
BIOETHICS OUTLOOK

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NSW Human Tissue Act

In October last year, the NSW Health Department released a discussion paper, entitled *Organ and Tissue Donation and Use and Post Mortem Examination*, as part of its current review of the NSW Human Tissue Act 1983. The Paper explains the current legal framework for a series of practices related to the use of human tissue and then raises questions about the desirability of changing the law with respect to them. In summary, the issues canvassed are: donation of tissue by living persons, donation of tissue by deceased persons; the liability of medical institutions and staff in the case of the transmission of an infectious disease through tissue transplant; the use of human tissue other than in the donation setting (for therapeutic or research purposes and in the case of foetal tissue); the removal of tissue in the course of *post mortem* examination and its use for other purposes without consent; and exemptions to the prohibition on trade in human tissue.

In this issue of *Bioethics Outlook*, we present a series of papers on these issues. Deborah Frew explains the purpose and scope of the current review of the *Human Tissue Act*. Gerald Gleeson considers whether it is legitimate to take regenerative tissue from young healthy children for the treatment of their siblings. Mary Byrne explains how two key ideas influence our thinking about the significance of the family's feelings about organ donation after death.

Ray Raper then argues that it would be legitimate to remove organs, *before the determination of death*, from someone who has made it known that he or she wishes to donate organs (so long as a diagnosis of irreversible coma and irreversible loss of all brain stem function had been made). Nicholas Tonti-Filippini argues that it would not.

Next, Robert O'Neill considers the vexed question of whether the state should facilitate contact between the families of donors who have deceased and the recipients of their organs. Finally, Helen McKelvie and Stephen Cordner explain the newly-agreed Victorian practice of requiring consent, from the next-of-kin of the person who has died, before tissue removed at *post-mortem* examination may be used for purposes other than that examination.

We hope that the papers presented here will not only inform our readers but also deepen their understanding of the ethical issues at stake in the resolution of these issues.

The Review of the *Human Tissue Act 1983*: organ and tissue donation and use and *post-mortem* examinations

Deborah J. Frew

The Department of Health is currently conducting a review of the *Human Tissue Act 1983*. This Act deals with a number of matters pertaining to the law surrounding the human body, including the removal of organs and tissue from the bodies of both living and deceased persons for the purposes of donation or other therapeutic or scientific purposes, post mortem examinations of deceased persons and the statutory definition of death.

The Act was based upon model legislation recommended by the Australian Law Reform Commission in 1977.¹ It is consistent with similar legislation in other Australian States and Territories, although there are some important differences.

The Department is reviewing the Act in three parts. One part consists of a review of those sections of the Act dealing with organ and tissue donation, post mortem examinations and the use of other kinds of human tissue. The other two parts of the review deal with Assisted Reproductive Technologies and Blood Donation and Supply.

The Department has conducted all three sections of the Review in a similar way, which is aimed at achieving a high level of community input into the review process. A discussion paper has been issued in relation to each of the three areas described above, and distributed to a wide range of community, medical, consumer, religious and government bodies. In addition, the

Department has encouraged and participated in consultation in various public forums.

The discussion paper relating to organ donation and post mortem examinations was issued in October 1999. It considers aspects of the *Human Tissue Act* which have been in operation since 1983 and examines whether those provisions are still appropriate for application in New South Wales today. The discussion paper also considers some issues which are not currently dealt with in the *Human Tissue Act*, such as the basis upon which foetal tissue may be used to treat the illnesses of living people, and to what extent surgically removed tissue can be used for purposes which may not have been contemplated by the person from whom the tissue was removed. In respect of these matters, it is questioned whether the *Human Tissue Act* should be amended to provide a legislative framework for dealing with these kinds of uses of human tissue.

These are questions which affect not only the health professionals involved in organ donation but the community generally. The role of the law with respect to the human body is a matter which is of interest to all individuals in society. It must reflect community values and be based upon sound ethical principles. It is for this reason that the Department seeks to obtain the widest possible community perspective, prior to considering possible legislative reform. Individuals and groups are therefore encouraged to participate in the review process by making a written submission upon the issues raised in the discussion paper.

An aspect of the review: the role of family members in the current system of post-mortem organ donation

One issue which is considered in the discussion paper is the role of family members in objecting to the removal of organs from a deceased relative when organ donation is contemplated.

The current system of donating organs after death which is set out in the *Human Tissue Act* was termed "consensual giving" by the Australian Law Reform Commission. It allows a person specifically appointed by a hospital to authorise the removal of organs or tissue from a deceased person's body, provided that a number of rules are complied with. That person is known as the "designated officer".

The designated officer *may* authorise removal of organs and tissues if, after making such inquiries as are reasonable in the circumstances, it appears to him or her that:

- the deceased, whilst alive, expressed a wish, or consented, to become an organ or tissue donor after death; and
- the deceased had not subsequently withdrawn the wish or revoked the consent.

In this situation, the Act does *not* go on to state that an objection by a next of kin will prevent authorisation from taking place.

Where a deceased person had not expressed a wish or a consent, the designated officer *may* authorise removal of organs and tissue if there is no objection by the senior available next of kin.

The use of the word "may" in the *Human Tissue Act* confers upon the designated officer a discretion as to whether or not to authorise removal of organs and tissues, even where all the pre-conditions in the legislation are met. Where the donor has consented to organ donation during his or her lifetime, the designated officer must still exercise his or her discretion as to whether to authorise that removal.

One reason for this is clear. It would not be appropriate for the designated officer to authorise removal of the organs and tissue if they could not be used, for example, because

the donor does not fit the relevant clinical criteria.

But the existence of the discretion has also led to a fear amongst some that designated officers will be persuaded not to authorise removal of organs and tissue, even where the consent of the deceased is clear, because of the objections of relatives. That is, even though the Act does not state that the objection of relatives will prevent donation, the designated officer may, none the less, decide to give precedence to the objection of relatives over the clearly expressed views of the deceased, and determine not to authorise removal. This is often expressed in terms of relatives "overriding" the decision of the deceased.

The Australian Law Reform Commission, when making its recommendations upon which the above provisions are based, stated that:

" a competent adult should have the right to give his body or any part of it for the purpose of transplantation or other therapy or for medical or scientific purposes. His wish should be paramount. No person (except the Coroner in a case falling within his jurisdiction) should have the power to overrule the decision." ¹

Many are of the view that, if the designated officer decides to follow the wishes of relatives when they are contrary to the wishes of the deceased, then the above principle expressed by the Australian Law Reform Commission is being contravened. The autonomy of the deceased person is not being respected.

A legislative amendment could be made which prevented designated officers from considering the views of relatives in circumstances in which the donor had clearly indicated a wish to become an organ donor and had not withdrawn that wish. That is, the discretion of the designated officer could be limited.

The following possible consequences of such an amendment should be considered.

First, such an amendment could cause immense stress to a grieving family, especially if they have a strong ethical, religious or cultural objection to organ donation. New

South Wales is a multi-cultural society, and many cultures value the burial of the body as a whole, and object to the dissection of a deceased body. It is to be remembered that death preceding organ donation often occurs in very tragic and unexpected circumstances. Families are often in shock and have difficulty comprehending the death, as well as suffering grief and distress.

Secondly, such an amendment could place stress on hospital staff, donor coordinators and designated officers in dealing with distressed families who feel that their wishes are being ignored. Whilst the autonomy of the deceased is a principle deserving of consideration, how is to be weighed up against the obligation these staff owe to living relatives, who are seeking their help and guidance? The difficulties this situation may present to hospital staff could lead to a reticence on their part to identify potential donors or to approach their families.

Thirdly, should a failure to take account of the wishes of relatives become a well known practice, it is possible that families will learn ways of overcoming this barrier. For example, families may state that the donor definitely withdrew consent to organ donation, even if this were not the case. This would remove the ability of the designated officer to authorise removal of organs and tissue without consulting the senior available next of kin. This leads to the possibility of families feeling that they cannot trust hospital staff and that they must be less than completely honest and open with the health professionals with whom they are engaging as a result of their relative's death.

Finally, a combination of the above factors, leading to the dissatisfaction of health professionals, families, as well as particular cultural and religious groups, may lead to a loss of confidence in the system of organ donation, and a fall in support for organ donation programs.

It warrants consideration whether the problem lies not in the law, but in the communication between individuals and their families. Perhaps, if individuals were encouraged to discuss donation with their families, explain their reasons, and make their wishes known in advance in a positive way,

family members would feel better equipped to respect that decision in the event that it was ever to be relied upon. Generally, the Australian Red Cross is of the view that where this is the case, surviving relatives very rarely make a decision which is not in accordance with the deceased's wishes. If this is so, then the solution may lie not in a legislative response, but in promotion of public debate and discussion regarding organ donation.

To be weighed against this is the view of the Australian Law Reform Commission that the autonomy of individuals is to be respected, both during their lifetime and after their death. It must be asked what right any individual has to prevent the altruistic wishes of the deceased from being followed, and hence to deprive the potential recipients of the benefits which transplantation can bring. Where an individual makes a decision to assist another person after his or her own death, should family members have the ability to prevent this from occurring?

Careful consideration must be given to the above points when making decisions upon this matter. Those with an interest in this issue are urged to consider both sides of the argument before reaching their conclusions.²

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¹ Australian Law Reform Commission, Report No 7, Human Tissue Transplants, AGPS, Canberra, 1977, para 144.

² Interested readers may obtain a copy of the Discussion Paper from the Legal and Legislative Services Branch of the NSW Health Department. The closing date for submissions from the public to this review is 30th April 2000.

Organ transplantation from living donors

Gerald Gleeson

Organ and tissue transplantation is one of the wonders of modern medicine. In time, of course, it may be possible to grow new organs and tissues from human cells, but for the present most organ and tissue replacement depends on the generosity of living donors, or on the removal of tissues and organs after a person has died. The ethical issues raised by "donation" after death are somewhat different from those concerning donation by a living person: the latter should remain the paradigm case for ethical reflection. An understanding of the ethics of living donation will help us consider the vexed question whether the law in NSW should be changed to allow the removal of tissue for transplantation from very young children who are not yet able to understand what is being done.

There are three main ethical considerations with respect to living donation. The first concerns the rationale for the transplant procedure itself — the extent of the expected benefit to the recipient, and the likelihood of success. The second concerns the burdens on the donor — the discomforts involved, and the potential harm to the donor (which depends on both the gravity of an expected harm and its likelihood of occurring). For donation and transplantation to be ethically justified, the expected benefits to the recipient must clearly outweigh the likely risks to the donor. The third consideration is the donor's decision — that the donor both understands what is involved and freely agrees to the procedure.

By reflecting on these considerations we are able to clarify two fundamental issues:

To *what* is the donor consenting? Is it *reasonable* for a person to consent to this? The second issue is crucial, for consent alone is

clearly not sufficient to justify donation (just as consent alone would not be sufficient to justify participation in an experimental trial which is not scientifically warranted).

Getting the issues in perspective

The most interesting ethical question surrounding donation concerns the way in which these three considerations are related to each other, and this will depend on the fundamental perspective taken on the ethics of human action.

The first perspective one might take — and this is the perspective most often taken in our culture — is "the external perspective", the view of an outsider looking on. From this external perspective, a decision about donation and transplantation is fundamentally a calculation of benefits and harms to all affected. The focus is on benefits to recipients (and perhaps indirectly to donors), on the availability of resources (organs and tissues), and on the harms to the donor (as well as side-effects for the recipient). From this perspective, the "consent" of the donor becomes a relatively secondary matter, a "side-constraint" — something we need to get, or "tick off", before the procedure may go ahead. From this perspective, for example, it seems obvious that it would be good to use very young children as a source of bone marrow, provided we can deal with, or get around, the consent issue (when the children are too young to understand and agree to the "donation").

The second perspective one might take — I believe this is the perspective one should take — is the "first person" perspective of the person as agent, i.e. of the person as the one

responsible for his or her action, as giving meaning to an action which is chosen as a means to a goal judged to be good and worthy of pursuit. From the perspective of the person as agent, organ donation is a case of "love of neighbour", an act of solidarity with another in need, an act of mercy or "rescue". From this perspective, granted that a person wants to come to the aid of another in need, the assessment of the benefits and harms of the procedure becomes the secondary issue of prudence or practical wisdom. The person asks, "To what discomfort and risk of harm may I rightly expose myself in coming to the aid of another?" (As will be seen, in the case of the very young child, the crucial question for parents is, "What may I as a parent legitimately ask of one child for the sake of another?")

The purpose of contrasting these two perspectives is to highlight the different ways in which they relate consent to the evaluation of the overall procedure. On the first perspective (the "utilitarian" perspective), the primary agents are the medical staff — they may be keen to undertake a procedure, and they need to obtain consent to do it. It is easy to see how this perspective makes consent relatively less important, and at times a potential nuisance.¹

The second perspective, by contrast, places the act of the donor — an act of generosity and solidarity, which goes beyond merely "consenting" to a procedure — at the very heart of ethical understanding. Only this perspective brings out the essential moral meaning of an act of donation as a human action, and not simply as a utilitarian transaction. The primary agent here is the donor, and the medical staff are assisting the donor to come to the aid of another. Within this perspective, emphasis is placed the person's self-understanding and motivation, on what he or she is doing and why, and on how the act of donation fits into the wider context or "narrative" of that life. It is for these reasons that we can speak of persons as properly the "authors" of their actions.

(The contrast between these two perspectives is relevant to the issue of how to increase donation rates. Australia has one of the lowest rates of donation in the developed

world. From a utilitarian perspective this is an obvious wrong that needs to be put right, hence the various suggestions about how to increase donation rates by altering the consent requirements (from "opting-in" to "opting-out", by allowing the wishes of relatives to be overruled, etc.). From the perspective of the donor, by contrast, strategies like these will never get to the heart of the issue, namely to the motives and intentions of donors and to the practical wisdom of an act of donation. Although our low donation rates could simply reflect a lack of generosity on the part of Australians, it could also be that these rates reflect instinctive and legitimate concerns on the part of Australians about the gap between the technological aspects of transplantation and the many "human aspects" which provide the context for these procedures.)

If we apply the donor's perspective to the problematic issue of the use of very young children as tissue "donors", what comes into focus are the questions that *parents* (and/or guardians) must ask themselves, rather than the questions which concern medical staff. Because the child is unable to give consent, strictly speaking the child cannot be a donor. Rather the child is being "used" as a source of tissue. So the ethical question here concerns the extent to which parents may "use" one child in order to help another child. Precisely because our question is about what *parents* may do, rather than what "strangers" (e.g. medical staff) may do, reflection on this question directs us to an understanding of why transplantation from young children may be justified, as well as to the ethical safeguards required by respect for the very young child.

Parental Responsibilities

There are two parental responsibilities which, I believe, provide a framework for considering the use of very young children as a source of tissue.

Firstly, and fundamentally, parents must respect their child as an "end in him or herself", i.e. truly as "a person" equal to themselves in dignity and value, and so never to be used *merely as a means* to an end,

however good that end may be. The word "merely" is important: there are numerous ways in which we "use" others (e.g. parents may "use" an older child to mind a younger child). Ethical problems arise when the "use" fails to respect the other as a person in his or her own right, and as someone whose freedom and capacity for understanding the reasons for what he or she is doing is also respected. Hence, e.g. parents should not ask an older child to mind a younger child if this involves the risk of harm to the older child, or conflicts with the older child's reasonable needs and wishes.

Secondly, parents have a general responsibility for the moral formation and education of their child, so that, for example, he or she grows up, not as a isolated individual, but as a family member, as a generous person who understands and appreciates his or her solidarity with others. This solidarity is modelled, in the first place, by family life itself. The child is thus introduced to the importance of what "we" do as a family, and of what we do for one another. This aspect of family life is especially evident when the family as a whole is affected by the special needs of one member, e.g. a disabled child or an ill parent. At times, therefore, parents will rightly make demands on their children, demands the children do not (yet) understand, for the sake of other family members and/or of the family as a whole.

Removal of tissue from a young child

In the case of organ and tissue donation, the critical question concerns what parents may legitimately ask of one child for the sake of another, where what is asked will impact on the donor child's health and well-being. Clearly, the removal of a non-regenerative organ would be unethical since this could not but harm the child or jeopardise the child's future health. In the case of regenerative tissue such as bone marrow the issue is more complex. While the tissue will regenerate, the method of removal — that is, one which involves a general anaesthetic — may pose a

remote risk of a life-threatening outcome. Would it be reasonable for a parent to expose a child to such a risk in order to obtain tissue for another child?

There are three major views among ethicists about the degree of risk that may be tolerated in these cases. For some, there must be no risk at all; for others (as for the law in Queensland) the risk must be "minimal"; others again say a justified risk must be "less than minimal". A "less than minimal" risk is like a purely theoretical risk, so small that it counts for nothing. Of these views, the "no risk at all" position is unhelpful, since it sets an unrealisable standard of absolutely no risk in principle. The real alternatives are "minimal" and "less than minimal", and the latter is the safer measure to follow, though there is, of course, no mathematical way of determining the line between minimal and less than minimal. We are dealing with *prudential* judgments, judgments of practical wisdom, and it will be for parents to determine whether a risk of serious harm is so remote that they would be warranted in exposing their child to it.

Does the risk posed by a general anaesthetic constitute a "minimal" or a "less than minimal" risk? The answer cannot be black and white, since it will depend on the health of the patient, and on the medical resources and skills available. Crucially, however, the notion of minimal risk combines *two* distinct ideas: that of the gravity of a harm, and that of its likelihood. While death is a grave harm that could result from a general anaesthetic, in our country it is unlikely in the case of healthy patients. Parents are thus being asked to evaluate two factors in determining whether it would be right to use a child as a source of tissue. Their aim should be to impose only a less than minimal risk on the child, but they may judge that the sheer unlikelihood of an adverse outcome is sufficient to make an otherwise significant risk less than minimal.

Parents will also bear in mind the adverse effects on the child if an older sibling dies because no transplantation is undertaken. In

this way, the well being of each child is linked to that of the others, and so the risk a child is being asked to bear finds some of its justification in a concern for the child's own welfare.

Conclusions

I have argued that our perspective on issues of donation and transplantation should be that of the donor who must make prudential judgments about the extent to which it would be right to expose himself or herself to harm in coming to the aid of another. In the case of parents using their children as "donors", this same question must be answered in the light of the solidarity and mutual concern which is essential to life as a family, along with the recognition that there is a qualitative difference between the risks one may take on oneself, and the risks one may impose on others. Children should never be treated merely as resources or as commodities, but should always be respected as persons of equal dignity and value to both parents and siblings. Judgments of practical moral wisdom are required to determine whether small risks are consistent with respect for the independent dignity of the donor child and justified in the interests of the well being of family members. Such judgments in turn presuppose that parents possess the moral virtues, above all the virtue of prudence, as they seek to do what is right for all concerned.

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I In the same way, *voluntary* euthanasia inevitably slides into *non-voluntary* euthanasia, because if euthanasia can be a good thing for those who want it, it is easy to conclude that it can also be a good thing for some who haven't said they want it. For development of this argument, see John Quilter's 'Against Legal Protection of Voluntary Active Euthanasia' in *Euthanasia* edited by Bernadette Tobin, Plunkett Centre for Ethics, 1994

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Increasing the rates of organ donation

Mary Byrne

While there have been great advances in the treatment of certain conditions, and while the range of tissues that can be donated by living donors is widening, certain organs and tissues can only be donated after death. The issues raised by donation of tissue and organs after death are discussed in Chapter Three of the discussion paper: *Organ and Tissue Donation Use and Post Mortem Examinations* prepared by the New South Wales Department of Health and relate to Part 4 of the *NSW Human Tissue Act 1983*.

The chapter begins with a discussion of the fact that, while there is a high level of acceptance in the community of organ donation and transplantation in principle, the rate of actual donation is very low. Although actual figures vary, there is a significant number of potential donors who do not become actual donors.

The overall focus of the chapter is on finding ways to increase the rate of organ donation. Two specific questions, pointing towards several potential changes to the current system, are presented for discussion:

- *Is there a need to change the provisions of the Human Tissue Act 1983 to prevent a designated officer from considering the wishes of a deceased's family where the deceased has consented to tissue donation during his or her life?*
- *Should there be alterations to the present legal framework in the Human Tissue Act 1983 for donation of tissue after death?*

Unfortunately the empirical evidence for the low rate of organ donation, and for the success of any one solution, is not conclusive. However, even if there were conclusive

evidence the ethical aspects still need to be considered. Two basic ethical concepts may enlighten our response to these questions and proposals. How we view our bodies and how we understand organ 'donation'. In this discussion I will consider each of these concepts and then use them to assess the proposals for increasing rates of organ donation.

The Significance of the Body

There is a range of views about our relationship with our bodies. Some people would argue that each person has full ownership of the body in the same way that a person owns possessions. This means that a person could sell parts of her or his body and has full control over the provisions for disposal of the body. In contrast, another view considers that the body, as the abode of the soul, is an essential element of the person.¹ We are embodied beings. Both our own perceptions of our identity and other people's perceptions of our identity are tied up with our bodies. It is through our bodies that we act, and interact with others, especially with the people to whom we are close. This is not a claim that a person's body is the totality of her or his identity. Rather it is simply an acknowledgement of the significant meaning our bodies have.

Both these views could lead to an acknowledgement that each person will have an interest in, and should be able to determine and control, what is done to her or his body. However, the idea of ownership does not enable a full understanding of the significance of the body of a person once that person has

died. As a possession or instrument that is no longer functional, the body could be simply discarded. In contrast, if we understand ourselves as embodied beings, then the body of a person after death is the ongoing form in which that person existed and interacted with others. This explains why respect is shown to the body of a person after death, and why certain actions are marked as appropriate or inappropriate treatment of a person's body. It also explains why the body has a significant meaning to others, particularly people who were close to the person who died.

While each of these views will explain some of the challenges of organ donation, in my view the notion of embodiment rather than ownership allows a deeper understanding of the significance of the body at death and the interest that both the person and others may have in the treatment of the body.

Organ Donation as 'Gift' or 'Societal Claim'

There are two very different ways in which we might conceive of organ donation. The first is that of organ donation as a gift. (Some of the possible changes proposed in the discussion paper could challenge and threaten this aspect of organ donation.) It is well described by two sociologists who have spent many years looking at the issues surrounding organ transplants and artificial organs.

The donor who offers a part of his [or her] body for transplantation is making an inestimably precious gift. The acutely ill patient who receives the organ accepts a priceless gift. The giving and receiving of a gift of enormous value, we believe, is the most significant meaning of human organ transplantation.²

Contrast this way of thinking of organ donation with that found in the Report of the Australian Law Reform Commission:

The principle issue for lawmaking on cadaveric tissue donation is whether the community has sufficient interest, or 'right' in dead bodies to support a claim to human tissues which can be used for

the public benefit, and if so, in what circumstances and with what restrictions.³

The difference between these two views can be summarised as the difference between the notion of organ donation as a gift and the notion that the community has a claim on any possible organs that may be available. On the latter view the public benefit that could be gained through ensuring access to as many organs as possible is of such significance that the community, through its agents, may assert this claim regardless of individual wishes. This is pressing strongly on the point made by the Australian Law Reform Commission, but I have done so to illuminate the difference between such an understanding and the notion that organ donation is just that, a *donation*, a freely given gift.

The challenge, then, is whether we should support a move from understanding organ donation as gift to understanding it in terms of a legitimate claim society may make on an individual. This links in with how we conceive of the significance of the body. As was stated above, as embodied beings we have an interest in what happens to our bodies until the point of final closure of our lives. This suggested move would override that legitimate interest. Therefore, it is important that organ donation remain a freely given gift.

Implications for Organ Donation

These two basic concepts (our view of the significance of the body and an understanding of organ donation) can be used to assess the suggested changes to the *Human Tissue Act 1983*.

The first suggested change is to prevent the designated officer from considering the family's wishes when it is known that the deceased person has consented to tissue donation. In addition to the pragmatic reasons for not requiring this, there is a basic ethical reason for continuing to take into consideration the thoughts of the family as

well as the wishes of the deceased person. The body of a person who has died continues to have special significance to the close relatives of that person, and how that body is treated is of importance for such relatives. The pragmatic reasons, such as not wishing to add to the trauma that relatives are already suffering from the circumstances of the death, add further weight to the argument for not disregarding the wishes of the family. This is not to say that we should not spend time working with such relatives, seeking to understand why they wish to ignore the known wishes of the deceased person and maybe helping the relatives come to an acceptance of the potential donor's wishes. However, there is a good ethical reason for not implementing an enforced overriding of family feelings and wishes.

The second suggested change relates to the possible model of obtaining consent for organ donation. The four proposed models are: "opting out" rather than "opting in", mandatory reporting, mandatory requesting, and seeking operational efficiencies. Each of these models could be implemented while still engaging the relatives at the time a person becomes a potential donor.

The current system in New South Wales is one of "opting in" in which a person signs a form indicating a willingness to donate. "Opting out" would reverse this: it would be assumed that a person is willing to donate unless she or he has signed a form indicating an objection. "Opting out" could be thought to derive from and to reinforce the idea that society has a legitimate claim on a person's organs unless a protest is registered. The organs should be available unless someone expressly objects. On a practical note, it cannot be shown that everyone who has not registered a protest has agreed to donate. Often people may simply have not registered a protest. This practical problem strengthens the idea that the assumption behind such a proposed change would be the view that society has a legitimate claim on organs.

A system of mandatory reporting would require everyone to consider the issue and indicate an acceptance or objection to possible organ donation. Mandatory requesting would require physicians to approach the family of

every potential donor. In both cases there would still be a freedom to give. The challenge with mandatory reporting is to ensure that people understand the choices and what is involved and do not fear receiving less treatment if it is known that they have agreed to be a donor.

Seeking operational efficiencies would not require any legislative change. Rather the onus would be on the organ donation co-ordinators and health care professionals to seek ways of increasing awareness, understanding and acceptance of organ donation. This would be based in the current premise that organ donation is a gift and would have a strong focus on supporting the families of organ donors.

The last three proposed models are consistent with the notion that organ donation is a gift. The ethical challenges with each of them lie in the way such proposals are implemented and the impact that any proposal will have on health professionals, families and recipients.

In conclusion, while it is a good aim to seek to increase the availability of organs for transplantation into people who are seriously ill, it is important to retain the basic ethical concepts of the significance of the body of a person, even at death, and the importance of understanding organ donation as a gift rather than as something that society may claim of us. These notions should shape the way organ and tissue donation after death is implemented.

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1. Pope John Paul II, "Many Ethical, Legal and Social Questions Must be Examined in Greater Depth" (June 20, 1991) *Dolentium Hominum* 21 (1991 n.3)pp. 12-13.
2. Fox, R.C. & Swazey, J.P. *The Courage to Fail. A Social View of Organ Transplants and Dialysis* (2nd ed. Rev.) Chicago: University of Chicago Press, 1978, p.5.
3. *Human Tissue Transplants*, Report No. 7, Australian Law Reform Commission, Canberra: AGPS, 1977 cited in the *Organ and tissue Donation Use and Post Mortem Examinations: Review of the Human Tissue Act 1983* New South Wales Department of Health, p.19.

The impact on medical practice in Intensive Care of proposed changes to the *Human Tissue Act*

Ray Raper

Several changes to the *Human Tissue Act* 1983 have been proposed. This paper is an attempt to provide a personal view of the possible impact of some of these changes on intensive care medical practice. It is neither comprehensive nor exhaustive.

It should first be recognised that any changes in legislation may take quite a long time to impact on clinical practice. Cadaveric organ donation was successfully undertaken before the establishment of any legislative framework. Further, technical breaches of the strict letter of the Act have been reasonably commonplace even up to current times.

Several of the proposed legislative changes relate to consent by patients and families. In this regard, it is important to understand that intensive care practice functions under a paradigm of primary responsibility for the interests of the patient with a secondary responsibility for the broader interests of the family and of society. While the secondary interests become more paramount as the patient's life ebbs, it is nevertheless an important part of intensive care practice to respect the interests and wishes of the patient even after death. In this context all requests for consent to organ donation should focus on the known or projected wishes of the patient. This reflects a respect for the basic dignity and autonomy of the individual.

This paradigm will have an influence on any consideration of 'opting in' versus 'opting out' legislation. Whatever the legal framework, it will always be necessary to discuss potential organ donation with the family of deceased patients, primarily in an attempt best to respect the wishes of the patient, but also to assist families dealing with the death of a close relative.

Out of consideration for the autonomy of patients, discussion of organ and tissue donation where medically appropriate should be as routine as, for instance, discussion of funeral arrangements. Failure to do so denies patients and their families the opportunity of participating in organ and tissue donation even when this was the wish of the patient while he or she were alive. However, legislation to mandate request for organ donation could be more harmful than helpful. It is clear that the nature of the request for organ donation is a very important factor in the success of the process. Insensitive or poorly framed requests may not only create a good deal of stress for families: they may lead to a good deal of negative public sentiment toward organ donation and transplantation in general. It is far better if this is managed at the level of education, training and audit. Providing patients with the opportunity for participation in organ and tissue donation for transplantation should be considered a 'quality assurance' issue in the management of dying patients.

It has been suggested that families ought not be able to overrule the advance directive of patients with regards to organ and tissue donation. Legislation to achieve this, while clearly feasible, would be potentially harmful. There is a significant possibility of considerable harm to both families and the organ and tissue donation process if *post mortem* organ and tissue donation proceeds in the face of strong objection from patients' families. Moreover, this potential harm needs to be weighed against the minimal benefit which might accrue as, at least for solid organs, it is most unusual for families not to respect the previously stated and/or known

wishes of patients with regard to organ and tissue donation.

There remains considerable controversy with regard to the certification of death based on a brain function criterion. In recent times there have been calls for a change from the current whole brain function criterion to either a brain stem or a higher centre criterion. This is a complex issue, but I do not believe there is sufficient support for a change in this regard at the present time. Legislation of the specific medical criteria used for establishing the universal loss of all brain function which the current definition requires would be difficult if not impossible. Not only would the legislation be unwieldy: it would not be able to reflect any temporal changes in medical practice and technology which may be applicable to this issue.

The current legislation maintains a direct link between the certification of death and the donation for transplantation of non-regenerative organs and tissues. If this link were removed, then at least some of the controversy which has surrounded the concept of 'brain death' in relation to organ donation would be resolved. This is a complex issue which has been discussed more fully elsewhere.¹ It has been argued that 'brain death' is a definition of convenience, essentially designed to facilitate organ donation. It has also been argued that current clinical practice does not establish the statutory requirement of 'irreversible loss of all function of the brain'. While current practice withstands both philosophical and practical criticism², it nevertheless remains problematic.

Fundamental to the controversy surrounding 'brain death' is the ambiguity surrounding the conception of death itself. Death is perceived in different ways by different people and, indeed, by the same individual at different times. At least a significant minority of donor families do not believe that their relative was dead at the time of organ donation. From personal experience, it is clear that a number of intensive care specialists are also not completely reconciled to a brain function criterion for the certification of death. This does not preclude

participation in organ donation either for the donor families or for intensive care specialists.

The current criteria for certification of death should be considered the prerequisite for proceeding to organ donation. It is important that families understand the irreversible and absolute nature of the profound brain injury which has occurred and which has resulted in the clinically documented loss of brain function. The issue then becomes respect for the wishes of the patient. The two potential courses of action are discontinuation of ventilation and other support measures (with inevitable cardiac standstill) or organ donation prior to termination of treatment if this was the known or projected wish of the patient. It seems not to be critically important that the family believe that the patient has indeed died at this time. Even if 'brain death' is fully understood and accepted, there is a clear discrepancy between the appearance of the patient at this stage and when viewed later (following the termination of treatment when respiration and circulation have ceased).

These observations would support a change in the legislative framework to enable organ donation to proceed in the presence of irreversible coma and irreversible loss of all clinically detectable brain stem function. Such an approach would be more honest and less ambiguous than the current situation. It would certainly be more practical. Ultimately, if accepted, it could also be less controversial as it does not require the philosophical underpinning of a brain function criterion. It is unlikely that such a legislative change would have any significant impact on the rate of organ donation for transplantation. It would however bring legislation more into line with currently accepted practices.

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¹ Halevy, A and Brody B: *Ann Internal Medicine*, 1993;119: 519-525, Raper, R and Fisher M: *Anaesth Intens Care*, 1995; 23: 16-19

² *Certifying Death: the Brain Function Criterion*, National Health and Medical Research Council, 1997

Diagnosis of death by the brain function criterion: a case for ancillary testing

Nicholas Tonti-Filippini

In 1968 a report entitled "A Definition of Irreversible Coma" prepared by an Ad Hoc Committee of the Harvard Medical School to Examine the Definition of Death, was published¹. The Committee listed the following purely clinical criteria for the diagnosis of death: unreceptivity and unresponsivity, no movements or breathing (or absence of spontaneous breathing after turning the respirator off for three minutes), and no reflexes, and the non-clinical criterion of a flat electroencephalogram. However the Committee held that it was not necessary to do the latter. Though it recognized that an EEG offered confirmatory data, the Committee found that the abolition of function at cerebral, brain stem and often spinal levels should be evident in all cases from clinical examination alone. They added that the neurological assessment gains in reliability if the aforementioned neurological signs persist over time and there is no accompanying hypothermia or evidence of drug intoxication. The clinical criteria specified became known as "the Harvard Criteria".

In 1976, the Conference of Medical Royal Colleges and their Faculties in the United Kingdom published a statement entitled "Diagnosis of Death"². The Royal Colleges were a little more specific about excluding hypothermia, metabolic and endocrine disturbances, depressant drugs or relaxants. They also required certainty of irremediable structural brain damage and an established diagnosis of a disorder which can lead to brain death. The clinical criteria then listed are more or less the same as the Harvard Criteria, although the Colleges are more confident that an EEG is not necessary. They

also held that other investigations such as cerebral angiography or cerebral blood flow measurements are not required for diagnosing brain death. In 1979 the Royal Colleges added a memorandum entitled "Diagnosis of Death" in which they proclaimed that brain death represents that stage at which a patient becomes truly dead.³ Medical practice, in English speaking countries since then, has been to diagnosis brain death by employing the Royal Colleges or Harvard criteria alone.

In recent times, however, it has become more and more evident that meeting those clinical criteria alone often does not satisfy the commonly accepted legal definition of irreversible cessation of all function of the brain: many studies now show continued function of a variety of parts of the brain after diagnosis of brain death⁴.

How significant is this? Robert Veatch claims that the legal definition of whole brain death does not in fact refer to the death of the whole brain any longer⁵, and he is troubled by the fact that individual neurologists, philosophers, theologians and public commentators seem to be determining just which brain functions are significant and which not. There is a lack of consistency in clinical practice and a failure to refer the matter to the community and to elicit informed community opinion about the *de facto* adoption of new and variable standards for what constitutes death. According to Veatch, higher brain functions are the only significant functions, and he wishes to have the irreversible lack of higher brain functions adopted as the universal standard. Veatch suggests that applying a higher brain definition of death is consistent with a Judeo-Christian concept of mind-body integration:

only when there is capacity for organic and mental function present together in a single living entity is there a living human being. He supports a higher brain definition with the possibility of conscientious objection in which those who wanted a more rigorous standard could object to organ donation.

Peter Singer argues similarly to the effect that the medical concept of brain death was more or less a fabrication, accepted to be so by the President's Commission⁶, never supported by the medical facts and adopted pragmatically as an arbitrary cut-off point. He would like to see it replaced by the criteria by which capacity for consciousness is the cut-off point⁷. Daniel Wikler attacks the notion of whole brain death itself contending that the central argument, the integration thesis⁸, which supports whole brain death, is incoherent and is likely to fall as soon as neurologists are able to diagnose persistent vegetative state (PVS) with certainty.⁹ John Catherwood goes one step further and argues that organ harvesting is permissible from the "irremediably dying" and hence that the discussion over the definition of death is irrelevant¹⁰. He would thus be satisfied with a prognosis rather than a diagnosis of death.

However, a major problem with adopting the looser determination, using death of the higher brain alone, is that cadaveric organ donation is not a one-to-one gift from donor or donor family to recipient which can be treated as a private matter subject only to the moral acceptance of those immediately engaged. First, the State has a responsibility to protect the right to life of members of the human family¹¹. Second, there are regional, state or national schemes or registers (and even international registers for some tissues) by which organs from a single donor are allocated to multiple recipients throughout a region. The recipients need to have confidence that the organs are, in fact, taken from people who are really dead according to the recipients' own understanding of death. For this reason, Veatch's proposal for a combination of higher brain death and provision for conscientious objection is an inadequate solution.

With the bureaucratically imposed secrecy about identifying the particular link between an organ donor and the recipients of his or

her organs, the recipients must trust the general national standards for diagnosing death. These having collapsed, though not to any great extent yet publicly, the situation of informed conscientious potential recipients whose moral beliefs equate with the common legal standard of whole brain death, is unenviable. If one adopts the contemporary, legally accepted, view that death has not occurred until there is irreversible cessation of all functions of the brain and yet knows the truth of the matter in regard to the practical collapse of its clinical application in recent times, then one may feel obliged to refuse organ donation and suffer the consequences. The proposition that one accept an organ taken from a person while still alive, in a process which may be such as to violate his or her bodily integrity and even to have caused his or her death, would be at least troubling by ordinary standards¹².

Have we no alternative but to adopt one or other of the radical solutions mentioned above which would involve a significant change in thinking about what constitutes death? There are two medical responses which would leave the legal status quo¹³ intact and not challenge the apparent community acceptance of whole brain death as the appropriate definition.

1 The French Practice

The first approach would be to follow the established French practice of requiring ancillary testing such as angiography which can now be supplemented by the range of newer diagnostic techniques in order to achieve greater certainty of the determination that complete cessation of all brain function has occurred. Laboratory assays establishing the presence of hormones originating from that part of the brain known as the hypothalamic-pituitary axis would also be significant. *While some activities of the brain continue and it communicates with the rest of the body hormonally, it is not true to say that the body has lost the integrating function of the brain.*

There does, however, seem to be resistance to this approach which may be partly a result both of a concern about limiting the availability of organs even further by excluding some donors who are now diagnosed as dead by the clinical criteria but would be shown

have some brain function if ancillary tests were done, and of the belief of many that some existing brain function in a person who will never regain consciousness is insignificant. The latter line is supported by Catherwood, Wikler, Veatch and Singer (above) amongst others, but it does involve a complete change in the accepted understanding either of death or of the legal status of those who suffer persistent coma. Whether such a change would be acceptable to the broader lay community is a matter that ought to be pursued.

The reality of the circumstances of organ procurement *and* *recipience* is that a conscience clause could not function to permit individuals to choose their own definitions of death based on their religious and philosophical convictions as Veatch suggests it would.

2 'Cardio-Respiratory Death'

A second medical alternative being pursued by some is the exploration of organ transplantation after cardio-respiratory death¹⁴. This would have the practical problems of reducing the number of potential donors and hence organs and of requiring that steps have to be taken immediately after cardiac death to preserve the organs. Brain death is a relatively unstable state (generally not a state that lasts more than twenty-four hours when properly diagnosed¹⁵) but does allow greater time between diagnosis and harvesting organs.

Interestingly, the Danish Ethics Council has rejected the brain death definition altogether and insisted on irreversible cessation of cardiac function as the end of the death process. Their argument is based upon what the Council claimed is the "ordinary everyday definition of death". The Council argues that relatives still relate to a brain dead person and that such a person should be treated as dying but not yet dead because of that relationship. However the Council believes that transplantation from the brain dead may occur (because such people are in the process of dying) and that the transplantation procedure should be taken as the end of the death process. However there remains both the problem of accepting organ harvesting

from a person judged to be still alive and the problem that, if the community consensus is that death has not occurred until cessation of cardiac activity, it would seem unlikely that the community would accept "beating-heart" donation?¹⁶

The Danish Ethics Council's argument that death has not occurred until cessation of cardiac activity would seem to be valid. But their overall approach would be sound only if the premise that the general community does not understand whole brain death to be death turned out to be true. It would indeed be quite wicked in practice to impose on the families of organ donors, and on transplant recipients, a concept of death determined by the brain death criteria, if their cultural belief was that the life continued until circulation had irreversibly ceased. A religious or cultural judgement that life continues while blood circulation continues even though there may be permanent loss of consciousness, need not be based upon a misunderstanding of the medical facts. In fact it may reflect belief in the sacredness of human beings in which the capacities which depend on consciousness constitute part of the reason for regarding human beings as sacred but that the reasons for holding each individual of human generation to be sacred may not be reduced to just consciousness or higher brain functions. The reductionism involved in seizing upon consciousness as a necessary feature for the many and complex aspects of the way in which we hold other human beings in high regard is by no means universally acceptable. *I suspect that the Danish Council was wrong in the assumption that whole brain death is not accepted by the general community. But it would be a mistake to go one step further and claim that permanent loss of consciousness with some brain activity continuing would be as acceptable as whole brain death. The solution is to require ancilliary testing so as to uphold the legal status quo.*

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¹ *JAMA*, Aug 5, Vol 205, No. 6 pp. 337-341

² *British Medical Journal* 13 November 1976, 2, pp. 1187-1188.

³ *British Medical Journal* 3 February 1979, 1, p. 332

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The vexed issue of communication between transplant recipients and families of organ donors: a sociological perspective

Robert D. O'Neill

The NSW *Human Tissue Act 1983* does not specifically prohibit communication between organ donor families and recipients. However, Section 37 of the Act makes it an offence for hospital and medical staff involved (directly or indirectly) in donation and transplantation to reveal, or cause to be revealed, the identity of an organ donor or that of a recipient.¹ This regulation effectively limits any communication between organ donor families and recipients to written correspondence mediated by transplant coordinators or others involved in donation and transplantation who act to ensure the anonymity of both parties.

The real issue is not communication *per se* but whether the confidentiality requirements in the current legislation should be removed, thus enabling face-to-face contact between organ donor families and recipients.

Philosophically, the argument is one of the right of individuals to establish and pursue social relationships without interference or prohibition against the perceived duty of the State to protect its citizens from real and potential harm. Those advocating face-to-face contact tend to support the former proposition.

It should not be assumed, however, that all organ donor families and all recipients want to meet. A 1999 survey of 113 organ donor families in NSW conducted by the NSW Red Cross found that only 43% of families wanted to meet the recipient.² It appears that the 'push' for face-to-face contact is coming from a minority of donor families and from particular donor family organisations. In stark contrast, anecdotal evidence suggests that

recipients are very rarely the prime instigators of face-to-face contact but tend, when asked, to accept the idea and acquiesce to suggestions that meeting the donor family would be appropriate.

The commonly suggested mechanism to facilitate meetings between organ donor families and recipients is that of a registry similar to that already in existence for adopted persons and their biological parents. This model appears appropriate and would not be difficult to implement. The transplant registry would operate on an 'opt-in' basis with organ donor families and recipients registering their willingness (or otherwise) to meet with the other party. However, some consideration would need to be given to when it would be appropriate for the respective parties to register. Possibly a 'time-lag' between the actual date of donation or transplantation and the time of registering would be beneficial to allow the parties to give full and informed consent to their decision. If a register were to be established, it would need to be a national register. Given that donated organs are allocated on a national basis, it would be pointless for New South Wales to 'go it alone' in extending contact between the relevant parties. For the registry to operate at any practical level, all Australian states and territories would need to amend the existing confidentiality clauses in their respective legislation on organ donation and transplantation to allow contact between organ donor families and recipients. Failure of any state or territory to do so could lead to some very interesting constitutional arguments about freedom of trade between states. However, before New South Wales (or

any state) proceeds too far down the track in allowing contact between organ donor families and recipients, there are two questions - two important questions - that need to be answered. 'Why do the parties want to meet?'. 'Assuming the parties do meet, what kind of relationship do they expect to have?'. The answers to these questions are not simple.

Why do the parties want to meet?

Organ donation is invariably described and promoted as 'gift-giving'. A cursory examination of the academic literature and promotional material associated with organ donation reveals the widespread use of the phrase 'the gift of life' and of the concept of the gift. 'The gift of life' is an emotive expression which has become part of the lexicon of transplantation. It is often used conveniently to symbolise the complexity of the process of organ donation and transplantation. In most societies, including contemporary Australian society, the giving and receiving of gifts embodies a complex set of social relationships and obligations including the obligation to give a gift, the obligation to receive a gift, and, most importantly, the obligation to reciprocate with a gift of equal or greater value.³ Anyone who gives a gift needs to know that the gift was well received, that it was wanted and appreciated. It is only natural, in the context of gift-giving, that an organ donor family wants to know that the organ was well received, that the transplant was successful and that the recipient is doing well. At present this need is met by the anonymous correspondence between recipients and donor families mediated by those in the organ donation/transplant community. If the motive for amending the current legislation is merely to satisfy the donor family's need to know that the recipient is doing well, I do not believe it is a sufficient reason to change the existing confidentiality requirements.

For recipients, the ideology of the gift leaves them with a social, moral and psychological obligation to reciprocate, in some way, the gift

given. This is very difficult for them when the party who gave the gift is unknown to them and when the gift is 'life' - a gift that cannot be reciprocated with any item of comparable value. Whilst I acknowledge the obligation to reciprocate the gift does place a burden upon recipients, if the purpose of meeting the donor family face-to-face is to offer an opportunity for the recipient to reciprocate the gift, it is, again, not a sufficient reason to amend the current legislation. On the other hand, if meeting assists the grieving process and improves the recovery of recipients then a stronger argument can readily be made for allowing contact between the parties and for removing the existing confidentiality requirements from the legislation. However, there is evidence that face-to-face contact between organ donor families and recipients does not necessarily contribute positively to the grieving process and may even be counter-productive to the psychological well-being of the parties involved.⁴

What kind of relationship do the parties expect to have?

This is a very vexed issue. I suggest that, whatever the relationship, it can never be equal due to the obligation to reciprocate placed upon the recipient arising from the gift-giving ideology employed in organ donation. The recipient is socially, psychologically and morally obligated to the family that donated the organ.

In the Red Cross Donor Family Survey mentioned above, 34% of respondents stated that part of the reason they donated their loved one's organs was so that 'the loved one would live on'.⁵ It was not clear from the findings whether they meant lived on *literally* or lived on *symbolically*. Either way, this concept of 'living on' has serious ramifications in relation to face-to-face contact between organ donor families and recipients. Consider these, not necessarily hypothetical, situations. A donor family believes their loved one 'lives on'. Upon meeting the recipient, they find that the recipient is poor, unemployed, unable

(due to his/her financial situation) to follow a satisfactory diet and living in conditions which the donor family consider unsatisfactory and unworthy of their loved one. Does the family feel an obligation (or pressure) to improve the economic and social situation of the recipient? Conversely, a recipient, upon meeting the donor family, discovers the family is poor. The recipient is financially well off. Does the recipient, grateful for the 'gift of life' given by the family, offer the family money or other material benefit? To do so would breach the existing law relating to trade in organs and payment for organs.⁶

There is a further aspect to donor family/recipient relationships which warrants consideration. It is what I term the *theory of equivalency* - the assumption that donated organs are allocated to recipients bearing similar socio-demographic characteristics to those of the donor. Many donor families state that one reason they donated their loved one's organs - particularly where the donor was a child or a teenager - was so 'other parents would not have to experience a loss such as ours (or words to that effect). This is a noble sentiment and should not be undervalued. However, implicit in such a statement is the expectation that the donated organs will go to someone 'equivalent' (in age) to the donor. This is not necessarily the case. In America, for example, 75% of donated hearts come from males aged 18-27 years old. The majority of heart recipients are males aged in their 50's.⁷ The assumption that donated organs are allocated to a recipient 'equivalent' to the donor raises the real possibility that recipients will not meet the expectations of donor families. This is in no way the fault of the recipients.

The idea of equivalency is not limited to equivalent age and may extend to equivalent sex, social class, race, ethnicity, social values, religion, etc. At present, the allocation of donated organs is based solely upon the criteria of medical need and biological compatibility between the recipient and the donated organ. It is not only possible but also probable that the liver of a teetotaling donor

may be transplanted into an alcoholic. Or the heart of a donor from a deeply religious family may be transplanted into an atheist. Or an organ from an avowed racist may be transplanted into a recipient from another race. Or an organ from a donor may be transplanted into an avowed political or historical enemy of the donor and his or her family.

If any of the above scenarios did occur, in an environment in which face-to-face contact between organ donor families and recipients was allowed, what type of relationship would possibly ensue? It would require only one or two donor families (or recipients) to be unhappy with the allocation of their loved one's organs for there to be long-lasting and detrimental effects on organ donation generally. The media would most certainly 'pounce' upon these cases and sensationalise them with the moral or social worth of the recipient being called into question. Such was the case with the first hand transplant operation. The recipient was a middle-aged, New Zealand man. The media not only reported the transplant operation but also the fact that the recipient had a criminal record and was facing further charges for fraud. What relevance does this man's personal situation have to his selection as a transplant recipient? I would argue no relevance at all - except to question his moral suitability as a recipient and, by implication, question whether such resources should be expended on that type of person.

If donor families knew that they could meet the recipient and that some type of relationship could ensue, they may, in all likelihood, imagine the recipient as having physical attributes, social standing, or moral and political values similar to their own or to those of the donor. Would the family be disappointed if the recipient were not as it imagined? What if the family voiced its disappointment publicly? Expectations as to who are appropriate and worthy recipients leads ultimately to *directed donation* - donation contingent upon the organs being allocated according to the preferences of those making

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Involving next-of-kin in decisions about research use of human tissue from *post-mortem* examinations

Helen McKelvie and Stephen Cordner

The Victorian Institute of Forensic Medicine (VIFM) and its Human Research Ethics Committee (HREC) has recently deliberated about, and changed its policies in relation to, some matters raised in the NSW Discussion Paper 'Organ and Tissue Donation, Use and *Post-Mortem* Examinations'.

Taking without asking

The major concern raised in the Discussion Paper relating to post-mortem examinations relates to tissue being removed for purposes other than diagnosis of the cause of death (and directly related matters such as understanding the circumstances of the death), without the consent of the deceased, while alive, or the deceased's next-of-kin. As in NSW, the law in Victoria currently allows for tissue removed for the purposes of the post-mortem examination to be retained and used for therapeutic, medical and scientific purposes¹. This legislative position is based on the reasoning of the Australian Law Reform Commission (ALRC) in its 1977 report on *Human Tissue Transplants*. In 1977 the Commission was of the view that departure from the principle of consensual giving was justified in relation to tissue removed for post-mortem examination purposes, on the basis of the considerable public benefit flowing from the proper conduct of medical and scientific research.

Accordingly, with the approval of the HREC, it was the VIFM's practice to rely on the provisions of the *Human Tissue Act* and retain tissue for research projects that had obtained HREC approval without specifically enquiring as to whether the deceased had expressed a view about tissue donation, whilst alive, or otherwise consulting next-of-kin. In recent years it has become increasingly clear that, since the ALRC report, there have

been significant changes relevant to this practice - for example: a shift away from dualistic understandings of the human body as separate from mind or spirit; the consumer movement's challenge to medical paternalism; a newly vocal multi-cultural population with different understandings and traditions around death; and increased commercialisation of the bio-technology industry. In acknowledgment of these factors, and in the face of concern expressed by VIFM staff and feedback from families of deceased people, the VIFM HREC called for a moratorium on retention of tissue for research purposes from July 1998. After nearly 18 months to consider the situation and develop a clear policy position, a new program is now operating.

A new approach

The new program involves increased availability of information about the coronial process and direct approaches to next-of-kin regarding an opportunity to donate tissue for research purposes. With respect to information provision, a comprehensive and user-friendly booklet about the coronial process is now made available to families of deceased people who die in circumstances requiring involvement in the coronial system². There is, of course, no guarantee that information delivered at a time of great stress will be taken in or understood. Nevertheless, the information is available at the time of the death and may be kept for later reference. The booklet clearly sets out the processes involved in a coronial investigation, including post-mortem examination, and the requirement that tissues (and in some cases, whole organs) are retained for diagnostic and/or related coronial purposes. An example of where a whole organ may be

retained is in the case of the sudden death of a young adult, where careful autopsy and histological (i.e. microscopic) examination of samples routinely retained fails to reveal a cause. Retention of the heart for closer examination may be the key to understanding the cause of death, and assisting the family to come to terms with their sudden loss.

In terms of tissue required for research purposes, a program has been implemented in which next-of-kin of deceased persons who meet set criteria are approached by trained staff of the the Donor Tissue Bank of Victoria, (which is incorporated within the VIFM) about an opportunity to donate specified tissue for use in medical/scientific research projects that have been approved by the VIFM HREC. The Coroner's approval is also sought before tissue is removed for these purposes. In this way the family is given information about the specific project to which their family member's tissue could contribute, and an opportunity for altruism is offered.

Does seeking next-of-kin consent reduce tissue availability for research?

One issue raised in the Discussion Paper relates to the argument that the availability of tissue for medical and scientific research may be unnecessarily impaired by the process of seeking the consent of next-of-kin. This has not been our experience so far at the VIFM. The Donor Tissue Bank coordinators have been approaching next-of-kin for specified tissue for approved research since October 1999. In that time 67 families have been approached about donations for specified approved research projects. From the 67 approaches, there have been 42 families which have taken up the opportunity to donate tissue for research (or to allow tissue to be used for educational purposes), which represents a 62.6% 'consent rate'.

At this early stage, we consider that, contrary to the idea that gaining consent impairs the availability of tissue, there is significant benefit in the process, being undertaken. The involvement of researchers in writing a plain language statement about their research project suitable for lay people to comprehend, and in liaising with VIFM staff about the next-of-kin consultation process, has given them a greater appreciation

of the source of their research material and the generosity of bereaved families. It has also provided families, in circumstances that they are experiencing as overwhelmingly negative, with an opportunity for altruism, by contributing to research that aims to benefit others. While not all families have chosen to donate, we are confident that the care and professionalism of the transplant coordinators responsible for the approaches is such that next-of-kin will not have been offended or upset.

Attempting to define "post-mortem examination"

The Discussion Paper puts forward one other option for dealing with concern about "the wide powers" of medical practitioners to "remove body tissue and use it for other purposes not related to the post-mortem" - to define "post-mortem" in the Act and restrict the scope of the examination to ascertaining the cause of death, in accordance with "the ordinary person's understanding of a post-mortem".⁴ During the development of the new policy and procedures at VIFM, it became clear that defining the scope of coronial and hospital autopsies is extremely difficult, due to the wider context in which the derived knowledge operates. Post-mortem examination information is valuable in a variety of related contexts: hospitals and clinicians are provided with accurate characterisations of the pathology present and the identification of the medical cause of deaths, contributing to poorly understood diseases and the evaluation of new medical therapies and surgical techniques; families of deceased may benefit from identification of diseases with genetic and acquired components, allowing for informed reproductive and lifestyle decisions; there is also a factual basis for counselling family members in relation to anxiety over perceptions of them having somehow contributed to the death; and the community generally benefits from the information's contribution to public health policy, in the form of mortality statistics, and the potential for early warning of public health and safety risks.

The concept of Quality Assurance is also relevant here. In this context pathologists are

obliged to keep their working knowledge and experience current and up-to-date, which may entail retention and testing of tissue samples that may not be strictly referable to the cause of death in the immediate case. An example would be where a claim is made in a medical journal about infants dying of SIDS having certain characteristics in a particular part of the brain. In order to have the knowledge to counter or confirm that claim and add to a useful debate about the cause of SIDS generally, a pathologist may take and analyse a small sample of the relevant part of the brain in the next 20 suspected SIDS cases, even though it may not necessarily directly relate to the causes of death in those cases. In this way the pathologist fulfils the expectation of the "ordinary person" and his or her understanding of the post-mortem examination being about the cause of death, as well as the "ordinary person's" less easily understood or articulated expectation that pathologists take a professionally enquiring approach to their work and acquire relevant medical knowledge that is intended to benefit the community as a whole.

Understandably the community is concerned about gratuitous or unethical tissue retention and use. An awareness of this concern was a significant motivating factor in the internal review conducted at VIFM. In developing our internal policy, we did not attempt strictly to define the scope of the post-mortem examination, but instead, for the purposes of HREC approval of tissue use, made the distinction between tissue being used for 'a research or related project' and that which is used for investigating the cause of death and relevant continuous learning for the pathologists routinely engaged in performing autopsies. This distinction places reliance on VIFM pathologists to exercise their expertise and use appropriate discretion to conclude what tissue to retain for the proper investigation and assessment of the death, or to contribute to relevant continuous learning. It was decided that, in doing so, it is right and proper that they, as far as is reasonably possible, (1) take account of general community and specific next-of-kin concerns about gratuitous or unethical tissue retention and use, and so retain the minimum amount of tissue required for the particular purpose;

and (2) have regard to current knowledge and literature in deciding which tissues are required, without necessarily being constrained by historical practice.

The VIFM and its HREC considered the combination of increased information and decision-making role for families, and self-regulation within prescribed boundaries, to be adequate to protect both the interests of families of deceased, and those of the community as a whole, which benefits from the information derived from autopsies. All aspects of the research tissue program will be monitored and evaluated over the next two years.

It remains to be seen what conclusions will be drawn by the NSW Health Department in its review of post-mortem examination provisions of the *Human Tissue Act 1983*. It is to be hoped that a balance may be struck between concern for proper consultation with next-of-kin, the interests of medical and scientific researchers, and the direct and indirect beneficiaries of their work. Hopefully, also, the NSW review will prompt consideration of the desirability of maintaining a substantially consistent approach to these matters, as was the case when States and Territories adopted the model legislation based on the ALRC's 1977 Report.⁴

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1 Under s.30 of the Human Tissue Act 1982, authority to conduct an autopsy is "authority for the use, for therapeutic, medical or scientific purposes, of tissue removed from the body of the deceased person for the purpose of post-mortem examination".

2 'When a person dies - The coroner's process - Information for family and friends' State Coroner's Office and Victorian Institute of Forensic Medicine, published by the Victorian Law Foundation, 1999.

3 See p.50-51 of the Discussion Paper

4 The authors would like to acknowledge the following people for their contribution in enabling this article to be written: Dr Douglas Fullerton; The VIFM Human Research Ethics Committee; VIFM pathologists and mortuary staff, the staff of the Donor Tissue Bank of Victoria and the Victorian State Coroner, Mr Graeme Johnstone

the donation. If organ donor families are allowed to place conditions upon their donation, equity in allocation is lost and particular recipients will be excluded from transplantation on very subjective and dubious grounds.

I have purposely taken a critical, and somewhat negative, position on organ donor family and recipient contact. I have done so to highlight the dilemmas that may arise from suggested amendments to Section 37 of the NSW *Human Tissue Act 1983*. I believe we need to spend much more time and involve ourselves in much more discussion before we create a situation from which there is no return.

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1 The confidentiality requirements of the NSW *Human Tissue Act 1983* do not apply to persons other than clinical and hospital staff involved in the removal and transplantation of tissue and organs. Free exchange of information about recipients, donor families and the media is not prohibited. Consequently, some donor families and some recipients have become aware of the identity of the other party involved in specific cases of donation or transplantation.

2 Co-ordination Centre for Organ and Tissue Donation NSW/ACT, 'NSW Donor Family Survey 1999', New South Wales Red Cross Blood Service, Sydney. Unpublished paper.

3 Robert D. O'Neill, 'The Gift Relationship: A Consideration of its Interpretation and Application in the Area of Organ Donation', European Transplant Coordinators' Organisation (ETCO) *Newsletter* 14.2 (1006) 10-14

4 Mal McKissock, 'Donor Family and Recipient Communication - A Bereavement Perspective'. Paper presented at the NSW Human Tissue Act Review Forum, Australian Red Cross Blood Service., Sydney. February 24th, 2000.

5 op cit

6 NSW *Human Tissue Act 1983*. Part 6, Section 32.

⁴ Hermeren-G "The new debate on brain death is a storm in cup of water" *Lakartidningen*. 1993 May 26; 90(21): 2067-8

⁵ Veatch is mistaken in this. There has been no change to the law. It still refers to the cessation of all function of the brain. What has happened is a *de facto* departure from the legal definition by those in the medical profession who still depend on the Harvard or Royal Colleges criteria alone.

⁶ President's Commission for the Study of Ethical Problems in Medicine, *Defining Death: A Report on the Medical, Legal and Ethical Issues in the Determination of Death*, US Government Printing Office, Washington DC 1981

⁷ Peter Singer *Rethinking Life and Death* The Text Publishing Company 1994 Chapter 2, pp. 20-35 "How Death Was Re-defined"

⁸ The view that functions of the various organs in a comatose patient are morally significant only if they are co-ordinated and thus functionally related to one another as functioning parts of a living whole. The integration of the body parts into one functioning living body is thought to depend on the integrating functions of the brain.

⁹ Wikler, Daniel "Brain Death: A Durable Consensus?" *Journal of Bioethics* Vol 7 Number 2/3 1993, p. 239-246

¹⁰ Catherwood, John F. "Rosencrantz and Guildenstern are "dead"" *Journal of Medical Ethics* 1992 18, 34-39

¹¹ "Universal Declaration of Human Rights" (1948) Article 3, in United Nations *A Compilation of International Instruments* Vol 1 (Part 1) Universal Instruments, United Nations, New York and Geneva, 1994, p. 1, and the "International Covenant on Civil and Political Rights" (1966) Article 6, *Ibid*. p. 22

¹² A utilitarian might have no moral difficulty with this in principle, but, even for a utilitarian, to accept the practice as a rule would raise serious social doubts about the security of one's own person once admitted to hospital in a brain damaged state.

¹³ The legal status quo, as distinct from the clinical status quo, is that death is defined as having occurred when there is irreversible cessation of all function of the brain.

¹⁴ Youngner-SJ; Arnold-RM "Ethical, psychosocial, and public policy implications of procuring organs from non-heart-beating cadaver donors" *JAMA*. 1993 Jun 2; 269(21): 2769-74; Fackler-JC; Truog-RD "Life, death, and solid organ transplantation without brain death" *Crit-Care-Med*. 1993 Sep; 21(9 Suppl): S356-7

¹⁵ Advice given to me in a personal communication by a senior neurologist Dr E. Byrne, St Vincent's Hospital Melbourne and published in Tonti-Filippini, Nicholas "Determining When Death Has Occurred" *Linacre Quarterly*, 58 February 1991 pp. 25-49.

¹⁶ Rix, B. A. "Danish ethics council rejects brain death as the criterion of death" *Journal of Medical Ethics* 1990, 16, 5-7

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