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The Allocation of Organs: Emerging Legal Issues

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Introduction

The allocation of any scarce health care resource, especially a life saving resource, can create profound ethical and legal challenges. For a number of reasons, the challenges associated with the allocation of organs are particularly acute. First, there is a critical shortage of organs for transplantation. In Canada, as of December 31, 2004, there were 4,004 people waiting for an organ transplant and, in 2003, there were just 1,794 single organ transplants (CIHI, 2005). In the United States, there is also a significant waitlist for organs: “As of August 5, 2005, there were 96,189 patients awaiting organ transplantation. During 2004 only 27,036 transplants were performed, highlighting a growing disparity between patients listed and organs available” (Smedira, 2006. See also Organ Procurement and Transplantation Network: <http://www.optn.org/latestData/rptData.asp>). Because supply of organs cannot meet the demand, tremendously difficult decisions must be made about just allocation of this scarce resource, in a context where decisions often have life and death implications.

Another reason that the allocation issues associated with organs are so challenging is that the shortage “is subject to limitations of supply unlikely to be alleviated simply by augmentation of funding” (NHMRC, 1997). In other words, organs are a truly finite resource. If one individual gets an organ, it means another may not – with death being a possible consequence (Hackler & Hester, 2005). Though organ procurement initiatives could undoubtedly benefit from more money, injecting more funds into the regular medical care of those with end-stage organ failure will not result in a significant increase in the scarce resource. Numerous strategies have been devised to increase available organs, but a rapid increase in available organs is not likely. Indeed, “Canada now has the dubious honour of having one of the lowest donation rates among developed countries” (Health Canada, 2005; Trpeski, 2006).

In this paper, we discuss important legal and ethical issues that arise in the context of organ allocation. First, we provide an overview of ethical principles of justice and equity and describe how these goals may conflict in transplantation decisions. Next, we discuss legal issues in health care resource allocation, focusing on potential legal challenges that may arise in efforts to prioritize organ recipients. We summarize various potential grounds for legal challenges, including violation of anti-discrimination laws and malpractice lawsuits. Finally, we comment on public engagement and education in developing allocation criteria and emerging strategies to increase the supply of available organs.

Ethics, Law and Resource Allocation

Resource allocation issues in organ transplantation emerge at the macro (e.g., national and provincial health care funding), meso (e.g., the spending decisions made by regional health authorities and hospitals) and micro levels (e.g., decisions about which individual patients get what resource). For the purposes of this paper, we focus primarily on the micro (patient) level, but also address possible legal challenges that may arise at the meso or macro level. There is, as we will see below, a rich ethics literature on the topic of resource allocation in the context of organ donation.

Early medical allocation literature often built on the concept of triage, first developed in the Napoleonic Wars. Basically, it involved ranking injured soldiers such that those who would benefit

most from immediate care received treatment first (Freeman, 2006). Though the general ethos of triage survives in modern allocation policies, there has been a continuing push to develop objective criteria to help ensure resources are allocated fairly and with maximum benefit.

Though alternate ethical perspectives have been proposed, such as a communitarian approach (Tauber, 2002; Mooney, 1998), in liberal democracies like Canada, most allocation policies are built on two fundamental principles: justice and utility (Veatch, 2004). Justice requires that we should strive to treat individuals equally and that unequal treatment is only justified when “resources are allocated in light of morally relevant differences, such as those pertaining to need or likely benefit” (McNeally, et al., 1997; see also Shevory, 1986). Characteristics that are normally considered morally irrelevant include religion, sex, sexual orientation and socioeconomic status. In the context of organs, what is considered morally relevant? It has been suggested that allocation policies for organs “should depart from equal opportunity mechanisms, such as time on the waitlist, only where there are very substantial differences in such factors as probable success” (Childress, 1996). However, what constitutes a “very substantial difference” remains open for interpretation.

The principle of utility requires that we “make optimal use of the resources, so that the greatest total benefit is obtained” (Hackler & Hester, 2005). In other words, in the context of organ donation, this principle would encourage the allocation of resources in a manner that would ensure that the individuals who would benefit the most receive the organs.

Clearly, the principles of justice and utility can often conflict. As Veatch (2004) summarizes:

Advocates of efficiency or utility maximizing have an eye toward doing as much good as possible with a limited resource; advocates of justice have their eye on some pattern of distribution of the resource that they consider fair such as giving benefits to the worst off.

In the context of life-saving organs, we must ask “to what degree should producing the best outcome be favoured over giving every patient an opportunity to compete for limited resources” (McNeally et al., 1997)? Though the current trend in organ allocation places increasing emphasis on utility and outcome, there is, as we discuss below, at least some evidence that the general public rates fairness (justice) over clinical outcome (utility) (Ubel & Loewenstein, 1999).

The tension created by the interplay between justice and utility is reflected in the changing approaches to transplantation allocation strategies. In the past, queuing has often been a favored approach to rationing because it appears to be objective and impersonal (Childress, 1996). More recently, however, evidence-based predictions of outcome and need have played an increasingly prominent role in allocation policies. For example, the US recently changed its approach to the allocation of livers. On February 27, 2002, the Model for End-Stage Liver Disease (MELD) was adopted, via UNOS and the Department of Health and Human Services, as the official, evidence-based means of allocation. The new approach is designed to ensure that “patients at highest risk of short-term, pretransplant mortality receive priority for cadaver liver allocation” (Voigt et al., 2004) and replaces a system that emphasized a more “waiting times” based process (Schaffer et al., 2003). The new approach coincides with recommendations of the World Health Organization: “donated organs should be made available to patients on the basis of medical need and not on the basis of financial or other considerations” (WHO, 1991).

One could argue that the new MELD approach displays a shift toward putting more weight on utility (e.g., clinical benefit) over justice (e.g., time on the waitlist) – an approach that is also reflected in many other countries' allocation systems (Persijn et al., 2004). As we will suggest below, it will likely be impossible to resolve the justice vs. utility dilemma. Various allocation policies have been studied for fairness and efficiency, illustrating flaws, both perceived and real, that may precipitate a legal challenge. In a US study it was found that “consistent structural deficits exist in the organ allocation process as it is applied by many individual transplant centres.” The irregularities lead to “idiosyncratic determinations, and a devaluation of rank waiting as a criterion, raise fundamental questions regarding justice, fairness, and equability in the application procedure at large” (Koch, 1996).

A more recent, and highly relevant, study was undertaken in the US to explore the impact and effectiveness of the new MELD approach. The study found that despite the use of MELD, an approach that strives to balance justice and utility, “there remains disparity in organ allocation with the study region.” MELD accurately predicts mortality, but it “does not ensure equitable organ distribution.” While these studies are of varying relevance to the Canadian situation, they all highlight how organ allocation processes can be analyzed for fairness¹ and highlight the possibility that inconsistent application of policies may fuel legal challenges. From legal and ethical perspectives, key points are to avoid discrimination on medically irrelevant grounds, and to consistently apply prioritization and transparency criteria in the allocation process.

Resource Allocation and the Law

People who are disadvantaged (or perceive themselves to be disadvantaged) by rationing of scarce health care resources may turn to legal challenges to contest the allocation of the resource at macro, meso or micro levels. Individuals may base challenges on claims of discrimination, asserting that they treated unfairly because of personal characteristics and made worse off than others who do not have that same characteristic. These claims may be based on rights protected under the *Canadian Charter of Rights and Freedoms* or provincial human rights codes. Patients may also attempt to bring medical malpractice lawsuits, arguing that health care providers fell below an acceptable standard of care.

Claims under the Charter and Human Rights Codes

The *Canadian Charter of Rights and Freedoms*, part of Canada's Constitution, has been used with mixed success to challenge governmental resource allocation decisions in health care. The *Charter* requires that individuals enjoy equal access to benefits provided by law (including public health care services under Canada's Medicare system) and prohibits discrimination on grounds such as physical/mental disability, sex, religion and race. It is important to understand that the *Charter* may only be used to challenge the actions of governmental bodies, such as federal or provincial health departments or

¹ However, a 1996 Canadian study explored the substantive and procedural criteria for planning patients on the waitlist for liver transplantation. At that time, they found that alcoholism, drug addiction, HIV positivity, primary liver cancer, noncompliance and hepatitis B “were the most important criteria that had a negative influence on decisions to place patients on waitlists for liver transplantation.” They found that “criteria for resource allocation decisions regarding liver transplantation are generally consistent among the centres across Canada.” (Mullen, 1996).

local health authorities. For example, parents of children with autism have used the *Charter* to challenge governmental decisions to restrict funding for autism programs. While these challenges were successful at lower court levels, the Supreme Court of Canada has ruled that courts should not interfere with government resource allocation decisions in regard to services that are beyond the core programs covered under the Medicare system (*Auton v. British Columbia*, 2004).

Publicly funded hospitals are only subject to the *Charter* to the extent they are applying government laws or policies. For example, in the Supreme Court of Canada decision in *Eldridge v. British Columbia* (1999), the court ruled that a hospital and the provincial Ministry of Health discriminated against deaf patients by refusing to provide sign language interpreters as an insured health care benefit. In their general daily operations, however, hospitals are not subject to the *Charter*. Thus, transplantation policies developed at the hospital level may not be subject to a legal challenge under the *Charter*, but policies that are promulgated as part of broader governmental policy may be subject to challenge.

While the *Charter* applies only to government, human rights laws apply to both public and private entities. The federal and provincial governments have enacted human rights laws across Canada to protect individuals from discrimination in the provision of public services, including health care services, on the basis of characteristics such as disability, sex, religion and race. Patients who experience discrimination in accessing care may file a complaint with a human rights tribunal that has legal power to hear and decide the case. For example, the British Columbia Human Rights Tribunal found that a physician who specialized in fertility treatments discriminated unfairly against a lesbian couple by refusing to provide artificial insemination to them on the basis of their sexual orientation (*Korn v. Potter*, 1996).

In adjudicating discrimination claims, courts or human rights tribunals are concerned with *unjustified* discrimination; if people are treated differently on the basis of legitimate characteristics, discrimination is justifiable and courts or tribunals will not interfere with resource allocation choices. In the organ transplantation context, giving priority to patients on the basis of their medically predicted success as a transplant recipient will clearly be more defensible than allocation on other grounds without medical relevance. For example, the Dutch Minister of Health provoked controversy in 2005 when he suggested that registered organ donors receive priority for organ transplants should they require one (see www.expatica.com). This proposal involved overtones of religious and ethnic discrimination as the Health Minister argued that Muslims often refuse to donate organs because of their religious beliefs, but are willing to receive transplants. The Minister also stated that immigrants to the Netherlands are often in worse health than native Dutch people and are more likely to require organ transplants, but are less likely to register as donors.

In another troublesome case, the UK Transplant Support Service Authority reportedly acceded to a request by an organ donor's family that the deceased's kidney not be offered to a "coloured" person (BCC News, 1999). However, the British Transplantation Society has explicit guidelines stipulating that "in general, society does not extend to donors the right to say to whom their organs should go."

Another area that has generated controversy is denial of organs for patients diagnosed with mental illness (Byrne, 2000). Various studies report instances where patients with schizophrenia, borderline personality disorder, and history of suicide attempts have been denied transplants and some commentators have argued these practices violate anti-discrimination laws (Orentlicher, 1996).

Age-related organ allocation may also be criticized as unjustifiable discrimination, particularly considering that “various forces – such as improved surgical techniques, immunosuppressive drugs, competition among new transplant centres, and the challenge to surpass existing limits – have weakened age based limits” (Hackler & Hester, 2005, 130). However, it has been suggested that organs from older donors be matched with older recipients to satisfy principles of both equity and fairness (Hackler & Hester, 2005).

One US commentator suggests that “*ad hoc* donor-recipient discrimination is common” (Lucey, 2004), but legal challenges are uncommon. If transplantation policies or practices were challenged before a court or human rights tribunal, the adjudicator would be unlikely to interfere with allocation choices that are supported by medical justification – that is, evidence that a particular recipient is more likely to benefit from a transplant than another. Where a person is denied an organ solely on grounds such as race or religion, a discrimination challenge is more likely to succeed.

Malpractice Law and Resource Allocation

In addition to discrimination claims, allocation schemes may also be challenged through a negligence claim (usually called a “malpractice law suit”). For example, a patient/plaintiff might argue that an allocation policy had been negligently applied or devised. In such a case, the plaintiff would need to establish that the defendants (e.g., the transplant team), had breached an appropriate professional standard of care and this breach resulted in an injury.

As in many common law jurisdictions, the legal standard of care in Canada is determined by examining what “could reasonably be expected of a normal, prudent practitioner” (*Crits v. Sylvester*, 1956, 508). The Supreme Court of Canada in *Ter Neuzen v. Korn* affirmed this rule where it was held that doctors “have a duty to conduct their practice in accordance with the conduct of a prudent and diligent doctor in the same circumstances” (*ter Neuzen v. Korn*, 1995, 588). Though clinical practice guidelines are becoming increasingly common, especially in areas such as transplantation, practice guidelines remain only one piece of evidence in the formulation of the legal standard of care. A case-by-case analysis remains the norm and, as such, the standard of care is re-examined in each lawsuit. That said, it seems likely that a court would place a good deal of emphasis on, for example, nationally developed allocation criteria.

There are no reported Canadian court decisions involving the alleged negligent allocation of organs. However, there are a variety of negligence cases that are relevant to allocation decisions more broadly. For example, in the well-known case of *Law Estate v. Simice* (1994; see also Caulfield, 2002) the court had to consider the impact of cost containment pressure on a physician’s clinical decision. In the case, a patient presented in the emergency room with a headache and later died of an aneurism. One of the issues in the case was why a CT scan was not provided. The defendants argued that resource constraints imposed by the hospital resulted in pressures to use fewer resources, including diagnostic tools like a CT. However, the court was not swayed by the resource constraint argument:

[I]f it comes to a choice between a physician's responsibility to his or her individual patient and his or her responsibility to the Medicare system overall, the former must take precedence in a case such as this. The severity of the harm that may occur to the patient who is permitted to go undiagnosed is far greater than the financial harm that

will occur to the Medicare system if one more CT procedure only shows the patient is not suffering from a serious medical condition.

There have been a handful of other cases that have come to a similar conclusion, emphasizing the responsibility of health care professionals to place the needs of the patient over broader allocation needs (e.g., *McLean v. Car*, 1994).

While these court decisions are relevant to the transplant situation (emphasizing the duty of the physician to the patient), there is an important difference; the resource in question, a CT scan, was available but the physician was being asked to constrain its use to save the system money. In other words, there was not an actual scarcity. As such, the court felt the patient's interests should prevail. In situations of *actual* scarcity, such as in the case of organ transplantation, courts are quite sympathetic to the challenges faced by the health care system. For example, in the decision of *Bateman v. Doiron* (1991), a case involving the allocation of emergency room specialists, even substandard care was acceptable so long as the defendants were doing their best with the resources available.

So, what does Canadian negligence law tell us about the law associated with the allocation of organs in Canada? Though actual scarcity is a legitimate response to not providing a needed resource, those resources must still be allocated in a manner that discharges a provider's duty to the patient – which likely means ensuring allocation criteria are applied in a manner consistent with the existing standard of care. Only a sharp departure from established criteria would seem likely to attract liability concerns. In addition, courts have long given a good deal of deference to the profession in the establishment of the standard of care (*ter Neuzen v. Korn*, 1995) and have been relatively reluctant to interfere with allocation decisions. As noted by McNeally, et al.:

Because courts have been extremely reluctant to become involved in how physicians, hospitals and health authorities use their resources, the legal review of individual decisions involving resource allocation is improbable (1997; see also Caulfield, 1994).

Fiduciary Obligations

Fiduciary law is another area that has tremendous significance in this context. Fiduciary obligations flow from the relationship of trust between physician and patient. Indeed, fiduciary law compels health care providers to focus, almost exclusively, on the best interests of the patient. "Loyalty is the core value of fiduciary relationships and hence the focus of fiduciary law" (Litman, 2002, 91). In Canada, fiduciary law requires physicians to act with the utmost good faith and loyalty toward their patients (*McInerney v. MacDonald*, 1992).

For transplant physicians, this legal duty creates a dilemma. How can a physician focus on the best interests of his/her patient, which would undoubtedly include receiving an organ as soon as possible, when the needs of other patients must also be considered? Again, we have no cases directly on point, but Canadian courts have consistently placed a tremendous emphasis on fidelity to the patient (e.g., as noted in the *Law Estate* case) and patients, understandably, expect their physicians to advocate on their behalf.

What is the best strategy to resolve this dilemma? Physicians should advocate vigorously for their patient, but do it within the established criteria. They should not manipulate the system “to gain unfair advantage” for their patients (McNeally et al., 1997).

Other Issues

Public Engagement and Education

Public perception of fairness of transplantation policies is a key issue. If the public believes criteria are not fair (or not transparent), this might motivate legal action. Interestingly, some research demonstrates that the public may hold different views from health care professionals on how best to allocate organs. A 1998 study in the UK, for example, found that the most important selection criteria are, in decreasing order of importance, “age, outcome, and time on the waitlist.” Family doctors rated “outcome, age, and likely work status after transplantation” as the most important factors and gastroenterologists list outcome, work status, and non-involvement of alcohol (Neuberger, 1998). A similar study by Ubel and Loewenstein found that the public rates fairness over clinical outcome. Specifically, the study found “that the public places a very high value on giving everyone a chance at receiving scarce resources, even if that means a significant decrease in the chance that available organs will save people's lives” (1999). The authors of the study note that the “results raise important questions about whether the aims of outcomes research and cost-effective studies agree with the values of the general public” (1999).

While these studies are hardly definitive, they do hint at how public perception may become an issue. Even thoughtful and well-intentioned allocation criteria may result in policy and decisions with which some members of the public disagree. On a practical level, the studies remind us of the importance of ensuring that both the criteria and rationales are explicit and transparent. In addition, they suggest that the development and implementation of guidelines should involve a degree of public engagement. Indeed, well-known bioethicist James Childress notes that, in a symbolic sense, organs “belong” to the community and should be viewed as a community resource. He concludes that, as a result of this view, “transplant professionals serve as trustees and stewards of those organs, and that organ allocation policies must be formulated with public as well as professional input” (Childress, 1996). However, while the public can judge on fairness issues, they are generally not able to give judgments on medical utility factors.

It is also important to emphasize that public views cannot justify organ allocation policies that run afoul of anti-discrimination laws. For instance, even if respondents in a public opinion consultation say that a patient with schizophrenia should receive lower priority for an organ, denying a transplant to that patient may still contravene human rights protections enshrined in Canadian law. The Supreme Court of Canada has emphasized that human rights laws exist to protect individuals from majoritarian discrimination.

Emerging Strategies to Increase Available Organs

New strategies to increase the supply of organs might also create new legal issues. Due to the shortage in organs, an increasing number of organs are coming from individuals who, in the past, might have been deemed inappropriate donors. The clinical outcome of individuals who receive

organs from “marginal donors” is generally considered to be poorer (Gutmann, 2004; Botha, et al., 2006). Would the use of “marginal donors” be considered within the legal standard of care? What processes/criteria should be in place to determine the allocation of such organs? And, perhaps most importantly, what consent mechanisms should be in place?

International Law and the Trade in Organs

While well beyond the scope of this paper, the growing trade in human organs should be noted. Naturally, the trade exists due to the shortage in organs throughout the world and this has led one commentator to note: “The contradictions and strains of globalization in the health care sector can be seen clearly in the legal issues raised by organ trafficking and health tourism. Legislation embodying particular national taboos is made obsolete by the development of crossborder trade in body parts. Case law supporting a nationally based rationing of health care is undone by the effect of international economic law” (Harrington, 2004).

Conclusions

Despite the unavoidable tensions that emerge in the application of the ethical principles of utility and justice and the difficulty in predicting legal challenges, some general themes and guidelines can be articulated (McNeally, et al., 1997; Hackler & Hester, 2005):

- Allocation criteria should be based on the best available evidence and should be, as much as possible, consistently applied.
- Criteria to prioritize patients should be based on the best available evidence and should relate to morally relevant factors, such as clinical outcome.
- Allocation criteria should be careful to avoid discrimination on medically irrelevant characteristics (such as religion and place of origin) and ensure that personal characteristics that may have medical relevance (such as age, co-morbidities) are carefully assessed and arbitrary denial of eligibility is avoided.
- Though the legal standard of care will always be evaluated on a case-by-case basis, a nationally agreed upon and consistently applied allocation policy will help moderate liability concerns.
- The concerned public should be made aware of the allocation criteria and should participate, as much as is feasible and rational, in generating a transparent allocation system.

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