Ethical issues raised by allocation of transplant resources

Ethical issues in organ donation
Discussion paper No. 3

National Health and Medical Research Council
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- Donating organs after death: ethical issues
- Ethical issues in donation of organs or tissues by living donors
- Ethical issues raised by allocation of transplant resources
- Certifying death: the brain function criterion

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Transplantation Ethics Working Party 33
Preamble

You must understand. You've got to understand and to face it. In every single one of those ten cases I have had to consider not only whether the man could be saved but whether he was worth saving. There were fifty cases to choose from and forty had to be condemned to death. Some of the forty had young wives and helpless children. If the hardness of their cases could have saved them they would have been saved ten times over.

G.B.Shaw, *The Doctor's Dilemma*.

The problems of allocation of scarce medical resources and the central role of the medical profession in their distribution remain as difficult today as they were when perceived and parodied by Shaw in 1906. The objective of this paper is to outline current practices in relation to organ allocation and the ethical issues raised by them. While it has been written primarily for health care professionals, it may also be of interest to members of the general community.

In identifying ethical issues raised by the distribution of transplantation resources, it may be helpful to recognise two distinct kinds of resource. A first category which includes commodities and services such as pharmaceutical agents, specialised skills and physical infrastructure, can generally be provided, given adequate time and funding. However, a second type of resource, namely the organs and tissues that make transplantation programs possible, is subject to limitations of supply unlikely to be alleviated simply by augmentation of funding.

Provision of funding for transplantation procedures may be decided at two levels, with ethical considerations ranking with medical and economic factors in decision-making processes. Firstly, funding may be considered at the level of transplantation programs. Secondly, decisions will be required at the level of individual patients when the number seeking transplantation exceeds the available resources.

All of the health care resources distributed to the community can, ultimately, be sourced to the community in that they have been funded by taxes. However, tissues and organs that are to be used in transplantation processes, like blood donated for transfusion, can be directly sourced to the community in a unique way that has no parallel in other forms of treatment. No other area of health care is as reliant upon the community’s support, through its willingness to donate organs and tissues. Whilst the community is entitled to know about, and to express its

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1 This is the third paper in a set of four discussion papers on transplantation ethics produced by the Australian Health Ethics Committee (AHEC). The other papers are: *Donating organs after death: ethical issues*; *Ethical issues in donation of organs and tissues by living donors*; and *Certifying death: the brain function criterion*.
views in relation to, any allocation of health care resources, this entitlement is especially strong in the case of allocation policies for transplantable tissues and organs that have been provided by members of the community. Medical personnel effectively act as trustees for the community in allocating them.

Failure to take the opportunity to assist another member of the community, when the willingness of the family of a medically suitable donor to give his or her organs for community use is ignored, is a significant ethical consideration. Loss of this asset can occur if the possibility of organ donation is not raised when a patient’s organs are likely to be medically suitable for transplantation and it appears likely that his or her family would wish to provide them. It could be argued that the medical personnel have a responsibility to those awaiting transplants to raise this question with potential donor families provided the pre-requisites mentioned above exist. Currently, the shortage of organs available for transplantation ensures that for every graft that is implanted, an unidentified patient, who could have been saved if selected, will die. The frequency with which patients on waiting lists die before receiving a transplanted organ ranges from around 5% of those on dialysis to 20 - 30% of potential liver and heart recipients. The responsibility of medical personnel should not be confused with the very different question of whether relatives have an obligation to provide organs for those on waiting lists. The latter concept, which would effectively abrogate the existing notion of ‘donation’, is likely to have much less support in the community than that of a responsibility on the part of doctors to discuss the subject of donation.

A second way in which an opportunity for transplantation can be lost is failure to retrieve and use organs that have been offered. The commonest reasons underlying a decision not to retrieve an organ that has been offered are lack of a suitable recipient and the likelihood of disease in the organ. Reasons for not using a retrieved organ include organ damage resulting from the fatal donor injury or the discovery of unsuspected disease in that organ. The transplant team’s duty of care to the potential recipient precludes the acceptance of an unreasonable risk from transplantation of an impaired organ. The wish to avoid waste of an organ that has been offered when no suitable recipient can be identified in the Australian and New Zealand communities can provide the ethical basis for a decision to offer that organ to a non-national recipient. Such offers, which are in practice confined to liver transplantation, and are usually associated with full cost recovery from the recipient, will be discussed more fully later.

The procedures underlying organ allocation in Australia continue to evolve and remain subject to ongoing ethical review. It is desirable that these be discussed extensively within the community. Procedures vary with different organs. Variations between procedures employed in the allocation of kidneys and livers, for example, reflect differences in factors such as the availability of the relevant transplantation services and the biological features of the two transplantation procedures.
1. Medical resource allocation in general

Whereas calls on medical resources are implicitly patient-based, the provision of those resources is likely to require the establishment and maintenance of programs targeted to meeting patients’ needs. Whilst a medical administrator may direct resources to one or other program, a distribution model based on the medical consumer would require that patients be provided with support to enable them to select the specific resources they need. The first (medical administrator) approach, requires selection of a program for support from among competing claims. The availability of services to the individual patient is then firmly settled by the general policy decision. Whilst there is a limited number of situations in which ‘support packages’ are allocated to individual patients to enable them to select medical services that they and their general practitioners consider to be most appropriate, most funding is directed to providing resources in the form of programs for access to which patients will then be selected. Transplantation programs exemplify this approach and should be regarded as means towards the end of providing a service rather than ends in themselves. The ethical issues considered in this paper relate predominantly to allocation of and access to transplantation services and to the structuring of transplantation programs.
Ethical issues raised by allocation of transplant resources
2. The structure of transplantation programs

To deliver any form of medical treatment whilst lacking appropriate expertise to do so is clearly unethical. Transplantation is a complex medical practice requiring high levels of surgical and medical expertise. The prestige that commonly attaches to a transplant program as a symbol of medical excellence does not justify the creation of new units that will be unable to achieve sufficient ongoing experience. It would not be justifiable to establish a large number of small transplantation programs to ensure proximity of a service to as many potential patients as possible. An inevitable consequence of a restricted number of transplant clinics is a requirement for equitable distribution of organs retrieved from geographic regions lacking clinics. The imposition upon patients and their families of long distances to travel and prolonged periods domiciled away from home are legitimate countervailing considerations. However, solutions to this disadvantage other than the proliferation of technically inferior units are required. The responsibility of medical personnel for any transplant recipient does not end with the transplantation procedure. Ongoing attention to the outcome of that procedure is required and the establishment and maintenance of national registries to document outcomes can be a valuable means of achieving this.
3. Entry of patients to transplantation programs

Decision-making becomes necessary at two stages of the process of organ and tissue allocation. The first stage deals with those considerations which should be taken into account in deciding on the identity of the individual patients to whom offers of transplants are to be made. Decisions of this type, by reason of the technical details involved, will remain a responsibility of medical personnel. Entry to, and exclusion from, a transplantation program both raise ethical issues. Entry to a program is offered following assessment of patients by the program personnel. Exclusion criteria include age restrictions, abnormalities in other organ systems, previous history of malignant disease and other medical considerations. In making decisions about which patients are to be admitted to a program, there is merit in more than one medical practitioner being involved. A medical practitioner whose patients become candidates for admission would have a conflict of interest if he or she had sole responsibility for selection.

The second stage of decision-making relates to whether an individual chooses to become a transplant recipient. This is a decision to be made by the patients in the light of advice received from their medical attendants and consultation with their families. Acceptance of the offer requires an informed decision on the part of a patient and/or their family. Prior to this decision, a patient should receive a full description of what is entailed in being in the program, what procedures can be expected and their possible risks and benefits.

On the other hand, if a patient is excluded from a transplantation program, he or she is entitled to know that the particular program exists and that, as a result of assessment, a decision has been taken not to offer him or her a place in it. The reasons for not being offered a place on the program should always be available to the patient, in particular when the reasons for exclusion are non-medical.
Ethical issues raised by allocation of transplant resources
4. Criteria applied in the allocation of specific organs

The system of allocation of organs for transplantation in Australia varies with the individual organ. The differences in transplantation requirements between organs which are responsible for this variation include the more limited availability of facilities for transplantation of livers, hearts and lungs in comparison with kidneys and the lesser emphasis on histocompatibility matching for organs other than kidneys. On the other hand, factors common to different organs which are important in allocation are ABO blood group compatibility (all organs) and the comparative sizes of donors and recipients (liver, heart, heart/lung, lung). Procedures that are currently utilised in allocating specific organs and tissues will be summarised in this section whilst subsequent sections will outline some of the general ethical considerations raised by any consideration of organ or tissue allocation. Though the practice of ‘directed gifting’ of organs and tissues to specified recipients has been accepted in some transplant programs in the United States, it has not gained any acceptance in Australia and will not be considered in this paper.

a) Allocation of kidneys

The allocation of kidneys occurs under circumstances not paralleled in the case of other organs because candidates for transplantation are drawn exclusively from patients already within a dialysis program. This introduces the difficulty that, whereas selection to receive a kidney is determined by clearly defined and promulgated criteria that are uniformly applicable nationally, selection to enter dialysis programs is affected by a variety of sets of guidelines. In some cases uniform criteria for entry to dialysis are being formulated. However, in other instances, individual clinics have their own guidelines, not all of which are readily available. This lack of transparency precludes ethical assessment of the procedures employed and this should occasion concern: it is an ethical issue in itself.

As kidneys can be preserved safely by simple cold storage for at least twenty-four hours, the results of a blood T-cell cross match and tissue matching can be available before transplantation is undertaken. Because of the length of waiting lists, several potential recipients are commonly equally well matched with each presenting donor. Allocation of kidneys is organised on a national basis so that recipients with the closest tissue matching with the donor are selected to receive the organs. This provides the best chance of success. Currently, kidneys are
allocated to potential recipients according to the best available tissue match. If there are no suitably matched potential recipients on the national waiting list, the kidneys are allocated locally, according to criteria established by the local transplant units. Such criteria are usually established by a committee with input from all of the units within that region or State. Where tissue matching is average or less, and there are several equally matched potential recipients, the length of time on dialysis usually determines the recipient. Factors such as recipient age, period on dialysis, presensitisation to tissue antigens, presence of diabetes mellitus and the previous receipt of a transplant are likely to be taken into account. The system of allocation is also designed, over a period, to balance donations and receipt of kidneys for each State.

In an attempt to ensure that transplanted kidneys have the best outcome possible for individual patients, concurrent medical conditions that introduce a potential risk following transplantation should be managed before acceptance on to the waiting list. Renal failure always brings some complications (for example, hypertension and vascular disease) which affect the results of transplantation in the short and long term. If a pre-existing condition is likely to be affected adversely by the ongoing immunosuppression required after transplantation (for example, immunosuppression increases the risk of recurrence of cancer and of persistence of chronic infection) a patient may be excluded from transplantation in his or her own interest. Though some may think it is unfair to deny a patient the opportunity to receive a transplanted kidney because of renal disease which could recur in the graft, others might consider it unreasonable to inflict repeated transplantation when there is a high risk of rejection. In rare circumstances, the kidney allocation system may be suspended to provide an organ for transplantation to a critically ill patient. To ensure fairness in allocation, the selection criteria and weighting of different criteria are subject to repeated review by personnel from all institutions involved in renal transplantation.

To the extent that accuracy of tissue matching is given priority in allocation, prospective recipients from some ethnic communities may be less likely to find histocompatible donors. This constraint can become apparent in relation to the use of renal transplantation in the management of renal disease in Aboriginal communities. However, it would be an oversimplification to infer that the ethical issues raised by renal disease in Aboriginal patients may be resolved merely by modifying allocation criteria to increase their opportunities of receiving a transplanted kidney. Other factors must be considered - such as reduction of the inordinately high incidence of renal disease in Aboriginal patients, their relatively impaired access to treatment, their responses to treatment and the existence of impediments to compliance in Aboriginal transplant recipients. Solutions to these problems are unlikely to occur until measures to deal with more fundamental causes of disadvantage in Aboriginal communities have been implemented.
b) Allocation of livers

The logistics of transplantation of livers (and of hearts and lungs) effectively preclude donor-recipient tissue matching in most instances because of the short time for which these organs can safely be stored between collection and implantation. The initial offer of each liver is made to its State of origin and, if it cannot be used there, an offer is made to other States in a pre-arranged order. Patients who meet a number of agreed medical criteria for classification as ‘urgent’ can receive priority across Australia. The existence of an urgent category for livers where none exists for kidneys reflects the adequacy of dialysis as a means of treating patients in renal failure but in contrast with the very limited means available for ‘tiding over’ patients with liver failure. The smaller number of clinics for liver transplantation reflects the lesser demand for this procedure, coupled to the requirement, already alluded to, that an adequate throughput of cases is required if any unit is to maintain optimal performance. At present, New Zealand patients receive liver transplants in Australia and livers from New Zealand donors are retrieved for transplantation in Australia.

As effective support systems do not exist for patients awaiting livers, hearts and lungs, waiting lists are comparatively short in comparison with those existing for renal transplantation. In the event that there is no suitable patient awaiting liver transplantation on Australian and New Zealand lists, a liver may be offered to an overseas patient. In this instance, the hospital responsible for transplantation of the liver will charge for the full associated costs. In the case of Australian or New Zealand residents, funding for these procedures is provided to the hospitals by the appropriate Department of Health. Some of the ethical concerns raised by transplantation to overseas patients are considered in Section 11.

c) Allocation of hearts and lungs

This is undertaken in the first instance by offering to the clinic, or clinics, within the State of origin, as is done with livers. As not all clinics able to undertake heart transplantation can also offer lung transplants, this sometimes results in the separated lungs being offered to a second clinic. The intention of this strategy is to ensure optimal utilization of organs. Patients who are not Australian or New Zealand nationals are only considered as possible recipients for any available organ when no suitable national recipient is available.

As tissue matching is less important in the transplantation of hearts and lungs than is the case for renal transplantation, a whole range of medical and psychosocial factors come into play. Considerable support exists for the appointment of committees to assist with the allocation of organs rather than leaving the process of allocation to the doctors involved in treating potential recipients. An alternative view is that more extensive training to broaden the outlook of transplant team members is preferable.
d) **Allocation of corneas**

Corneas may be obtained either from patients who are concurrently donating other organs or from other individuals who have died, often some hours before collection. Patients awaiting corneal grafts are placed on a waiting list and are then treated in the order of entry to it. As the supply of corneas generally meets the demand, and as most operations are non-urgent, corneas can usually be allocated according to the requirements of patient and surgeon. In practice, this is likely to result in patients receiving treatment in order of entry to the waiting list unless the general surgical waiting list prevents this (as may happen with public patients in some States).

Medicare patients receive corneas free of charge. However, as corneas are classified as prostheses, a charge for the cornea may be raised for private patients, with those costs associated with the retrieval, preparation/testing and supply of the cornea permitted to be included in the charge. The classification of corneas as prostheses for which a charge may be levied has raised ethical concerns in some sectors of the community. However, it should be made clear that any charges that are to be levied relate only to the recovery of costs incurred in supplying the corneas. Commonwealth regulations explicitly preclude both the inclusion of margins for profit or other non-related costs and the charging for tissues.

e) **Allocation of multiple organs to one recipient**

Special problems arise when the question of allocation of more than one organ to a patient is considered. For instance, when a patient who needs liver or heart transplantation also requires renal transplantation, there is clearly benefit to that patient if both organs are derived from a common donor. Against this advantage, only one patient has been treated instead of two. Furthermore, as the waiting time for heart or liver transplantation is relatively short compared with that applicable to renal transplantation, simultaneous renal allocation effectively confers priority ahead of others waiting for renal transplantation alone.
5. General ethical considerations influencing entry to, and ranking in, a transplantation program

Many of the ethical issues that require consideration in decisions to offer transplantation to one patient in preference to another are shared in common, irrespective of the specific organ or tissue to be transplanted. These issues will be discussed initially in a general context and their relevance to particular transplantation programs will be indicated when the latter are discussed. It would be unwise to regard either the ethical issues raised by transplant allocation or the existing solutions to them as fixed. Both demands on transplantation programs and the capacity to support those programs are likely to change in the future.

The criteria that have been applied to select patients for transplantation programs and, once within a program, to assign them a priority, may be separated into medical and non-medical categories with the qualification that substantial overlap can occur. The misrepresentation of non-medical criteria as medical as a means of strengthening their impact on decision-making is unethical. To ensure the fairest possible distribution of available resources and to reassure the community on this point, the selection process ought to be transparent and intelligible to all.

Factors which could be taken into account in organ allocation include:

a) **Selection of the sickest patient**

An offer of an organ to the patient most likely to die without it might appear the most reasonable basis for organ allocation. However, this method may also select the poorest outcome. This is not necessarily the ‘best use’ of a limited resource.

b) **Selection of the patient most likely to benefit based on medical or other criteria**

If the major emphasis in organ allocation is placed on guaranteeing that the greatest number of transplanted organs are accepted and survive (together with their recipients) for the longest time, a preference should be for the best possible tissue match in the patient with the best outlook (for example, optimal medical
condition at the time of the operation, least risk of recurrence of the diseases occasioning transplantation, younger age etc). Whilst this approach appears acceptable in isolation, it conflicts with a number of other criteria. Rigorous application would disadvantage any potential recipient with advanced disease and resulting impaired chance of success. The criterion of most likely success might be more appropriate ethically when applied secondarily. That is, having identified patients with similar priority for allocation on other grounds, further choice might favour that case most likely to be successful.

Whereas factors such as the severity of illness and the probability of success may be assessed with some accuracy using defined medical observations, and length of time on a waiting list can be reliably quantified, the assessment of likely benefit will necessitate application of non-medical considerations as well as, or perhaps instead of, purely medical ones (the chances of success will obviously influence the extent of benefit). This has ethical implications when one comes to the question of who is to have the responsibility for applying selection criteria. In purporting to assess ‘benefit’, the risk will always arise that less significant, albeit readily quantifiable, parameters may take precedence over others that are of more substance but less amenable to measurement.

c) **Selection of the patient on the waiting list for the longest period**

Commonly held notions of fairness in distributing any benefit provides strong support for priority on the basis of length of prior waiting period. This criterion has the administrative advantages of ready identifiability and defensibility. Against its adoption, it could be argued that the fact that a patient has survived for a long period after meeting the requirements for entry to a waiting list might indicate that he or she was in better condition than others on that list. The question might then be put whether, for this reason, his or her ‘need’ was less.

d) **All patients on the waiting list should have an equal chance of selection**

One solution to the problem of dispersing a limited number of benefits among a greater number of applicants would be to select recipients by ballot. This strategy is often found to be acceptable to the community in allocating licences for various commercial activities. It has the advantage of being seen to be free of any taint of favouritism. However, its application to the allocation of transplants each time an organ became available is inappropriate as other important selection criteria are by-passed. The method could only have a place in rare situations where several possible recipients are judged to have equal priority on medical and other grounds.
e) **Selection of patients on the basis of their importance for the well-being of others**

Taking a broader view of the situation of potential recipients, a patient with a young family dependent upon him or her for support, or an individual with the capacity to make a unique beneficial contribution to his or her community, might be accorded priority. This overtly non-medical criterion would raise questions about the manner in which selection attributes are to be quantitated and of who is entitled to do so. Versions of it were employed in the United States of America during the early years of kidney transplantation programs and were subsequently rejected.

f) **Preference in selection to patients who have previously had one or more transplants**

Patients who have already endured the discomforts of being a transplant recipient but who have had the misfortune of a failed graft, and so received no benefit, might be seen to have a claim for priority for another try. Here the type of organ graft is of importance. For example, recipients with failing liver or heart grafts face imminent death and may achieve priority for this reason. Renal recipients may return to dialysis following graft failure, but the basis of loss of the first graft may persist (for example, high antibody titres) and remain operative.

g) **Capacity of the patient to pay**

Equal access to medical care for all, irrespective of capacity to pay, is a basic principle in Australian health care. Some would argue that expedited entry to a program because of ability to pay may, by augmenting the resources available to that program, permit the treatment of other non-paying patients who would otherwise have missed out. However, most Australians would find the concept of buying accelerated access to an organ transplant ethically repugnant. Any specific proposal for accelerated access on these grounds would have to establish that those displaced in the queue did not suffer medical disadvantages as a consequence, and that the improved services resulting from the funds generated were real. If such a system (similar to that which now operates in relation to access to higher education) were introduced into health care the problem of identifying which ethical principle should regulate its operation would remain. The possible impact of a prospective recipient’s capacity to pay upon his or her access to transplantation is, nevertheless, an issue in the treatment of non-nationals (Section 11).
6. Admissibility of patient lifestyle and attitudes in selection for transplant allocation

In some situations, a prospective recipient’s lifestyle and attitudes may affect the outcome of transplantation and, consequently, require consideration at the stage of recipient selection. As discussed above, fairness in distribution requires that any general policies formed in response to this possibility and the rationale for them, should be explicit. Whilst some lifestyle factors are likely to exert their influence on selection of a patient for transplant receipt by means of their effects on identifiable medical factors which, in their turn, impact upon the patient’s suitability, others may be less clearly definable. Of the following four examples of potential impact of lifestyle on suitability as a transplant recipient, the first two can readily be translated into medical factors.

a) Exclusion of patients whose need for transplantation has arisen substantially as a consequence of a behavioural pattern that is potentially ongoing

There is the likelihood that an ongoing behavioural pattern may influence a patient’s suitability as a recipient in at least two ways. In the first instance, the continuation of a pattern that has contributed to the need for transplantation, or reversion to that pattern, may compromise the chances of survival of the transplanted organ. An example of this situation would be an alcoholic patient who requires a liver transplant but who may revert to alcohol abuse in the future. The extent to which recurrence of alcoholism may compromise a successful outcome to transplantation may be a medical factor as relevant as compromise of liver transplantation by recurrent viral infection or recurrent malignancy.

Alternatively, the existence of a behavioural pattern which has already been substantially responsible for the disease which has occasioned transplantation may be argued by some to lessen a patient’s eligibility for that procedure. Applying the same analogy used above, any case for exclusion from organ transplantation because illness, such as alcoholism, is primarily self-inflicted necessarily involves non-medical ‘social’ judgements. This issue of differential
treatment (albeit non-medical) of a medical condition on the basis of its causative circumstances, has been tested most recently in public and legal (as distinct from ethical) arenas in the case of HIV/AIDS. However, on that occasion, it was a compensatory preference (ie financial compensation of one group) rather than positive penalisation (withdrawal of treatment from the other) which was accorded to some patients with ‘medically acquired’ AIDS.

Whenever the issue of possible exclusion of patients with a particular lifestyle from access to any form of treatment that remains available to others is considered, it is essential that attention be given to the development of processes that will ensure adequate representation of the views and needs of marginalised groups.

b) Exclusion of patients on the basis of anticipated lack of compliance

Apart from recidivism leading to a recurrence of the disease which required treatment originally, grounds for exclusion might arise if there was considerable likelihood that a patient would not be prepared to participate in essential post-transplant treatment, for example the use of immunosuppressive agents (the likelihood of adverse effects from compliance with use of immune suppression may also be grounds for exclusion as will be discussed in considering transplantation of specific organs). The reliability of any prediction leading to exclusion would then be a substantial ethical issue.

c) Inclusion of patients in a transplantation program because the long term support and resources available to them increases the likelihood of a successful outcome

The chance of success following transplantation may predictably vary with the patient’s family and social circumstances. Viewed in isolation, it might be argued that limited medical resources should be preferentially allocated, for example, to a child from what are considered the most positive circumstances to increase the likelihood that benefit would accrue from the procedure. Whether or not such a consideration may have force in other countries, it is inappropriate in Australia where there is a clear ethical responsibility for the community to address the post-transplant circumstances that are likely to affect the outcome adversely. If those circumstances result from social deprivation or marginalisation, a proper response would be to improve the situation of the potential recipients rather than exclude them from transplantation.
d) Linkage of admissibility to a transplantation program with willingness and availability of patient and/or family to donate organs

There has been advocacy for the proposition that eligibility to receive a transplanted organ should be dependent upon a commitment from a potential recipient and their family to be organ donors should the occasion arise. While frequently proposed, to date, no country has enacted such a regulation. A wish to restrict organ allocation to the pool from which donor organs can be drawn may be one factor underlying the common view that needed organs should not be allocated to non-nationals who are not members of the community from which those organs were obtained. However, though antipathy to the transplantation of organs from Australian donors to overseas visitors who have travelled to receive a transplant is common, identification of the boundaries of the community on behalf of which organs are held in trust is not a simple matter.
7. Relative roles of medical and non-medical criteria in patient selection

As indicated in the above examples distinction between medical and non-medical criteria can be blurred. Nevertheless, there are sets of criteria that are clearly demarcated as one or the other. Fairness and transparency in the distribution process requires that the order in which different classes of criteria are applied in considering any patient, and the extent of any relative weighting, be disclosed in advance of the assessment exercise. Should non-medical criteria that may be inherently less quantifiable come into play as a tie-breaker only when the medical indications in favour of two candidates are equal? Alternatively, ought they be factored into the assessment in the early stages? Is there a danger that social considerations that are intuitively judged to be important will be swamped by the technological precision of medical data? Although some selection criteria can be identified as medical, this should not indicate that they are automatically to be placed beyond the reach of community scrutiny. The general community should have the right to be informed about, and to query, the equity of ranking accorded to medical criteria.
8. Updating of selection criteria an ethical requirement

The scientific grounds on which medical criteria have been established are subject to change. Technology is continually improving with the possibility of making transplantation available to patients who were previously considered unsuitable. Community values with influence on non-medical criteria are also subject to evolution, especially under media influence. A practice that was reasonable and fair in guiding transplant resource allocation during one decade may be neither in the next. Tissue typing appears to be less crucial for some organs (for example, hearts) than it is for others (especially kidneys). Cyclosporin reduced the impact of tissue mismatching in renal transplantation and newer immunosuppressive agents are being introduced. The decreased relevance of precise tissue histocompatibility matching between organ donor and prospective recipient as the efficacy of non-specific immunosuppressive agents increases should change the selection criteria. If improved therapeutic immunosuppression ensures that the likelihood of successful acceptance of a transplanted organ is no longer constrained by HLA matching, the continued use of this as a selection criterion could become not only irrelevant but also unfair and even discriminatory. Updating of criteria should then be seen as an ethical imperative.
9. Potential disadvantage to minority groups in transplant programs

Rigid adherence to optimal tissue cross-matching of donor and recipient may reduce the opportunities for prospective recipients with infrequently occurring histocompatibility profiles to receive a transplant. This problem can be exacerbated if the minority population has a requirement for transplantation in excess of that of the community as a whole because of an increased incidence of a disease, or diseases, which generate a need for a specific type of transplant. One implication of this situation is that compromising access of minority groups to transplants on the basis of histocompatibility testing would be quite improper unless complete histocompatibility is such an advantage that it becomes unreasonable not to aim for it.

Assuming that histocompatibility between donor and recipient retains a primary role in selection as it does in renal transplantation, it would seem to be an ethical requirement to attempt to augment the provision of organs from donors within affected minority groups. As mentioned in Section 6(a), Aboriginal patients are likely to have a requirement for renal transplantation in excess of the remainder of the community. Obstacles to improving donation of organs from particular community groups and ethnic minorities can include cultural and religious customs which make donation less likely and a relatively greater percentage of that community resident in areas geographically inaccessible to organ retrieval. There may be a case for attempting to incorporate into existing protocols some provisions specifically designed both to increase donation rates from those communities and to upgrade the opportunities for organ receipt by members of minority groups.
Ethical issues raised by allocation of transplant resources
10. Responsibility for allocation of transplant resources

Responsibility for provision of the infrastructural resources underlying clinical transplantation rests with politicians and senior public servants and will, accordingly, be subject to ethical and political considerations that influence their decisions. It is necessary to recognise that the host hospital of a transplant unit is entitled, and required, to represent the interests of its patients when competing demands for urgent availability of resources such as operating theatres and transfusion services, arise. Responsibility for operating the criteria for patient selection at the level of the individual transplant unit devolves upon the personnel in that unit. The operation of a fair process requires that decision-making extend beyond medically qualified personnel and also that representation occur on behalf of patients who may be disadvantaged by its operations. The day when ‘best interests’ decisions are taken on behalf of patients exclusively by their medical attendants is passing. When ‘best interests’ and cognate issues are to be assessed in allocating priority for transplantation, a patient is entitled to be assisted and advised by those with a wide body of experience.

A final consideration in summarising ethical obligations incurred by those responsible for allocating resources (both organs and services) to individual patients is to emphasise the basis on which the resources have been provided. Irrespective of the legal ‘ownership’ status of organs that are to be transplanted, it would appear unarguable that they have been provided ‘on trust’ to be used for the community. Accordingly, anyone involved in organ allocation is obliged to operate to the standard required of a trustee.
11. Cost recovery in transplantation

It is implicit within the Australian and New Zealand system of transplantation that donated organs and tissues are provided free of charge to other members of the community. The formal allocation patterns for specific organs reflect this expectation with preference being shown to recipients in the state of origin if an optimal match is not possible elsewhere (in the case of kidneys) or as the first preference provided a medically suitable recipient is available (for livers, hearts and lungs). Variations from the likely expectation of donor families that organs and tissues will be allocated to Australian and New Zealand recipients raise a number of ethical issues.

If it is possible that, because of the lack of medically suitable Australian or New Zealand recipients, an organ or tissue could be offered to a non-national recipient, donor families are entitled to this information together with an explanation of the underlying reasons. Deceit of a donor family in relation to the use of organs or tissues is unethical. Whilst the direct sale for profit of donated organs or tissue for use overseas is clearly unethical, it may be argued that the use of tissues and organs which cannot be used for Australian citizens to save the lives of non-nationals may be ethically permissible. It may also be argued that, in this situation, the foreign governments or individuals should cover the full cost of the procedure together with a premium, so contributing to the costs of provision of transplant services for Australian citizens. However, the ethical issues involved are complex in further ways.

For example, the guidelines employed to select which non-national is referred to receive a transplant may differ substantially from what is regarded as reasonable in this country. Secondly, an individual’s capacity to meet the costs of treatment will determine who receives the transplant - a selection requirement that is very much at odds with what the Australian community, including the donor family, would consider acceptable. In addressing the possible ethical difficulties generated by the transplantation of organs and tissues to patients from overseas, clear and uniform guidelines would be desirable. Unless practised with full public support, there is the risk of bringing transplantation into disrepute, with possible adverse effects on organ donation.
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12. Willingness of potential recipient to participate in an experimental procedure as grounds for upgrading priority for access to a transplantation program

As clinical transplantation continues to evolve, there will be a need for testing new procedures. An extreme example of this need is provided by attempts to develop xenografting. Experimental procedures often entail undefined risks of adverse consequences together with unestablished prospects of success. Recruitment of patients for experimentation may only be undertaken ethically if the subjects are conversant with the risks they are incurring. If this requirement has been met, it could be appropriate to consider the legitimacy of offering accelerated access to transplantation in recognition of the patient’s volunteering for the experiment. However, this linkage would no longer be ethically sound if accelerated access was found to be acting as an inducement to patients to incur risks that they would not otherwise accept. The 1992 NHMRC Statement on Human Experimentation and Supplementary Notes sets out guidelines for investigators in developing research protocols. Research protocols must be approved by an Institutional Ethics Committee. The Statement requires investigators to provide the research participant, prior to obtaining consent, with sufficient information at his or her level of comprehension about the purpose, methods, demands, risks, inconveniences and discomforts of the study.
Appendix 1

Transplantation Ethics Working Party

Terms of Reference
The aim of the Australian Health Ethics Committee’s (AHEC’s) work in this area is to address in a broad fashion social issues not dealt with in the guidelines for donation of cadaveric organs and tissues currently being developed by the National Health Advisory Committee of the National Health and Medical Research Council (NHMRC)\(^1\).

The aim of the overall project is to produce information that:

a) is both practical and informative;

b) provides guidance to clinicians, policy makers and support services on ethical aspects of organ donation and transplantation; and

c) provides a basis for informed community debate.

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\(^1\) The NHMRC report *Recommendations for the donation of cadaveric organs and tissues* was finalised in June 1996 and is currently available for purchase through the Australian Government Publishing Service (AGPS) on phone: 132 447 (freecall).
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The National Health and Medical Research Council

The National Health and Medical Research Council (NHMRC) is a statutory authority within the portfolio of the Commonwealth Minister for Health and Family Services established by the National Health and Medical Research Council Act 1992. The NHMRC advises the Australian community and Commonwealth, State and Territory Governments on standards of individual and public health, and supports research to improve those standards. The NHMRC advises the Commonwealth Government on the funding of medical and public health research and training in Australia and supports many of the medical advances made by Australians.

The Council comprises nominees of Commonwealth, State and Territory health authorities, professional and scientific colleges and associations, unions, universities, business, consumer groups, welfare organisations, conservation groups and the Aboriginal and Torres Strait Islander Commission.

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