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Guidelines for Local Research Ethics Committees: Distinguishing between Patient and Population Research in the Multicentre Research Project

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A multicentre population research study was undertaken, involving ethical approval from 28 local research ethics committees. The major problems encountered were delays, which fell into three categories: requests to complete separate application forms, delay in processing applications and additional requests for patient and consultant consent. We examine these sources of delay in the context of the recently published DoH guidelines for local research ethics committees. Our findings reveal that there is not only an absence of adequate guidelines for multicentre research studies but that the new guidelines for local research ethics committees fail to distinguish between patient research and the population study.

Introduction

Attention has recently been drawn to the inadequacy of the Department of Health's 1991 revised guidelines for local research ethics committees (LRECS)[1] both generally and with specific reference to the multicentre research trial.[2,3,4,5] We undertook a multicentre research study just prior to the publication of the revised guidelines. The problems encountered in obtaining ethical approval are examined in the context of the extent to which the new guidelines will resolve these issues.

Methods

The Thames Cancer Registry Project involved the analysis of data from 23 non-teaching hospital and five teaching hospital districts in South West and South East Thames Regions in 1991. The aim of the study was to describe and evaluate differences in treatment and survival in colo-rectal cancer in the South Thames Districts between 1982 and 1988.

Twenty-eight district ethics committees were sent the study protocol (a retrospective case-note study) which included the statement that data analysis would ensure patient and consultant anonymity and would not involve patient contact or intervention.

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Results

Conditions of approval

Of the 28 districts, 19 requested completion of separate application forms in addition to the original protocol and questionnaire. Of the 28 districts, three granted approval without formal application to the ethical committee; in a further three, chairman's action was granted. Of the 22 applications which went before an ethics committee, 11 districts gave approval with no conditions, while nine districts gave approval subject to consultant's permission being sought prior to accessing the notes, one district was prepared to grant ethical approval after a sole clinical representative had given permission, and one chair of the ethics committee insisted that we obtain permission from every consultant whose notes we wished to review *before* ethical committee consideration would be given.

Three districts requested that the researchers attend the LREC meetings before ethical permission could be given.

Time to approval

Most districts replied within three months, but three took more than three months to reply from the time of sending in additional information. The mean approval time was 11.9 weeks (Figure 1).

Teaching hospitals

All five teaching hospitals replied within three months of initial contact and three did not require ethics committee approval.

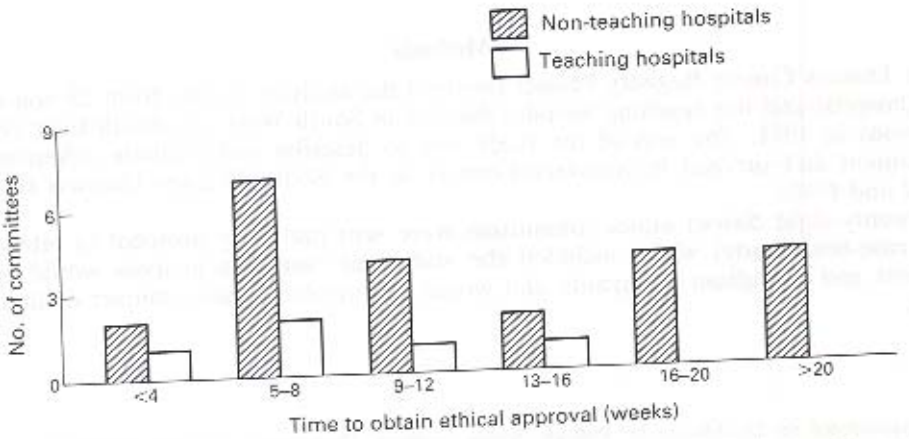

Figure 1 Length of time from request for application form to obtaining written ethical approval ($n = 28$)

Inappropriate requests

Despite the assurance that there would be no patient contact in the study there were three inappropriate requests, two from teaching hospitals and one from a non-teaching hospital. The requests were: all patients should be given a copy of the patient information sheet; a requirement 'to report to this committee at once any adverse experience affecting subjects' and, third, 'all trials, unless there are exceptional circumstances [should] include written consent'.

Discussion

Delay and the 1991 DoH guidelines

This study supports the findings of Ginzler *et al.* that no clear universal policies or standards for health services research operate in LRECS.[6] This is reflected in the wide variation in responses which contributed to three types of delay being identified: requests to complete separate application forms, delay in processing applications and finally additional requests for patient and consultant.

The new guidelines do little to resolve these problems. Since the DoH guidelines make no recommendations for a standard application form nor with respect to the timing of ethics committee meetings it is unlikely that these two sources of delay will be eliminated.

As for delay due to patient and consultant consent, if local LRECS apply the new DoH guidelines 'wherever possible consent should be sought from the health professional responsible for the relevant aspect of the subject's care' to all research projects, the delay experienced by multicentre population research studies will be perpetuated. This is likely to be exacerbated by the 1991 DoH guidelines on patients' consent, which recommends that patients should give their consent before their records are released to research workers carrying out epidemiological research unless 'the LREC is satisfied that the value of the project outweighs, in the public interest, the principle that individual consent should be obtained'.

Patient versus population research

A major problem for the multicentre research study is the failure of the new guidelines to distinguish between the clinical trial and population research. This contrasts with the Royal College of Physicians guidelines for medical ethics which state that 'ethical review is not required for studies ... of ... quality control or medical audit such as the aggregation or analysis of information for the purpose of monitoring the provision and effectiveness of health care services or for enquiries designed to establish indices of morbidity or mortality in various fields of practice, so long as patients cannot be identified'.[7]

A clinical study involves research on individuals, so that the subject is always directly affected by the proposed interventions. In contrast, population research does not usually involve patient interventions, neither does it intrude upon the doctor–patient relationship, nor does it have any direct application for the individual patient. Most retrospective case-note studies fall into the latter category.

The failure to distinguish between population and patient research may be a legacy of LRECS, which were originally established to consider clinical studies with the

primary aim of safeguarding patients' interests. The protection of the patient–doctor relationship forms the basis of obtaining the permission of the doctor primarily in charge of the patients. Health services research and population research is a relatively new development in the history of ethics committees.

A national ethics committee

The DoH has attempted to get round the problem of multicentre research by suggesting that one local research ethics committee (LREC) could consider protocols on behalf of them all. This raises many problems including the nomination of the LREC, its funding and coordination, and cooperation with other LRECs.

In view of the emerging consensus in the literature for a national ethics committee, why has the DoH sidestepped a possible solution, despite the obvious advantages?[8,9,10,11,12] A central committee would improve the public visibility of medical ethics and could ensure that local ethics committees' judgements were not covert or concealed.[13] It could ensure a national forum for strategy and public debate. Currently the general public are dependent on *ad hoc* reports of controversial issues.[14] A central ethics committee could act as an honest broker between researchers and committees and take into account their differences and difficulties. Finally, a national ethics committee could also ensure monitoring and proper accountability of LRECs to the public.

The DoH now recommends that LRECs should publish an annual report; in the absence of monitoring and audit this is likely to remain a process activity and will not shape policies.

Ethics and the internal market

It is a curious anomaly that the guidelines do not make passing reference to the NHS changes. Since LRECS are staffed by volunteers and meet on a voluntary basis could it be that the government feels uncomfortable about imposing regulations on a free good? The establishment of a national ethics committee could have significant resource implications which would include information and monitoring systems for policy making and research and perhaps, too, a requirement to fund LRECs.[15]

Conclusion

This study illustrates the absence of clear guidelines for the multicentre research application and in particular the failure to distinguish between patient and population research. The revised 1991 Department of Health guidelines contain no clear recommendations for the three main sources of delay, completing different application forms, processing, and obtaining consultant and patient consent. The implication from this study is that delay will continue to be a serious problem for researchers.

References

1. Department of Health (1991). *Local Research Ethics Committees*. (HSG (91) 5). London: Department of Health.
2. Moodie, P. C. E. & Marshall, T. (1992). Guidelines for Local Research Ethics Committees. *British Medical Journal*, **304**, 1293–1295.

3. Moodie, P. (1992). The role of local research ethics committees: maintaining the pressure for improvement. *British Medical Journal*, **304**, 1129–1130.
4. Neuberger, J. (1992). *Ethics and Health Care: the Role of Research Ethics Committees in the United Kingdom*. London: King's Fund Institute.
5. Horwitz, R. & Cheetham, C. H. (1992). Ethics and multicentre research projects. *British Medical Journal*, **304**, 1446.
6. Ginzler, M., Davies, J., McPherson, K. & Black, N. (1990). Ethics committees and health services research. *Journal of Public Health Medicine*, **12** (3 and 4): 190–196.
7. The Royal College of Physicians (1991, January). *Guidelines on the Practices of Ethics Committees in Medical Research involving Human Subjects*. London: The Royal College of Physicians.
8. Marshall, T. & Moodie, P. (1988). Scrutinising research ethics committees. *British Medical Journal*, **297**, 753.
9. Moodie, P. & Marshall, T. (1989). A national ethics committee. *British Medical Journal*, **298**, 524.
10. British Medical Association (1981). Local ethical committees. *British Medical Journal*, **282**, 1010.
11. Nicholson, R. (1987). Research ethics committees. *Times Health Supplement*, **4** (1), 3.
12. Thompson, I., French, K. & Melia, K. M. (1981). Research ethics committees in Scotland. *British Medical Journal*, **282**, 718–720.
13. Warnock, M. (1988). A national ethics committee. *British Medical Journal*, **297**, 1626–1627.
14. Department of Health and Social Security (Chairman Dame Mary Warnock). *Committee of Enquiry into Human Fertilization and Embryology*. Command Paper 9314. London: HMSO.
15. Nott, P. & Steel, E. (1988). Scrutinising research ethics committees. *British Medical Journal*, **297**, 1333.