BIOETHICS OUTLOOK

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In this issue

There are two articles in this number which have something to say about the moral principle of respect for patient autonomy.

- In the first article John Quilter discusses what he calls the 'autonomous strangers model' of the relationship between doctor and patient, the idea that doctor and patient are free and equal partners to a voluntary contract which is transacted in a free market. He argues that this is a deeply misleading way of thinking about that relationship, and that the idea of respect for patient autonomy does not commit us to thinking of the relationship in those terms.
- In the second Max Charlesworth replies to a critical note by Bernadette Tobin of some issues in his book *Bioethics in a Liberal Society.*

The other main feature in this number is a three-part discussion of the role and functioning of Institutional Ethics Committees. These are committees set up in the main by hospitals and universities to consider, approve (or disapprove) and monitor the subsequent conduct of research projects on human subjects. Institutional Ethics Committees are currently the subject of review by both a Ministerial Review Committee and the Research Ethics Subcommittee of the Australian Health Ethics Committee, a principal committee of the National Health and Medical Research Council.

Professional-Patient Relationships and Patient Self-Determination

by John G. Quilter

The evolution of Bioethics over the last thirty years has seen the emergence of a Bioethical mainstream whose characteristic idea is that the proper sources of guidance in the making of ethical decisions in the delivery of health care are four principles or rules:

1. Respect patient autonomy;
2. Do not harm the patient;
3. Benefit or do good to your patients;

   and
4. Act justly to all those affected by your decisions, especially to patients with rival claims on resources: give everyone their fair share.

Further to this identification of principles, Classical Bioethics maintains that the first principle is the most important one: where one can, one must seek first to obey the autonomous wish of the patient (consistently with obeying your own autonomous wishes or conscience, of course). Difficult cases for such an approach are still handled with an "autonomy first" starting point. So, for those who are currently

incompetent, one needs to determine, as far as one can, what the patient would have wanted had he or she been able to say. Some go so far as to apply this approach to those who have never been competent, such as the new born who are critically ill or the adult but severely intellectually disabled.

Reasons for this strong stress on respect for patient autonomy vary. For some, it is a matter of foundations of public morality in individual freedom; for others it is a matter of ensuring that our rules of conduct conduce to the long term satisfaction of individual preferences; for others, it is a matter of acknowledging the intuitive basis of ethical reflection in the right to self-determination. And there will be other reasons as well as thinkers who combine these and other reasons. However, one thing that writers in the Classical Bioethics mould have in common is a rejection of Medical Paternalism as the model of the good professional-patient relationship. In this, most Classical Bioethicists concur on the following characterisation of the professional-patient relationship.

Classical Bioethics is usually driven by a fairly atomistic individualistic idea of the professional-patient relationship: the patient is one person, the doctor another; they are separate from each other, free and equal to each other. The patient has come to strike a contract. She is quite in control of her life - "I'll pay you if you'll fix me". In effect professional and patient are strangers to each other, transacting a voluntary exchange in a free market. What the professional knows about the patient is that she is a person with a right to self-determination. Respect for patient autonomy is valuable because it honours that right she has as a person as a serious limit to his will. Here the American bias is obvious.

> We might say that the source of the right to become involved as a health care professional in the patient's life is the patient herself.

If the exchange is to be genuinely voluntary, the doctor must inform the patient of everything she needs to know and must not dissemble or manipulate the patient at all. The doctor must tell her honestly and in clear language her condition, treatment options, the material risks and likely prognoses and apply no pressure on the patient to decide one way or another. The standard of what the health care provider is obliged to explain is the particular patient and her situation and values: things it is important for her to know as someone in her situation in life. If she does anything else, the doctor violates the patient as an equal, exploits her, takes advantage of her ignorance or otherwise wrongs her. It does not matter how silly, unreasonable or unethical the patient's decision is. (Of course, it matters whether it is legal or not...)

Call this general approach to decision making the "Autonomous Strangers" Model of the Professional-Patient Relationship. This model is typical of Classical Bioethics in its conception of the way the patient's autonomy defines the professional-patient relationship. It is endorsed at times explicitly by Robert Veatch, Tristram Englehardt and others.

The exploration of the nature, importance and limits of patient autonomy and its place in grounding the professional-patient relationship is something we owe to Classical Bioethics. This exploration is necessary and I will return to it shortly. Still, there are problems with the conception of informed consent and patient autonomy as long as we adhere to the Autonomous Strangers model of the Professional-Patient Relationship. For that model thinks of the Professional-Patient Relationship as just a result of the interaction of two self-contained, utterly separate individualistic atoms. While we do this, while we think of the professional-patient relationship as a transaction between two self-contained perspectives, I think the dangers are palpable.

The first is that by concentrating on the issues from the health care professional's perspective we will not have progressed far beyond Medical Paternalism even if we put firm emphasis on respect for patient autonomy in the way Classical Bioethics does, that is, as a right of the patient. The reason is that the perspective is defined by a question of the form "How I am going to work out what I should do?" as if in the mouth only of the health care professional. The

patient's autonomous wishes are one factor, even if the most important one, among others. The danger here is that by constructing the issues in terms exclusively of decisions which the health care professional has to make, we lose sight of the fact that the health care professional only has any business making any decisions or receiving any information concerning this patient because the patient is the source of such authority in her life. We might say that the source of the right to become involved as a health care professional in the patient's life is the patient herself. That is, the shape of the relationship is that its point is patient-centred service on the patient's terms (compatibly with her proper respect for the health care professional's autonomy, dignity and reasonable practical constraints and other interests, etc.) as a service to the patient.

On the other hand, if we see the relationship exclusively from the perspective of the patient, and emphasise patient autonomy we will have left the patient high and dry without guidance as to how she should exercise her autonomy. Patients do not always exercise their autonomy well - reasonably, practically or ethically. Patients are not immune to rational moral criticism. It is not true that just anything that patients say goes. They need guidance in their health care decisions as in the rest of life; we all do.

Further, not all patients relish the role of being the autonomous author of their own health care decisions. Many would prefer to be cared for where they occupy a fairly passive role; they do not come wanting to be in the saddle. Sometimes this is alright, sometimes it is not. The abilities (a) to make decisions and accept responsibility for oneself and (b) to make good decisions are not evenly distributed in the community. Some are more self-motivated than others; some have clearer ideas about what they value and believe than others; some have these elements of self-understanding but do care to exercise them. In contrast, much contemporary moral philosophical talk about patient autonomy (and political liberty) is inspired by an idea of individual liberty which traces back to an essentially Romantic conception of the individual as the source of her own nature and self-development and as the origin of all that she is and does. But against such a conception of freedom and autonomy, there are many everyday observations about human behaviour of the sort I have mentioned. Autonomy or voluntary decision-making comes in degrees; it can be uncertain of itself and what it wants, it has many dimensions of assessment and one cannot always be confident that someone whom one may influence has acted freely.

What is mistaken about the lines of thought associated with the Autonomous Strangers Model is the conception of the professional-patient relationship. Each assumes there is a closed, self-contained perspective which enters into the relationship: the patient's which needs supplementation with factual information from the doctor or nurse; and the health care professional's which needs supplementation with knowledge of the patient's values, moral views and preferences. This one form of professional-patient relationship explains them all. But this is just mistaken.

First, there is a sense in which the professional-patient relationship is bigger that the both of them. There are social roles which individual professionals inherit upon admission into the profession and there a "sick role" which the patient is expected to play and often does not mind playing. These roles and socio-cultural patterns impact on the individual professional and patient whether they like it or not (not that they cannot transcend them, of course; it is only that in a system of health care delivery, social roles are virtually inevitable). These facts about the social environment make a difference to the nature of patient and professional autonomy and its place in making decisions about the patient's health care.

Secondly, there is not just one kind of professional-patient relationship: some indeed are somewhat like the Autonomous Stranger model (eg. the relationship between the surgeon and the patient referred to her); others are more like a relationship between a lonely dependent misfit and a pastor; and others are like a relationship between friends who look out for each other. These differences are important. There are different ethical questions arising where years of care, a history of shared golf days

and dinner parties stands behind the taking of a crucial health care decision from the questions arising where the nurse or surgeon is a pretty well anonymous party to the relationship with the patient who is in hospital for one day surgery. Issues of loyalty and the honesty due a friend arise in the first sort of case; issues of professional deporture, the intimidation of the patient by the haste and indifference of an institution or professional offices, and time for the assimilation of expert information arise in the latter sort of case.

Thirdly, in all such relationships, important differences aside, the patient's trust in her care giver is not just a trust in that person's technical expertise: in that she will often have to trust somewhat blindly. It is also trust in the good character of the health care provider to put his or her expertise at the service of the patient.

Many professionals like to emphasise this point in their criticism of the Autonomous Strangers Model. They point out that that model has developed historically out of responses to abuse of human subjects in medical research. In response to such unethical medical conduct, the Autonomous Strangers Model is a valuable antidote. But most professionals, especially doctors, point out that their motivations in paternalistic decision making are those of carers - people whose focus is on the care of the patient taken to be valuable for her own sake and not as providing an opportunity for playing God. The idea is that anyone who cares for other people will be prepared to take on certain responsibilities for them in order to lighten their load, relieve their stress or give them protection or guidance and direction. The professional who decides paternalistically is simply responding to this appropriate expectation.

The right answer to this is not the Autonomous Stranger Model for the reasons I have already outlined. The right response, I would like to suggest, is that such observations may be true for certain professional-patient relationships but not for all. Caregiving can be good care even when the patient is given time to assimilate difficult information at difficult times. To be sure, sometimes it is better for a carer to assume another's responsibility and act paternalistically as a gesture of care. But not always. Where it is, a degree of intimacy is typically required that is not ordinary in contemporary health care delivery except perhaps in certain general practices or in country towns with frequently-seen patients or personal friends. Moreover, the social roles health professionals have are changing - the old paternalistic carer is not expected by everyone as it used to be. Individual practitioners are insensitive to this at the risk of ethically less-than-satisfactory care. In general, I would suggest that we owe it to the patient to help her be lucid in the trust she shows us.

So, in trying to interpret the meaning and importance of respect for the patient's autonomy in the professional-patient relationship, I would urge that we be clear on the sort of background relationship(s) we have to deal with. I have argued that we have a background which

(a) recalls that the professional-patient relationship is something bigger than the participants in it;

(b) is sensitive to important differences that exist between different professional-patient relationships;

(c) acknowledges the readiness of the patient to trust in the expertise and good character of the health care professional and the service due the patient; and

(d) bears in mind the lucidity which the patient's trust needs if we treat the patient properly as an equal, as a person, as someone who is a limit on our will.

It is against this background that we should ask what is required for the recognition and respect it is proper to give the patient as the person whose life, health and so on we are making decisions about. Progress in our understanding of the sorts of relationships that there are or should be between patients and professionals requires careful sociological examination. Under such an understanding of the professional-patient relationship, we might think of patient autonomy, the moral importance of informed consent, in terms which avoid the excesses both Paternalism and the Romantic idea of liberty involved in the Autonomous Stranger Model.

Personal Autonomy

A reply to Bernadette Tobin[1]

Max Charlesworth

I would like to thank Bernadette Tobin for her civilised and generous review of my little book, *Bioethics in a Liberal Society*. At the same time I have an uneasy feeling that we are, in a sense, at cross purposes. I certainly do not mean by the notion of personal autonomy what she thinks I mean, and I am afraid that I do not fully understand what she means when she says that 'it is not the concept of personal autonomy which illuminates the dignity of a human being'.

In my view (and, I would argue, in the classical tradition - Aristotle, Boethius, Aquinas *et al.*) personal autonomy is the very definition of a *person*. To put it baldly, unless a human being is an autonomous agent in some sense then he or she is not a person in the paradigmatic sense. This does not mean, as Tobin fears, that human beings who do not have the capacity to act autonomously can be treated without any concern for their dignity. There is a variety of reasons why we impute some degree of personhood to, for example, the human fetus in the later stages of its development, anencephalic infants, young children, those in persistent vegetative states, etc.

In my book I argue that personal autonomy is the condition for any human act to have moral value. It is not one value among others in competition, so to speak, with other values and I fail to understand what Tobin means when she says that it is 'no more than one expression of human value'. I agree, of course, with Tobin that we value human beings for their affection and love and courage and perseverance and creativity, but acts of affection, courage and creativity etc., are distinctively *human* acts only if they are autonomously done.

I find it astonishing that Tobin should accuse my argument of being 'reductive' as though I wanted to reduce all human values to the value of personal autonomy. She says:

> *'We will need a deeper account of how we stand towards other human beings than one which reduces that relationship to a respect for them as autonomous agents'.*

To me this is tantamount to saying that giving primacy to respect for persons is in some way 'reductive'. In any case in my book I speak at length about values such as justice and equity, although I also argue that they presuppose the value of personal autonomy.

In my book I spend a good deal of time arguing that personal autonomy has nothing to do with any kind of self-interested individualism which simply means that one has a right to pursue life in one's own way and that one's responsibility towards other autonomous agents is simply to let them be in a spirit of passive indifference. The realisation that one is an autonomous person with a moral vocation of one's own and that one is totally responsible for the shaping of one's life, and the corresponding realisation that other persons have their own unique moral vocations that one must respect, has nothing to do with what Tobin calls 'the shallow capacity to pursue life in one's own way' which is at odds with 'a deep capacity to make oneself into a certain kind of person'. A deep capacity to make oneself into a certain kind of person is in fact precisely what the exercise of personal autonomy is all about. Newman, in his magnificent essay on the 'individuality of the soul', which I cite in my book, shows how deeply Christian the idea of autonomy is and I urge those who have not read the essay to do so.

Again, in a brilliant book on the 'pastoral anthropology' of St Paul, the biblical scholar Jerome Murphy-O'Connor argues that St Paul's

idea of 'agape' or love is that it is essentially a way of empowering others:

> *'The distinctive characteristic of authentic humanity is a creativity which effectively opens new horizons of being to others.'*

This involves letting others be but it is also far from being an attitude of *laissez faire* indifference to others. Murphy-O'Connor cites another theologian who says,

> *'Love is letting be, not of course, in the sense of a standing off from someone or something, but in the positive and active sense of enabling to be'.* [2]

I emphasise in my book that reference to the value of personal autonomy will not 'solve' all the difficult problems in bioethics. But it seems to me that respect for the human person as an autonomous moral agent provides a basic perspective within which we can fruitfully reflect on those problems.

A final point: I do not argue, as Tobin suggest, for 'euthanasia' in my book. As I note, the term 'euthanasia' is so hopelessly confused and compromised that it is better to avoid it. I argue that in certain circumstances a person may conscientiously decide for good reasons - even religious reasons - that prolongation of her life is humanly meaningless and then decide to end her life by her own hand or with the voluntary assistance of another. (I do not know what to call this, since 'suicide' and 'assisted suicide' are terms that have been compromised by the classical philosophical and religious arguments (defective in my view) so that 'suicide' has the connotation of moral weakness or insanity ('suicide while of unsound mind')).

When we consider the case of incompetent patients we must as far as possible put ourselves in the position of the patient and try to decide whether the patient in question would want treatment to be withdrawn or active measures taken to hasten her death. If, for example, the patient were an Orthodox Jew then, regardless of my own views about his 'quality of life' or the meaningless prolonging of his life, I would be bound to conclude that his life should be prolonged. I emphasise in my book that 'quality of life' is not something that can be 'objectively' assessed and measured by an outside person. It is essentially a 'subjective' matter of how a person sees her own life. To Job's neighbours his life had very little 'quality', but to Job himself it was full of meaning. Tobin's characterisation of my position is that 'we ought to be free to decide for someone else ... that his or her future quality of life is likely to be so minimal that medical treatment should be withheld or withdrawn'. But this is a position I absolutely reject (see, for example, pp. 53-5).

[1] Tobin, Bernadette: 'Respect for personal autonomy: is it the supreme value?: A note on *Bioethics in a Liberal Society* by Max Charlesworth, *Bioethics Outlook*, 5: 3, p. 1-4; 8, 1994.

[2] Murphy-O'Connor, Jerome: *Becoming Human Together: The Pastoral Anthropology of St Paul*, Michael Glazier, 1982, p. 48.

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Australian Bioethics Association Fourth National Conference: Theme: *Autonomy, Community & Justice in Bioethics*

The conference will take place from 25 until 28 September 1995 at St John's College, The University of Queensland. The keynote speaker will be Professor William May, Cary Maguire Professor of Ethics, Southern Methodist University, Dallas, Texas, author of *The Physician's Covenant* and *The Patient's Ordeal*. For further information contact:

The ABA Conference Secretary
St John's College, College Road
St Lucia, QLD 4067 Australia
Telephone (07) 871 8312

Australian Association for Professional and Applied Ethics Second National Conference: Theme: *Ethics in Practice: Applying Ethics in Workplace and Society*

The conference will follow the Australian Bioethics Association Conference, from 28until 30 September, 1995 at St John's College, The University of Queensland. Professor William May will again be guest speaker. Registration forms can be obtained from:

The AAPAE Conference Secretary
St John's College, College Road
St Lucia, QLD 4067 Australia
Telephone (07) 871 8312

Research Ethics Committees: do institutional committees sufficiently protect the human subjects of research?

1 Introduction: the case of RU 486

Keith Joseph

In August this year clinical trials conducted under the auspices of the Family Planning Association of Victoria using the drug called RU 486 came to media attention. This drug, known colloquially as the "Morning After Pill" or the "Abortion Pill", is an abortifacient. In these trials RU486 was used in combination with mysoprostol, a synthetic prostaglandin, in order to increase its efficacy. The trials, which were being conducted on three hundred women by the Sydney Centre for Reproductive Health and the Monash University Department of Obstetrics and Gynaecology at the Family Planning Association of Victoria, have since been suspended.

Prior to 1991 the approval of the Therapeutic Goods Administration (TGA) was required for the use of drugs for the purposes of human experimentation. In May 1991, this arrangement was changed. Since then, the Therpeutic Goods Administration has not been involved in scrutinising clinical data on specific drugs. Provided that a clinical trial is approved by an Institutional Ethics Committee (IEC) operating in accordance with National Health and Medical Research Council (NHMRC) guidelines, the Therapeutic Goods Admininistration will approve the trial and authorise the importation of drugs.

However, RU486 is a prohibited import: its importation required an exemption from the Department of Human Services and Health. A former Minister for Health had given an undertaking to parliament that the import of RU 486 would not be approved unless the Minister had been consulted. Nevertheless an unnamed official cleared the trials and allowed importation of the drug without reference to the current Minister, Dr. Carmen Lawrence.

At the basis of much of the controversy about RU486 are questions about

(a) the ethics (and the legality) of abortion;

(b) the safety of the women subjects of these trials;

(c) the way in which the trials had been approved. NHMRC guidelines require that committees include a 'minister of religion': it emerged that the minister of religion had taken no part in the approval process. He had not attended a meeting since August 1993 and, when he formally resigned in May 1994, he was not replaced;

(d) the adequacy of the consent given by the women who agreed to be subjects of the research. The consent form itself was criticised by Dr Lynette Dumble for failing to mention "the cardiovascular risks of RU 486/prostaglandin abortion [and] the unknown effects of these two chemicals on ... future fertility and overall health", and

(e) the adequacy of the whole system of institutional ethics committees for assessing and monitoring the ethics of research projects on human subjects.

As a result of the seriousness of these issues, the Commonwealth Minister for Health has instituted a review of the role and functioning of Institutional Ethics Committees. The review, to be chaired by Professor Don Chalmers (who is also Chairman of the Australian Health Ethics Committee) will:

- investigate the operation of existing arrangements for IECs, particularly in terms of their appropriateness for the discharge of responsibilities under the Clinical Trials Notification (CTN) scheme;

- consider the suitability of the existing arrangements for the monitoring of IECs by the Australian Health Ethics Committee of the National Health and Medical Research Council;

- make recommendations on any changes which need to be made in the NHMRC Guidelines on Human Experimentation, in the operation of IECs and the level and degree of support required for IECs to operate effectively;

- have special regard to issues of concern to women particularly in trials relating to reproductive technology; and

- examine and report on recommendation 10 of the Report of Inquiry into the use of Pituitary Derived Hormones in Australian and Creutzfeldt-Jacob disease (the Allars Report).

The deadline for public submission to this review was 15 December 1994.

References:

Dumble, Lynette: "Real trials of abortion pill users", *The Australian*, 17 August 1994, p. 13

Kingston, Margo: "Ethics imbroglio over RU 486", *Canberra Times*, 8 August 1994, p. 9

Kingston, Margo & Brough, Jodie: "Trial of abortion drug suspended 'indefinitely'", *Canberra Times*, 18 August 1994, p. 2

Tankard Reist, Melinda: "RU 486 Trials - Controversy in Australia", *Bioethics Research Notes*, Vol. 6 No. 3, September 1994, pp. 1-2

National Health and Medical Research Council: The Clinical Trial Notification Scheme: *Draft Guidelines for Institutional Ethics Committees*, June 1992

2 Criticisms of Institutional Ethics Committees

Martin Kelly

The recent controversy involving the mechanism by which approval was given for clinical trials of the abortifacient drug RU 486 highlights the importance of the media in shaping the debate about the adequacy of Insititutional Ethics Committees. There are good reasons for being attentive to these public concerns.

The need to balance the importance of academic freedom with the need to ensure that research on human subjects is conducted in ethically-permissible ways is well known. There are both irresponsible and responsible researchers. Remember the clinical study of cervical cancer conducted at the National Woman's Hospital in Auckland. For more than ten years, and without their informed consent, women were denied standard treatment for carcinoma-in-situ so that researchers could study this potentially life-threatening disease. These researchers had neither scientific nor moral reservations about the trial: the trial was stopped only after exposure and public outcry.

The situation is somewhat different in the RU486 case, but public discussion has raised questions and doubts about the role and function of research ethics committees. In what follows I shall set out the main criticisms of the arrangement in which approval for the running of a clinical trial on human subjects is the responsibility of local Institutional Ethics Committees. This matter is now under review by both a review committee established by the Minister for Health and the Research Ethics Subcommittee of the Australian Health Ethics Committee.

Criticisms of IECs raised by this case include:

- Conflicts of interest experienced by members of committees: commitment to the research profile of the institution on

the one hand and the principle of ethical scutiny of research on the other;

- Involvement in research projects by committee members who then take part in a decision to approve their own research project;
- Composition of committees : the fact that many committees are dominated by medical or research personnel and the fact that the lay members often feel unequal to the task of seriously questioning a research project;
- Loopholes in the system of review itself: the fact that in the past organizations have sometimes set up their own ethics committee to approve their own research projects when they have failed to gain approval by another committee;
- The fact that approval by a committee is sometimes used (for example, by drug companies) for the purposes of recommending a certain drug;
- Lack of monitoring of drug trials once they are approved by a committee;
- Lack of accountability or central supervision of Institutional Ethics Committees; the fact that there exists no means of ensuring that committees enforce NHMRC guidelines on the conduct of research using human subjects;
- Lack of public accountability of Institutional Ethics Committees; the fact that by and large the public has no idea of the clinical trials which are approved by specific committees.

In what follows I shall develop just two of these criticisms.

The Composition of Institutional Ethics Committees.

The NHMRC guidelines specify that a range of men and women should be on committees, and that the members include a layman and lay woman not associated with the institution, a minister of religion, a lawyer and a medical graduate with research experience. The guidelines specify that these, and other members who may be appointed, act as individuals and not in a representative capacity.

Most research ethics committees have a preponderance of medical or research personnel. Commonly they are employed by the institution in which the research is to be conducted. These researchers can be expected to be committed to their own research institution and to the research enterprise itself. Concerns about conflicts of interest go deeper than furtherance of career, prestige, tenure, or the requirements of training. Medical and research personnel value research as a good in itself. They believe in it! Yet the interests of scientific research may conflict with those of human subjects. Further, the interests of research may not be identical with the public good, despite the genuine convictions of individual scientists about the importance of their own research projects.

No one on these committees specifically represents the interests of human subjects. No one is accountable to the subjects of the research. Lay members on committees speak in their own voice, as individuals. There are good reasons for this. The United States experience of having the ethics debate hijacked and derailed by powerful lobby groups makes one wary of having sectional interests represented on committees.

One problem is that the medical-research community is, in fact, a sectional interest. Its members are accountable *de facto* to their profession, its values and practitioners. Where this is not recognised, this representation and accountability function is a problem.

Though there are several non-medical people on these committees, many of them are also committed to the institution. In addition, some of the researchers ask "Why should non-scientists be there?" But it seems clear that, if a scientist cannot demonstrate the value of his or her research to an educated layperson on the committee, then it is unlikely that he or she would be able to obtain meaningful consent from the subjects of proposed research.

The Role and Function of Institutional Ethics Committees

The NHMRC guidelines recognise the importance of ongoing research in the interests of human health. They specify that committees

should ensure research is conducted according to generally accepted moral and scientific principles. There is great stress on protecting the rights, wishes and freedom of subjects, and the role of appropriately informed consent as a way of securing this. The guidelines are an attempt to balance the (at times conflicting) interests of researchers and subjects.

The primary role of institutional ethics committees is to protect the interests of the subjects of research. They are forums for considering the issues raised by research. They should consider potential risks and potential benefits of research to the extent these can be known. They should offer a multi-disciplinary evaluation of proposals. Ideally, they should reassure the public that research is responsible, reputable and useful, and that researchers are adhering to the high ethical standards they claim for themselves.

At present there are many reasons why these committees may not accomplish their primary role:

1 **No standard terms of reference.** The NHMRC guidelines are basic: individual committees establish their own guidelines. There are no performance criteria or objective standards to compare one committee with another. Further, sponsors could select an ethics committee on the basis of anticipated ease in having their trial approved.

2 **Lack of funding.** This may restrict the capacity of a committee to represent the interests of subjects. Ethics committees involve considerable cost to institutions. Only a proportion of those costs are met: many members giving their time on a voluntary basis. There is little scope for education of new members. The contribultion of lay members particularly may be restricted until they "pick-up" education on the job.

3 **Lack of guidelines** means that decisions about complex issues may be made "on the run" as and when they arise for different committees.

4 **Lack of supervision.** There is little scope for monitoring the functioning of individual committees. More importantly it is very difficult for a committee to monitor a clinical trial once it is approved. Nor are there enforcement provisions for non-compliance. It is difficult to see how the claim that they look after the interests of human subjects can be made good.

5 **Lack of accountability** to government, to the public and to the subjects of research. Indeed, few among the public would be aware of the existence of these committees. There is a need for greater transparency in the operations of these committees, and for greater monitoring and supervision of their modes of operation and decision-making.

Conclusion

No doubt some individual committees operate perfectly well. However, the system needs a greater degree of standardisation, better exchange of information, better guidelines and more accountability. And the question of membership needs to be reviewed.

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3 Some Solutions

John Quilter

Forming a response to this case, we need to be very careful to distinguish between its problematic aspects that are related to the public debate about abortion and those related to general issues of preserving decent ethics in research on human subjects.

First, I take it that there is a great deal *against* centralisation of the ethical review of research. It is inefficient, it would slow research down immensely, it would be *very* costly and it would pose potential threats to intellectual freedoms necessary for good science.

We do better to pursue what is tempting about centralisation in the current, broadly and effectively self-regulating framework.

Thiscase raises questions about how better to protect the interests of these human beings who are the subjects of scientific research. I would favour some kind of subject's representative. Currently, research ethics committee members in theory deliberate in their own voice (certainly, the layman and woman do) although the religious minister can clearly be thought to represent her religion. Research is in effect represented by the majority of members in most committees. It is desirable to have a member specifically representing subjects. Any subjects' representatives need not have been subjects, arguably, but *should be accountable* to research subjects if only by way of justifying their contributions to and eventual vote *in* their research ethics committee. Where specifiable groups of people will be involved in research or affected by it, subjects' representatives should be included from (or nominated by or approved by) an organisation of good repute recognised for its advocacy role.

I have in mind in particular people with HIV/AIDS, Indigenous Australians, and women. Organisations could include the AIDS Council, or the Aboriginal and Torres Strait Islander Commission or a local Land Council person or women's health consumers groups. Such members could be invited in as occasional participants as needed, acting in a more or less consultant role. They would be bound by the principles of confidentiality, etc., which apply to all members. It would be the Secretary's responsibility to see to this being arranged and the research ethics committee's protocols should request researchers to specify any kinds of person who will be affected or targeted as subjects.

Additionally, for general purposes, research ethics committees should include another subjects' representative, in particular for studies which lack a subject pool as easily identified as the three mentioned already. A group such as Consumers' Health Forum could be invited to nominate someone or one of its member associations could. A central advantage of having subjects' representatives is that they can for themselves protect their own interests rather than have others doing it for them without consultation (as is the case now).

I would distinguish such members from the layman and lay woman. The latter should be included as injecting into the committee the element of pluralism of the broader community. They are there in their own voices. Committees should be more honest about the impartiality permitted lay members in the selection process. Perhaps advertising, as some institutions currently do, to fill these positions is desirable. Shortlisting, followed by lots, would perhaps do the trick.

It is also desirable that research ethics committees be formed independently of particular projects: both in the temporal and organisational sense:

(a) a research ethics committee should not be formed at an institution for the precise purpose of getting a project through; membership should be settled and only then should projects be reviewed;

(b) conflicts of interest should be avoided: persons with a stake in the project should absent themselves from the committee even if there are no problems with the research project; this is not any real inconvenience where there are no difficulties with the research; and if there are, their role is to discuss it with the committee *as researchers*. Again, ethical decency needs not just to be done but to be seen to be done.

I doubt that much centralisation is really justified. However, I think I can see a role for some kind of public justification of membership and membership selection criteria. There should be a declaration of potential conflicts of interest and an account of the element of public accountability which particular members introduce into a committee. Such information could be kept at the National Health and Medical Research Council and the Australian Health Ethics Committee. These bodies should review such information and raise any problems they can see, perhaps offering recommendations or advice to the institutions.

NOTEBOOK

Graduate Certificate and Master of Arts in Applied Ethics (Health Care)

Australian Catholic University invites applications for the Graduate Certificate in Applied Ethics (Health Care) and for the Master of Arts in Applied Ethics (Health Care) for 1995. The courses will be offered part-time at MacKillop Campus and require attendance on a weekly basis.

The Graduate Certificate course has been especially developed for professional staff in the area of Health Care who have had no opportunity for formal study of ethical issues. The course is made up of four units: Reason and Ethics; Religion and Ethics; Principles of Bioethics, and Health Care and the Law.

The Master of Arts course comprises four core units: Ethical Decision Making Parts 1 and 2, Religions and Ethics in a Pluralist Society and Research Methods and Critical Thinking, together with four speciality units chosen from: Ethical Aspects of Health Care Practices Parts 1 and 2, The Social Context of Health Care Delivery: Ethical Dimensions Parts 1 and 2, a Project 1 or 2 units in length or an appropriate 1 unit elective selected from other Master programs.

Application form may be obtained by contacting:

The Admissions Officer
Australian Catholic University
179 Albert Road
Strathfield NSW 2135
Telephone: (02) 739 2218

Further information may be obtained from the Office of the School of Religion and Philosophy on (02) 739 2252.

Intensive Bioethics Course

Our second annual Intensive Bioethics Course will take place at St Patrick's College, Manly on the weekend of 30 June - 2 July next year.

The course will provide a general introduction to ethical, theological, legal and economic aspects of health care.

As so much is gained through the opportunities for informal discussions over the weekend, participants are encouraged to live in at the College from Friday evening until late Sunday afternoon.

The first course which was held in June this year at the College proved very popular.

Application forms may be obtained by contacting Barbara Reen at the John Plunkett Centre on (02) 361 2869.

Advanced Bioethics Course

Our first Advanced Bioethics Course will take place on the weekend of 15-17 September 1995 at a venue to be decided.

This course provides an opportunity for participants to deepen the knowledge they gained from participation in the Intensive Bioethics Course.

The topic for study during the weekend will be: *The contribution of Christian moral theology to contemporary bioethics.*

Please note the date of both weekends in your diary. Further details will be provided in the next issue of *Bioethics Outlook.*

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