Research ethics committees – time for change?

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ABSTRACT – Research ethics committees have developed over the last 30 years in the UK. As their roles and responsibilities have grown, so too has the complexity of their work. This poses increasing problems which cannot be solved within the current structure. This article suggests that the present large number of volunteer committees be replaced by a much smaller number of fully professional bodies in order to increase speed, efficiency and consistency of working.

KEY WORDS: clinical research, ethics, guidelines, research ethics committee, research protocols

Background

Ethical review of clinical research made slow progress in Britain. When the RCP first recommended that research should be approved by a group of doctors[1] – a committee – the *BMJ* loftily declared:

> *It is questionable whether the more difficult basic problems can be solved by having a committee… Such a system will not deter the very person at whom it is aimed – the man determined to finish a project unrestrained by any scruples. But it could cause appreciable delay to workers whose ethical integrity cannot be questioned. Furthermore, the mere creation of a committee will do little to satisfy those laymen or medical men who have called for more far-reaching action*[2].

It concluded:

> *in the final reckoning the decision about a particular project is one for the doctor concerned, and for him alone.*

That view now seems as outdated as the sexist language in which it was couched. But the RCP moved slowly. The first *Guidelines on the practice of ethics committees in medical research* were published in September 1984, and following that, research ethics committees (RECs) were established widely. They differed greatly in working methods, size and composition, some conducting business entirely by post[3]. In 1991, the Department of Health at last published definitive guidance[4]. Responsibility for establishing RECs was given to health authorities and the composition of committees broadly standardised. The history of informed consent in medical research has been told elsewhere[5].

Past and present problems

Problems surfaced even at the outset of this development. Multi-centre research in particular could involve application to over 150 committees, involving a colossal waste of time, paper and expense[6]. In 1992, the Centre for Philosophy & Health Care in Swansea was commissioned to research and develop proposals to address multi-centre research[7] but, even after their report, it was a further three years before the current system of multi-centre research ethics committees (MRECs) was established[8]. Essentially the system consists of ten committees reviewing research taking place in five or more health authority areas and making decisions on a national basis. While this improved consistency, standards and accountability, local RECs (LRECs) still review protocols for local issues. In epidemiological research, where local involvement often meant no more than data collection, this continued to involve a vast amount of unnecessary paper work[9,10]. In November 2000, supplementary guidelines for epidemiological research were issued to address this[11]. These guidelines were long in coming, but have undoubtedly enabled an enormous improvement where there is no local researcher. Further development for better clarification and to cover such research in NHS staff will probably appear with the completion of the revised document on Governance for Research Ethics Committees. This still leaves in place a two-tier system for other projects. LRECs remain idiosyncratic in their opinions and decisions. Unnecessary delays engendered by the system has led to fear that research is being hindered in the UK by RECs and is moving abroad as a result[12].

All this must change. A draft European Directive[13] requires a single-tier system (article 5) and a maximum of 60 days in which to make a decision (article 4). It defines multi-centre research as taking place in two sites, not five.

Local research ethics committees

As a MREC chairman, I can attest to the inconsistent working practices of LRECs: one will oppose informing patients that the research has been approved by the REC (because it is 'coercive'), the next insisting this information must be given; one

will oppose any payment to research subjects, the next will support it; one will accept family members as translators for the non-English speaker, the next insist on accredited professionals only; and so on. Multi-centre protocols have frequently been delayed for reasons that are not local – even for reasons of grammar in the patient information sheet! Understandably, leading voices in the pharmaceutical industry are unhappy with the working of the current system. RECs are seen as an obstruction to be negotiated.

Standardised paperwork and regular discussions of MREC chairmen have established a fair degree of consistency in MRECs, but the work of LRECs remains difficult to judge. Whereas extensive data have been collected for MRECs, the only accountability of LRECs is through the annual report to their health authorities, the content of which is not standardised[14], making comparisons difficult. At the time of writing, LRECs do not even use a standardised application form. A protocol approved by the MREC may be reviewed free of charge by one LREC, while the neighbouring LREC charges three or four hundred pounds for the same task. The establishment of a central office for RECs (COREC) has been a major step forward and the relatively consistent working patterns of MRECs owes much to this (as well as its excellent website), but achieving the same degree of consistency among more than 200 LRECs is a bigger challenge.

The 1991 guidance has lasted well. In 2001, it was superseded by the first section of a new document[15], covering general principles and standards. The next section will offer more detailed guidance on operating procedures and support procedures. Uncertainty was reflected in a letter to RECs from Professor Sir John Pattison dated 16 October 2001, explaining that there would be delay in issuing such further guidance, which has yet to appear pending the establishment of strategic health authorities and agreement on new structures resulting from this.

The untenability of the present system

How might matters be improved? Can this be achieved without major changes to the system itself? The current system appears increasingly unsustainable for at least five reasons.

Firstly, the remit of the REC is widening and should widen further. The new governance document is much more explicit in requiring research involving NHS staff, 'recruited as research participants by virtue of their professional role' (section 3.1g, ref 15), to be subject to REC review. Any questionnaire study of staff, for example, must now be submitted to the REC. The same document also suggests that research on clients of social services should have the favourable opinion of an REC which 'meets the same general standards as NHS RECs' (section 3.11) – for which the logical solution might be to extend the remit of the NHS REC with some additional representation. Research activity is probably going to grow in the private sector: some healthcare is dominated by the private sector, such as assisted reproduction and plastic surgery. This too should be subject to ethical review and the NHS REC is the body best equipped to take this on. A fourth area is alternative and complementary medicine (CAM). The Foundation for Integrative Medicine is eager to encourage research and the number of CAM practitioners exceeds the number of GPs in the NHS. There is now an active dialogue between orthodox medicine and CAM, evidenced, for example, by the establishment of a CAM committee at the RCP. So again, the NHS REC would probably be the best body to take on ethical review of such research. Research projects are likely to continue to play a significant part in master's degree courses and growth here also seems likely. 'Research to be undertaken by students primarily for educational purposes shall be considered according to the same ethical and operational standards as are applied to other research' (section 10.4, ref 15).

A sixth area of potential extension to the remit of the REC is market research. Typically this takes place at present without review beyond the ethics of the industry. Yet consider the sort of request many doctors receive for anonymous, yet quite specific details of the last few patients treated with antibiotics or lipid-lowering drugs. The only reason this avoids the REC at present is because it is not construed as 'science'. Yet the results are generalisable enough to be worth rewarding the doctor with £7 per completed patient profile (to take the last one I received) and, presumably, to guide the marketing of pharmaceuticals. If the survey was *bona fide* 'traditional' science, there would be no debate that it needed REC review.

A seventh area is university research into health hazards or health-related behaviour: for example, smoking in schools, the health risks in agriculture or in certain occupational groups. As the recent guidance points out,

> *not all medical, other health-related or social care research takes place within the NHS or public sector social services. All those conducting such external research should be encouraged to submit their research proposals to an NHS REC for advice, and the REC should accept for consideration all such valid applications.* (section 7.22)

RECs are sometimes asked for advice before a protocol is finalised or before funding has been agreed. Some are unhappy to offer such advice. But if the promotion of good quality research is a valuable social good, then surely a dialogue with the research community should be encouraged. There is no reason why this should necessarily compromise independence.

We may conclude that REC workloads should and will rise. Indeed there is some evidence that they are doing so. As they do, meetings will lengthen, the lunchtime meeting will disappear and the volume and variety of papers to study will grow.

The second reason concerns recruitment. Many RECs are finding it increasingly difficult to attract members. This has especially been true for GP members. The MREC for Wales, for example, has had 0.5 GP membership (one GP with 50% attendance) instead of two for the first two years of its existence and has now elected to replace one GP vacancy with a primary care nurse. Consultant members are also hard to recruit in some areas, especially where the venue of the meeting is far from the consultant's place of work. Public advertisement for lay members may often yield a good number of applicants, but even here a representative cross-section may be hard to obtain. Clergy

Key Points

- **Research ethics committees (RECs) were developed over the last 30 years. There are now over 200 local and multi-centre committees**
- **The system of ethical review of research is highly bureaucratic, wasteful of time, money, energy and paper. It is also unnecessarily slow and inconsistent**
- **RECs should widen their remit, improve their efficiency and consistency of working and offer greater expertise in ethical review among their members**
- **The present system of RECs staffed entirely by volunteers is unlikely to be able to expand its workload as well as offer the above improvements. A smaller number of full-time committees of paid members (or committees meeting much more frequently) is proposed for discussion**

have made an enormous contribution to many RECs, but it is debatable whether this professional group should have such a disproportionate representation among lay members. Indeed, the status of a full-time NHS hospital chaplain employed under Whitley Council conditions of service might be better considered as a professional allied to medicine than as a lay person. The definition of a quorum of seven members in the new guidance (section 6.11) is likely to involve a larger membership in many RECs, exacerbating these difficulties further.

Third, while Pattison wrote of the need for training, many REC members have minimal training or none at all. Often members lead busy professional lives in which educational time is thought best devoted to further medical, pharmaceutical or nursing education – not to REC matters. Documents of relevance to the REC's work appear in increasing numbers. In the last year or so, drafts of revised guidelines from the Council of International Organisations of Medical Sciences (CIOMS), General Medical Council guidelines on research, the Department of Health's (DH) *Research governance framework for health and social care,* its documents on Governance for RECs, on Consent, on Good Practice in Consent, on Removal, Retention and Use of Stored Organs and Tissue, the Medical Research Council's guidelines on Human tissue and biological samples for use in research and on Personal information in medical research, the interim guidance from the Royal College of Pathologists on Research on stored tissue, the report of the Alder Hey Inquiry, the recommendations of the Bristol Inquiry – and others – would all have been studied by the assiduous REC member. Most will not have read such a list, of course, let alone studied so much advice; some REC members will be barely aware of them. In practice, it is impossible to insist on such training in a voluntary system. REC membership has been compared to joining the Bench, but hardly carries the prestige of a magistrate in a local community. Training may be stated as an expectation at appointment, but is hard to enforce. No detailed curriculum has yet been published by the DH (its development is in progress), although the *Briefing pack for research ethics committee members* (1997) is an excellent resource[16].

Fourthly, the response to increasing workloads may be to increase the number of committees – already two more MRECs are planned in England and one more in Scotland. As the number of RECs increases – there are already over 200 – consistency of working will be harder to achieve. For example, it has always seemed advisable to invite the investigator to the meeting: problems can be solved on the spot, the mentality of 'them' and 'us' can be prevented or ameliorated, lengthy correspondence and misunderstanding avoided. Yet this policy is practised variably even by MRECs – in Wales it is routine, in some English committees it happens occasionally, in others never. Standard operating procedures may help resolve some of these inconsistencies, but one can only observe that such guidance has already been published with little observed effect[17–19].

Fifth, the voluntary principle upon which RECs have been based is increasingly being breached. There has been much discussion of whether certain committee members should be paid. Statisticians, in particular, have been singled out as members whose place on the REC is to offer their particular specialist expertise and not their general ethical wisdom; hence payment should be given. Predictably, the same argument has been used for pharmacists, to be followed by the suggestion that an honorarium should be offered to chairmen as the individuals who carry the greatest burden of work. No action has yet been taken on these suggestions, but the new guidance does distinguish between members. Thus (section 6.9) 'the time required for undertaking such service (i.e. REC membership) and the necessary training should be protected, and form a recognised part of the individual's job plan'. In essence, this means that professional NHS employees will be paid for their REC work. While currently most professionals give all or most of their time to the REC out of contracted working hours, this recommendation drives an increasing wedge between lay and professional members.

A new approach

The logic of the above developments is obvious. Faster working, as envisaged in the European Draft Directive and surely desired by the research community, means more frequent meetings; so too does a wider remit. The monthly meeting will be too infrequent; in truth, it already is. Good quality review takes time and no committee should be reviewing more than 10–12 protocols at a meeting, as some do currently. RECs need to meet weekly, if not more frequently. Consistency of working means fewer committees, not more. Expanding the membership is likely to prolong discussion and to increase the idiosyncrasies that already dog the system.

Accountability of members for training and familiarity with new recommendations will be best achieved by a clearer contract of membership. This contract should be enforceable and audited. Quality review implies a detailed knowledge of current guidance, both national, European and international.

Time should be set aside for this within the REC's working time, not as an extra for the exceptional enthusiast. Time to prepare for REC meetings will be increasingly difficult to squeeze into busy working schedules or home life as the volume increases. This too needs time to be formally allocated.

These ends can only be met by a professional, paid committee, which would professionalise the system and abolish its amateurism. By using the term 'professionalise', I imply that the members would be substantially dedicated to ethical review and not to other activities; and that they would be paid appropriately. The new REC would meet for at least one full day per week and perhaps be full time: one full-time committee might be adequate for the whole of Wales for example, replacing both its MREC and its ten local committees. Possibly 10 to 20 full-time RECs would be enough for the entire UK. Adequate preparation and administrative time would be built in. Proper recruitment procedures would be instituted with pay comparable to the professional status of the members – including the 'lay' members. Nolan standards of appointment would be easier and cheaper to achieve. The committees would need to be bigger than the current LRECs to cover social care research and possibly even phase 1 industry research, given guarantees of commercial confidentiality.

It has been argued that the public service ethos would be lost. Yet nobody believes that courts of law are unjust because the judge is paid. A five-year term of office as REC member would not be so different from a similar term as a medical manager and a return to ordinary clinical practice should be possible; alternatively, on the legal model, it could be a career commitment for some. A regular forum for chairmen would be easy to organise on a regional, supra-regional or national basis to encourage greater consistency and for problem sharing. There would be vast savings in the paper work engendered by the current system and the costs may be more modest than envisaged. At present, industry pays £1,000 per protocol to MRECs and variable amounts to LRECs. It will not fully finance a professional system, of course, but the current system is enormously wasteful of money and time. Further joint initiatives between industry and government could be considered, building on the work of the Pharmaceutical Industry Competitiveness Task Force, whose clinical research report was updated this year[20]. The detail can be worked out once the principle of the professional committee is agreed. Perhaps there will even be a residual role for a local REC for questionnaire degree-type studies, where it may be easier to offer consistent and rigorous standards. But invasive studies deserve to be scrutinised at a level free from cronyism, where saying 'no' does not mean saying it to a colleague – and where this can be clearly seen to be so by an increasingly sceptical public. A committee that is further removed from the investigator could offer this. What may be lost in distance would be more than gained in efficiency and improved standards.

Megone *et al* suggest that one role for lay members is to make the REC more democratically representative, more representative of the community as a whole, or more accountable to the community as a whole[21]. It is doubtful whether lay members really fulfil this role – many reside outside the catchment areas of the institutions in which research is to take place, especially in big cities. Perhaps the main role for the lay member remains that of providing insights into how research might affect its subjects and on the provision of information to them. The latter role would not change under these proposals. A local role for ethics committees is often suggested in assessing local facilities or local investigators, but standards for such assessments have never been defined and represent a function for which current RECs are not trained or equipped or have the time. This is surely best taken over entirely by the structures for research governance in line with the DH's recent document[22]. In fact, there is very little of research design that requires local assessment of its ethics.

Conclusion

In summary, there is little to necessitate the continuation of the present system in terms of quality of review. There is little to lose and much to gain from a new approach. If nothing else, perhaps this paper, along with a recent editorial published elsewhere while this paper was in preparation[23], will initiate a vigorous but civilised debate. The current system of RECs has served well in a typically British amateur way. But we need to discuss a more radical change – soon.

Conflict of interest: JS is chairman of the MREC for Wales, immediate past chairman of Gwent LREC, a former member of the Ethics Advisory Committee of the Royal College of Paediatrics & Child Health and Honorary Secretary of the Committee for Ethical Issues in Medicine at the Royal College of Physicians. The views he expresses are his own.

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Shakespeare's doctors

There are seven physicians in Shakespeare's plays, of whom two are worthy of note.

In *Macbeth* a doctor takes part in an important scene, interesting medically as it reflects a physician practising his art. Lady Macbeth is sleepwalking due to the murders on her conscience. Her maid summons the doctor who questions her:

In this slumberly agitation, besides her walking and other actual performances, what, at any time, have you heard her say?

The maid refuses to break confidence:

neither to you or anyone, having no witness to confirm my speech.

Suddenly, Lady Macbeth appears. The doctor says:

Hark, she speaks. I will set down what comes from her to satisfy my remembrance the more strongly.

Lady Macbeth confesses to being behind the murder of Banquo. This puts the doctor in an unenviable position. He decides, wisely, that:

This disease is beyond my practise.

And leaves saying:

Infected minds
To their pillows will discharge their secrets.
More needs she the divine than the physician[1].

Making careful clinical observation, writing down a thorough history, ensuring confidentiality, acknowledging the limitations of one's skills and referring to a specialist when required are therefore far from new.

All's well that ends well is based on a medical problem – the King of France is very ill with a 'fistula'. Gerard de Narbon dies before the action of the play, but is remembered as a highly respected physician:

...whose skill was almost as great as his honesty; had it stretch'd so far, would have made nature immortal, and death should have play for lack of work[2].

His daughter Helena, using her father's recipe, is able to cure the King of his fistulae. This arouses suspicion, particularly as the Royal College of Physicians has pronounced the condition incurable:

We thank you, maiden;
But may not be so credulous of cure,
When our most learned doctors leave us, and
The congregated colleges [Royal College of Physicians] have concluded
That labouring art can never ransom nature
From her inaidable estate [incurable condition] – I say we must not
So stain our judgement, or corrupt our hope,
To prostitute our past-cure malady to empirics [quacks][3].

In other words, if a member of the Royal College of Physicians cannot heal a disease, it is better to live with the disease than to seek help from others.

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