Committees should devise special forms for the social sciences

EDITOR,—We welcome the recent editorial and papers on research ethics committees,[1-4] which were published at the time when we were revising our ethical and scientific standards. Our organisation deals with questionnaire surveys relating to reproductive health carried out in various European and Asian countries. We are all too familiar with the problems recognised in the articles. In our view, many are related to the fact that, apart from general principles of scientific credibility and quality, there are no clear guidelines about the ethical aspects of social medical research.

Our organisation is a private one and, like many others, funded by the pharmaceutical industry. The sponsor often generates suggestions for research. An international board of trustees, comprising four experts in reproductive health based in universities and the chairman (DdeW), reviews the suggestions as well as the protocols subsequently designed by the staff, determines the research programme, and carries responsibility for the scientific quality of the activities undertaken.

Given the source of funding and suggestions for research, we felt we needed to be explicit about our procedures. We were also motivated by experiences with some research ethics committees, which reacted to our protocols as if we were amateurs even though most of our studies have been published in peer reviewed journals.

We therefore decided to submit, for each study, the protocols and memorandum explaining our ethical, methodological, and data management standards to research ethics committees, even when their approval is not formally required by national regulations. We have found that it is often not clear which committees, if any, are in charge of national surveys of knowledge, attitudes, and practice. In the case of clinic based surveys, none of the committees approached ever sent us forms that were specially adapted for social medical studies. We share Garfield's experience of inconsistent (and sometimes conflicting) recommendations of various committees for the same study.[3]

Our initiative to develop standards was related to our specific source of funding. In our experience, however, there is a wider need for clear and uniform ethical guidance for researchers and ethics committees involved in social medical research. Our standards are available on request for critical comments and wider use. We advise research ethics committees to design special application forms for social medical studies.

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1 Alberti KGMM. Local research ethics committees. *BMJ* 1995; 311:639-40. (9 September.)
2 Middle C, Johnson A, Petty T, Sims L, Macfarlane A. Ethics approval for a national postal survey: recent experience. *BMJ* 1995;311:659-60. (9 September.)
3 Garfield P. Cross district comparison of applications to research ethics committees. *BMJ* 1995;311:660-1. (9 September.)
4 While AE. Ethics committees: impediments to research or guardians of ethical standards? *BMJ* 1995;311:661. (9 September.)

Differences in application process cause problems

EDITOR,—We wish to contribute to the debate on the role of local research ethics committees.[1-4] Recently, we carried out a pilot study investigating the cost effectiveness of specialist outreach clinics in general practice in two specialties, dermatology and orthopaedic surgery. We sought approval from nine local research ethics committees to approach patients attending outpatient clinics in hospitals and general practice. We asked patients to complete a questionnaire about their health status and experience of attending the clinic and to give their consent for us to access medical records.

Details of applications to nine local research ethics committees for approval for study, and time taken to receive approval

Committee	No of pages on form	Format of application	No of copies required	Approval	Attendance required at meeting	Changes required	Time from submission to approval (weeks)
A	0	Typed form	12	After two meetings	Yes	Yes	12·5
B	1	Headings	11	By chairperson	No	No	2
C	7	Form on disk	1	By chairperson	No	No	1
D	2	Headings given	1	By chairperson	No	No	5
E	10	Form on disk	18	By committee	No	No	2·5
F	5	Typed form	12	Outside terms of reference	Yes	Yes	5·5
G	9	Typed form	11	After two meetings	No	Yes	10·5
H	11	Typed form	1	By chairperson	No	No	6
I	3	Typed form	1	By chairperson	No	No	8

We echo the comments made in the recent papers concerning the amount of work caused by non-standard forms, on which details had to be typed.[1-4] Forms ranged in length from one to 11 pages (mean 6·3) (table). Many sections of the forms related to invasive treatment and were inappropriate for research seeking the views of patients. Only two of the committees provided copies of the form on disk. We also found the photocopying required (up to 18 copies of the forms and protocol (mean 7·6)) daunting, though four committees initially requested one copy of the documentation.

Our submissions were approved by the chairperson of five committees. Our most exasperating experience entailed a long journey to attend a meeting where the committee members gave advice on the content of the questionnaire, although they stated that the study was outside their terms of reference. Two committees, one of which met each month and the other every two months, did not approve our submission until it had been discussed at two meetings. The time taken to approve our application ranged from one to 12·5 weeks (mean 5·9); approval by the committee was not always slower than approval by the chairperson.

Having carried out the pilot study, we are now looking for a feasible research design for our main study of outreach clinics. As sets of forms usually have to be submitted two weeks before the meeting we think it should be possible to approve applications within a month of submission. We strongly support the suggestions for a national committee or regional committees having a role in multicentre studies.[1-4] Clarification of the chairperson's role in approving applications and the legitimacy of requiring researchers to attend meetings would also make the application process less like a lottery and make planning fieldwork more straightforward.

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1 Garfield P. Applying to research ethics committees: a cross district comparison. *BMJ* 1995;311:660-1. (9 September.)
2 Alberti KGMM. Local research ethics committees. *BMJ* 1995; 311:639-40. (9 September.)
3 Middle C, Johnson A, Petty T, Sims L, Macfarlane A. Ethics approval for a national postal survey: recent experience. *BMJ* 1995;311:659-60. (9 September.)
4 While A. Ethics committees: impediments to research or guardians of ethical standards? *BMJ* 1995;311:661. (9 September.)

Medical insurance in Republic of Ireland

EDITOR,—Alan Murdoch's report on medical insurance in the Republic of Ireland is misleading.[1] He states that the Voluntary Health Insurance Board was set up "to provide medical cover for those who were not eligible for free services under Ireland's means tested public health system." This is historically correct, but the reality for the past decade has been that all hospital services, maintenance, and fees have been free (except for some nominal charges) to all of the population. The Voluntary Health Insurance Board covers the 30% who wish to choose their consultant, the institution, and the timing of their treatment. The premiums do not increase with greater risk, such as getting older, and are tax deductible at the standard rate of income tax.

The public seems to accept the balance provided, and the health services are no longer at the centre of election manifestos.

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1 Murdoch A. Irish psychiatrists are worried about foreign insurers. *BMJ* 1995;311:527. (26 August.)

Improving oral examinations

Interobserver agreement does not necessarily imply reliability

EDITOR,—Richard Wakeford and colleagues describe the work that has gone into developing the vivas for membership of the Royal College of General Practitioners and recommend this process to other organisations.[1] The main point of improving examiners' training and the structure of examinations, however, is to improve the reliability of the examinations. The part of the article's discussion that deals with reliability is brief and confusing. There are two separate vivas, each carried out by a different pair of examiners. The 94% agreement quoted by the authors seems to be between the two examiners in each viva, although the text is contradictory on this.

The analysis in the article is insufficient to make the figure of 94% mean much. Factors that should be considered include whether examiners' marks congregate around the middle of the scale. If this is the case such concordance could explain a lot of the apparent agreement. Examiners can and do change their gradings after discussion, which clearly makes for agreement. Although examiners do not discuss their views on candidates until after the

initial marking, it is impossible to sit beside one's coexaminer for 30 minutes without forming a (usually accurate) impression of what the co-examiner's mark is likely to be. All of these factors would tend to increase the interexaminer agreement but not necessarily increase the reliability of the vivas.

A more thorough analysis would enable us to judge whether the commonly held view that vivas are inherently unreliable can now be revised.[2]

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1 Wakeford R, Southgate L, Wass V. Improving oral examinations: selecting, training, and monitoring examiners for the MRCGP. *BMJ* 1995;311:931-5. (7 October.)
2 Hubbard JP, Levit EJ, Schumacher CF, Schnabel TG. An objective evaluation of clinical competence. *N Engl J Med* 1965;272:1321-37.

Authors' reply

EDITOR,—L M Campbell and T S Murray's statistical orientation and skill are well known, but the primary purpose of our article was descriptive—to document the development of the oral examinations for membership of the Royal College of General Practitioners. We have evidence that the agreement of examiners in a single oral examination, corrected for chance, is improving as a result of our approaches, but it is difficult to evaluate the reliability of an oral examination in any sophisticated way when each examiner records only a single, overall mark, as at present. Thus we are currently asking examiners to record their grades for each component topic in oral examinations; this will permit calculation of the internal consistency of the examinations, and these data will be reported as soon as possible.

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Summative assessment for general practitioner registrars

Has been implemented experimentally in Yorkshire

EDITOR,—Linda Beecham's report concerning summative assessment for general practitioner registrars states that "no English region has written to all its registrars,"[1] but this is not true. In Yorkshire (since 1993 and at regular intervals) the progress of summative assessment has been communicated to all the registrars, trainers, course organisers, and others involved in postgraduate medical education. In addition, my associate advisers and I have visited our various training schemes in the past two years, discussing assessment with the various groups of registrars and trainers. Also, at our unique annual summer school, which most of our registrars in general practice attend, we have for several years openly and frankly discussed the proposed package of summative assessment.

In addition, in 1994 we implemented summative assessment on an experimental basis—being the only English region to do so—to test our infrastructure and to help us select and train an appropriate number of assessors. All this has been achieved without causing any major disquiet or, indeed, giving rise to any costs for registrars.

At a recent meeting of the executive council of the Conference of Postgraduate Advisers and Universities of the United Kingdom it was decided that, regardless of the delay in regulatory changes, summative assessment would be introduced as a professionally led system of assessment from September 1996 without any financial cost to registrars. It may be reassuring to the registrars and others who may be misled by the current barrage of ill informed speculation in the media to learn that the current package satisfies the test of reliability and validity set by the joint committee.

In addition, other methods of assessment are being developed and tested—for instance, in Yorkshire for the past two years we have assessed a range of projects that may become part of the written submission necessary for summative assessment. We have also invested a great deal of time and resources in developing patient simulated surgery as an alternative method to video assessment to test clinical skills.

In brief, whether we like it or not, summative assessment will be introduced. The present package is good and workable. To improve the package and develop other and perhaps better methods of assessment, however, we need the wholehearted involvement of registrars in general practice, even though for the time being this will be on a voluntary basis. The time has come to stop mixing politics with education: let us get on with the task in hand.

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1 Beecham L. Registrars may withdraw from summative assessments. *BMJ* 1995;311:1170. (28 October.)

Proposals may damage one of finest examples of postgraduate medical education

EDITOR,—Registrars in general practice neither are ill informed about nor misunderstand the proposals for summative assessment, as is suggested by T Stuart Murray and Jacky Hayden respectively.[1,2] It is precisely because they perceive both the dangers to training that the plans threaten and the precipitate and unprofessional manner in which they are being implemented that so many future general practitioners are expressing so much concern.

The two authors indicate the inconsistency and lack of rigour that are reflected in the assessment as proposed. One of the principal tenets of the package is that a national standard of competence should be applied. Hayden, however, indicates what many have found—that in some regions, as a result of funding difficulties and practical difficulties, the only component that will be used this year will be the structured trainers' report, which has not yet been fully tested, let alone validated. This makes it difficult to support the assertion that the package is either national or fair.

While there may now be "awareness" of the proposals for summative assessment among registrars in general practice, this is hardly an adequate level of information for people whose future depends on an examination process that began three months ago and for which no syllabus, firm timetable, or arrangements for further education for those who fail have yet been arranged. It is disgraceful that no national communication to doctors has been made in advance of the proposals and that what little communication there has been has been devolved to regional advisers in general practice, almost half of whom last year were unable even to supply data on the numbers of registrars in general practice in their region.

Registrars in general practice are in favour of assessment that is valid, reliable, and equitable and welcome any procedure that will improve their training. For their own reasons the Joint Committee for Postgraduate Training in General Practice and the Conference of Postgraduate Advisers have chosen to press ahead with plans that fulfil none of these criteria. It is particularly disturbing that these plans are being forced through by some senior members of the profession in a manner that, if applied by an outside body such as the government, would be condemned by all.

In the meantime, as no regulatory changes will be made before September 1996, registrars in general practice should be reassured that, provided their trainer agrees with them, the current procedure for accreditation is the only requirement and the summative package is entirely optional.

A system must be devised that does not require every general practitioner in training to be subjected to arbitrary and meaningless tests, has the full support of the profession and educationalists, is well planned in advance, and includes both recurring new funding and any necessary regulatory changes. Not to ensure this minimum standard will further worsen the perception of general practice and will damage what has become one of the finest examples of postgraduate medical education.

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1 Murray TS. Summative assessment for general practitioner registrars. *BMJ* 1995;311:1299-300. (11 November.)
2 Hayden J. Summative assessment for general practitioner registrars. *BMJ* 1995;311:1300. (11 November.)

Attitudes of consultant physicians to Calman proposals

Royal College of Physicians gave qualified support to proposals

EDITOR,—Several aspects of Hugh M Mather and Robert S Elkeles's paper giving the attitudes of consultant physicians to the Calman proposals require correction and clarification.[1]

Firstly, it is wrong to say that the Royal College of Physicians "made no attempt to ascertain the views of those colleagues who are most directly affected." The president and other officers of the college travelled throughout Britain to discuss the Calman proposals with consultants and trainees both before the report was finalised and after its publication. In addition, the report was regularly on the agenda of meetings open to all fellows, at which they can speak, and of meetings of the council, some of whose members are elected fellows and members. We also published our concerns in the college's commentary and newsletter.

Secondly, contrary to what was originally thought, detailed predictions by the college working with the specialist societies indicate that there will not be a reduction in middle grade staff, and this view is largely accepted by the Specialist Workforce Advisory Group. There will, however, be a reduction in the contact time between patients and doctors as trainees spend time away from clinical work to be formally educated and consultants deliver the education.

Thirdly, we did indeed, as contributors to the response of the conference of royal medical colleges, give qualified support to the proposals, which carry two important benefits: they bring structure to training schemes that hitherto have been haphazard and have used time served as a proxy for content; and the training programmes