

society is an important but complex task for research. We know from other research on social identity that respondents are likely to report problems and coping strategies that are acceptable within particular communities, and de-emphasise those that are seen as more difficult.^{9 10} For example, an implicit message from Riordan's study is that homophobia is a problem mainly in dealings with patients rather than fellow professionals. This may support earlier research, which shows that over time professionals have become more accepting of lesbian, gay, and bisexual colleagues but which could also reflect reluctance to talk about a painful issue.¹¹

Clearly, we need a larger dataset before we can be sure about this and other matters of detail. In the meantime, exploratory research like that of Riordan can play a valuable role in widening professional awareness of a taboo subject and suggesting hypotheses for further investigation in larger, more systematic studies.

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Another threat to research in the United Kingdom

Research ethics committees may be unable to function because of political control

Medical research in the United Kingdom is under a substantial and immediate threat that was mentioned neither in the editorial on the European Union clinical trials directive nor in Moulton's letter in the same issue.^{1 2} Many research ethics committees may be unable to function fully after 1 May 2004 and may not comply with international regulations. This will be the result both of regulations drafted by the Medicines and Healthcare products Regulatory Agency and of arbitrary decisions taken by the Central Office for Research Ethics Committees.

Research ethics committees are not in general worried about the requirements of the European Union directive itself. However, the regulations to implement the directive in the United Kingdom, recently laid before parliament, include several elements of great concern to research ethics committees.³ Although these concerns were drawn to the attention of the Medicines and Healthcare products Regulatory Agency last year, only one has been dealt with. Originally the regulations were written so as to disbar large categories of people from membership of research ethics committees; the version now before parliament is more sensible.

Two main concerns remain, the removal of the independence of research ethics committees and the arrangements for obtaining "consent" for an incapacitated adult to be entered into a clinical trial.

The regulations will set up the UK Ethics Committees Authority as an overtly political body, its members include the secretary of state for health, the Scottish ministers, and the National Assembly of Wales. The authority will have the power to set up or abolish any research ethics committee and to appoint all chairs, vice chairs, and members of research ethics committees for which it is the "appointing authority"—in practice all current NHS research ethics committees. This proposal for direct political control of their member-

ship and very existence does not meet the requirements of the European Union's directive that research ethics committees be independent. The minister responsible has said that members and chairs will be appointed locally, but this is not specified in the regulations (Lord Warner, personal communication, 2004). He has also said that the important part of independence is that research ethics committees should be independent in forming an ethical view, yet that too is under threat in the regulations. They require, for example, that clinical trials be conducted according to the ethical principles of an out of date version of the Declaration of Helsinki, rather than the substantially rewritten version approved in 2000 from which research ethics committees work.

An alternative approach would be to set up a national research ethics committee, as exists in several European countries and has also been recommended in the past by the BMA. As a committee of experts it could give advice on tricky issues in research ethics, something that the Central Office for Research Ethics Committees is not in a position to do. With a small secretariat it could also take on accreditation of research ethics committees, in a similar way to the licensing functions of the Human Fertilisation and Embryology Authority. Most importantly, it would remove the current risk that research ethics committees in the United Kingdom may be held not to conform to the good clinical practice requirement of independence, so that the results of clinical trials performed in the United Kingdom could not be used for licensing or marketing purposes.

The second concern is how the regulations define the legal representative of an adult lacking capacity for the purpose of giving consent to that adult's inclusion in a clinical trial. If no suitable personal representative is available, either the doctor responsible for the patient's care—if not involved in the clinical trial—may

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be the legal representative or anyone nominated by the health service body providing care to the patient. The substantial ethical and legal problems of including incapacitated adults in research projects have been widely discussed in the last decade by, for example, the BMA, the Law Society, and the Law Commission. None of these bodies nor the Scottish Parliament, which has legislated in this area, has ever suggested such a solution.⁴ The conflicts of interest it presents, and the risks to the safety of patients inherent in giving such power to the nominee of a health service body who may know nothing about the patient, make the proposal quite unethical, and unacceptable to many research ethics committees.

Decisions by the Central Office for Research Ethics Committees also threaten the membership and independence of research ethics committees. Committees will no longer be allowed to review protocols on which any of their members are named, even if they take no part in the discussion or decision. Some investigator members of research ethics committees are talking of resigning because they strongly believe in the importance of local review. This possibility is exacerbated by the decision of the Central Office for Research Ethics Committee that only a small minority of local research ethics committees will in future be allowed to review clinical trials: no criteria have been given for how such research ethics committees will be chosen. Taken with micromanagement of research ethics committees by the Central Office for Research Ethics Committees—115 pages of standard operating procedures, for example, with an additional 31

standard letters that research ethics committees must use—that decision is a further encroachment on the independence of research ethics committees. The micromanagement is adding greatly to the workload of administrators of research ethics committees, many of whom are on inappropriately low salary scales.

Although academic researchers are obviously concerned at the increased cost and bureaucracy introduced by the directive, they should also be aware that problems with approval from research ethics committees may increase rather than diminish after 1 May. Research ethics committees in the United Kingdom may be held not to be independent and therefore not compliant with good clinical practice, and some members of research ethics committees and administrators may no longer be willing to serve, which might possibly result in the collapse of some research ethics committees. In that case all research, not just clinical trials, would come to a halt in those centres.

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Competing interests: RN runs training courses for members of research ethics committees and some research ethics committees subscribe to the *Bulletin of Medical Ethics*, which he edits.

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Affirmative action: the lessons for health care

Governments are becoming more assertive about reducing ethnic inequalities

Even the richest multiethnic societies have so far failed to ensure a fair distribution of health and health care among people with different racial and ethnic backgrounds.^{1,2} Persisting inequalities have been ascribed largely to societies' moral failures and social injustice.¹ We discuss here whether the rationale for the use of civil rights remedies such as affirmative action may be extended to the formulation of health policies aimed at addressing disadvantage among minority groups.

In two landmark rulings in June 2003 the US Supreme Court upheld the use of affirmative action policies in admissions to higher education but rejected a formula based system assigning points to minority status.³ The court had made similar distinctions before on a wide variety of civil rights policies, including voting, mental health treatment, and employment. The proviso has always been that such policies must be "narrowly tailored" to serve a "compelling interest," and the trend has been towards an increasingly narrow interpretation. In the current case several justices recognised that disparities in education are set in the wider context of disparity of opportunity and outcomes among racial and ethnic groups: "Unemployment, poverty and access to health care vary disproportionately by race."³ A key question is whether such judicial endorsement may lead to

sweeping changes in other areas of public policy, in the United States, in Britain, and elsewhere. Health care is one such area where existing disparities could be drastically changed by implementing appropriate, "narrowly tailored" measures.

In the United Kingdom the emphasis on ethnic health inequalities is relatively recent, as government policy has traditionally focused on inequalities associated with socioeconomic position. A programme for action on tackling health inequalities, published in July 2003,⁴ cites "black and ethnic minority groups" in virtually every target and action plan. In the United States, an initiative to eliminate racial and ethnic disparities in health was launched in 2000 by the Clinton administration, set to achieve its goal by 2010, as the culminating point of a series of efforts dating back to 1985.⁵ Major government agencies in the United States have since established programmes dealing with racial and ethnic health disparities. With express reference to affirmative action, governments in South and Central America have also adopted special health programmes for their indigenous populations.⁶

Evidence of the effectiveness of interventions to reduce racial and ethnic disparities has built up in recent years.⁷ For example, the national programme for early detection of breast and cervical cancer in the