The ethics of medical progress

Innovation in Medical Technology: Ethical Issues and Challenges

Margaret L. Eaton & Donald Kennedy

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Reviewed by Angelique M Reitsma

Despite an ongoing debate, boundaries between research and practice in medicine are often still unclear. New surgical procedures, assisted reproduction technologies and brain imaging techniques are being offered to patients while essentially unproven; drugs are being prescribed for other than their approved purpose. This is of concern because of uncertainty regarding which ethical rules should prevail: regulations for human subjects research or professional guidelines? Medical progress is needed, but it must occur in an ethically and scientifically sound manner.

So how then should medical innovations be regarded and regulated? This dilemma prompted the 2003 Lasker Forum on Ethical Challenges in Biomedical Research and Practice. Participants at the forum discussed the question of whether medical innovation should be regarded as research or as variation in clinical practice. This book, which grew out of these discussions, focuses on this 'gray area' in medicine and attempts to provide suggestions for guidelines to ensure that innovation in medical technology can continue, but with adequate oversight.

Eaton and Kennedy describe how medical innovations have traditionally been deployed and the ethical issues that arise during their deployment. A considerable amount of information on medical innovation and human subject research is offered, including case scenarios about unproven therapies and documents that provide national and international guidance for biomedical research. The authors start by discussing how dissemination of innovations happens, including by word-of-mouth, by publications of reports and pilot studies, and by the mass media. An important factor that influences dissemination is insurance coverage, as exemplified by high-dose chemotherapy combined with bone marrow transplant for breast cancer. In this generally compelling introduction, I found only two weak points. First is the minimal mention of the internet as a powerful new force driving (sometimes premature) reports of innovations. Second is the lack of discussion about financial interests for innovators, which can sometimes conflict with patient interests.

The authors provide an extensive if slightly obligatory account of the historical abuses, national and international, of human research subjects,

and the regulations that were prompted by these abuses. These serve as a reminder of why we should be concerned about how medical innovation is implemented.

The interest of the book picks up with discussion of the four areas of greatest innovation and therefore greatest concern, as identified by the Lasker Forum. The first area is the off-label use of drugs. This case scenario showcases the ethical dilemmas of this widespread practice, posing questions that require the reader to consider the responsibilities of the involved parties (pharmaceutical companies, doctors and patients). Ideally, the demand for access to unapproved drugs by terminally ill patients should have been mentioned here. Access to drugs that are still under investigation and essentially 'prelabel' is a highly contentious subject that has passionate proponents (patients and their loved ones) and equally convinced opposing parties (pharmaceutical companies and insurers).

The second area of concern is innovative surgery—a particularly complex area. The tendency of surgeons to introduce new procedures as 'innovative practice' and not as research—with the effect that clinical trials are not done to test the effectiveness of the surgery—has many ethical ramifications. These implications are clarified here in great detail yet with sensitivity to the viewpoint of pioneering surgeons. Unfortunately, all examples given are from cardiac or cardiovascular surgery, which falsely creates the impression that only these surgeons innovate. In discussing the difficulty with randomized placebo-controlled trials in surgery, the authors fail to mention a landmark study that has shown that placebos can sometimes be ethically employed in surgical research.

The third area is assisted reproduction, where the authors show a command of and appreciation for its history and ethical issues. The rich and provocative case study touches on a host of issues, including the potential for birth defects after assisted reproduction, preimplantation genetic diagnosis and the emotional impact on parental hopefuls.

The newest technology of the four described, neuroimaging, is the subject of the most speculative chapter. The authors focus on the potential ethical, legal and social consequences of functional imaging applications. Access to brain-imaging information raises compelling questions. For example: will the data be used to define normality or personal identity, and is it stigmatizing?

The authors are to be commended for making some of the more decisive statements about the introduction of medical technological innovations in the recent literature. They confirm that the current federal definition of research is not helpful in deciding how innovations should be viewed and supervised. Second, they fear that physicians' overconfidence about the prospects of success of medical innovations may jeopardize their objectivity. Lastly, they find the current divide between research and practice to be too rigid, with many innovations falling in a middle category. To better regulate this category, the authors offer some excellent practical suggestions. These include appropriate models for oversight of innovations and their possible implementation, information to be disclosed to patients, and the professional duties of innovators to learn and to educate others. The recommendations lay the groundwork for ensuring ethically sound innovation without stifling medical progress by adding too much red tape.

COMPETING INTERESTS STATEMENT

The author declares no competing financial interests.

Angelique M. Reitsma is a Visiting Scholar at the Center for Bioethics, University of Pennsylvania, Philadelphia, Pennsylvania, USA.
e-mail: ar6j@cms.mail.virginia.edu