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Why an Alternate Recipient List for Heart Transplantation Is Not a Form of Ageism

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Abstract

Numerous studies have shown that the use of marginal hearts for organ transplantation produces clinically favourable results, however the association of these marginal hearts with a separate list of potential recipients, often the elderly, is ethically disturbing for some transplant facilities. Examination of the outcome data alone is not enough to justify the use of an alternate recipient list (ARL) as an ethical practice. However, upon analysis and reflection on the allocation process and the goals of medicine, the operating principles of medical ethics clearly emerge. Based upon this ethical analysis, an ARL for heart transplantation is not a form of ageism but rather a method of technology stewardship that operates by way of facilitating transplant eligibility to those with the capacity to benefit.

The thirty-year history of heart transplantation has seen the emergence of new technologies and improved clinical outcomes. At the same time, the UNOS (United Network for Organ Sharing) heart transplantation waiting list continues to grow and the supply of donor hearts is in constant shortfall. With approximately 4,100 patients on the United States waiting list and a yearly supply of 2,200 donor hearts, approximately 25% of waiting patients die (United Network for Organ Sharing, 1999). Efforts to expand the donor heart pool have largely consisted of educating the public about the needs and benefits of organ donation, and educating hospitals about the function and utility of organ procurement organizations. Other efforts to assist waiting patients have included clinical trials of total artificial replacement organs (Joyce *et al*, 1983) and xenografts (Bailey *et al*, 1985) as either bridging or destination therapies. At present, these two strategies cannot be employed as solutions to the dilemma and they have an uncertain future. In the United States, ventricular assist devices are frequently used as bridging technology prior to heart transplantation; however, these devices are not approved by the Food and Drug Administration for permanent implantation. Some hospitals have engaged another strategy, namely, an alternate recipient list (ARL) for heart transplantation, yet examination of their outcome data alone is not enough to justify its use as an ethical practice. Specifically, issues regarding using age as a transplant eligibility criterion must be explored.

An ARL for heart transplantation functions by attempting to match donor organs for which the long term outcome is unknown with recipients who are elderly. Generally, these patients are over age 60, however age criteria vary among transplant centres. The use of the term 'alternate' can carry with it emotionally charged visions of organs that are defective or recipients who are 'second class'. These perceptions are both unfortunate and inaccurate. Organs allocated through an alternate list program are those for which the long-term clinical outcome is uncertain due to variables such as increased donor age, the presence of coronary artery disease, prolonged ischemic time, elevated central venous pressure, elevated dopamine exposure and reduced ejection fraction (Laks & Marelli, 1999). Data (Livi *et al*, 1996; Laks *et al*, 1997) have shown that these variables do not necessarily impart statistically significant negative impact on the short or medium-term outcomes of recipients, nor do they significantly impact ejection fraction, the number of rejection episodes, or the length of post-transplant hospitalization when compared to 'standard' donor heart transplantation. However, because ARLs have been used in only a few transplant centres for approximately five years (single centre data varies widely), the long-term outcome of these transplants is not known.

There have been reports of older donor hearts transmitting coronary artery disease (Livi and Caforio, 2000) and

prostate cancer (Loh *et al*, 1997). Not all centres evidence similar atherosclerosis results, and it may be that this is related to variables such as organ screening, donor/recipient risk screening, donor recipient/viral screening, and immunosuppressive regimen. Some older hearts also evidence chronotropic incompetence after implantation and require placement of a pacemaker for treatment of the conduction abnormality (Chau *et al*, 1995). The combination of positive and negative clinical findings (some treatable or screenable), as well as an unclear long-term outcome, creates a unique dilemma in determining the criteria for recipient selection. Some have suggested donor testing, balancing the resulting risk with the risk of dying without a heart transplant (Detry *et al*, 2000).

The University of California, Los Angeles is one of the largest volume users of marginal hearts in older recipients, reporting a 4yr survival of 78%. They report no significant difference in early mortality or actuarial survival between patients on the ARL and patients on the standard waiting list (Laks *et al*, 1997). The University of Padova, Italy reports a 4yr survival of 81% for older patients receiving a marginal heart and 80% for older patients receiving non-marginal hearts (Luciani *et al*, 1992). International transplantation registry data (1991-1997) indicates a 4yr survival rate of 68% for patients receiving a marginal heart (Hosenpud *et al*, 1997). Several centres report that the use of standard hearts and marginal hearts has not shown significant difference with regards to the incidence of post-transplant acute rejection or infection, however, older recipients are more likely to die of infection or malignant disease. Many older patients receiving a marginal heart have shown significant reduction in their New York Heart Association (NHYA) score which can be correlated to an improved quality of life due to less pain and fatigue, and more mobility which can facilitate independence (Laks *et al*, 1997; Luciani *et al*, 1992).

Regarding marginal hearts, it is likely that single centre survival data are more favorable than registry data as single centres with a distinct ARL protocol will have adopted logistical and surgical expertise as compared to the pooled registry data that includes non-ARL protocol facilities. Poor outcomes can be affected by organ-recipient size matching issues, as well as the quality of the heart, namely, a history of donor substance abuse, myocardial contusion due to chest

trauma, hepatitis B, and low left ventricular function. In the absence of problems related to the donor heart, and in the presence of immunosuppression, the 6 year survival for a 61 year old transplant recipient free from other co-morbidity has been reported to be 54% (Bull *et al*, 1996). For all US heart transplants (regular and marginal), UNOS reports a 5yr survival rate of 66% (Keck *et al*, 1998).

Accepting that these 'marginal' hearts are indeed clinically effective (with or without pre-implantation revascularization) it could be problematic not to use them due to the fact that their potential benefit (though possibly time-limited) will be discarded along with the organ. Probing further it could also be problematic to give a marginal heart to a patient who would optimally benefit from a long-term implant due to their anticipated life expectancy. While each patient's life span is unknown because humans can theoretically die at any moment, it is nonetheless reasonable to assume that the potential quantity of years remaining for a young person is greater than that remaining for an elderly person. If there is reason to believe that long-term transplant outcomes might be reduced with marginal hearts, then these organs should be offered to a patient pool that includes those of advanced age as they have a shorter span of life ahead of them as part of their baseline presentation. Patients who are likely candidates for a long-term result, should be in line for a long-term organ, and transplant centres may have to adjust their ARL entry criteria as further morbidity and survival data is gained while using these protocols.

The fact that ARLs are predominantly comprised of elderly patients does not make their use an ageist practice (that is, treatment discrimination based solely on a patient's age). It would seem that as long as these marginal hearts are offered to the most critical patients first (UNOS Status I) with complete disclosure as to the heart's marginal classification and the risks and uncertainties associated with it, there is no discrimination against those on the standard waiting list (e.g., the non-elderly). Additionally, there is no discrimination against the potential elderly recipients as they are offered organs that have a close match of potential life span. An ARL allocation strategy respects a patient's capacity to benefit from transplantation regardless of their age, prevents the discard of usable organs, respects the urgency of the Status I category, and overall, represents

transplant medicine's striving for ethical technology stewardship. Restated, alternate recipients make use of hearts that will go to waste if not used by those on the standard list. It gives them a chance they would otherwise not have because their age automatically excludes them from the Status I UNOS list. Those placed on the ARL accept the fact that younger, urgent patients (Status I UNOS) will be offered the marginal heart first because they would receive more benefit if in fact the marginal heart did hold out for their lifetime.

Understanding technology stewardship as the prudent exercise of evaluation and application of technology, the practice of using an ARL for heart transplantation can be argued to be compliant. The value of any technology is tied to its appropriate use, and the elimination of age as a categorical treatment variable helps to level the playing field so that there is equal eligibility for a technology (in the light of the capacity of the patient to benefit from it). Several studies (Luciani *et al*, 1992; Livi *et al*, 1994) evidence clinical support for patients in their sixties and seventies to receive hearts from elderly donors, even donors in their sixties (Chau *et al*, 1995; Potapov *et al*, 1999). Given this, formal rules that completely exclude patients from receiving a heart transplant on the basis of their age alone (categorical age limits) are problematic and could cause the wastage of organs rejected by other potential recipients. In fact, excluding older patients from receiving a transplant on the basis of their age alone could result in multiple implants of marginal hearts in single patients on the standard waiting list while elderly patients are banned from the opportunity for even their first transplant. Additionally, multiple implants have implications for medical costs both in terms of risk and resource expenditure. Further, if we allow the donation of hearts from older donors yet decline their implant into older patients are we not using these older donors as a means to an end (e.g., mere warehouses for donor organs)? If the capacity to benefit from transplantation is evident in these older patients, then it is ethically problematic to exclude them from the technology while at the same time accepting their donated organs for use in younger patients.

In the light of ethical technology stewardship, and the structure and function of an ARL, it appears that age-based exclusions to transplantation are unacceptable. The reasons which make such an exclusion unnecessary (the inability to

determine each potential recipient's life span, the potential diminution of capacity to benefit towards the end of an elderly patient's life when they have clinical exclusion factors or elevated surgical risks, the availability of marginal organs that will go unused or be placed in patients who are unsuitably matched for potential long term outcome) are the same reasons which render aged-based categorical limits unethical. Further, instead of making transplantation age-based, using capacity to benefit (with the organ matching concept espoused by an ARL) is more just because it defines eligibility in a non-arbitrary way.

Certainly there will be those who will argue that ARL programs are ethically troublesome because while potentially allowing transplant eligibility for the elderly and reducing organ wastage, there is no economic mechanism to increase the financial resources to pay for these additional surgical procedures (and their related medical expenses).

An argument could be made that short- and medium-term outcomes are economically burdensome from the standpoint of dollars spent and years of life gained post-transplant, and that only those patients with the potential for long-term outcomes should be considered. However even non-marginal hearts can evidence short- or medium-term clinical outcomes due to a variety of potential transplant complications such as rejection and infection. There is no accurate way of predicting how long a donor heart will optimally function or how long an organ recipient will live. Generalizations can be made using transplant registry data, however, each patient is as unique as the donor organ they receive and variables abound. If one argues that only long-term outcomes are ethically appropriate, then those who would benefit from an improved quality of life, even if only short- or medium-term, would be automatically excluded from transplant eligibility (and these would most likely be older persons). Also, the definition of short-, medium-, and long-term outcome will likely change over time as medical and surgical techniques improve, and as donor-recipient matching strategies are continually optimized. The act of limiting heart transplantation endeavours will not serve to address these matters, but rather it will complicate them due to the limitation of data and experience that can be potentially gained. The economic issue should not be an automatic barrier to the use of this technology, but rather it should be recognized as an unsolved problem to be reflected

upon in conjunction with the clinical beneficence that an ARL program can provide.

It is acknowledged that use of an ARL will not resolve the significant shortfall of donor organs experienced by transplant centres each year. It is possible however that the ethical acceptance of ARLs could cause an increase in organ donation by the elderly community and an increasing availability of heart transplant technology to older patients. As of November 30, 2000 there were 484 geriatric patients (age 65 and older) on the UNOS heart transplant waiting list. It is unknown how many clinically eligible patients are not placed on this waiting list due to hospitals deterring patients from transplantation based on age value alone. The number of geriatric patients receiving a heart transplant is growing each year with 208 recipients in 1999, up from 104 recipients in 1993. It is hoped that this trend will continue by way of more transplant centres adopting the ARL philosophy as clinically and ethically permissible.

In my argument, I interpret justice in terms of treating equals as equals via the concept of life-span matching. In simplistic terms, tallying the good that can potentially be realized from allowing clinically appropriate elderly to be eligible to receive an organ that would otherwise go to waste is enough to justify the concept of an ARL, even if ARLs do not simultaneously possess the solution to the economic problem of 'more transplant operations'. This tallying means that the transplantation playing field becomes more level in the face of an ARL because age as an arbitrary exclusion criteria is no longer allowed. It maximises the potential for life extension and improved quality of life that marginal hearts have been empirically shown to provide. Additionally, empirical evidence shifts the elderly from being only donor-capable (a means to transplantation) to both donor- and recipient-capable (an end of transplantation). Lastly, ARLs are not an injustice to those currently waiting for a heart on the 'standard' list because all donor hearts (marginal and standard) are offered to these patients first, and only those declined by these patients and thus destined for the waste bin are then re-routed to the ARL. Justice is dealt to those waiting on the standard list as they do not lose their chance at any organ. Justice is dealt to the elderly by way of the fact that they have a chance at a life span-matched organ that they would otherwise not be considered for (due to an age-based exclusion).

In the face of an ever present allograft shortfall for the entire pool of clinically indicated patients, alongside the fact that there will likely forever be an uneven distribution of organ sizes and other characteristics, I suggest that this results in an even spread of injustice due to the general nature of competing for an organ. In spite of this 'evenly spread' injustice, there is still the eligibility imbalance within the current system that is the result of disregarding the empirical evidence that some elderly can potentially benefit from an allograft. Knowing the scarcity of allografts, and the prolific measures taken to increase organ donation, it is ironic to think that any rate of organ discard would be acceptable when, in fact, these organs are clinically suitable for implantation, yet unimplanted due to an arbitrary age-based cut-off. By not discarding organs that are suitable for transplant, the potential for beneficence is maximized. Organ discard that does occur is justified by non-arbitrary criteria.

Some might argue that my argument is a flawed consequentialist approach, looking only to the outcome, not the nature of the act itself or the foundation out of which the act arises. I accept that the nature of the act, providing a transplantation eligibility slot, does swell the size of the waiting list pool, but the current pool size is already large in relation to the number of allografts that become available. Yet, the use of ARLs might actually result in an increase in organ donation from the elderly as previously described. Also, the foundation out of which the act arises is that of attempting to level the playing field for all those who are clinically indicated for a transplant but who might otherwise be excluded due to a variable (age value) that is not empirically substantiated. Based upon this ethical construction, the use of an ARL is ethically justified.

Certainly comorbidity reduces the number of geriatric organs suitable for transplant, but a significant step to increasing geriatric organ donation and transplantation might be a heightened awareness of the ethical appropriateness and potential clinical beneficence of an ARL. Adopting an ARL policy will cause enlargement of the heart transplant waiting pool and should require an obligation to expand the allograft donor pool (or allow for access to mechanical technology). The US Census Bureau estimates an American's life expectancy in 2025 at nearly 81 years of age. Accordingly, the definitions of elderly and

geriatric may need revision and, based upon UNOS trends, older people will likely comprise a larger percentage of those on the heart transplant waiting list. Ethical stewardship of transplantation technology is fostered when surgeons consider each patient's unique capacity to benefit, rather than their age value alone.

In a society where \$52 billion is spent annually on cut flowers and candy (Corporateinformation.com), the cost of additional geriatric heart transplants each year doesn't seem so significant considering the quality of life benefit that can be potentially achieved. To know the price tag of a particular medical technology is one thing; to witness or experience the value of it is another. Even if one accepts the notion that due to the process of aging, a 60 year old might not be as 'economically productive' as a 45 year old, neither this concept nor age value alone should be accepted as a variable of human dignity or societal value, and neither should affect a person's eligibility for beneficent medicine. ARLs could result in an increase in organ donation by the elderly community and an increasing availability of heart transplant technology to older patients. Transplantation ARLs are not a form of ageism but rather a method of technology stewardship that operates by way of facilitating transplants for those with the capacity to benefit.

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