

BOOK REVIEW

Case studies in biomedical research ethics

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James V Lavery, Christine Grady, Elizabeth R Wahl and Ezekiel J Emanuel (eds). *Ethical issues in international biomedical research: A casebook*. 400 pages. Oxford University Press, 2007. ISBN 978-0-19-517922-4.

The volume under review, edited by James V Lavery of the Department of Public Health Sciences and the Joint Center for Bioethics, University of Toronto, Canada, and colleagues is a welcome addition in this era of global health in which boundaries, including those surrounding the sites of clinical research, continually dissolve. These boundaries are not only geographical ones, but also those within science and medicine itself. As the case studies in this book illustrate, all of us in the diverse fields of health, medicine, philosophy or the social sciences face hard work to comprehend the scientific and ethical parameters of a drug or practice under study, as well as the social, cultural, political, economic and professional milieu in which research trials and studies are conducted. The majority of the formulations of guidelines for clinical research emerged in American and European institutions of medicine; the transposition of these models to the rest of the world is neither a clear, or self-evident, nor an easy process.

Moreover, as medical research is increasingly conducted worldwide, often in countries new to this type of undertaking, development of ethics relevant to the researchers, patients and their community is critical. The format and content of this book, as will be outlined in the following paragraphs, make this an ideal platform for discussion and for teaching of ethics in research to a variety of audiences – health professionals, researchers and administrators, as well as community-based organisations working to advance ethics-based research in their locales.

The editors of this volume undertook this effort with the realisation that the discussion of ethical research needed to move beyond a focus on “standards of care” which emerged in international debates over research trials evaluating means of reducing mother-to-child transmission of HIV (p. 3). To achieve this end, they developed this casebook, dividing it into segments covering eight previously established principles in the ethics of research conduct: 1. collaborative partnership; 2. social value; 3. scientific validity; 4. fair subject and community selection; 5. favourable risk-benefit ratio; 6. independent review; 7. informed consent; and 8. respect for enrolled subjects and study communities.

Twenty-one actual case studies are presented, each case accompanied by two expert commentaries. A minimum of two case studies is presented to illustrate the ethical standard in each section. In each of the twenty-one case studies, through an introductory section that highlights the social demography, economic and political characteristics of the society, we travel around the world learning about the countries and societies in which the trial is being conducted. The case study itself is then presented, characterising the conditions, intervention or disease under study, the drug or method to be evaluated, and the goals of the research. Next, discussion of the conduct, methods, problems and key players in the study is carried out, presenting the ethical issues raised. Two accompanying commentaries by experts, some of whom may disagree with the research itself, its methods and/or its ethical stance, challenge the reader to continually re-evaluate his or her own understanding of ethical principles. Clear-cut solutions are not always provided, thus continually alerting the reader that one is deep in debates about medicine, science, economics, philosophy and culture – all of the interplays that characterise health and medicine based in a particular society.

To indicate the geographic range covered, the countries and societies represented in these case studies include Mexico, Tonga, Iceland, Nicaragua, Thailand, Ethiopia, Bolivia, the Pygmy people in the Central African Republic, Mali, the United States of America, native Amazonian populations in Brazil, South Africa, Guatemala and Uganda.

India is represented in two case studies, one on development of the drug paromomycin for visceral leishmaniasis, focused in Bihar. This study falls under the “social value” section with the designation of “study of neglected diseases”. The second India-based review, in the “scientific validity” section, critiques an evaluation of home-based treatment strategies for neonatal sepsis in the Gadchiroli district of Maharashtra.

Additional topics researched include diseases such as HIV/AIDS and malaria; testing of various drugs and devices for disease, disease prevention or health conditions; social problems such as domestic violence; biodiversity (the protection of indigenous resources for pharmaceuticals); population-based genetic research; and nutritional interventions for women. As these diverse topics indicate, the range of research is wide, as are the geographic locations.

The editors and authors provide an important contribution

in these varied case studies through discussion of the often overlapping regulations guiding research. A complex interaction takes place when institutions of different countries are involved in the same research project; each may have their own guidelines for informed consent requirements, for example. In these cases the debates as to which guideline should prevail may become intense, and delay or derail the research. Funding organisations may also enter into these debates, as their regulations may differ from other donor organisations or institutions involved in the same project. Here, the tensions between more established institutions, such as the National Institutes of Health (USA), and neophyte research institutions in developing countries may need to be sorted out

before research can proceed.

Also in newly formed research ethics committees, hierarchical status and power distribution in medical or related institutions may threaten the autonomy of committee members in their deliberations and decision making. In small or marginal communities problems of stigma associated with a disease or condition demand protection of the subject's identity, which may be difficult to ensure over the course of the research undertaking. These unresolved thorny issues of variant guidelines, unequal power and potential stigma indicate the need for future publications in the vein of this work, as this brave new world of medical research bridging geographical, social and disciplinary boundaries forges ahead.

IJME ANTHOLOGIES

Technology in health care: current controversies

Editors: Sandhya Srinivasan, George Thomas **Published by:** Forum for Medical Ethics Society and Centre for Studies in Ethics and Rights, Mumbai. December 2007. 288 pages. Rs 200

This collection of essays covers important discussions related to medical technology that have been carried in the *Indian Journal of Medical Ethics*. Each of the nine sections is preceded by a commentary by an expert in the field. The nine chapters cover placebo controls in research; intellectual property rights; family planning and population control; the HIV/AIDS programme and research; electro convulsive therapy without anaesthesia; liver transplant technologies; end-of-life care; medical professionals and law enforcement, and technology in public health programmes.

Indian Journal of Medical Ethics: selected readings 1993-2003

Editorial collective: Neha Madhiwalla, Bashir Mamdani, Meenal Mamdani, Sanjay A Pai, Nobhojit Roy, Sandhya Srinivasan **Published by:** the Forum for Medical Ethics Society and the Centre for Studies in Ethics and Rights, Mumbai. November 2005. 248 pages. Rs 150.

This selection of essays previously published in the *Indian Journal of Medical Ethics* can serve as a short education on healthcare ethics in the Indian context. The articles are divided into five sections: personal integrity, communication, technology and social justice, research ethics, and law, policy and public health. **The preface** provides an overview on the emergence of medical ethics as a topic of interest in India. **Introductions** to each section and article give the reader a background to the discussions and their relevance today.

The topics covered include: the Hippocratic oath; ancient and modern medical ethics in India; problems in medical education; the relationship between physicians; the role of the pharmaceutical industry; informed consent; debates on medical technology; ethics committees; whistle blowing; how to interact with patients intending to try another system of medicine; AIDS vaccine trials; sexuality research; authorship, and violence and the ethical responsibilities of the medical profession.

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