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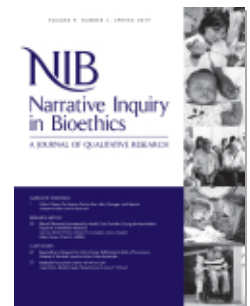
## Malleable Transplant Criteria: At What Cost?

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## Malleable Transplant Criteria: At What Cost?

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**Abstract.** An 18-year-old male who had been diagnosed at age 7 with a rare, progressive liver disease was referred to the transplant center and received a transplant, even though he did not meet the center's criteria for a patient with hepatopulmonary syndrome (HPS). Complications required relisting the patient urgently, but he eventually fully recovered; total hospital charges for his treatment exceeded \$5 million. Reflection upon the case resulted in analysis of two ethical questions: primarily, clinician obligation to balance the provision of actuarially fair health care to society against the healing of a single patient; secondarily, the effects of malleable transplant criteria on trust in the patient selection process. We affirmed that physicians should not be principally responsible for justifying financial investment to society or for upholding beneficence beyond the individual physician and patient relationship in order to contain costs. We concluded, however, that such instances, when combined with manipulation of transplant center criteria, pose a potential threat to public trust. We therefore suggested that transplant centers maintain independent ethics committees to review such cases.

**Keywords.** Beneficence, Organ Donation, Organ Transplant, Rationing, Transplant Criteria, Ethics Committees, Hospital Charges, Moral Obligations, Hepatopulmonary Syndrome

### The Case

A young man from a large, tightly knit family (for purposes of confidentiality, referred to as "Alec") had been a pediatric patient at a distant transplant center, over 200 miles away and close to the state line. He had been diagnosed with icterus (jaundice), severe pruritis (itching and irritation) caused by bile deposits in the skin, and dyspnea (difficulty breathing) on exertion. However, Alec's family and the center had agreed that the distance between his

home and the facility made it impossible to complete his evaluation at that time. When he was 18 years old, he was referred to this center for transplant consideration with a history including rectal bleeding, low levels of oxygen in the blood (hypoxemia) from hepatopulmonary syndrome (HPS), splenic infarct, and esophageal varices, which are enlarged veins occurring due to blocked blood flow to the liver. HPS is a common complication of liver disease, resolved through liver transplantation.

Alec's Model End Stage Liver Disease (MELD) score, the calculation applied to patients aged 12 and older to evaluate their risk of mortality from end-stage liver disease, was 17 on a scale from 6 to 40, indicating possible eligibility; however, his oxygen levels were below our transplant center's acceptable threshold for HPS. Despite this he was accepted by the medical review board, which is not an established ethics committee, and subsequently received a transplant.

Unfortunately, Alec's hypoxemia could not be corrected, complicating his postoperative course and leading to renal insufficiency requiring dialysis, hepatic artery stenosis, and massive hepatic necrosis, which was evident on the first week post-transplant. Alec was then relisted as status 1, indicating a risk of imminent death due to acute liver failure. Retransplantation was carried out nine days later, following a second approval by the medical review board. Extra-corporeal membrane oxygenator (ECMO) was utilized for 28 days to support heart and lung function. Fungemia and serious infections necessitated temporary withdrawal of immunosuppression, which increased the risk of the new liver being rejected. Alec's parents remained at his bedside during the more than two months he was ventilator-dependent.

Total hospital charges for Alec's care exceeded \$5 million. The largest costs (in millions) were: pharmacy (\$1.5), laboratory (\$1.09), operating room (\$0.53), and ICU/ward (\$0.48). The remaining charges included supplies (\$0.36), radiology (\$0.20), respiratory and physical therapy (\$0.36), hemodialysis (\$0.076), and administrative costs (\$0.12). Including the initial pretransplant period, Alec remained in the ICU for 93 days, and 118 days in the ward. However, he is fully independent and functional over two years post-transplant.

Alec's initial hypoxemia contributed to his complications and the loss of his first transplant. The center accepted substantial risk by providing Alec with the transplant, and his extreme issues throughout his time in the hospital led some staff to question whether they would want to participate in such a complex case again. The cascade of events and resources required prompted the surgical

director and the authors of this study to delve into the ethical aspects of this case, as candidates with similar risks will likely present in the future.

## Ethical Analysis

The first ethical dilemma associated with Alec's case centered upon balancing cost containment with the standard practice of providing individualized, specialized transplant care. The principle-based concept of beneficence does not address resource utilization, yet physicians face increasing institutional pressure to contain costs. Should costs be considered, or at least acknowledged, when the risk of not moving forward is certain death?

The second ethical dilemma focused on the transplant center as microcosm, and its role in the larger environment of public trust. A constellation of questions stemmed from this secondary issue, including whether the transplant center is obligated to uphold its own criteria. Can disregarding established acceptance criteria contribute to the erosion of public trust in the transplant system? Does the fact that transplant centers impose their own criteria indicate inherent malleability? Is altruism enough justification for bending the rules?

This case study will include a review of general aspects of transplantation, commonly discussed financial issues, and the application of beneficence toward the individual versus the good of society as a whole. Following this exploration, we will share our considerations and recommendations.

## Organ donation and transplantation

The national transplant waitlist is not truly a list, but rather a pool of discrete profiles. Each time these data are accessed to identify potential recipients, a new subset of profiles is retrieved in order to maximize the likelihood of a strong match between recipient and donor. Under a contract with the federal government, The United Network for Organ Sharing (UNOS) manages the list with the utilitarian approach of providing the greatest good for the most people possible (Deshpande, Hirose, & Mulligan, 2017) and facilitating impartiality.

Utilitarianism is concerned with consequences, relying on possible outcomes to determine the moral permissibility of an action. This requires identifying major stakeholders and attempting to calculate the benefit versus the burden on each of them from every potential action. Promoting fairness is the motivation for concentrating on benefit to a large group rather than to an individual. However, UNOS also applies the ethical tenet of justice to the allocation system, incorporating medical urgency as a factor in the decision-making process. The principle of justice is upheld in liver transplant evaluation by the influence of MELD scores on list ranking, which ensures that the sickest patient receives the first available organ matching his or her blood type. Honoring justice therefore shifts emphasis from aggregate to individual benefit, and the UNOS Ethics Committee has acknowledged that the utilitarian approach can be “in conflict” with justice (U.S. Department of Health and Human Services, 2015).

Transplant medicine, however, is not practiced in the same manner as the organ allocation system is managed. Less sequential and deeply individualized, the practice of evaluating and approving patients for transplant can flout methodological process. Although there are regulated, nationally imposed cut-offs, UNOS allows individual transplant centers to interpret clinical and social information independently when determining a patient’s appropriateness for transplant. Also, because patients requiring liver transplantation are closely followed by physicians, they must be in close proximity to the transplant center in order to be placed on the waitlist.

### Cost containment versus beneficence

The high-level, multidisciplinary care required for all transplant patients makes cost containment difficult. When transplants are provided to sicker patients, costs increase and the opportunity to realize revenue is diminished. This suggests that fiscally sound behavior compels transplant center staff to focus on building a waitlist of relatively healthier patients. In the early 2000s, however, the organ allocation system adopted the opposite

approach, seeking to provide donated livers to the sickest patients (Axelrod et al., 2005). Alec qualified as the sickest of the sick. His case progressed to the extreme, defying identified goals of transplant medicine: maximizing outcomes while minimizing costs (Evans, 2013). These costs reflected the many risks taken by the clinical team in ensuring Alec’s survival. Abecassis (2006) noted that transplantation is generally viewed as a cost-reducing therapy but affirmed that high-risk cases can result in enormous charges, most of which are not paid by insurers, although Medicare does employ a payment formula for “outlier” cases that incur unusually high costs (U.S. Centers for Medicare & Medicaid Services, 2006). Motivated by the feeling that they could “get Alec through,” the clinical team moved forward without considering costs.

Discussions regarding costs naturally include the concept of rationing—when to withhold treatment, and why—in which the juxtaposition of monetary value and human life can offend some sensibilities, particularly in cases of life and death. Transplant cases are always a matter of life or death at some point, though, and cost is an established factor in the specialty. Scheunemann and White (2011) declared rationing inevitable, noting that physicians “admitted” to the practice of rationing and saw “just allocation . . . as part of physicians’ ethical duties”; “Only 60%” of intensivists reported providing all possible beneficial treatments to patients “without regard to costs” (p. 1625). Waitlist placement is contingent upon the potential recipient’s ability to retain the donated organ as well as his or her financial eligibility, based on a range of factors from the ability to pay for expensive immunosuppressive regimens to access to reliable transportation. These factors are examined during the patient selection process to maximize the gift of a donor organ; such vetting results in resource stewardship in its most elegant sense. But clinician responsibility for stewardship also extends to the transplant center and the hospital in which it is housed. In an essay on the Rule of Rescue—the conviction that all lives in obvious danger must be saved regardless of expense—Haughom (n.d.) noted that the United States achieves better outcomes in emergency

situations than its European counterparts. Alec's eventual recovery, then, is a testament to our country's application of the Rule of Rescue. At the same time, however, adherence to this tenet—considered by many a moral imperative—is recognized as unsustainable. This acknowledgment does not so much raise the question of whether some lives are too expensive to save, but whether it is morally acceptable to practice medicine as though this reality didn't exist.

While transplant physicians and surgeons are removed from the financial segment of the evaluation process, their continued practice depends upon it. In Alec's case, the medical review board upheld their obligation to care for the individual patient but ignored the realities and implications of the cost of that care. This was a reasonable approach, as clinicians are often unaware of fees associated with specific treatment and there is no accurate way to forecast potential costs, particularly in complex cases. On an individual level, overriding transplant criteria and continuing Alec's intensive care after the second surgery upheld beneficence through the effort to bring about a positive good and remove inflicted harm. But when beneficence is considered on a societal level, the correctness of these decisions is not so self-evident. Numerous other patients could have benefited from resources allotted to Alec, and the transplant center faced a strong likelihood of receiving minimal reimbursement or suffering financial loss.

The public has communicated disbelief in physicians' general willingness to control health care costs as well as decreased trust in the physician community (Levey, 2015). In Alec's case, while the dedication of the health care team may have intensified his parents' trust, we cannot know what the public would have thought about a single patient receiving \$5 million worth of care while the topic of rising health care costs remains so controversial. To resolve this dilemma, we distinguished advocating for the individual patient, rather than for the institution, as the higher moral duty. Physicians do have a role in protecting the solvency of the institution, and attentiveness to this is a function of bringing about positive good for society. Commitment to that role, though, cannot eclipse the duty

to uphold beneficence for a single patient. In their discussion of "over-a-lifetime need versus present need," Veatch and Ross posited that younger patients needing transplants could be considered at a greater disadvantage than their elder counterparts because of the shorter time that they have lived (2015, p. 351). In the absence of disease, Alec might accomplish anything. The impossibility of predicting a patient's future, both immediately post-treatment and long-term, becomes a mechanism for rejecting rationing (Scheunemann & White, 2011). Denying a transplant due to potential financial institutional consequences violates beneficence, as the transplant center represents the entity truly at risk. In contrast, the patient receives the greatest benefit: prolonged life. Prioritizing institutional well-being over that of a patient also creates another breach of ethics, presenting a conflict of interest because physicians are reliant upon the hospital for their own income. As the provision of unnecessary care to inflate costs and increase reimbursement is unethical, so is denying care for the purpose of decreasing financial loss. We therefore concluded that while it is appropriate for clinicians to acknowledge the importance of cost containment, it is not ethically appropriate for physicians to withhold treatment because of it.

### The purpose and integrity of criteria

Although Alec did not meet our center's subset of internal criteria, he was approved for transplant. This decision was deontological in nature. Deontology requires the fulfillment of moral duty, defining such duty as informed by reason and intuition rather than by instruction (Scruton, 2001). Kantian deontology characterizes a good act as one that is performed with good intent, and the clinical team's intentions were certainly good. The team perceived that evaluation metrics pitted center against patient, and this assertion buoyed efforts throughout the cascade of events. Yet after Alec's discharge a raft of ethical dilemmas arose, including acknowledgment of the tension between the singular nature of caring for a patient and the reality that each patient/clinician relationship is part of a larger sum (Garbutt & Davies, 2011).

Had Alec not been approved for transplant, the first donor liver might have saved the life of someone who met the transplant center's criteria; the second organ provided to Alec would have then gone to another patient on the waiting list. While organ transplantation does not function according to utilitarianism, the practice is intended to work in concert with those principles. It is not evident, especially in cases like Alec's, that harmony is reached.

A singular aspect of transplant medicine is the mechanism for treatment: other human beings. Graft rejections automatically result in the recipient being placed at the top of the waiting list because such patients are the most fragile; without a second transplant, they will certainly die. Engelschalk et al. (2018) asked whether the sickest patients are indeed the most appropriate recipients, since others may possess a higher prospect of success. Scheunemann and White (2011) explored rationing on the macro- and microlevel, stating that microallocation decisions are made "bedside" (p. 1626). Since transplant medicine already provides an extremely candid process for rationing, might it make sense to perform microallocation in an instance such as Alec's? His successful recovery depended not only on the competency and compassion of the clinical team but also on the selfless donation of deceased persons' organs. The donation and transplantation community relies upon the trifecta of willingness to donate, selection of an appropriate recipient, and the gift of a donated organ not going to waste. In the absence of such trust, reducing the variance between need and supply is impossible ("Organ Donation," 2016). Upon request, many organ recovery organizations provide information to donor families regarding their loved ones' specific gifts; families may learn which organs were responsible for saving lives. They are not necessarily informed of bent rules and whether their loved one's organ failed once transplanted. A foundation of trust in systemic decision-making, and those who work within that system, facilitates organ donation and transplantation. This has been defined as a "trust beyond rational confidence" ("Organ Donation," 2016, p. 2575).

There have been instances of patients and families successfully challenging waitlist ineligibility;

when such challenges are conducted in the public forum, it is not unusual for them to garner support. More than 50,000 Americans signed a petition to ensure that a 3-year-old girl with cognitive impairments received a kidney transplant after a center declined to place her on the waitlist (Stilwel, 2012). More than 370,000 signed another petition to ensure that a 10-year-old girl received a lung transplant after initial denial (Garrity, 2013). The latter case led to formal organ transplant policy changes on the national level, an outcome that demonstrated the waitlist's evolving nature. This sampling of cases demonstrates the public's willingness to allow tweaks and exceptions, but does not necessarily prove that discretionary procedure would be tolerated on a long-term basis. Formal policy changes that take place after intense media attention can contribute to skepticism regarding the system's original fairness, representing a danger to the specialty that depends more than others on the public's support.

There is no requirement for transplant centers to disclose internal criteria. Bramstedt and Young (2006) found disparate approaches to disclosing internal policy online by transplant centers across the United States, noting that some centers may provide specific information through more traditional channels such as mail, face-to-face discussions, or during telephone conversations. As this information may or may not be provided by the center without prompting from patients and their advocates, in the absence of such knowledge patients must rely upon the integrity of the process. Since those on the waitlist are unaware when others are offered or receive an organ, when contacted by the center they are likely to assume that there had not previously been a potential match. Cases such as Alec's challenge the precept of maximizing outcomes, as the decision to approve him for transplant was subjective. Our center follows guidelines developed by the American Association for the Study of Liver Diseases (AASLD), which consist of recommendations by hepatologists, based on conclusive data when available or else expert opinion (American Association for the Study of Liver Diseases, n.d.). The AASLD publishes these guidelines to support evidence-based and appropriate clinical decision-making but



cannot compel transplant centers to follow them. Most determinations at our center are based on internal criteria and are formulated according to the clinical team's confidence in providing optimal care to each waitlisted patient, which can evolve and regress depending on the makeup of the clinical team at a certain point in time.

Opinions differed among the clinical team regarding Alec's eligibility, as transplant center policy is informed by objective, evidence-based data. In Alec's case, these data demonstrated that he was not necessarily going to benefit from transplant. His full recovery does not negate the experience of past patients with similar profiles or the inability of some clinical teams to save such patients, and therefore does not indicate that he was an appropriate recipient. Rather, allowing pliability in criteria demonstrates a questionable application of beneficence, both to Alec and to waitlisted patients in general. Although the team wanted to save his life, they knowingly put Alec in a situation where his status deteriorated almost past the point of the institution's ability to care for him. As his condition worsened, the plausibility of his recovery was not discussed at length; it was the invested resources that prompted thought. However, several team members stated that they found his case so stressful, they no longer wanted to work in this field. This incontrovertibly translates to damage on a larger scale; just as donor organs are a finite resource, so too are clinicians trained in transplantation. We therefore concluded that while the application of deontology is important to transplant medicine, it does not justify risking the public trust, and that bending the rules based on hope limits a center's ability to provide care to other, qualified patients on the waitlist.

## Conclusion

Alec's case typified the conflict in health care between providing benefit to individual patients and to society as a whole. Estimating benefit versus burden results in only that—an estimate. Transplant centers, of course, are not exempt from the need to reconcile sound business and medicine. But the final cost of Alec's care could not have been known

with accuracy at any point, and many interventions and procedures were carried out without clinician awareness of cost. It was the cost of Alec's care that, after the fact, prompted an exploration of ethical issues and aroused uncertainty about the moral permissibility of expending so many resources on one patient.

Although a union between bioethics and economics has yet to evolve, detachment from financial implications is not a viable long-term response. This sensible concern cannot and should not be ethically resolved by clinicians alone, as transplant programs affect numerous people in addition to clinicians and patients. Alec's situation warranted dialogue between clinicians, ethicists, and health policy professionals. We recommended that a community-based group such as this would not be responsible for approving care, but for retrospectively developing case studies and crafting analyses. In cases like Alec's, such output would reinforce the institutional obligation to monitor and manage costs for the good of society and perhaps bolster meaningful health care finance reform. For example, in cases where continued treatment is provided with no reasonable hope of benefit, discussions about futility occur. Alec's care, though, was never deemed futile. The team did not have access to a framework for thought such as exists for end-of-life issues, and so were at a disadvantage when trying to reconcile decision-making, patient preferences, and public perceptions in the face of such a difficult case. In addition, contributions on the topic of extraordinary costs could lead to a deeper understanding of society's tolerance regarding financial commitment to individual cases, and perhaps provide a basis for openly accepting or rejecting rationing. Finally, implementation of such a committee could address the growing problems associated with the pressure on clinicians to be cognizant of resource management without requiring them to participate in formal discussions about payment models and financial constraints.

Furthermore, we endorsed a commitment on the part of transplant centers to increasing transparency regarding the patient selection process, including but not limited to incorporating explanations of

philosophical approaches in public and professional education programs. The level of public understanding of the selection process is unclear, and numerous avenues exist for such edification, including social media and continuing education courses. Blendon, Benson, and Hero found that out of 29 industrialized nations, the United States tied for 24th place “in terms of the proportion of adults who agree with the statement, ‘All things considered, doctors in [your country] can be trusted’” (2014, p. 1570). They further posited that in order for physicians to distinguish themselves as leaders capable of shaping health care policy, the public must have abundant confidence in them. The intense need for organ donors and continually growing waitlist cannot be further compromised by damaged trust. We must never forget that Alec’s life-saving liver was only available because someone said “yes” to donation. Therefore, we recommend that the same group tasked with developing case studies on costs should also document dilemmas such as Alec’s situation, with the intention of creating a repository for use by all clinicians within the transplant center and its surrounding community.

Alec’s recovery is witness to both the assiduous dedication of the transplant center staff and, ultimately, an individual organ donation and transplantation success story. But there are many untold stories, replete with staff layoffs, hospital closures, persistent myths about organ donation and transplantation, and patients who die while waiting for an organ. Malleability of criteria cannot be accepted practice, particularly when applied in a vacuum; our transplant center experienced clinician duress due to the prolonged and complex care that Alec required, and consensus was reached that the HPS criteria must be applied in the future. Transplantation not only requires financial and human resources, but also a uniquely personal donation from the public. Alec’s outcome cannot be everyone’s outcome, and his situation underscores the obligation to apply judicious principles when placing patients on the waitlist. It is not unrealistic to anticipate that a similar case will present itself to either our institution or another transplant center. Duties to the patient and to the transplant system

itself demand a variety of perspectives and talents to provide support to clinicians and contribute to the literature regarding such dilemmas.

## Reflection Questions

1. The authors mention rationing and affirm the tenet that it is unethical to withhold care because of exorbitant costs. What are the ethical implications of this practice, given that the United States has acknowledged the current system as unsustainable? Would you defend providing heroic, expensive care to every patient, regardless of the effect such behavior would have on the future of health care?
2. The authors noted the difference between the allocation of organs and patient selection. A number of ethical principles are applied to donation and transplantation, and they often contradict each other. Is it possible to reconcile utilitarianism and deontology? What other principles collided in this case, and how could these conflicts have been avoided?
3. A recent study in *JAMA* found that “prices of labor and goods, including pharmaceuticals and devices, and administrative costs appeared to be the main drivers” of high health care costs in the United States (Papanicolaos, Woskie, & Jha, 2018, p. 1024). Growing attention is being paid to the income of nonclinical health care professionals, and Commins (2018) noted that compensation for nonclinician chief executive officers in over 20 US health systems almost doubled between 2005 and 2015. How much of an issue is compensation for nonclinicians, given the rising amount of health care spending in the country? Would adjustments to administrative costs necessarily result in more money being spent on patient care?

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