CORRESPONDENCE

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Research ethics committees

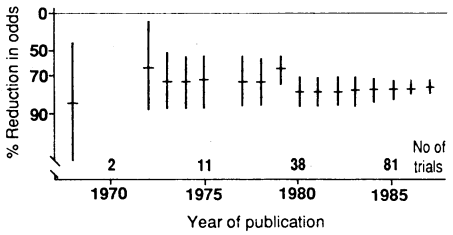
SIR,—Dr Stephen Lock's editorial[1] prompts us to raise three aspects of the responsibilities of ethics committees that he did not discuss.

Firstly, these committees have a responsibility to confront more honestly the blurred boundary between clinical practice and clinical research. The *BMJ* recently published a report of a poorly controlled therapeutic experiment conducted in a well known medical research establishment in which the following statement was made: "After formal discussion with this hospital's drug committee and informal discussion with its ethics committee, it was decided that the usage we report was merely an extension of the drug's regular use, and that formal ethical approval was not necessary as our study was not a randomised trial."

More than 15 years ago Smithelis pointed out the indefensible anomaly whereby he needed permission to give a new drug (at random) to only half of his patients.[2] The decisions of some ethics committees have promoted this ethically indefensible experimentation.[3] In addition, these committees have endorsed the idea of excluding very sick and elderly patients from uncontrolled trials of treatments that are believed to be effective when including such patients was judged by the researchers to be likely to compromise the chances of "confirming" efficacy.[4] By continuing to acquiesce in these double standards ethics committees and others—on both sides of the Atlantic—are not simply turning a blind eye to poorly controlled experimentation on inadequately informed patients (as in Auckland and the London Bridge Hospital)—they are actively promoting it.

Secondly, ethics committees must accept greater responsibility for ensuring that they have access to the information required to enable them to make ethical decisions. Not only must they be satisfied that the proposed research has been appropriately designed but they must also ensure that they do not endorse proposals for unnecessary research. This point was made some years ago with respect to studies to evaluate the effects of prophylactic antibiotics in colon surgery.[5] At what point, for example, does it become unethical for committees to assent to prophylactic antibiotics being withheld from women undergoing caesarean section? The figure has been derived from data generated by a series of almost one hundred relevant controlled trials that have been reported since 1968.[6] It gives cumulative estimates of the extent to which the odds of serious postoperative infection can be reduced by prophylactic antibiotics. The ethics committees that approved the trials conducted in the later years of the series could have made more informed and ethical judgments if they had had access to systematically assembled information of this kind.

Lastly, ethics committees have a responsibility to play their part in controlling a tendency among



Cumulative estimates of extent to which prophylactic antibodies reduce odds of postoperative infection

clinical researchers not to report well designed experiments when the results suggest that new treatments are at best equivalent or definitely inferior to existing treatments (K Dickersin, first international conference on peer review, 1989, Chicago). It will become easier to detect this form of scientific misconduct if ethics committees maintain publicly accessible registers of the projects submitted to them—as recommended in the draft circular recently issued by the Department of Health.[7]

IAIN CHALMERS

National Perinatal Epidemiology Unit, Radcliffe Infirmary, Oxford OX2 6HE

THOMAS C CHALMERS

Technology Assessment Group, Harvard School of Public Health, Boston, Massachusetts 02115, United States

1 Lock S. Monitoring research ethical committees. *Br Med J* 1990;**300**:61-2. (13 January.)
2 Smithells RW. Iatrogenic hazards and their effects. *Postgrad Med J* 1975;**15**:39-52.
3 Anonymous. Vitamins, neural tube defects, and ethics committees. *Lancet* 1980;i:1061-2.
4 Chalmers TC. Ethical implications of rejecting patients for clinical trials. *JAMA* (in press).
5 Baum ML, Anish DS, Chalmers TC, Sacks HS, Smith H, Fagerstrom RM. A survey of clinical trials of antibiotic prophylaxis in colon surgery: evidence against further use of no-treatment controls. *N Engl J Med* 1981;**305**:795-9.
6 Enkin M. Prophylactic antibiotics in caesarean section. In: Chalmers I, ed. *The Oxford database of perinatal trials*. Oxford: Oxford University Press, 1989. (Version 1.0.)
7 Department of Health. *Draft guidelines for research ethics committees*. London: DoH, 1989.

SIR,—I share Dr Stephen Lock's[1] enthusiasm for a national ethics committee if only to make sense of the vagaries of local ethical committees when coming to terms with the needs of multicentre trials.[2] I would like to propose, however, that membership of such a committee should be for those selected for their knowledge of the scientific basis of medicine or their scholarship in medical ethics. Tokenism alone is not adequate. For example, the reference to the fact that 65% of all committees without a nurse approved all proposals unchanged and that this proportion fell to 30% when a nurse was a member does not mean that nurses are necessarily twice as ethical as doctors.[3] It could equally mean that nurses knew half as much about the ethical imperatives for making scientific progress. Thus it was the well meaning nurses who secretly turned up the oxygen supply to the incubators of neonates, thus sabotaging the first randomised controlled trial studying the effects of high oxygen concentrations in the aetiology of retrolental fibroplasia. These nurses unwittingly added to the number of babies blinded by this condition in their zealous attempts to prevent what they perceived as the unethical human experimentation of the paediatricians concerned.[4]

MICHAEL BAUM

Rayne Institute, London SE5 9NU

1 Lock S. Monitoring research ethical committees. *Br Med J* 1990;**300**:61-2. (13 January.)
2 Baum M, Zilkha K, Houghton J. Ethics of clinical research: lessons for the future. *Br Med J* 1989;**299**:251-3. (22 July.)
3 Institute of Medical Ethics. *Research ethics committees in England and Wales: the institute's survey*. Suppl 2. London: Institute of Medical Ethics, 1986.
4 Silverman WA. *Retrolental fibroplasia. A modern parable*. New York: Grune and Stratton, 1980.

SIR,—Your editorial on research ethics committees provides an excellent summary of their history and present shortcomings.[1] It says less than it might have, however, about ways of improving committee performance, and does so rather late in the day.

One way that you do mention as being proposed in the departmental draft circular is to require committees to produce an annual report available for public scrutiny. Less direct ways of improving committee performance are also available. It could be made a contractual requirement on all NHS employees to submit research proposals for review by an ethics committee. The medical defence organisations, and bodies providing similar indemnity to other health professionals, could refuse to provide cover for problems arising out of research not approved by an ethics committee. The General Medical Council could, and should, review its present position that performing research on patients without their knowledge or consent will not of itself constitute serious professional misconduct.

These measures would increase the interest of both health authorities and researchers in ensuring that local research ethics committees function well. Any of these measures could have been introduced during the past decade, had the will—in the medical profession particularly—existed.

The difficulty is that ethical aspects of medical practice and research are still too often considered as optional extras and not as integral to the medical enterprise. Thus, one week after your editorial, you published an article on how to organise a multicentre trial that made, in four pages, not a single reference to the need for ethical review.[2] That was a curious omission when so many trialists assert that obtaining ethical approval is one of the greatest problems in such trials.