

Book Review

DOUBLE STANDARDS IN MEDICAL RESEARCH IN DEVELOPING COUNTRIES

Ruth Macklin,

Cambridge University Press, 2004. vii and 280 pp (incl index). ISBN 0 521 83388 4 (hb). £50.00. ISBN 0 521 54170 0 (pb). £22.99.

In 1997 an editor of *The New England Journal of Medicine*, one of the world's most prestigious medical journals, published a leading article condemning as unethical placebo-controlled trials then underway in several developing countries to evaluate new drug regimens to reduce perinatal transmission of HIV infection. It was argued that because an anti-retroviral treatment that reduced perinatal HIV transmission had already been tested and shown to be effective in the US and France, this should be used as the "control" arm in trials in developing countries, which were being conducted to find a regimen more affordable than the \$800 treatment available in the US and other developed countries. Defenders of the trials, including one of the major sponsors, the US National Institutes of Health, argued that placebo-controlled trials were justified because at that time no effective interventions were in use in developing countries and the regimen that had been shown to be effective in the US would be way beyond the budgets of developing countries, where the total per capita health expenditure of some was less than \$10. The critics of the studies argued that because it would be unethical to conduct a placebo-controlled study in the US, to support such studies in developing countries would be advocating a "double standard" in medical research.

The debate that ensued was heated and vigorous, and continues. It has had both detrimental and beneficial effects. Funding agencies are understandably sensitive about attacks on their ethics and a negative consequence of the debate was that some became more cautious about funding research in developing countries. A beneficial effect of the debate has been that it has turned a spotlight on an area that had previously received relatively little attention and has led to a number of groups conducting in-depth reviews of ethical issues surrounding medical research in developing countries that is sponsored by agencies in developed countries.

Ruth Macklin, a distinguished US bioethicist, has been a participant in, and a close observer of, these deliberations and in this book she attempts to summarise the arguments that have been advanced relating to key issues and gives her own perspective on these issues, which is reflected in the title she chose to give the book.

The approach she adopts in the 8 chapters is to highlight major issues, such as: what "standard of care" should be provided to trial participants; how informed consent should be sought for participation in research; what post-trial obligations there are for the implementation of efficacious interventions, and; how and where studies should be ethically reviewed. For each issue, she first sketches the principal areas of ethical debate, then summarises the, sometimes conflicting, guidance published by different bodies in recent years, including the revised Declaration of Helsinki of the World Medical Association and publications from the Council of the International Organisation of Medical Societies (CIOMS), UNAIDS on preventive HIV vaccines,

the US National Bioethics Advisory Commission and the UK Nuffield Council on Bioethics. She quotes extensively from evidence or opinion submitted to these groups and concludes by summarising her own position on the ethical issues under discussion. Also included, and highly relevant to the debate, is a chapter on the pricing of drugs and how ways may be found to make these more affordable for those in developing countries.

For those who have not followed the controversies surrounding the external financing of medical research in developing countries, the book provides a good and reasonably focussed summary of the discussions that have taken place over the last 7-8 years. For those who have been involved in the debates there is probably little that will be seen as providing new insights into the issues and I doubt that the arguments presented will cause many of these to change their own stance.

Macklin's basic thesis is that it is not ethical to conduct research in poor countries that would be judged unethical to conduct in rich countries, if the research funding is coming from a rich country, though she appears to concede that some such research may be judged ethical if not externally funded. She opposes the view that it is ethically acceptable to provide a lower level of care and treatment in less developed countries than research subjects receive in the US and Europe. She maintains that a departure from this position constitutes advocating a double standard. But the argument is not so simple and Macklin retreats from this position if, for example, the research would require the construction of a cardiac intensive care unit to achieve a similar standard of care in the developing country. Surely a key question in judging the ethics of research in a developing country is whether it is responsive to local needs. Certainly in conditions of enormous disparity in wealth, which is inherently unethical, the needs in rich and poor countries are different and the research agendas and research designs must be consequently different. However, there is much in this book with which I would take little issue. It is written in an interesting and informative way and is one of the few substantial books on the topic.

Peter Smith

London School of Hygiene & Tropical Medicine

DOI: 10.2966/scrip.010404.639

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