

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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- 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.
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Psychiatric Research: What ethical concerns do LRECs encounter? A postal survey.

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Abstract

Background and objectives

Psychiatric research can occasionally present particular ethical dilemmas. Ethics committees have been criticised for their approach to psychiatric research. There has been little attention to 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.

Method

Postal survey of 211 LRECs with open questions requesting details of the quantity and type of problems they experience with psychiatric research applications.

Results

107 (51%) of those written to replied within the time limit. 28 (26%) of these experienced few problems with psychiatric applications. 26 (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 over-use of psychiatric "jargon" (n=14, 13%) in psychiatric applications also raised concern.

Conclusions

Whilst some caution must be exercised when applying quantitative methods to qualitative research such as this, our results suggest that LRECs have specific concerns regarding methodology, consent and confidentiality in psychiatric research. Psychiatric input is invaluable when reviewing mental health research, and the expert involved should be acquainted with the arguments concerning consent and guidance offered by the Royal College of Psychiatrists.

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Local Research Ethics Committees (LRECs) have a central role in the ethical conduct of research. The 211 LRECs in the United Kingdom work on behalf of potential research participants to ensure ethical standards, to consider the risks and benefits of research and to advise researchers. However, the efficiency and consistency of LRECs has been a source of discontent amongst clinical researchers (both in and outside psychiatry) for some time. Before the introduction of multi-centre ethics committees (MRECs), widely varying practice and opinion was demonstrated amongst ethics committees. Quantitative assessment of the decisions of committees [1,2] revealed major discrepancies. Additionally, a study of committees' beliefs, conduct and membership [3] also showed a range of differences. One paper specifically detailed the reactions to a psychiatric project in which an identical application was made to six different LRECs. This application received inconsistent responses from each of the committees [4]. Further complaints focussed on the application processes involving multiple non-standardised forms, resulting in unnecessary work burden for researchers [5]. Despite the introduction of MRECs, delays & inconsistencies between committees have continued to be demonstrated [6], with the burden of paperwork during the application process remaining a cause for concern [7].

Despite years of criticism of LRECs by researchers, there is little information regarding the functioning and problems of the committees themselves. Blunt et al [8], writing with extensive experience of LRECs, acknowledged some of the criticisms levied at LRECs. They also highlighted the extensive workload faced by such committees and suggested adoption of national guidelines as an effort to standardise practice and decision making. In addition, there has been little written concerning problems for ethics committees specifically relating to psychiatric research, despite the fact that psychiatric research is often believed to pose more difficult and numerous ethical dilemmas, requiring additional scrutiny. Organisations such as the Medical Research Council [9], Medical Defence Union [10] and the Royal College of Physicians [11]

express caution when patients with mental health problems are invited to participate in research. Guidelines often question the appropriateness of including psychiatric patients in research projects, viewing them as a vulnerable group. In addition, the process of gaining informed consent is frequently emphasised as a potential source of difficulty. Informed consent may be influenced by a number of factors such as the capacity of the mentally unwell participants by the pressures from the institution, particularly in the case of detained patients. A contemporary example of a potential ethical problem in psychiatric research is 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? 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 she is detained in? On the other hand, it is important that people with mental health problems are not disenfranchised from research, simply on account of their diagnosis. Specific guidelines for psychiatric research, addressing these and a variety of other concerns, were originally published by the Royal College of Psychiatrists in 1990 [12].

The Royal College of Psychiatrists recently convened a working party to review guidelines regarding various ethical issues relating to psychiatric research with human participants. Fully revised guidelines have now been published [13]. As a contribution to this process, we aimed to survey United Kingdom LRECs to determine what issues and problems they perceived as important in the ethical consideration of psychiatric research. We report the method and findings of this survey in this paper.

Method

An open questionnaire was sent to all chairs of the 211 LRECs in the United Kingdom. The letter outlined the aims of the Royal College of Psychiatrists working party, and the fact that there was little hard evidence regarding problems raised by psychiatric research. The letter then went on to ask two open questions. The first asked for details of any problems each committee had

experienced regarding applications for research relating to mental disorders. The second question asked for opinion regarding the type of guidelines (both in form and content) that might be helpful.

The replies were scrutinised for common themes by both authors. We listed all problems and conditions reported by LRECs, and calculated frequencies for items mentioned by more than one respondent.

Results

107/211 (51%) of LRECs responded to the letter within 3 months of the original posting date. While all responses came directly from the chairs of the LRECs, 34 (32%) explicitly indicated that they had discussed the issues with their committee. 28 responses (26%) replied that their committee rarely experienced problems in dealing with psychiatric applications. Reasons for a lack of problems included small numbers of psychiatric applications, absence of ethical dilemmas within psychiatric applications or presence of psychiatric experts to assist the committee. Of those who did detail ethical difficulties, their difficulties could be divided into three main categories. These categories were adopted to organise the data and may be viewed in table 1. The first category was general ethical principles and issues, such as informed consent in psychiatric patients. Secondly, a number of psychiatric conditions or groups of patients were singled out as presenting particular concerns for ethics committees, (for instance dementia). The third type of problem encountered related to scientific methodology, such as the reliability of questionnaires or the use of placebo washout periods.

Regarding the guidance required by LRECs in dealing with psychiatric applications, some respondents (n=9; 8%) felt that no further guidance, or a simple checklist was all that was required. Other comments are included in table 1. In particular, a number of committees (n=14;

13%) reported difficulty dealing with psychiatric "jargon", and several (n=26; 24%) emphasised the value of including a psychiatric expert on the committee when discussing specialist applications. One reply suggested that such expertise should be mandatory for committees reviewing psychiatric applications.

Discussion

The response rate of just over 50% of LRECs was somewhat disappointing, but consistent with many postal surveys. The results are striking in that any common themes were generated only through spontaneous responses. The questions posed were deliberately open, rather than presenting a checklist of possible ethical concerns for respondents to consider. The results may well represent the real concerns of LRECs regarding psychiatric research. However, it is noteworthy that whilst many LREC chairs did consult their committees, this was not always the case. There is therefore the risk that our results only reflect the views of many of the chairs of the LRECs.

Many LRECs did not experience great problems with psychiatric applications overall. This may explain several LRECs expressing little requirement for further guidelines in this area. The wealth of guidelines available from a range of bodies and institutions could potentially confuse issues and the need for consistency between existing guidelines raised concern for a number of committees.

The main concern of ethics committees clearly relates to informed consent. More than half the respondents cited this as a potential difficulty in psychiatric research. In addition, certain specific groups of patients were singled out as requiring specific attention, particularly regarding the consent process. These groups included those with cognitive impairment, children, and those

with learning disability. Acute psychiatric patients and those with schizophrenia were occasionally mentioned, although it is noteworthy that these groups of patients do not, in fact, prove overly problematic for committees. The focus on the *process* of informed consent, rather than specific groups per se is interesting. We have previously discussed a trend towards emphasising the process of gaining consent, rather than labelling certain diagnostic categories as unable to consent [14]. Although it may sometimes be more difficult to gain understanding necessary for informed consent in conditions such as schizophrenia or learning disability, improving the consent process may indeed increase the numbers of people with these conditions who are able to consent to participate in research. The conditions themselves are not barriers to research.

The value of a psychiatric expert on an LREC is evident from our results. This person could be co-opted when psychiatric applications to a particular LREC are infrequent. In addition to explaining psychiatric research issues, they might help with two further problems identified by respondents, namely over-use of psychiatric jargon in applications and clarification regarding the validity of psychiatric questionnaires. Researchers would gain by using plain language in their applications. It would also be useful to include data which verifies the validity of less well known psychiatric instruments.

The methodological concerns highlighted by the LRECs were in many ways a reflection of contemporary ethical research issues, suggesting that LRECs are indeed in touch with ethical debate. Confidentiality in research has been a key focus in the light of the United Kingdom Data Protection Act. The appropriateness of placebos in clinical trials has also caused controversy within and outside psychiatry in recent times. The revision of the Declaration of Helsinki spawned diverse comment throughout academic medicine, with strong arguments for and against the use of placebos being published in major medical and psychiatric journals in Europe and the USA. In addition, these contemporary ethical concerns naturally formed a considerable contribution to the Royal College of Psychiatrists' final report on ethical psychiatric research involving human participants [12].

Finally, it is important to recognise the limitations of applying a quantitative approach to our essentially qualitative data. Whilst few LRECs reported specific problems with psychiatric research, the low response rate might conceal a number of problems undetected by our survey. Of course the rates of problems in our results represent the number of people recalling these ethical problems, rather than representing any accurate estimate of the prevalence of such problems. Although few ethical problems were reported with psychiatric research in general, this must not detract from the importance of the few occasions when real ethical problems do indeed exist, whether identified or not. 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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Table 1.
Spontaneous responses from LRECs regarding psychiatric studies.

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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