BRIEF REPORT

Psychiatric research: what ethical concerns do LRECs encounter? A postal survey

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Background and methods: Psychiatric research can occasionally present particular ethical dilemmas, but it is not clear what kind of problems local research ethics committees (LRECs) actually experience in this field. We aimed to assess the type of problems that committees encounter with psychiatric research, using a postal survey of 211 LRECs.

Results: One hundred and seven (51%) of those written to replied within the time limit. Twenty eight (26%) experienced few problems with psychiatric applications. Twenty six (24%) emphasised the value of a psychiatric expert on the committee. The most common issues raised were informed consent (n=64, 60%) and confidentiality (n=17, 16%). The use of placebos (and washout periods) (n=18, 17%), the validity of psychiatric questionnaires (n=16, 15%) and overuse of psychiatric "jargon" (n=14, 13%) in psychiatric applications also raised concern.

Conclusions: Our results suggest that LRECs have specific concerns regarding methodology, consent, and confidentiality in psychiatric research, and that they find psychiatric input invaluable.

The 211 United Kingdom local research ethics committees (LRECs) have a central role in the ethical conduct of research. Their efficiency and consistency have, however, caused discontent among researchers (both in and outside psychiatry). Studies have reported wide ranging opinions, decisions, conduct, and membership among LRECs, and have suggested that this diversity results in great difficulty for researchers submitting research proposals for ethical review.[1 2] There has been less focus on the problems experienced by LRECs themselves, and as academics in psychiatry we were particularly interested to explore what ethical concerns LRECs have in connection with mental health.

Psychiatric research is often believed to pose more difficult and numerous ethical dilemmas. Caution is often advised when patients with mental health problems are invited to participate in research.[3] Psychiatric patients are seen as particularly vulnerable by virtue of their illnesses. The process of gaining informed consent is frequently emphasised as a potential source of difficulty. Contemporary examples of potential ethical problems in psychiatric research include the recruitment to trials of new agents for Alzheimer's disease. How do we ethically involve participants who may not have capacity to give informed consent? Alternatively, if a patient with schizophrenia is detained under the Mental Health Act, how can we be sure that she does not feel unduly pressurised to participate in research hosted by the institution in which she is detained?

The Royal College of Psychiatrists recently reviewed ethical guidelines relating to psychiatric research with human participants. Fully revised guidelines have now been published.[4] During the review, we surveyed UK LRECs regarding their experiences of psychiatric research.

METHOD

An open questionnaire was sent to all chairs of the 211 UK LRECs . The letter asked two questions: firstly, what problems the LREC experienced with psychiatric research, and secondly, what type of guidelines they would find useful in this field.

Replies were scrutinised for common themes by both authors. We listed all problems and conditions reported, and calculated frequencies for items mentioned more than once.

RESULTS

One hundred and seven of the 211 (51%) LRECs responded and 34 LREC chairs (32%) explicitly indicated that they had discussed the issues with their committee. Twenty eight responses (26%) "rarely experienced problems with psychiatric applications", either due to small numbers of such applications, absence of ethical dilemmas within such applications, or presence of psychiatric experts to assist the committee. For those who did detail ethical difficulties, these could be divided into three main categories. These categories and respondents' views about future ethical guidelines, are detailed in the table. Several (n=26; 24%) valued a psychiatric expert on the committee. One reply suggested that such expertise should be mandatory for committees reviewing psychiatric applications.

DISCUSSION

The response rate was somewhat disappointing, but consistent with many postal surveys. The results are striking in that any common themes were generated only through spontaneous responses. Since we are not sure that all LREC chairs consulted their committees, there is the risk that results only really reflect the views of a minority of LRECs.

The main concerns clearly relate to informed consent. More than half the respondents cited this as a potential difficulty. In addition, certain specific groups of patients were singled out as requiring specific attention, including those with cognitive impairment, children, and those with learning disability. Acute psychiatric patients and those with schizophrenia were occasionally mentioned, perhaps less frequently than might have been expected. The greater emphasis on the *process* of informed consent, rather than specific groups as such is interesting. We have argued that there is a move towards focusing on the process of gaining consent in psychiatric patients, rather than labelling certain diagnostic categories as unable to consent.[5] Although it may sometimes be more difficult to gain the understanding necessary for informed consent in conditions such as schizophrenia or learning disability, improving the consent process can increase the numbers of people with these conditions who are able to consent to participating in research. The conditions themselves are not necessarily barriers to research participation.

Many LRECs value specialist psychiatric advice, which could be coopted when necessary. This person might also help with two further problems that were identified: psychiatric jargon in applications, and the validity of psychiatric instruments. The methodological concerns, such as use of placebos and confidentiality, were in many ways a reflection of

Table 1 Spontaneous responses from LRECs regarding psychiatric studies

Response	Number giving response (total=107)	Percentage
Level of problems with psychiatric studies		
Few problems	28	26
Few if psychiatrist available	26	24
Problematic ethical issues		
Informed consent	64	60
Confidentiality	17	16
Continuation of a beneficial therapy, (post trial)	03	03
Genetics & psychiatry	03	03
Specific groups and conditions raising concern		
Acute psychiatric patients	03	03
Patients compulsorily detained	07	07
Schizophrenia	03	03
Dementia	07	07
Children	02	02
Learning disability	03	03
Concerns relating to methodology		
Use of placebo & "washout" periods	18	17
Validity of psychiatric questionnaires & instruments	16	15
Inexperienced researchers & adequacy of supervision	05	05
Deception	04	04
Recording (video/audio) of interviews	02	02
Same patients in multiple studies - 'research fatigue'	04	04
Access to patients should be via responsible doctor	03	03
Qualitative research	07	07
Inaccessible psychiatric "jargon"	14	13
Guidelines required regarding psychiatric research		
None, or a simple checklist	09	08
Guidance that does not conflict with existing advice	08	07
Guidance about what psychiatric research is valuable	05	05

contemporary ethical issues debated in the literature, for instance as a result of the revision of the Declaration of Helsinki and the UK Data Protection Act.

Finally, it is important to recognise the limitations of our somewhat quantitative approach to essentially qualitative research. Whilst few LRECs reported specific problems with psychiatric research, the low response rate might conceal a number of problems undetected by our survey. Our results only show the number of ethical issues that are *recognised* by LRECs, rather than the true prevalence of such problems in proposals submitted to LRECs. Although many of the common ethical concerns of psychiatric research were mentioned by our respondents, it is essential that our results do not provide any false reassurances about the need for careful scrutiny of all research proposals, whether psychiatric in nature or not.

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REFERENCES

1 **Hotopf M**, Wessley S, Noah N. Are ethical committees reliable? *Journal of the Royal Society of Medicine* 1995;**88**:31–3.
2 **Lux AL**, Edwards SW, Osborne JP. Responses of local research ethics committees to a study with approval from a multicentre research ethics committee. *British Medical Journal* 2000;**320**:1182–3.
3 **Royal College of Physicians**. *Guidelines on the practice of ethics committees in medical research involving human subjects* [3rd ed]. London: The Royal College of Physicians, 1996
4 **Royal College of Psychiatrists**. *Guidelines for researchers and for research ethics committees on psychiatric research involving human participants. Council report CR82*. London: The Royal College of Psychiatrists, 2001.
5 **Osborn DPJ**. Research and ethics. Leaving exclusion behind. *Current Opinion in Psychiatry* 1999;**12**:601–4.