

CONSISTENCY IN RESEARCH ETHICS COMMITTEE

DECISION-MAKING: A CONTROLLED COMPARISON

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ABSTRACT

There has been long-standing interest in the consistency of decisions made by Research Ethics Committees (RECs) in the UK, but most of the evidence has come from single studies submitted to multiple committees. We undertook a systematic comparison of decisions made about 18 purposively selected applications, each of which was reviewed independently by three different RECs in a single Strategic Health Authority. Decisions about 11 applications were consistent, but there were disparities among RECs on decisions for 7 applications. Analysis of agreement of RECs' decisions yielded an overall measure of agreement of $\kappa = 0.286$ (95% CI -0.06 to 0.73), indicating a level of agreement that, while probably better than chance, might be described as "slight". The small sample size limits the robustness of these findings. Further research is needed into reasons for inconsistencies in decision-making between RECs, and into the significance of such inconsistencies for a range of arguments.

Consistency in Research Ethics Committee decision-making: a controlled comparison

Research Ethics Committees (RECs) in the UK aim to make decisions about research proposals in line with published guidance.¹ The importance of systematic and consistent decision-making by RECs has been repeatedly emphasised, most recently in the national Standard Operating Procedures (SOPs) for RECs,² prompted partly by EU legislation.³ Much of the evidence about consistency in REC decision-making in the UK is based on studies of a single proposal being submitted to multiple committees, and is authored by the investigators themselves, usually in response to frustrating experiences.^{4 5 6} There is little evidence about the extent to which RECs agree about proposals. We aimed to compare decisions about the same proposals made by different RECs.

Methods

The three RECs in the Leicestershire, Northamptonshire and Rutland (LNR) Strategic Health Authority were included in the project, which ran between February 2004 and February 2005. Members of the committees gave their verbal consent to participation in Autumn 2003. Purposive sampling was used to select applications for inclusion in the project. Sampling was conducted by EA, a REC administrator, and aimed to represent different types of study and different types of applicant. Types of study were:

- **Intervention:** a study that intervenes in the normal clinical care of a patient/health service user.
- **Non-intervention:** a study that does not involve an intervention but seeks to measure outcomes or processes.
- **Qualitative:** a study that uses distinctive qualitative research methods.

Types of applicant were:

- **Novice:** applicants who had not previously applied to the REC.

- **Experienced:** applicants who had submitted at least one previous application to the REC.

Over a 12 month period each application was reviewed by all three RECs and all three prepared a decision letter. Each application was assigned a “lead” REC before the application was considered by any committee, and applicants received the decision letter of the lead REC only. The two non-lead RECs were sent this application as a “dummy”, dispatched as one of the many applications for each meeting, and not labelled as “the dummy” (though it might sometimes have been possible for members to guess). Over the course of the project, each committee reviewed 12 “dummy” applications and six applications as the “lead” committee.

Three decision letters for each application were generated for analysis. Under Governance Arrangements for Research Ethics Committees (GAfREC)¹ and SOPs² guidance, there were four formal decisions available to RECs:

- **Favourable:** The application is ethically acceptable.
- **Provisional:** Amendments to the application or further information are required before a final decision can be made.
- **Unfavourable:** The application is ethically unacceptable.
- **Outside remit:** The application is deemed to fall outside the remit of GAfREC.

Patterns of agreement in decisions were assessed descriptively. Agreement was further assessed using the kappa statistic, which indicates the proportion of observed agreement that cannot be explained by chance. The one “favourable” decision was grouped as “provisional” for purposes of this analysis.

Results

Table 1 Types of study, types of applicant, and decisions

No.	Study type	Applicant type	REC1	REC2	REC3
1	Non-intervention	Novice	Provisional	Provisional	Provisional
2	Non-intervention	Novice	Unfavourable	Unfavourable	Unfavourable
3	Qualitative	Expert	Provisional	Provisional	Provisional
4	Intervention	Expert	Provisional	Provisional	Provisional
5	Qualitative	Novice	Provisional	Provisional	Provisional
6	Non-intervention	Novice	Provisional	Unfavourable	Unfavourable
7	Intervention	Expert	Provisional	Provisional	Unfavourable
8	Intervention	Expert	Provisional	Provisional	Favourable
9	Intervention	Expert	Unfavourable	Outside remit	Provisional
10	Qualitative	Novice	Provisional	Provisional	Unfavourable
11	Qualitative	Novice	Provisional	Provisional	Provisional
12	Qualitative	Novice	Provisional	Outside remit	Provisional
13	Qualitative	Expert	Provisional	Provisional	Unfavourable
14	Intervention	Novice	Provisional	Provisional	Provisional
15	Non-intervention	Novice	Provisional	Provisional	Provisional
16	Non-intervention	Expert	Provisional	Provisional	Provisional
17	Non-intervention	Expert	Provisional	Provisional	Provisional
18	Qualitative	Novice	Provisional	Provisional	Provisional

Eleven of the 18 applications received consistent decisions from all three committees (Table 1). “Provisional” was the most frequent decision for all three RECs. REC3 had a higher

incidence of unfavourable decisions (five, compared with two in REC1 and REC2), but was also the only REC to give a favourable decision. REC2 was the only one to give “outside remit” decisions.

Of the seven applications that received inconsistent decisions, six received consistent decisions from two committees. One application received different decisions from all three committees. Of the six applications where two committees agreed, four received consistent decisions from REC1 and REC2, one received consistent decisions from REC2 and REC3, and one received consistent decisions from REC1 and REC3. All three committees agreed on seven novice and four expert applications, and all three did not agree on three novice and four expert applications. The committees agreed on five non-intervention, four qualitative and two intervention studies, but did not agree on one non-intervention, three qualitative, and three intervention studies.

Analysis of agreement of RECs’ decisions yielded an overall measure of agreement of $\kappa = 0.286$ (95% CI -0.06 to 0.73), indicating a level of agreement that, while probably better than chance, might be described as “slight”.

Discussion

This study provides evidence about consistency of outcomes of REC decision-making. It was limited by its location within a single SHA. Variations in the types of application submitted over time imposed constrained the extent to which it was possible to select equal proportions of different types of study and applicant, though a reasonable balance was achieved. More importantly, the difficulties of conducting this type of research, which necessarily results in additional burdens on RECs, limited the size of the sample that could be obtained. The wide confidence interval demonstrates that there is considerable uncertainty about the point estimate, and polarised response categories such as those found in our dataset make the interpretation of the kappa statistic difficult. This inherently low-powered analysis nonetheless addresses an important question in an area where it is difficult to obtain data.

Although 11 of 18 applications considered by three RECs in our project received consistent decisions, seven – over a third of the sample - received inconsistent decisions. This evidence raises the bigger question of the significance of consistency of decision-making for various arguments.⁷ There is little doubt that disparities in process and outcome are a source of frustration and delay for researchers.⁸ There is also the possibility that, in a context where research governance is constructed as a regulatory and managerial enterprise,⁹ variations in outcome will be read as evidence of problems in “performance”. Further research is needed into reasons for variations in decision-making, including further analysis of the content of decision letters in our own study. Such research may help to further an understanding of what kinds of issues are identified by RECs as being “ethical” issues, how they can be resolved, and what kinds of ideas and principles appear to inform opinions about ethical issues. This kind of research could afford an exploration of whether disparities are due, as previous authors have suggested, to inconsistencies in moral judgements (which might be unavoidable, acceptable, or even desirable) or to irrationality, carelessness, or operation of conflicting interests (which should be reduced or removed).¹⁰

Conflict of interest

EA was employed as the Administrator to the Leicestershire, Northamptonshire and Rutland Research Ethics Committees during the period of the study. No other author has a conflict of interest.

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Ethics approval

Support was sought and obtained from COREC in summer 2003. COREC confirmed that the project constituted service evaluation and development and therefore need not be reviewed by a Research Ethics Committee.

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