PAPER

In the lion's den? Experiences of interaction with research ethics committees

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Received 30 August 2011
Accepted 10 September 2011
Published Online First
2 November 2011

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ABSTRACT

Research ethics review is an important process, designed to protect participants in medical research. However, it is increasingly criticised for failing to meet its aims. Here, two researchers reflect on their experiences of applying for ethical approval of observational research in clinical settings. They highlight some problems faced by reviewers and researchers and propose a two-stage ethical review process that would alert researchers to the committee's concerns and allow them to give a more considered response.

'The purpose of a REC in reviewing the proposed study is to protect the dignity, rights, safety and well-being of all actual or potential research participants.'[1]

Historical examples demonstrate both the need for some means of ensuring that research participants are not mistreated and the fact that regulatory frameworks do not always achieve this aim.[2 3] Formal processes for reviewing proposed research involving human participants have been developed in recent years, although the precise details vary between different countries. For example, in Australia individual hospitals are required to constitute a human research committee in accordance with the National Health and Medical Council requirements. However, in practice individual committees may not be properly constituted and therefore may lack necessary expertise and, moreover, the lack of a coordinated approach may impede the conduct of large multicentre trials.[4] The UK, by contrast, has developed a centralised coordinated system of research ethics committees (REC) to review research that recruits the staff and patients of the National Health Service as participants. The committees of seven to 18 members are constituted to include at least one-third 'lay' members while the remaining members are specialists including doctors, other healthcare professionals and academics.[5] Despite these differences, the regulatory processes that have been developed in a variety of highly economically developed countries have been criticised, both for failing to protect participants and for stifling worthwhile research.[6–10]

Reforms in the UK, including a move from self-regulation to political control, have been criticised for transforming ethics review into a symbolic activity centred on completing and approving paperwork, with little to do with the control of risks to research subjects.[8] Similarly, researchers from Australia and New Zealand have described the development of an institutional discourse of ethics, which requires researchers to give certain 'right' answers and may inhibit the exploration of new ways of conducting research that respect the needs and values of hard-to-reach participants.[10 11]

In this paper, we describe two doctoral applications to UK National Health Service REC that were not granted ethical approval. We consider our experiences from the emerging perspective introduced above, in the hope that others will learn from our accounts.

ETHICS COMMITTEES: TOOTHLESS OR TOO FIERCE?

Dissatisfaction with current processes takes two forms. Some authors argue that they are too weak, favouring the facilitation of research over the protection of lives and the dignity and welfare of research participants.[6 7] However, recent criticism raises a counterargument: processes are too restrictive. REC have been accused of unjustified paternalism and academics claim that over-regulation is stifling research.[12 13] A recent UK study found that only approximately 17% of applications receive approval at first consideration (data are based on the period October 2005–March 2008 from the National Research Ethics Service website and refer to all applications).[14]

In the face of this criticism, REC and their regulators in government (the UK National Research Ethics Service is part of the National Patient Safety Agency, a body of the UK government's Department of Health) have been compelled to attempt a delicate balancing act. On the one hand, REC must ensure that potential participants are adequately protected from unjustified risks. On the other hand, they must avoid overly paternalistic interference with the agency of potential participants. Moreover, the correct balance is a matter of judgement rather than fact; determined by the relative value placed on principles such as 'protecting wellbeing' and 'respecting autonomy'. In the remainder of this paper we describe the ways in which different conceptions of these principles are enacted in the process of conducting ethical review, highlight some difficulties that arise when attempting to negotiate plurality of values in the context of institutional mandates, and make some practical suggestions that might help researchers and reviewers in the future.

REVIEWERS' CONCERNS

A brief description of the two projects is given in Box 1

In line with General Medical Council guidance and current research practice, both protocols proposed

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that consent from all participants be sought in two stages, before recording took place and afterwards.[16] This would enable participants to decide whether they wanted recordings to be analysed once they were aware of the content.

Initial consent (or assent in cases in which potential participants lacked capacity) would be sought before recording the encounters. Both REC, following accepted practice guidelines, considered it unacceptable to approach potential participants immediately before the clinical encounter to be observed. REC 1 suggested including patient information sheets and a reply slip with appointment letters, to be returned indicating whether patients wished to opt in or out of the study. REC 2 considered it unlikely that a service user involved in a Mental Health Act (MHA) assessment would have 'the capacity to make a rational decision' about participation and suggested approaching service users in remission, to seek advance consent for participation should they become the subject of a MHA assessment in the future.

Both REC expressed concern about the two-stage consent process, but for different reasons. REC 1 suggested a three-stage process, seeking consent for recording in advance and consent for analysis immediately after the appointment and again 1 week later. In contrast, REC 2 considered it unacceptable to approach participants after the recording as they may be either unable or unwilling to recall the MHA assessment.

Recording clinical encounters

Study 1 would have used videorecording, allowing collection of data on non-verbal communication. Study 2 would have used audiorecording supplemented by handwritten field notes, a more practical method for collecting data in the acute psychiatric care setting.

Both REC expressed concern that the act of recording would interfere with clinical care, either by inhibiting doctor–patient discussion (study 1) or damaging the therapeutic relationship and reinforcing persecutory beliefs (study 2).

REC 1 considered the use of videorecording unacceptable on the grounds that, in comparison with audiorecording, it would involve collecting more data than was needed to answer the research questions. Videorecording is, however, generally considered good practice whenever possible in studies involving the microanalysis of data.

REC 2 expressed concern about the nature of the encounter to be audiorecorded, characterising it as being inherently sensitive, 'like childbirth', and considered it unacceptable to record such an encounter. The application cited numerous studies that have successfully used recordings of equally sensitive interactions to improve practice.[17 18] The committee did, however, think it acceptable for an observer to be present and to take notes.

REC 2 expressed additional concerns about the possible consequences for clinicians, citing the possibility that service users may 'demand to hear the tapes or for them to be released to be used in court proceedings'.

Maintaining confidentiality

Study 1 proposed the use of a healthcare transcription agency, bound by a confidentiality agreement, to maximise time available for analysis. REC 1 did not agree to this arrangement, citing concerns about increased risk of breach of confidentiality.

In accordance with good practice in qualitative research, both studies proposed the sharing of researcher-selected anonymised extracts with other researchers and (in the case of study 1) focus groups of clinicians, to improve the credibility of the qualitative analysis. This would be done only with the explicit consent of participants. Both REC considered this unacceptable. REC 1 took the view that this practice risked participant confidentiality and would be scientifically flawed, and suggested conducting a purely quantitative content analysis focused on the question 'is summary used in practice?' REC 2 also took the view that this practice would represent an unacceptable risk to participant confidentiality. They expressed the belief that recordings could never be effectively anonymised, due to the risk that the sound of the speaker's voice may be recognised, and suggested conducting an interview-based study instead of observation.

RESEARCHERS' REFLECTIONS

We wholeheartedly agree that it is important that REC are committed to the protection of potential research participants and take a robust approach to the consideration of risk. As such, we formed both positive and negative impressions of the ethics review process.

As we were both inexperienced in our methodologies we were pleased that our proposals were scrutinised and that we were not given an 'easy ride' by the committees. However, we both felt overwhelmed during our meetings with the committees. The effect of this was that we felt put on the spot and unable effectively to voice an effective defence of our protocols, even when we believed the committee had made factual misunderstandings or when divergent evaluations of the risk to participants represented legitimate areas for debate. We do not suggest that committee members intended to intimidate, rather that features of the process, such as the size of the committees and the time available for discussion may have the effect of silencing applicants when values diverge.

We appreciated the willingness of committee members to assist us by suggesting alternative ways in which the research questions could be addressed. However, on reflection, we were left with concerns about the practice of suggesting modifications to protocols for a number of reasons.

The REC suggested that the studies be re-conceptualised as a pilot study (study 1) and an audit (study 2). Ethical approval is not required for audit and service evaluation studies in the National Health Service. The response of committee 1 indicated that they believed their approval would not be required for a pilot study. The minutes of the review stated that 'the Committee felt strongly that the study should be structured initially as a pilot study. This would help understand whether the method of approaching patients and doctors is appropriate and if data collection would be practicable in a larger study…. If the pilot study is positive then another application could be submitted.' While the committees' suggested approaches would make it easier to conduct the research, as ethical approval would no longer be required, it would also remove some of the safeguards for participants. These experiences may be instantiations of the transformation of ethics review into symbolic activity. We wonder whether these suggestions arose from a dilemma that REC find themselves in: anxious to facilitate research that seems worthwhile but aware of their accountability to a complex and seemingly inflexible regulatory process if they grant approval. Promoting the continuation of research 'by other means' may be their solution.

We felt that the suggested modifications to the consent process may have been based upon a misinterpretation of statutory regulations and professional guidelines. This interpretation is supported by evidence that REC in the UK have had difficulty interpreting the Mental Capacity Act, 2005, and have given advice to applicants that was not consistent with the provisions of the Act.[11] For example, REC 2 may have

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misinterpreted the principles of the Mental Capacity Act, 2005, and made a presumption of incapacity, rather than capacity to consent.

Studies of the experiences of health researchers demonstrate that governance procedures can favour quantitative and clinical, over qualitative and experiential, research.[19] This perspective was reflected in our experiences. Study 1 was critiqued in front of REC 1 predominantly by two members who adopted a perspective based in the positivist paradigm, leading the committee to recommend a quantitative study focusing only on the question 'is summary used in practice?' REC 2's suggestion that observational/recorded data could be replaced by interview data suggest that they had not fully appreciated the importance of collecting objective recorded data on what was actually said during assessments, rather than studying post-hoc accounts. Modification of protocols may be driven by divergence of values. Both researchers and reviewers may have made the error of assuming that potential participants would share their own values, and that research that enacts their own values is therefore 'ethical'. All of the criticisms of the REC outlined in this paper could be viewed as instances of differences of opinion regarding the appropriate evaluation of conflicting principles during the construction of an understanding of 'ethical research':

1. REC 1's recommendation that information sheets be sent out with appointment letters reflects a conception of autonomy that favours minimising the possibility of undue influence over building trusting relationships by giving opportunities to discuss the study and ask questions.[20]
2. REC 1's recommendation of a three-stage consent process prioritises protection of participants from potential harm over respect for their autonomous decisions.
3. In contrast, REC 2's recommendation of a one-stage consent process could be viewed as prioritising protection from the potential harm of being reminded of an unpleasant experience over maximising opportunities for autonomous decision-making.
4. The concerns expressed by both REC about the collection of recorded data could be viewed as enactments of particular evaluations of the invasiveness and risks of being recorded and the potential benefits of using such data.

Finally, these reconstructions of protocols to match the committees' conceptions of 'ethical research' may, paradoxically, promote practice that is less respectful of the needs of participants. Busy clinicians may be presented with detailed information sheets that they do not have time to read. Users of mental health services may disengage from treatment through fear of being made subject to involuntary treatment in the future. Outpatients may be irritated or feel patronised by repeated requests for confirmation of their consent. More fundamentally, possibilities for conducting the kind of observational research that can shed light on practices that usually only occur behind closed doors may be lost, along with the opportunity for evidence-based improvements. In future, traditional ethical review processes might be supplemented by a dialogical process that encourages both researchers and reviewers to reflect on the values enacted in the protocol and how they might affect potential participants.[21]

WHAT WE HAVE LEARNT

Our key learning points for novice researchers are given in Box 2

We also propose a change to the ethical review process. Perhaps, doctoral research should have a two-stage ethical review process.

Box 1 Two case studies of failure to obtain ethical approval

Summaries of the proposed research projects

Study 1: a study of the use of the communication skill 'summary' in doctor–patient interactions. The aim was to investigate how often summary is used during outpatient appointments, what prompts its use and what effect it has on clinical interactions. The participants would have been medical practitioners and patients attending appointments in the medical and surgical clinics of a teaching hospital. People who lacked capacity to consent to participation would not be included. The protocol was reviewed by REC 1.

Study 2: a study of the process of MHA assessments. The aim was to investigate the application of new legislation by describing how patients and clinicians represent their views of whether compulsory treatment is needed and how the interaction affects the weight those views are given. The participants would have been clinicians and service users involved in MHA assessments. People who lacked the capacity to consent to participation would not necessarily be excluded: the procedures and safeguards laid out in the Mental Capacity Act, 2005, would be followed.[15] The protocol was reviewed by REC 2.

Both studies used established methodologies committed to the analysis of naturally occurring interaction in order to investigate what people actually do in clinical encounters (discourse analysis and conversation analysis). Therefore, both proposed the recording and transcribing of clinical encounters, to collect an objective record of what people said and investigate the effect this had on outcomes.

The researcher would be initially contacted by one member of the committee to discuss their proposal and highlight areas the committee will need them to address. This meeting would provide an opportunity to: explain briefly the process of the REC meeting itself; outline expectations of the researcher; enable

Box 2 Key learning points for researchers

- Don't assume detailed knowledge of law or codes of practice. Providing these in advance and quoting relevant sections verbatim may help the committee, which will consist of lay members, clinicians and scientists.
- Take great care explaining methodology, especially if you diverge from the dominant paradigm of clinical trials into areas where the committee may have less experience.
- Consider whether or not to attend alone. Novice researchers may feel more confident defending their protocols to a committee of 12 members (the norm for a UK NHS REC) if they are accompanied by an advisor or supervisor.
- Keep an open mind. A divergence in values between you and the committee is not a personal attack on you. Their opinions are valid and deserve consideration.
- Don't give up. Although only a minority of protocols receive approval on first consideration, the majority are approved following amendments; we have both now had projects successfully approved by ethics committees.

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familiarisation with the application; provide an atmosphere more conducive to debate about divergent value judgements and enable the researcher effectively to prepare for the REC meeting. While this approach would be more time consuming and expensive, we feel it is worth considering on the grounds that it might reduce researchers' sense of preparing to be thrown into the 'lion's den', open up lines of enquiry, and encourage others to follow in their footsteps. Ultimately, this could lead to the production of better quality, ethically justifiable research in the future.

Competing interests None.

Contributors EF and SQ designed this article together and both contributed their experiences and reflections as early career researchers. EF wrote the first draft and SQ reviewed and made significant changes.

Provenance and peer review Not commissioned; externally peer reviewed.

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