Observational study of 353 applications to London multicentre research ethics committee 1997–2000

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Since 1997 British studies involving five or more centres have required approval from both a multicentre research ethics committee¹ and the local research ethics committee for each centre. A local committee can reject the protocol for local reasons but cannot amend it. Some researchers have criticised the process of obtaining ethical approval for multicentre studies,^{2–4} but little is known about the work of the 10 multicentre research ethics committees. I describe here the work of one of them.

Methods and results

I gathered and analysed data from the following documents sent to me as a member of London (formerly North Thames) multicentre research ethics committee before each monthly meeting during October 1997–November 2000: new applications, correspondence about continuing applications, list of recently approved applications, and minutes of previous meeting.

There were 353 new applications and 38 scheduled meetings. The median number of members at each meeting was 14 (range 11–16). Median numbers of new and continuing applications discussed at each meeting were 10 (range 3–14) and 4 (range 0–8) respectively. Of 353 new applications discussed at a first meeting, 14 (4%) were approved, 217 (62%) approved conditionally, 103 (29%) deferred, and 19 (5%) rejected and the researchers invited to resubmit. Deferred or rejected applications were reconsidered at up to four other meetings (table). Forty eight researchers whose applications were deferred or rejected were invited to attend the next meeting. 330 (93%) of 353 applications were eventually approved. Only one decision required a vote; others were made by consensus.

At some stage of the review process the committee conditionally approved 306 (87%) applications at scheduled meetings and delegated responsibility to the chairman and other members to resolve remaining queries.

Of 339 applications conditionally approved, deferred, or rejected at first meeting, 287 (85%) had queries about the patient information leaflet (such as inadequate information, jargon, poor clarity, need for proofreading) and 171 (50%) had queries about study design (such as use of placebo, stopping current treatment, choice of comparator drug). Rejected and deferred applications had proportionally more queries about study design, and also safety and statistics, than conditionally approved applications (see table on bmj.com).

I used correspondence for the 122 applications deferred or rejected at first meeting to calculate times taken to notify researchers and for them to respond: median times were 6 days (range 1–9) and 13 days (range 4–277), respectively.

Members were not given copies of approval letters to researchers so I could not calculate precise times from first meeting to approval. However, dates of meetings when an application was first considered and

Progress of all 353 applications

No of meetings where application discussed	No of applications discussed	Outcome of application (No (%))				
		Approved	Conditionally approved	Deferred	Rejected	Withdrawn
1	353	14 (4)	217 (62)	103 (29)	19 (5)	0
2	122	14 (12)	71 (58)	24 (20)	4 (3)	9 (7)
3	28	2 (7)	14 (50)	9 (32)	1 (4)	2 (7)
4	10	2 (20)	4 (40)	1 (10)	1 (10)	2 (20)
5	2	1 (50)	0	0	1 (50)	0
1–5	353	330 (93)	9* (3)	0	1 (0.3)	13 (3.7)

*Not pursued by researchers.

when members were informed of its approval were available for 266 applications. I took the difference as the best estimate of approval time. Median time was 64 days (range 7–386). Using the same method of calculation, median time from conditional approval to approval was 62 days (range 21–408).

Comment

Ethical review was often protracted, and few applications were approved unconditionally at first meeting. As expected, rejected or deferred applications had more profound queries than conditionally approved applications. Most patient information leaflets required changes, some extensive. More care and effort by researchers in preparing applications, particularly information leaflets,¹ would shorten approval time.

The committee met its requirement of notifying researchers within 10 days of initial decision.¹ But when the Clinical Trials Directive⁵ and governance arrangements for research ethics committees¹ are implemented the committee will have to shorten the review process for continuing applications or reject more. The directive allows committees 60 days for a decision, and only one request for supplementary information (60 day period suspended until information received).

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1 Central Office for Research Ethics Committees. www.corec.org.uk [accessed 1 April 2002]

2 Tully J, Ninis N, Booy R, Viner R. The new system of review by multicentre research ethics committees: prospective study. *BMJ* 2000;320:1179–82.

3 Lux AL, Edwards SW, Osborne JP. Responses of local research ethics committees to a study with approval from a multicentre research ethics committee. *BMJ* 2000;320:1182–3.

4 Alberti KG. Multicentre research ethics committees: has the cure been worse than the disease? *BMJ* 2000;320:1157–8.

5 Directive 2001/20/EC. Good clinical practice in the conduct of clinical trials on medicinal products for human use. *Off J Eur Comm* 2001;L121:34–44.

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