

BOOK REVIEW

Women and health research: ethical and legal issues of including women in clinical studies. Volume 1.

Editors: Anna C. Mastroianni, Ruth Faden, Daniel Fiderman. (Pp 271)
Washington D.C.: National Academy Press, 1994.

(This volume was gifted to the Forum by Dr. Ruth Macklin.)

The book is a report by a committee consisting of leading experts in ethics, research, medicine, industry and law. It deals with the ethical, scientific and legal issues relating to the inclusion of women in clinical studies.

These concerns have come into focus because of increasing attention both from the public and from women's health activists who perceive that biomedical research has not given the same attention to the health problems of women as has been given to those of men. They also feel that women have not benefited from advances in medical diagnosis and therapy as seen from their lower participation in clinical studies.

Key questions are raised: Have women

been truly equally represented in clinical research? How do social biases influence research agendas? What about liability for harm ensuing as a consequence of research studies? Do pregnant women and those of child-bearing age need special consideration?

Although the Congress of the United States of America passed an act (National Institutes of Health Revitalisation Act 1993) aimed at providing equal representation to women in clinical research, the committee is of the opinion that this goal is far from attainment. Among the reasons provided by it are the great cost of implementing the provisions of the Act and practical issues such as legal liability.

The book begins by addressing matters that form the crux of the report such as the role clinical trials play in the development of knowledge and the current status of women as regards their active participation in medical research.

Subsequent chapters are devoted to the ethical, social and legal dilemmas that

must be resolved before women can be provided genuine equality of representation in clinical studies.

The concluding chapter gives the committee's recommendations for effective implementation of the NIH Revitalisation Act 1993. These pertain to the investigators, institutional review boards, initial review groups and technical evaluation groups.

The Appendices cover forty abstracts of papers dealing with women's participation in clinical studies between 1977 and 1993, the diethylstilbestrol case study, an excerpt from the NIH Revitalisation Act 1993, information regarding compensation systems for injuries related to research and short biographies of members of the committee.

In essence it is a book for all those who believe in the critical importance of justice in clinical research.

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MEDICAL ETHICS IN OTHER JOURNALS

Hastings Center Report 1995;25:1-52

As this journal enters the 25th year of its publication, Dr. Bette-Jane Crigger, Editor reminisces on its evolution from a twelve-page newsletter into the leading journal in this field. "We will, of course, continue to explore a range of philosophical paradigms, principlism, casuism, feminism and narrative ethics... (and) how best to understand and manage the thickness of lived moral experience... We need to attend more carefully to what 'moral discourse' sounds like spoken in ordinary voices. The trick, always, is not simply to reflect the current state of play in bioethics, but to press new questions and probe new analytic paradigms as well..."

Among essays published in this issue are those on caring for patients in cross-cultural settings, refusal of treatment by Christian Scientists and abortion. A special supplement (pages S1 - S32) deals with long-acting contraception. The issue also contains a symposium (pages 36-46) on research involving embryos.

The case study in this issue discusses *The forgetful mourner*, an eighty-six year old woman with Alzheimer's disease who kept forgetting that her son had died. Each time she was reminded of this she experienced the pain of her loss as if for the first time. Sustained deception was considered and 'ruled out by her attendants. An aide solved the problem by dressing her in the black dress she had worn whilst attending the funeral. Tony Yang-Lewis and Harry Moody discuss questions such as whether a patient with Alzheimer's disease should be told the truth, whether the patient's receptivity to truth was relevant and whether it was correct to attempt to shield such a patient from a painful truth.

Otago Bioethics Report 1994;3:1-15

Two essays (pages 4-7) review assisted human reproduction.

Alison Douglass offers for debate thoughts on surveys aimed at studying patient satisfaction (pages S-9). She

stresses the need to recognise the limitation of such surveys and the avoidance of bias from non-response and poor selection of sample. It is necessary to assess both the quality of care afforded to patients as well as what could be termed 'hotel services', the distinction between these being clearly understood by responding patients. She highlights as key points the need for statistical integrity, voluntary and informed participation by responding patients, protection of the privacy and confidentiality of these vulnerable patients who are undergoing stressful experiences and ensuring justice and equality so that participants have access to the results of the survey.

Katherine Hall and Jan Crosthwaite offer commentaries on the case notes on Karen L whose parents wanted all treatment on their seriously ill daughter stopped as they believed that she would not survive. (Karen's treatment was continued by the doctors, She recovered and returned to employment.)