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Ethics Committees and Medical Research: The Australian Experience

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Abstract: Australian ethics committees have a central role in the regulation of medical research. Recently this role has come under public criticism despite the fact that there are almost no Australian studies of the workings of ethics committees. This paper looks at the problems and advantages of ethics committees in the light of some studies, including two recent Australian investigations. It concludes by proposing a model of regulation that utilizes the strengths of ethics committees while avoiding the problems which can arise as a result of their self-regulating nature.

Introduction

In Australia the role of institutional ethics committees (IECs) in the regulation of medical research has recently and for the first time come under public scrutiny. IECs came quietly onto the Australian medical research scene in the late 1960's when most institutions undertaking research involving human subjects established such committees [1]. These committes occupy a central place in the system for the control of medical research in Australia. They operate under and apply guidelines laid down for medical research by a federally-created body called the National Health and Medical Research Council (NHMRC).

IECs have recently attracted some public attention because the 1980's have seen the development of successful *in vitro* fertilization programmes in all the States of Australia. Accompanying this development has been a considerable amount of social debate and controversy, much revolving around the difficult issue of embryo experimentation. Government response, both State and Federal, has been to establish committees to examine the issues raised by *in vitro* fertilization (IVF) and reproductive technology generally [2]. Many of these committees have been critical of the present system for controlling medical research. A Federal Senate Select Committee, for example, stated in its report that the present system of IECs was inadequate and ought to be replaced by, amongst other things, penal legislation [3].

Criticisms of IECs in Australia have not been preceded by any careful study of them.

Symptomatic of this fact is the absence in the various committee reports of any reference to studies of the workings of IECs. Systematic empirical evidence concerning the operation of IECs (number of meetings, selection procedures, manner of making decisions, etc) is needed, but there are reports of two investigations conducted by the NHMRC which provide some information on the operation of IECs [4]. There is also a body of literature outside Australia concerning their workings, much of it from America [5].

This paper, then, focuses on the critcisms commonly made of IECs in medical research and evaluates them in the light of some relevant studies. The paper concludes by suggesting some modifications to the present regulatory scheme which will help overcome the weakenesses of using IECs while retaining their strengths.

Ethics Committees in Australia: The Official Framework

At the apex of the framework for IECs in Australia is the NHMRC. One function of this body is to make recommendations to the Commonwealth and States on matters relating to medical research. Partly influenced by the Declaration of Helsinki, the NHMRC has formulated a set of national guidelines in relation to human experimentation. The guidelines consist of the NHMRC's Statement on Human Experimentation and a series of Supplementary Notes to be read in conjunction with the Statement [6]. The Statement on Human Experimentation contains a set of general principles to which research must conform. For example, research protocols should contain a statement of the ethical considerations involved. The subject should be properly informed of the risks and purposes of the study and consent obtained in writing. The subject must be free to withdraw at any time from the project.

Under the guidelines, every institution carrying on human experimentation must have an IEC (Supplementary Note 1). IECs attached to research institutions must adhere to the guidelines laid down in Supplementary Note 1 concerning composition and function. IECs must be composed of at least the following five people: a laywoman and a layman not associated with the institution, a minister of religion, a lawyer and a medical graduate with research experience. Supplementary Note 1 requires IECs to consider the ethical merits of research projects, to provide for their surveillance and to maintain a record of all proposed research projects. In carrying out these functions IECs must conform to any other relevant NHMRC guidelines. So, for example, where an institution has an IVF programme it is, in addition, subject to special guidelines (Supplementary Note 4). Finally, IECs must also take account of local cultural and social attitudes and ensure that research is not done at the expense of the rights of patients.

While the NHMRC is responsible for the system of IECs in the context of medical research, another body, created administratively by the Federal Government and known as the Genetic Manipulation Advisory Committee (GMAC), is responsible for the safe use of genetic manipulation techniques. One of its functions is the preparation of bio-safety committees. While the role of the GMAC is to assess the safety of various genetic techniques rather than the ethical issues raised by the techniques, fields such as human gene therapy conflate the distinction between safety and ethics, creating overlapping areas of responsibility between the NHMRC and GMAC.

Recently the Federal Government has also created the National Bioethics Consultative Committee [7]. Essentially its role is to advise the Government on bioethical issues. In short, at a Federal level the regulation of medical research is characterized by administrative complexity and a reliance on IECs and biosafety committees properly administering the relevant guidelines. This position can be partly explained by the fact that the Federal government lacks express condititutional power to legislate the regulation of medical or scientific research and must, to some extent, therefore, hope that the relevant Federal guidelines gain voluntary acceptance.

The Federal scheme of regulation has been further complicated by State initiatives in particular areas of medical research. In the field of IVF, two States have acted on the recommendations of their committees and enacted legislation which specifically deals with medical research in that field [8]. Under the legislation researchers are required to obtain permission from a statutory body for their projects. Failure to do so is an offence which incurs heavy financial penalties or a term of imprisonment.

Ethics Committees: Problems and Advantages

A frequent criticism of the NHMRC system of IECs and guidelines is that it is ineffective as a means of control because it is not specifically supported by criminal sanctions. A researcher who fails to comply with the guidelines does not commit a criminal offence, nor is an IEC which fails properly to carry out its duties subject to legal penalty. However, it is not true that there are no sanctions which could be applied against an IEC and the institution to which it belongs. There are financial sanctions. The NHMRC has stated that only institutions conforming with its guidelines are eligible to receive funds for research. Naturally, this sanction can be applied only to research bodies which seek the NHMRC's financial help. Often overlooked in the context of sanctions is that medical research programmes are located within a very broad framework of State and Federal public health legislation and administration [9]. This legislation offers a number of options concerning the control of IECs. For example, medical practitioners who, as members of IECs, refuse to follow the NHMRC guidelines in respect of research with humans would be guilty of professional misconduct under legislation dealing with the registration of medical practitioners. A research institution with the registration which continued to breach the guidelines could possibly be the subject of an inquiry under public health legislation.

Another point, usually forgotten in the context of guidelines, is that, in certain circumstances, they can become incorporated into parts of the legal system. For example, if a negligence suit is brought against a researcher a court, in determining the appropriate standard of care, would certainly consider the guidelines for researchers issued by a body like the NHMRC. Similarly, guidelines can enter the legal system by being incorporated into the terms of a research contract. While the point should not be over-emphasized, 'non-legal' guidelines can, in some cases, have many of the qualities of a law. They may also form basis of a legal standard. More importantly, the fact that a rule exists in the form of a guideline does not deprive it of normative value. As has been observed, governments and their departments have come increas-

ingly to rely on informal rules in the form of guidelines, policy statements, practice notes, standards, codes of practice and so on as part of the administration of legal rules [10].

A study of IECs in Scotland suggests that there is more to fear from a poorly organized system of IECs than from a system dependent on guidelines [11]. Each IEC was sent a questionnaire requesting information on matters such as composition, mode of operation, ethical problems faced by the committee, etc. The survey showed that there were considerable differences between IECs on the question of their function. Some saw their function as an advisory one, others were unsure of their function and none mentioned the direct control of research as function. The study showed an astonishing variation in the number of members on any given IEC, the range being from one to seventy three members. Selection procedures differed and a little more than half the committees had non-medical members. Modes of operation varied greatly. Some (approximately one third) of the IECs had not met in twelve months while others met less than three times a year. Of the 370 research proposals evaluated by these committees, seven were rejected outright and fifty-three returned for modification. There was no regular monitoring of research and over one third of the committees did not know whether the projects they approved had ever been started. The study concluded that IECs satisfied neither the interests of the researcher nor the public.

Does the conclusion of the Scottish study apply to the Australian system of IECs? The NHMRC has carried out the two investigations of IECs in Australia. Their findings are set out below:

Report on Workshops on the Constitution and Functions of Institutional Ethics Committees in Australia 1984-85.

This investigation consisted of a questionnaire sent to institutions involved members of IECs and the NHMRC. Ninety-six replies were received from 109 institutions active in research.

The questionnaire revealed:

1 many IECs were still in the process of implementing NHMRC guidelines;
2 membership of IECs did not conform to NHMRC guidelines in two out of three cases;
3 most IECs attempted to carry out some form of surveillance of approved research projects;
4 most IECs maintained a register of research projects, although not always in the form suggested by the NHMRC;
5 in 1983 1 827 research protocols were considered. Of these, 73 percent were approved, 23,5 percent were approved after further consideration and 3,5 percent were rejected.

The workshop programme revealed a number of interesting views and concerns:

1 there was concern about the meaning of the term 'research'. Did it include innovative medical practice?
2 another concern was how IECs could be informed about all relevant research projects, for instance, a research project initiated and funded by a drug firm with the co-operation of an individual doctor;
3 on the issue of publication of IECs proceedings the consensus was that, provided good records were kept, publication was unnecessary.

In Vitro Fertilization Centres in Australia: Their Observance of the National Health and Medical Research Council's Guidelines 1986

The report on IVF centres involved members of the NHMRC auditing the operations of 12 institutions known to be conducting IVF and related research. The report made these findings:

1 all IVF centres had an IEC, but in three cases they were not constituted in accordance with NHMRC guidelines;
2 all IECs kept records, varying in detail;
3 no surrogacy arrangements had been made;
4 no cloning experiments had occurred;
5 opinions varied about what constituted research; some centres took the view that minor changes to existing procedures did not constitute research.

These two studies constitute only a beginning of the investigation of IECs in Australia. More information is needed. For example, the NHMRC investigation revealed no information on the actual number of members on each IEC. (The NHMRC guidelines stipulate a minimum membership only.) Nor was there information on how these members are recruited. There was no information on what constituted a quorum at meetings of IECs and the methods employed at meetings, particularly when disagreements arose. More detailed information is needed on surveillance practices and the kinds of sanctions available to IECs. Some work needs to be done on the interaction between medical and non-medical members, and the institutional support IECs receive. The high rate of approval by IECs of research projects should be scrutinized. Little can be inferred from the one statistic cited in the first NHMRC study. Some IECs may be doing their job properly and some may be functioning merely as rubber stamps. Nevertheless, the NHMRC investigations constitute an important start in the assessment of IECs and show that more work needs to be done before serious judgment can be passed on them.

In making this judgment some points in favour of a system of IECs should not be ignored. First, the formal establishment of an IEC in a research institution means that the potential exists for carrying out an ethical review. Furthermore, because an IEC is local to the institution carrying on the research, it is well placed to obtain information about the research proposal. This is important, because ethical review made in ignorance of relevant facts or with a poor grasp of the facts runs the risk of error. An external body attempting to review research proposals in a particular institution might find it more difficult to obtain all the relevant information.

A common objection to IECs is that, while they are mainly staffed by medical researchers and scientists, research proposals do not receive the independent and critical scrutiny they deserve because researchers cannot, by virtue of their commitment to research and the values that commitment implies, operate with the necessary objectivity. The NHMRC guidelines attempt to overcome this problem by stipulating that membership of IECs includes non-medical persons. The value of non-medical members on an IEC depends very much on the competence and confidence of those members, but it is suggested that even if an IEC were made up predominantly of medical researchers, its objectivity would not automatically be impaired.

The media today is eager to publicize the errors of medical science, particularly when they involve human subjects and individual suffering. Moreover, in Australia research institutions must compete for a limited number of research dollars. Institutions cannot, in circumstances in which funds are difficult to obtain, risk their reputations. There is also the possibility of litigation. Although medical researchers and practitioners in Australia may not exposed to the levels of litigation in the United States, it is true that the medical profession must operate in a social environment in which an error of judgment brings a much higher probability of litigation than was previously the case. In sum, an IEC in Australia, in making a decision about a research project within its institution has to consider that approving an unethical project could result in adverse publicity, could jeopardize the institution's chances of obtaining further funding and could incur legal action against the institution. IECs, whatever their membership, cannot afford to operate in a completely self-serving and short-sighted fashion.

A recent survey of attitudes towards IECs by members of the medical profession in the United Kingdom indicated a range of attitudes towards the importance of IECs and their role [12]. Should this diversity of attitude also occur in members of IECs the quality of IECs could vary considerably. Nevertheless, there is some evidence coming from the United States to suggest that Institutional Review Boards (the equivalent of Australian IECs) have some benefit for human subjects of research [13]. Fewer subjects are dying and more research protocols are being modified. Irrespective of their quality, IECs fulfil, at least in part, an educational need. It is true that in Australia medical and science degrees are little concerned with ethics. A recent report on medical education suggests that in Australia medical graduates leave university with almost no formal training in approaches to ethical problems [14]. The presence of an IEC at a research institution is a reminder that research has a public and social dimension and that the silent intuitions of researchers on ethical matters in research are inadequate. Naturally, the more active an IEC is in an institution the greater will be its educative effect.

Ethics Committees and the Model of Enforced Self-regulation

A notable feature of the Australian discussion of IECs has been its failure to consider models of regulation that exploit their advantages [15]. Alternative models have usually involved penal legislation. The weakness of using penal legislation in this field merits separate discussion, but an obvious source of difficulty lies in the level of enforcement. For example, although it is possible to prohibit certain research in molecular biology, how would illegal research be detected? Where would the state find the necessary highly trained inspectors? Would researchers want to spend their careers policing other researchers? There is one model known as 'enforced self-regulation' has been proposed as a new way of approaching the control of corporate crime [16]. Despite its corporate crime context, some features of the model could be usefully adapted to regulate research institutions. Basically, under a model of enforced self-regulation, the state requires each corporation to develop a set of rules in the light of policy standards legislatively enacted by the state. A regulatory agency reviews and has the power publicly to ratify these rules. Public interest groups are able to participate in the development of these rules and the policing of rules is carried out by a compliance

group which the corporation would be required to establish. Much of the cost of regulation is, therefore, borne by the corporation itself. Government inspectors monitor the effectiveness of the corporate compliance group. If the corporation does not act on the advice of its compliance unit, the director of the unit is statutorily required to report this to the relevant regulatory agency. Violations of the rules devised by the corporation for itself are punishable by law. In summary, enforced self-regulation attempts to produce a set of specifically tailored rules that both the regulator and the party regulated can live with, in the enforcement of which both parties participate.

Under a scheme of enforced self-regulation, a research institution would be legally obliged to have an IEC. The IEC would function as a compliance unit. Working as a compliance unit, an IEC would be required critically to examine research protocols according to a set of approved guidelines. It must be emphasized that an IEC would not, in its role as a compliance unit, be required to police laboratories. In the words of one writer: 'We cannot sustain our university communities if we require colleagues to police and harass each other because they think there is a high likelihood that any particular other is dishonest. Argument and dialogue, so crucial to the existence of the academic community, are impossible in an environment of distrust' [17].

Whether IECs should be allowed to draft some of their own guidelines is difficult to decide, but provided such guidelines are subject to review by an independent agency, the suggestion is not without merit. One of its potential strengths is that research institutions could develop guidelines suited to the research activity in question, rather than relying on a very general set of guidelines designed to cover many different types of research. Enforced self-regulation could also lead to more effective monitoring. It has been pointed out that corporate inspectors in the pharmaceutical industry have a higher level of training than their government counterparts and a better knowledge of the corporation, making them more effective [18]. Similarly, medical researchers, by virtue of their expertise, knowledge and location within a research institution, would be better placed to scrutinize research protocols than are those external to the institution and untrained in particular fields. The model of enforced self-regulation could also help overcome some of the weaknesses of the existing system. One aspect of IECs which both of the NHMRC investigations failed to cover is how research institutions recruit non-medical members to IECs. The proper exercise of the power of recruitment is vital to the success of any system of IECs. It is no use appointing non-medical members to an IEC if those non-medical members have hidden allegiances to medical members. Abuses of the recruitment power could be avoided if appointments were screened by a government agency, or were the agency periodically to review a research institution's recruitment procedures.

Related to the recruitment question is that of public participation and consultation in the development of guidelines. Codes of self-regulation often attract criticism on the ground that, while the wider community is affected by the practices a code endorses, that community often has little or no say in the development and drafting of the code. In the development of the NHMRC guidelines, there is little evidence that public participation took place on a systematic and institutionalized basis. Enforced self-regulation would involve the participation of public interest groups in the creation of self-regulation, rules which would reduce much of the criticism of the use of guidelines in this field.

It is not crucial to the control of medical research that every decision by medical researchers be vetted or inspected by a regulatory agency. It is, however, vital that the structure of decision-making in medical and scientific research on ethical matters operate fairly and efficiently. IECs have a genuine contribution to make. Under a model of enforced self-regulation, a public monitoring agency would ensure that the structure of decision-making in IECs worked properly, rather than attempting to police the individual decisions of those committees. The model of enforced self-regulation deserves sympathetic consideration in the context of medical research, for it gives researchers the opportunity to become involved in their own regulation while providing safeguards against the worst excesses of self-regulation.

Notes

1 Osborne LW (1983) Research on human subjects: Australian ethics committees take tentative steps. 9 Journal of Medical Ethics: 66

2 There have been approximately 15 reports. The following are the more substantial ones: Attorney-General's Department (1985). Creating children: a uniform approach to the law and practice of reproductive technology in Australia, AGPS, Canberra; Senate Select Committee on the Human Embryo Experimentation Bill 1985. (1986) Human embryo experimentation in Australia AGPS, Canberra; New South Wales Law Reform Commission (1988). *In vitro* fertilization LRC 58; (1984). Report of the Special Committee appointed by the Queensland Government to enquire into the laws relating to artificial insemination, *in vitro* fertilization and other related matters volume 1; (1985). Committee to investigate artificial conception and related matters, Final Report Hobart; Committee consider the social, ethical and legal issues arising from *in vitro* fertilization (1983). Report on donor gametes in IVF Victoria; Committee to consider the social, ethical and legal issues arising from *in vitro* fertilization (1984). Report on the disposition of embryos produced by *in vitro* fertilization Victoria.

3 Senate Select Committee Report *supra* 44n2.

4 See, NHMRC (1985) Report on workshops on the constitution and functions of Institutional Ethics Committees in Australia 1984-1985 (1986). In Vitro Fertilization Centres in Australia: their observance of the National Health and Medical Research Council's Guildelines (Report to the National Health and Medical Research Council by the Medical Research Ethics Committee)

5 For a discussion of Institutional Review Boards (IRBs) see, Levine RJ (1981) Ethics and regulation of clinical research Urban & Schwarzenberg, Baltimore-Munich, ch 13. Discussion concerning the value of IRBs has gone on for some time in the U.S. See, for example, (1979) Lipsett MB *et al* Research review at NIH; Veatch RM The national commission on IRBs: an evolutionary approach, Robertson JA Ten ways to improve IRBs. Hastings Centre 9(1): 18-21, 22-28, 29-33, respectively. Aside from IRBs there are institutional ethics committes in the US, see (1984) Cranford RE & Doudra AE (eds) Institutional ethics committees and health care decision making, (1984). Health Administration Press, Ann Arbor, Michigan. Sources of information outside the US are, for example, Lewis PJ (1982) The drawbacks of research ethics committees. Journal of Medical Ethics 8:61-64: Denham MJ *et al* (1979) Work of a district ethical committee BMJ: 1042-1045; (1981) Ethical Committee, University College Hospital. Experience at a clinical research ethical review committee, BMJ :1312-1314.

6 NHMRC Statement on Human Experimentation and Supplementary notes (1985) NHMRC

7 See (18 December 1987) Government response to the Report of the Senate Select Committee on the Human Embryo Experimentation Bill 1985 and the report of the Family Law Council 'Creating Children' Senate Hansard Australia: 3481

8 Infertility (Medical Procedures) Act 1984 (Vic); Reproductive Technology Act 1988 (South Australia)

9. For example, Health Act of 1937 (Qld); Public Health Act 1902 (NSW); South Australian Health Commission Act 1976 (South Australia); Health Act 1911-1979 (WA); Public Health Act 1962 (Tas); Medical Practioners' Act 1970 (Vic)

10. See Baldwin R, Houghton J (1986) Circular arguments: the status and legitimacy of administraive rules. Public Law: 239-284

11 Thompson IE *et al* (1981) Research ethnical committees in Scotland (1981) BMJ: 718-720

12 Allen P & Walters WE (1983). Attitudes to research ethical committees. Journal of Medical Ethics 9:61

13 See Classen HW (1986). Institutional Review Boards: have they achieved their goal? Medicine and Law 5:387, 389-390

14 (1988) Australian medical education and workforce into the 21st century. AGPS, Canberra: 164-172

15 For an exception see Scott R (1986). Experimenting and the new biology: a consummation devoutly to be wished. Law, Medicine and Health Care 14(3-4):123

16 Braithwaite J (1981-82). Enforced self-regulation: a new strategy for corporate crime control. Michigan Law Review 80:1466-1507

17 Levine *supra* 232n5

18 Braithwaite *supra* 1468n16. See also, Braithwaite J (1984) Corporate crime in the pharmaceutical industry. Routledge & Kegan Paul, London