Costs of seeking ethics approval before and after the introduction of multicentre research ethics committees

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SUMMARY

With the advent of multicentre research ethics committees in the UK, local research ethics committees (LRECs) are required to advise only on issues relating to the local acceptability of a project. We looked at the handling of two commercially sponsored studies, one initiated before the change and one after, confining the analysis to 21 LRECs approached in both. As judged by the amount of paper per application, the new system for LRECs is simpler and should be less costly. However, there was an increasing tendency for LRECs to charge for their services (30% study 1, 47% study 2) and these charges varied by more than 400%. If such fees must be levied, a common scale is desirable.

INTRODUCTION

The first multicentre research ethics committees (MRECs) in the UK were set up in early 1997. This was in response to concerns over the ethical review procedure for multicentre research dating from 1991, when local research ethics committees (LRECs) were established in every health district[1]. The purpose of MRECs is to consider the ethics of any research projects conducted within the geographical boundaries of 5 or more LRECs, and to provide approval, where appropriate, that applies wherever the project is carried out in the UK[2]. In the context of multicentre research, therefore, the LRECs' role has changed to providing advice only on issues affecting local acceptability of the research project. They cannot seek changes in the study protocol or research instruments. The process is designed to ensure that a decision on a research project is made without unnecessary delays, and to reduce the administrative burden associated with multicentre research applications. This aim may not have been achieved: researchers have reported considerable delays in gaining LREC approval despite having MREC approval, together with a great volume of paperwork[3,4]. Each of these reports gives an estimate of some of the costs in terms of paper, postage and researcher's time, but there is no mention of LREC fees, possibly because the research had no commercial sponsorship and none were charged. We report here on the costs and administration associated with gaining ethics approval for two commercially sponsored studies conducted before and after the introduction of MRECs.

METHODS AND RESULTS

The MICA study (study 1) was a case–control study of myocardial infarction in relation to oral contraception, conducted in England, Scotland and Wales; the main results have been published elsewhere[5]. The Evohaler Validation Study (study 2) was a randomized cross-sectional survey of patient notes, to validate a questionnaire completed by general practitioners; it was conducted in southern England only. Both these studies were sponsored by pharmaceutical companies. We applied for ethics approval for study 1 during 1996 and early 1997, and for study 2 during 1999. Study 1 required 197 LREC applications; study 2 required 1 MREC and 26 LREC applications. 21 LRECs were approached for both studies and this paper is restricted to our experience with these LRECs. When we did not know the normal fee for commercially sponsored studies in the appropriate year, we wrote and requested the information from the LREC, since in some cases we had not been asked to pay because of the charitable status enjoyed by the Drug Safety Research Unit.

The median number of copies of the application per LREC for study 1 was 13, range 1 to 34. Each application consisted of about 1000 sides of A4. For study 2 the number of copies per application ranged from 1 to 16, median 4. Each application consisted of a mean of 450 sides of A4, but there was wide variation in the amount and type of documentation required. In both studies the number of potential study subjects per LREC area could be as few as three or four.

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Table 1 **Proportion of local research ethics committees charging fee, and amount of fee, in those committees common to both studies**

			Distribution of charges (£)*		
	No. of LRECs	No. (%) making no charge	Median	75%	Maximum
Study 1	20†	14 (70.0)	0	175	500
Study 2	21	11 (52.4)	0	275	940

*Those 20 LRECs for which both charges were known
†1 LERC did not reply

Table 1 shows that more than half the LRECs made no charge in either study. Study 2 charges tended to be higher than those for study 1 (Wilcoxon signed rank test, P=0.05).

DISCUSSION

As judged by the number of copies and amount of paper per application, the administration associated with the new ethics committee system has been simplified. However, there appeared to be wide variation in the mode of operation of individual LRECs. If the number of copies submitted reflects the number of committee members considering each application, this ranged from one to sixteen; we know, however, that some committees ask for only one copy and do their own photocopying. In study 2 many of the LREC applications could have been dealt with by chairman's action or by an executive subcommittee, as recommended by recent guidelines[6], which would surely have reduced the administration (and thus costs) imposed on the LREC. When a charge was made, the fee for gaining LREC approval varied by greater than 400%, and the charge tended to increase between 1996 and 1999. This is surprising, since the task assigned to the LREC has been considerably eased. Members of LRECs are not directly remunerated for their work[7]. In fact, some LRECs told us that they regard the charging of fees as either unethical or impermissible. If the fee structure for study 2 was applied to a commercially sponsored national study in England, Scotland and Wales now, ethical approval involving 200 LRECs would add about £34 000 to study costs, in fees alone, excluding paper, postage and researcher's time. An agreement on a common scale of fees (if appropriate at all) would help with budgeting and would be fairer to all. These fees should reflect the administration costs of the LREC and possibly such items as travel expenses incurred by the committee members. The costs will, of course, vary according to the extent of research activity within the LREC boundaries, but the present lack of transparency does not reflect well on the vital function of these committees.

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