Local research ethics committees

REPORT OF THE 2ND NATIONAL CONFERENCE

This Conference, held on 7 June 1992, was organised by the Royal College of Physicians with the aid of a grant from the Department of Health. The views expressed at the conference and reported here are not necessarily the views of the Department or the College unless specifically stated to be so.

The major theme of this conference was the present variable performance of local research ethics committees (LRECs). Opening the meeting, Dame Margaret Turner-Warwick pointed to the tremendous advances that were taking place in medical practice and science and that this was therefore an opportune moment to 'see where we are, and share solutions as well as problems in the discussion and debate of this meeting'.

Introduction

Major themes explored within the presentations and debated in the all important discussion sessions, centred around the present performance of research ethical review committees and how best to help them meet the demands likely to be made on them in the future. **Dr Kenneth Calman** (Chief Medical Officer at the Department of Health (DoH)) summarised some important additions to the working practices of ethics committees that had been proposed in the past year.

- The *Red book* was published by the DoH, to give guidance on the formation, composition and duties of LRECs. The DoH had commissioned a research programme from the University College of Swansea to identify the training needs of LRECs and to consider the ethical implications of multi-location research studies. This programme is now completed and is under consideration by the DoH.
- The Nuffield Bio-Ethics Council was established.
- The World Health Organisation has revised the targets in the programme 'Health for All', to include a specific target relating to ethical issues (No. 38 in the revision).
- A standing committee has been formed from the *ad hoc* committee of the Council of Europe on bioethics. The intention is to develop a framework convention on bioethics with specific protocols on particular topics, eg organ transplantation.

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Dr Calman emphasised that LREC members needed appropriate training and guidance to enable them to work effectively. That need could be complex. For example he wondered how many LREC members knew that the administration of radioactive substances in a research setting required a special licence, that a licence to treat individuals for therapeutic purposes was not sufficient. The DoH sets great store by the autonomy of LRECs and wants to ensure that their status should not be compromised by future developments. He also suggested that the focus within the DoH, dealing with general issues of medical ethics, could establish and make available to LRECs and other bodies information about ethical matters. Dr Calman said he would be interested in hearing views on that proposal.

LRECs, purchasers, providers and the ethics of service provision

Independence is one of the most important features of LRECs. In their work, they cut across the 'purchaser–provider' distinction. They have a key role in advising health authorities as to whether or not a particular research proposal should take place whenever such research proposals involve NHS patients, premises or records. The decision to give permission to proceed is, of course, the responsibility of the NHS management.

John Grimley Evans (Professor of Geriatric Medicine, Oxford) commented on the ethics of service provision and the contribution that LRECs may be asked to make within the revised framework of the NHS. A debate on the ethics of health service provision took place at Oxford in 1991. It had been called by the health authority and involved its members and officers and those working with the authority. A group of doctors and nurses was asked to prepare a discussion document outlining a view on the ethics of professional practice in provider units. This document formed part of a collection of papers concerned with the new arrangements in health care. A modified version was later published in the *Journal of the Royal College of Physicians* (1992; **26**:20–21). 'It is timely for provider units to develop and publish a specification of the ethical structure within which they will negotiate and co-operate with purchasing authorities.' In simple terms, an ethical dilemma arises when conflicting opinions are held by the providers and the purchasing arm of the health authority over what is to be regarded as comprehensive service provision. Comprehensive service provision carries with it the obligation to see that the treatment is carried through to optimum conclusion.

Local research ethics committees may become involved in the process of decision making on the evaluation and deployment of innovative types and delivery of health care as a response to the changing needs of the local population. Such evaluations are likely to work to community based, experimental rather than descriptive models if they are to achieve the best outcomes and take account of local conditions. Institutions such as the Royal College of Physicians may play a role in the design and evaluation of packages planned to capture this essential local information. When rationing of health care resources has to be introduced, it should be on the basis of limiting volume rather than lowering standards. This will give an 'unprecedented opportunity' for an ethically defensible evaluation of forms of treatment that at present ethical considerations do not allow. Randomised, controlled trials of the effects of withholding treatment may become powerful methodological tools for comparative evaluation of treatments; alternatively, one could randomise referrals rather than types of treatment. 'Ethics committees could come to play a positive role in encouraging such research and aiding the evolution of the health care services. I raise the possibility that LRECs have to start demanding research', concluded Professor Grimley Evans.

This last point was taken up by LREC chairman **Dr G. Robb** (Epsom, Mid-Surrey HA). His committee had been asked by their DHA about setting clinical priorities and whether the LREC should involve itself in this and in discussions on the rationing of health care. In the event, the LREC members decided that they could not give these issues the attention they deserved in addition to carrying out their functions as a research ethics committee. Their DHA has since set up a 'principles' committee with fairly wide and representative membership to discuss these questions.

LRECs and the health authorities

Dr Roisin Pill (chairman of the South Glamorgan Research Ethics Committee) brought her own experiences of ethical review to her analysis of the relationships between the LRECs and other local bodies such as the FHSA, the LMC, the CHCs, and, naturally, the DHA. Other contacts for an LREC would be local Trust hospitals and academic institutions. South Glamorgan is a teaching authority and this imposes a duty to provide a service of ethical review for research and training in medicine—an important subject of national debate at the moment. The REC membership consists of representatives from the health authority, the College of Medicine of the University of Wales and the Community Health Council. The committee meets quarterly and functions as a court of appeal and a forum for debate. It issues guidelines for reserachers, receives details of all research projects that have been approved and holds them in a central register. Dr Pill pointed out that the actual work of reviewing protocols is *not* done centrally, but is the task of the seventeen divisional ethics committees currently operating within the authority. Dr Pill also noted that her ethics committee has been approached by the University to assist with review of research on human volunteers.

Within the past year the constitution of the REC has been revised to bring it into line with current DoH recommendations regarding lay representation and continues to meet the need to provide peer review of research proposals from the academic medical research centre. The new South Glamorgan LREC will consist of 18 lay members and 12 professional members, the latter appointed jointly by the DHA, the FHSA and the College of Medicine. Three main tasks await the new committee which will meet quarterly. It will establish the ground rules for the conduct of ethical review and monitoring of research in South Glamorgan, act as a forum for debate on general ethical issues and approve the annual report to the DHA. Members of the LREC will be appointed according to the DoH/Welsh Office guidelines. Protocol review will be undertaken by three panels of eight to 12 representatives from the core group of 30 LREC members, under the chairmanship of a lay member. They will meet monthly in order to deal with the expected volume of work. A significant change is the appointment of a full-time LREC executive officer funded by the DHA to provide the panels with administrative support. The divisional committees will be retained to ensure peer group review of research protocols because they will undertake the initial scrutiny of the scientific content of the protocols.

The main advantages of the reorganisation are the opportunity for greater efficiency in protocol review and of monitoring research, made possible by the DHA's acceptance of the importance of a properly resourced secretariat. For the first time, a sanction exists for those researchers who 'jump the gun' and start a study before ethical approval is gained. Noncompliance of this nature will become a disciplinary offence within the DHA. Research carried out in Trust hospitals will be brought under the wing of the system of ethical review by including in contracts between Trusts and the DHA the requirement for such research to be submitted for review to the LREC. If this is not done, South Glamorgan patients cannot be included in studies. Dr Pill welcomed the suggestion of a forum for information on ethical issues for the use of LRECs. On the same theme, the training package for the LRECs is 'vital' to their proper functioning in relation to the welfare of their local community.

Ethical review of multicentre research

Mutilocation epidemiology studies

Professor Tom Meade (Director of the MRC Epidemiology and Medical Care Unit, St Batholomew's Hospital, London) considers the two cardinal assets of

LRECs to be their indepdendence and invaluable local knowledge.

The MRC's General Practice Research Centre, which covers 250 group practices in England, Wales, Scotland and Northern Ireland, was originally set up to conduct the two MRC hypertension trials. In the past, most of the work of the MRC was hospital based but now more of it is community based and may be in the form of randomised controlled trials such as those carried out by the MRC Centre and the Oxford-based ISIS (International Studies of Infarct Survival) group. This requires logistical skills when administering a multilocation study over the network of LREC districts. Representatives of the ISIS study group have made public their concerns over avoidable administrative delays to their work arising from the process of seeking ethical approval and are asking for the co-operation of LRECs in the matter. The most recent MRC trial will take place in more than one hundred group general practices in over 80 LREC districts. A further study discussion will involve 400 practices encompassing nearly all LREC districts. Scheduling patient entry into a study over a three-year period becomes an administrative and financial headache, given that there is considerable variation between LRECs in the time between submitting an application and their response to it. Professor Meade feels strongly that these bureaucratic delays significantly effect morbidity and mortality of the very people the LRECs are trying to help. He is looking for improvements in the system of research ethical review for multilocational studies. Some of the problems encountered in the MRC studies are described in Professor Catherine Peckham's analysis, as they are not unique to the experience of the MRC.

Supposing that a multilocation study received ethical approval from only two-thirds of the relevant LRECs, should that halt the trial? Is there any mechanism for resolving such disputed decisions? Not one that is effective at the moment, commented Professor Meade, and the structure and location of the appeals mechanism would be the subject of further debate. That is one of the key factors behind the recommendation for a central system for ethical approval of multilocation and multicentre studies. Although the DoH guidelines for LRECs, circulated in 1991, support the concept of a central review for multicentre studies, they also recommend that the right of individual committees to call for review of a protocol should be retained. There will be severe practical difficulties in trying to implement both strategies at once, noted Professor Meade. Such a central committee would need to have been approved by the constituency of LRECs in order to achieve the authority and respect required for centralised approval. Might centralised ethical approval of these studies erode the independence of LRECs? Professor Meade has conducted an informal survey of LRECs to discover how great an impact on their independence of operation would be made by the introduction of a central committee. The results showed that multi-centre studies accounted for 18% of the workload of the LRECs in the period covered by the survey; 14% of these studies were initiated by industry and 4% by the MRC and academic departments of medicine. Since a central committee with the right constitution would be largely concerned with the adjudication of this percentage of the total workload of LRECs, Professor Meade considers that there is little danger of their independence being eroded. In addition, he feels strongly that the decision made by the proposed central ethical committee should be binding on the local committees except in 'exceptional local circumstances'.

Working group on multidistrict epidemiological studies

The objectives of the working group on ethical approval for epidemiological studies, set up in 1991, were to examine the problems that had arisen and to make recommendations for future practice to the Royal College of Physicians' Standing Committee on Ethical Issues in Medicine. **Catherine Peckham** (Professor of Paediatric Epidemiology, Institute of Child Health, London) explained that it was hoped to incorporate the recommendations into the College *Guidelines on the practice of ethics committees in medical research involving human subjects.* The aim was to seek a solution to the problems posed by multidistrict epidemiological studies without either jeopardising the process of ethical review or undermining the independence of the LRECs themselves. The working group used the term 'multidistrict' to illustrate the fact that epidemiological studies cover a number of health districts in a wide geographical area and therefore come within the ambit of many LRECs. The fact that the Public Health Laboratory had to seek ethical approval from a large number of LRECs with attendant delays and duplications of effort, gave rise to some of the problems addressed by the working group. Professor Peckham noted that these were problems arising from administrative delays rather than delays in adjudication.

Two major recommendations were considered workable in the present system.

1. A standard application form for investigators seeking LREC approval for multidistrict epidemiological studies should be agreed upon and be acceptable to LRECs nationwide. LREC representatives themselves welcomed this proposal. A suggestion was made that such a form should have a number of agreed, multipurpose core headings which would be useful not only for application for approval for epidemiological studies but for all other types of research.
2. A central committee should be set up to give *conditional* ethical approval for multidistrict studies. The three-fold aim of such a committee should be: to be helpful, to minimise the burden on the

LRECs and not to impose decisions on them. Professor Peckham noted that such a committee would require resources and administrative support and that this would need further discussion. Meanwhile, under the present system there is abundant evidence that useful public health research is being delayed.

If a standard application form were available, the researcher would approach his or her LREC with the proposal *before* submitting it to the central committee. The researcher's local committee would be the first to be advised of the study and hold the data on the application form. The central committee would then review the proposal and send *a summary protocol* to all the LRECs in the geographical areas concerned, with a copy of their letter of approval. To do this efficiently it would be necessary to hold an up to date list of all the names and addresses of chairmen of LRECs, as is held by the Royal College of Physicians. The LREC would then be asked to respond within a limited period, with options either of chairman's action or a request for a full committee review of the summary protocol, or if necessary, of the protocol in full. Outcomes of this process could be approval of the protocol, request for its modifications, or rejection. Although it is hoped that amicable discussions would result in a summary protocol acceptable to the LRECs, modifications of the consent forms and patient information might be requested, or translations into other languages performed. The secretariat of the central committee would inform the investigator of the decision reached.

Professor Peckham encouraged LREC representatives to consider this proposal for three main reasons: it would speed up the process of research and minimise the burden on LRECs but would not impose decisions on local committees. **Dr Michael Drury** (a member of the ethics committee of the Royal College of General Practitioners) commented that on the basis of the experience of his committee in adjudicating multicentre studies centrally, he felt that the proposal could be made to work well to the benefit of all concerned.

Central ethical approval of multilocation studies—the University College of Swansea report to the Department of Health

A new structure for ethical approval of multilocation clinical research studies has been proposed by the centre for Philosophy and Healthcare of the University College of Swansea in its report to the DoH. **Dr Donald Evans** (Director of the Centre) summarised the results of a programme of research commissioned from the Centre by the DoH.

The report, which contains recommendations, was based on the Centre's findings from a questionnaire sent out to the chairmen and members of 134 properly constituted LRECs that were known to be in operation at the end of February 1992. The questionnaire received a full response from the LRECs and the special health authorities. Interviews were conducted with chairmen from each of the health authorities in England and with 20 to 30 key personnel at the heart of research—the MRC, Royal Colleges, University departments, the Public Health Laboratory and pharmaceutical houses. In a comparative arm of the study, interviews were conducted with personnel from institutes outside the UK who were responsible for ethical review of medical research.

How many centres constitute a 'multicentre' programme? In Dr Evans' view, this seems to depend on the decision of the researcher(s) involved: 'A piece of research shall be subjected to the multilocation system of ethical review when the researcher feels that he or she cannot expeditiously handle the obtaining of review from the centres that are to be involved'.

Role of specialist centralised committees

The new route of approval for multicentre study protocols will involve passing through local, regional and central ethical review committees. It will mean setting up three centralised government sponsored committees to undertake the initial scientific and medical scrutiny of the protocols. The committees would be the sole point of contact for the researcher who is acting as the clinical co-ordinator for the study and would be responsible for identifying what research should be submitted to ethical review. Experts would consider epidemiological and behavioural study proposals, others would handle Phase III, including surgical research, among others. After the initial review by the central committee, a report would be sent out to the regional committees to aid them in their decisions. The central committees would also offer training in the design of trials and associated ethical issues.

Role of regional committees

Dr Evans described a regional structure of fourteen research ethics committees made up of representatives from each local LREC in the region, meeting quarterly. These LREC representatives would receive the protocols six weeks before the regional meeting to ensure that LRECs have the chance to see the protocol for any multicentre study they wish to review. Collaborative decision by LRECs would be taken at the regional meetings and conveyed to the central committee within one week.

Role of LRECs

LRECs would have the chance to review the protocols for multicentre studies and would contribute to the collaborative regional designs; their power of veto over the progress of research in their area would be limited

to a set of reasons involving special local considerations. They would not have the right to amend the protocol once it had received regional approval; a consensus is therefore necessary at regional level. The LRECs would also be responsible for monitoring the progress of research, a task that the project team feels has largely been neglected. For a straightforward case, the recommended timescale is two months from initial review at the centre to final agreement.

Central committees would be financed by the DoH, the regional committees by the RHAs and the local research ethics committees by the DHAs. Dr Evans noted that pharmaceutical houses in the UK would be willing to pay a reasonable fee for review of protocols, as they do in the US.

LREC representatives at the conference pointed out that there was still a potential for duplication of effort and for delays while the protocol voyaged out from the centre to the regions and back again. They were also concerned that their knowledge and understanding of local issues should contribute to the new system. In summary, the proposals from the Swansea group are to be circulated to the LRECs and other interested parties for their comments. Dr R. Hangartner, representing the DoH at the meeting, assured the LRECs that they would be involved in the final decision making process and their views taken into consideration.

How well do LRECs fulfil their purpose?

Rabbi Julia Neuberger is past chairman of the Patients' Association and author of the King's Fund Institute report on *The role of research ethics committees in the UK*. For the research purposes of the report, 28 randomly selected committees were visited over a period of 15 months. During the visits, detailed information was obtained and some of the concerns of committees that could not be expressed in a postal survey were discussed. She summarised the main concerns of LREC members to whom she spoke.

Confusion of role

Are the LRECs *ethics* committees or *research* ethics committees? Should they be concerned to look first at the quality of research and then at whether it is ethical to carry it out? Or are they in fact mainly concerned with ethics? Some LRECs deal with large numbers of research applications a year, some with very complex protocols that may not necessarily be part of a multicentre study. Moves are underway in some health authorities to set up a research committee, or reactivate or use in a different way the research committees that already exist, to do some of the vetting of the research, thereby allowing the multidisciplinary research ethics committee to concentrate on judging the ethical issues rather than looking at the scientific details of the protocol.

Student research

Many LRECs, not only those in teaching hospital districts, wondered how best to handle student research as medical, nursing and physiotherapy students are increasingly being asked to do a research project as part of their training. Is some case, the application was simply dealt with by transaction but in other cases it was not dealth with at all. Some committees took the view that student research was more invasive for patients than other forms of research because these were new researchers who needed supervision. Overall, there was a wide disparity in practice. Two of the committees visited had set up a subcommittee to deal with student research and this system seemed to work well.

Payment

Payment for researchers is an issue causing much concern up and down the country. Although the Royal College of Physicians and the DoH state that research ethics committees ought to ask questions about financing, six out of 28 LRECs did not ask these questions at all. Much of the financial doubt centres around Phase IV studies carried out in general practice and financed by pharmaceutical houses. The number of GP studies that come to LRECs is relatively small and Julia Neuberger reported LREC chairmen's concern as to how best to encourage GP studies and nursing studies to be submitted to the LREC for ethical approval.

LREC membership

DoH guidelines published in 1991 describe the LREC membership profile. For the King's Fund report, the composition of 222 LRECs was examined. Despite the recommendations of the guidelines, 25% had fewer than eight members, and 19% had more than the twelve members recommended as the maximum. One LREC had no medical doctor, and 15% had no general practitioner member. One third of the committees had no lay members, or only one, when the recommendation stresses that there should be two. Julia Neuberger was perturbed to find that only two committees of the 28 visited contained members from ethnic minorities. Of the total, 28% had less than 20% female members and 8% no female members. The medical representatives were mainly physicians 'which may explain why no surgical research comes to LRECs', she suggested.

Lay members

Of the 28 committees studied, clergy formed 14% of the lay membership. Other professions providing lay members included lawyers; retired nurses, noted Julia Neuberger, are also counted as 'lay' members. Some chairmen of committees thought that a professional

philosopher on the LREC could be an asset. Lay members and the professionals on the LREC would also welcome tea or coffee breaks after a long day in order to remain alert and help to 'break the ice' between members of the LREC.

The strongest recommendation made within the King's Fund report is for legislation to reinforce the LREC guidelines and for financial backing to ensure adequate administrative support for the committees whose workload is substantial. Should researchers be interviewed rather than make a wholly paper-based application? It was suggested that this would produce a quicker response to questions. Committees that hold elections for the LREC posts have a higher status: 'a point to consider', suggested Julia Neuberger.

Beyond the LRECs

Nuffield Bio-ethics Council

The starting point of the Nuffield Council on Bio-ethics is the application of molecular and cell biology to clinical research and practice, according to **Sir Patrick Nairne** (past Permanent Secretary, Department of Health and Social Security, and architect and member of the Nuffield Bio-ethics Council). As a trustee of the Joseph Rowntree Foundation which supports 65,000 families with members with disabilities, some with a genetic component, he is fully aware of the potential value of developments arising from gene-based technologies, such as genetic screening programmes.

Nuffield Council on Bio-ethics is an independent advisory body with an initial three-year lifespan, quite distinct from other bodies concerned with medical research ethics, and seeks no supervisory role over other national committees studying the same field. There is a balance of lay and professional members on the Council and the majority are women. The Council, which met in July 1991, intends to concentrate on advances in bio-medicine and biological sciences.
It has set itself three specific tasks:

1. To identify and define the ethical questions likely to give rise to public concern, and so eagerly dramatised by the media;
2. To undertake studies on selected bio-ethical problems and to promote, in consultation with a wide-ranging public discussion, as far as possible, the results of those studies;
3. In the light of reports and subsequent discussion, to make representations which may lead to new guidelines and action by the government.

Two working parties are already in operation. The working party on human tissue, chaired by Professor Dame Rosalinde Hurley, has the brief to identify, define and explore the related ethical issues; it will report to Nuffield in nine months. The second working party with a similar brief is looking at the issues surrounding genetic screening and will report to Nuffield within eighteen months. Sir Patrick does not expect the result of the Nuffield Council's activities to be a bio-ethical 'cook-book' or provide textbook solutions that do not relate to the complexities and varieties of the situations that may confront different people in real life. When the working party reports come into the public forum, the views of many people will be needed, importantly those of the LRECs, to assist in promoting informed public discussion; not an easy task. Looking ahead, Sir Patrick hopes that when the problems that are now anticipated by the working parties are with us, the results of the Council's work will be reflected in national guidelines which may help LRECs at local level. When the reports are produced, the Council would like to initiate discussions at various levels such as the Royal Society and the local authority, including also ethics committee chairmen and interested groups such as the Alzheimer's Society and others. **Dame Margaret Turner-Warwick** invited the LREC representatives to suggest how the network of LRECs could be used, jointly with the Nuffield Council, to get the message through to the public.

In response, **Dr Geoffrey Power** (medical director of the North Essex Health Consortium) described the regular meetings of the public health forum in Essex. The forum is an amalgamation of the voluntary health organisations throughout mid-Essex and the aim of these meetings is to determine approaches to setting health priorities and choices on resource allocation. Similar bodies or regular public debates would seem to be a suitable way for the Nuffield Council and the LRECs to bring their reports into the wider public domain.

The College Committee on Ethical Issues in Medicine

From per capita payments to xenografting, the Royal College of Physicians Committee on Ethical Issues in Medicine has quite a wide remit and is 'not just a research ethics committee', noted **Dr Peter Beck** (Glamorgan HA). He gave a report of some of the issues covered in the Committee's meeting over the past year.

Per capita payments for clinical trial researchers. The arguments surrounding per capita payments have been widely debated, as the financial arrangements and contracts to which they give rise, do themselves introduce new ethical considerations into the conduct of clinical research. In 1991, the Committee analysed the whole subject further, and the need to provide some form of remuneration in recognition of time spent and work done was acknowledged. However, this remuneration should go hand-in-hand with arrangements to ensure that only suitable patients are recruited and retained in the study strictly in accord with the study protocol. The current views of the College on this subject are set out in the Supplement to the Guidelines. A working party is considering this whole

question against the background of financial arrangements negotiated between industry and hospitals, research institutes and general practice research groups. Will this be the last word?

Compensation for non-negligent injury to a research subject. The three sets of guidelines produced by the Royal College of Physicians took the view that sponsors of research should agree beforehand to pay without delay compensation for injury, accident, ill-health or death incurred during a research study without regard to proof of negligence. Pharmaceutical industry guidelines on the conduct of clincical trials also recommend payment without requiring proof of negligence. The Medical Research Council has formally accepted a similar recommendation of the Medicines Commission in respect of healthy volunteers and the Royal College of Physicians supported this view. But in the recent publication *Local research ethics committees,* the DoH expects that LRECs should seek evidence from the sponsor that arrangements for the compensation have adequate financial backing. Their report then goes on to state 'The National Health Service bodies are not empowered to offer advance indemnity to participants in research projects. A person suffering injury through taking part in research would be able to persue a claim through litigation. Each case would of course have to be considered on its merits'. Thus, if a person is taking part in a trial not sponsored by a pharmaceutical company and suffers non-negligent injury, that individual can expect no indemnity. If the injury is due to negligence, the sufferer will face a lengthy and costly legal process through the courts for compensation. The College feels the position is therefore unsatisfactory and has asked the DoH to go at least as far as the MRC in accepting the proposals of the Medicines Commission referred to earlier. To date, there has been no response.

Scrutiny panel for risk assessment in medical research. An example of how one ethics committee has addressed this problem was presented by **Dr Roisin Pill** (chairman of South Glamorgan Research Ethics Committee). The lack of indemnity for non-negligent injury to subjects taking part in non-sponsored research projects had severe repercussions on some of the research programmes in the College of Medicine of the University of Wales. The solution that emerged from discusisons between the DHA, the Joint Ethics Committee and the College of Medicine, was to establish a Joint Panel of Scrutiny consisting of the three most recent former chairmen of the HMSSC and the Provost of the College of Medicine. The 'three wise men' make judgements on the financial risks of uninsured research projects involving more than minimally invasive treatment or procedures but which are otherwise regarded as ethically and scientifically sound by the appropriate ethics committee. Where projects are deemed to be of low risk, the College of Medicine and the Health Authority are advised accordingly and the research goes ahead. In case of an untoward incident, an ex-gratia payment in compensation will be considered. Dr Pill reported that since the first meeting in April 1991, the scrutiny panel has had nine meetings and considered 61 protocols. So far the panel has not advised the DHA to reject any of these protocols on the grounds of unacceptable risk, although in several cases additional information was requested and the applicants questioned further.

Dr Beck reminded LREC chairman of their vital role in this regard and also commented that the existance of the LREC does not absolve the clinical researchers from their personal responsibilities to the patients entered in such studies. LREC approval cannot be sought retrospectively.

Ethical issues in clinical genetics. Does the practice and use of clinical genetics raise any moral problems of a kind significantly different from those encountered elsewhere in medicine? A joint working party was set up to classify and clarify the issues surrounding developments in this fast moving field. The working party was composed of members from the College Committees on Clinical Genetics and on Ethical Issues in Medicine. Professor Martin Bobrow and philosopher Janet Radcliffe Richards, both committee members, prepared the report on the basis of the written, expert evidence contributed to the working party. The report, *Ethical issues in clinical genetics,* was published in October 1991.

Most of the problems encountered were no different from those familiar to other areas of medical practice. Problems that are uniquely associated with clinical genetics are concerned with the ownership of genes or the genetic information contained therein. The report of the working party, perhaps controversially, raised the question whether in certain cases the accepted rights of patients to autonomy and confidentiality should be reconsidered. This would apply in cases concerning the special connection of genetic screening and counselling with descisions about having children, and the problems concerning ownership of genes, with far reaching consequences for law and public policy. No prescriptive guidelines were proposed from the working group. These questions were raised so that people could consider them further.

Xenografting. A xenograft is the transfer of biological material from a member of one species to a member of another. The term applies to cells, tissues and whole organs that can be used to prolong or improve human life in the absence of human replacement organs. Research is taking place with the aim of genetically modifying the expression of the species-specific, immune-regulating proteins responsible for the rejection response of the human immune system to transplanted tissues from another species. Although the wider clinical applications of this technique are still in the future, it is prudent to consider these matters now

rather than in haste when the scientific and technical problems have been overcome, public discussion has begun and the ethical dilemmas have become urgent.

Issues debated in the final discussion

The panel for the final debate was chaired by **Sir Douglas Black** (past President of the Royal College of Physicians). Panellists were: **Miss Sue MacGregor** (BBC radio presenter and a member of the RCP Committee on Ethical Issues in Medicine), **Professor G. M. Besser** (Professor of Endocrinology, St Bartholomew's Hospital, London), **Professor D. Laurence** (Emeritus Professor of Therapeutics and Pharmacology, University College, London), **Professor T. W. Meade** (Director, MRC Epidemiology and Medical Care Unit, St Bartholomew's Hospital, London) and the **Rt Hon Sir Kenneth Robinson** (former Minister of Health and member of the RCP Committee on Ethical Issues in Medicine).

The place of central as against local committees

Sir Kenneth Robinson admitted that he is a recent convert to the idea of a national or central research ethics committee, as he is now satisfied that there is no other way of handling multilocation research. The analysis of the problems presented by Dr Evans on behalf of the Swansea Group was admirable, he thought, but the solution he presented is too complex to work well. The central committee requires much more authority than is provided for in the pathways to and from the regional committees and there is also the question of unanimity of decision making. **Miss MacGregor** agreed that the system proposed would be too cumbersome but the analysis had pin-pointed some useful ways to improve procedures. Agreement on a standard protocol form, a mutually agreed consent form written in standard English and easily translatable, a standard make-up of LRECs, and more standard guidelines, not necessarily enforceable by law, would be immediately initiated to everyone's benefit. **Professor Besser** agreed that a central committee is required but emphasised that it is the local ethics committees, not the central committee, that have the right to consent to researchers having access to patients' records for the purposes of a multilocation study, as only they know the implications for their local population; his view was heartily supported from the floor.

Sir Douglas Black noted that the respect and esteem paid to a committee depends on the quality of its decisions and this depends in turn on its membership. Once such a central committee was properly set up it would be accepted as a useful source of guidance, and not as an irritant for LRECs. The vital first step is to achieve a credible organisation and then let it work itself into the problems and hope that evolution ensured the survival of the fittest.

Dame Margaret Turner-Warwick reached for the best of both worlds, balancing two essential contributions to the process of ethical approval of multicentre research—local knowledge and central expertise. Central guidance would be given by those with great experience in the particular research field, leavened by the breadth of lay experience. Such guidance could be helpful and supportive when hard pressed LRECs are asked to make decisions on very large-scale or unusual studies. She felt that the system of multicentre ethical approval described by Dr Evans, would tip the balance too far to the centre. A general consensus existed among LREC representatives at the meeting that a simpler system would help research workers without depriving the LRECs of their autonomy and indepdendence of action.

Professor Meade also agreed with the principle of centrality and with the excellent analysis of the Swansea Group, but he too though the proposed system unworkable. He noted that for many randomised controlled trials and epidemiological studies, expert involvement by pharmacologists and other specialists would be required and would need to be incorporated into any system of centralised approval. **Professor Besser** accepted the concept of a central co-ordinating committee for multicentre trials to act as the reviewer for the scientific base of the trial. But he urged all chairmen of LRECs to insist in the final event on the primacy of the LRECs, arguing that it is impossible to concede that a regional committee could approve a consent form that is appropriate for all the localities of that region.

Training and information for LRECs

There is a plethora of courses on offer and it was suggested by **Dr Brian Nash** (North Devon HA) that some form of assessing the effectiveness of these courses would be helpful. The most effective way of training LREC members, it was felt, is through studying appropriate case histories and providing a suitable training package, such as that prepared for the Department of Health by the University of Wales. **Sir Douglas Black** noted that the Department of Medical Ethics of King's College London is trying to get together an informal gathering of chairpersons of ethics committees. **Miss MacGregor** suggested that the recommendation for an LREC newsletter, made in the King's Fund Institute report, be taken up and that this would remove a perceived sense of isolation by lay members, help to disseminate information, and improve communication with LRECs.

Lay or medical chairmen for LRECs?

Dr Martin Kendall, South Birmingham HA, chairs an LREC that serves a teaching hospital group. He commented that his job as chairman entailed giving advice

and guidance on complex medical issues both during meetings and outside meetings; a lay chairman would find it difficult to take on such an advisory workload. **Sir Kenneth Robinson** agreed, feeling that the tasks of the LREC chairman in identifying those applications that need only chairman's action is not one that a lay member can undertake. Likewise, guiding the committee through their deliberations is a task perhaps best suited to the medical members. **Sir Douglas Black** noted that the DoH first intended to make the appointment of a lay chairman mandatory but this had been amended on further advice, to a qualified favour. Other combinations that are reported to work well include a lay chairman and a medical vice-chairman.

A national association LRECs?

Sir Raymond Hoffenberg commented that the whole point about ethical descisions is the inherent difference of opinion. If there were total agreement it would cease to be an ethical problem. If there is any uncertainty about the research and its outcome, that is justification to conduct research into the problem, but not if there is no unanimity on the ethical problem. He noted that the Royal College of Phyicians is uniquely placed, as it has the only list of chairmen on ethics committees in the country. There is at present no national organisation of chairmen of ethics committees and so no united voice to make representations to government. He asked whether the meeting agreed to the preparation of a circular to be signed by all chairmen of all ethics committees, demanding that the proper service be supplied.