What of the ethical aspects of these guidelines? These are set out, in part 2, along lines which mirror almost exactly the current Helsinki Declaration revision; the declaration does, of course, deal with broad principles. The actual places where most difficulties arise are not in relation to the principles but in their application. For example the guidelines barely discuss, or omit entirely, reference to many well-known "minefields": the problems of justice and "equipoise"; those of indemnity (factors which jeopardise it, how non-negligent injury is compensable in its various sectors); those of product importation and registration (as set out in recent revisions of MAL30 and European directives); those of volunteer groups who are specially vulnerable; those of consent v assent and of the ascertainment, elicitation and validation of informed consent; those of the implications for volunteers of divulgence to themselves of personally sensitive information (for example test results), and those of payments made to participants. There are also the important issues of concurrent therapy which is not part of the trial comparison, and of the definition (given in the guidelines) of what is a "serious adverse event"; this seems to be largely confined to injury or illness caused as opposed to other potential harms. The issues of partially informed consent are raised and helpfully presented, as are those of data-handling and of confidentiality.

It is welcome to see a clear statement, in line with the Helsinki Declaration, that the clinical participants' safety and benefit are paramount over social and scientific interests, and that part of ensuring this relies on there being adequately qualified clinical staff who are to be responsible for patient care. It is less clear what is implied by the statements that there are pieces of information to which a participant "should have access"; these are about compensation, treatment after harm, and progress with, and the eventual outcome of, the trial. This is a special concern since the MRC like the National Health Service and other public bodies is unable to insure and so cannot offer advance indemnity for non-negligent injury to participants in its studies.

The guidelines end with appendices which include some helpful checklists for applicants for MRC funding and for those setting up the committees required for clinical trials.

The council clearly aims to draft guidelines which will be useful not only to its own research groups but to all institutions conducting clinical trials outside the pharmaceutical industry. What has been set down is an excellent template for such work in general, but it cannot be held to be mandatory in every such situation, nor can it absolve anyone from careful ethical review.

There will be room for much detailed comment on clinical trial proposals by local or national ethics committees in view of the difficulties of applying the ethical principles listed here. Perhaps a further appendix outlining some of these questions might be helpful; they are of frequent importance in the design and execution of clinical trials.

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Assisted Reproductive Technologies: Analysis and Recommendations for Public Policy

The New York State Task Force on Life and the Law, New York, 1998, 474+ix–xxxiv pages, $12.00.

Assisted Reproductive Technologies (ARTs) include in vitro fertilisation (IVF) and artificial insemination (AI). They raise similar moral, ethical and legal issues throughout the world. What procedures should be permitted - and who should have access to them?

Should ART be limited to married couples or should single and gay people be admitted to IVF programmes? Should they be limited to using their own gametes or should donor gametes and embryos be allowed? Should embryos be frozen if that increases the likelihood of a successful pregnancy? Should fetal reduction (the killing of embryos in utero) be permitted in multiple pregnancies to increase the chance of survival for some of the embryos? Should children born from donated gametes or embryos in ART be entitled to know their biological parents? Should research be permitted on embryos - and in what circumstances? All of these questions - and many others in a similar vein - are extensively discussed in this report.

The New York State Task Force on Life and the Law was created in 1985 to recommend policy for New York state in the form of legislation, regulation, public education or other measures. Medical advances on which it has advised to date include the determination of death, the withholding and withdrawal of life-sustaining treatment, organ transplantation and ARTs. Six of its recommendations for legislation or regulation have been enacted in New York state. For this reason alone, this report is likely to be influential, at least in the United States.

For readers in the United States or elsewhere, whether medical or other experts or general readers, the report will be informative and stimulating. It is written in a readily accessible style with summaries of submissions made by many and diverse people during the task force's consultation process - infertile couples, participants in ART programmes, support groups of various types, ART practitioners, representatives of religious groups and the general public. The range of views that