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## SECOND THOUGHTS

### Ethical Considerations of Transplantation and Living Donation for Patients with Alcoholic Liver Diseases

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Given organ shortages and social and cultural concerns about alcohol use, transplantation for patients with alcoholic liver disease (ALD) remains controversial. Ethical concerns pertain to equity and utility in the allocation of scarce resources and [social stigmatization](#) of patients with a disease that is thought to be self-inflicted [1-5]. Moreover, patients with ALD have been subjected to additional protocols in [the evaluation for transplant candidacy](#) that are unique to ALD and can influence one's waitlist status for liver transplantation (LT).

#### Background

In 2010, alcohol-related cirrhosis was responsible for 493,000 deaths worldwide (1 percent of all deaths) [6]. In the US, ALD is the second most common indication for LT, behind chronic hepatitis C infection [6, 7]. Before the National Institute of Health Consensus Conference on Liver Transplantation in 1983, LT was rarely performed in patients with ALD [8]. After multiple studies found that patients with ALD undergoing LT had favorable outcomes and low relapse rates [9, 10], transplant centers began performing LT on patients with ALD, but not without imposing conditions on recipients. These strong recommendations include a six-month abstinence rule, enrollment in a structured program to prevent alcohol relapse, and ensuring good psychosocial support prior to and after transplant [11].

In 1991, based on studies demonstrating benefits of transplant in ALD patients, the Health Care Financing Administration (now the Centers for Medicare and Medicaid Services) identified ALD as one of the seven conditions for which it approved payment for LT [12]. Despite the controversy surrounding donation of organs to patients with perceived self-inflicted injury or illness and the concern about relapse of alcoholism, public opinion has gradually become less negative and more favorable towards LT for ALD patients [13]. This shift in public opinion might have contributed to an increase in the number of these transplants performed, with 1,088 LT transplants for ALD in 2013, compared to 901 in 2003 [14].

Many who oppose LT for ALD argue that graft survival rates—i.e., rates of the transplant functioning well enough to preclude the need for another organ—are lower in ALD

patients than in patients with other liver diseases and attribute that to relapses of alcoholism [15]. Yet studies have shown that, for ALD patients overall, the five-year graft survival rate is 72 percent with a five-year relapse rate of 20–50 percent [16, 17], which is comparable to the five-year average graft survival rate (59 percent) for all LT recipients [18]. However, the most up-to-date deceased and living donor graft survival rate data, from 2007, show that graft survival for ALD patients at five years posttransplant is lower than that for patients with cholestatic disease, but higher than for patients with hepatitis C and other diseases [19]. Despite the increase in LT for patients with ALD over the past decades, they still experience a large unmet need for LT. As of November 2015, 64 percent of patients with ALD were on the waitlist for LT more than 1 year, compared to 52 percent of patients with nonalcoholic fatty liver disease, and many were dying of comorbidities secondary to their liver disease as they waited [20].

This paper delineates some of the ethical concerns that commonly arise when transplant professionals evaluate patients with ALD for LT and highlights how sociocultural values and assumptions inform those professionals' considerations.

### **Sociocultural Values and Assumptions**

*Stigma and personal responsibility for health.* Transplantation for patients with ALD has generated widespread debate among the general public, health care professionals, patients, living donors, and family members [4]. A commonly expressed concern pertains to a patient's personal responsibility for his or her own health [5]. Specifically, opponents argue that, in ALD, liver damage is self-induced—alcoholism leading to end-stage liver disease was due to a patient's voluntary actions—and, accordingly, providing a deceased donor LT to patients with ALD means taking a scarce resource away from patients who are purportedly "more deserving." As one ethicist posits, "what justifies giving them lower priority for a liver transplant is that they are not only causally but also morally responsible for liver failure" [21].

This kind of advocacy of personal responsibility for health [22] relies on a punitive conception of "giving people what they deserve." By focusing on personal responsibility for health among alcoholics, transplant clinicians and ethicists subject patients with ALD to a different level of scrutiny than other patients with liver disease, utilizing dissimilar definitions of justice in granting access to the waitlist. It appears that this viewpoint espouses a notion of justice for patients with ALD that means maximizing graft survival by imposing abstinence periods intended to reduce recidivism, while justice for all other liver patients means helping patients who have the greatest medical need, as assessed by their MELD score. In delaying access to transplantation among patients with ALD regardless of their medical need, transplant clinicians and ethicists allow the MELD score to become overshadowed by the patient's personal behavior. This inequality expresses condemnation of alcohol consumption and a belief that engaging in socially disparaged behavior makes one less deserving of treatment.

Equity in access to transplantation is an ethical requirement [3]. Using different definitions of justice for, or standards of evaluating, the same patient population (liver patients) is unethical. Treating all liver patients the same way would eliminate the possibility that some patients gain quicker access to transplantation than others because of a trait, such as demographics, experiences, or behaviors. A commitment to equity demands that “the only reason to give alcoholic patients lower priority for transplantation is if subgroups of alcoholics can be shown to have unacceptably poor transplant prognoses” [23].

The ideology of personal responsibility for health is used to argue that LT would be better suited to patients with diseases that are not behavior-associated, such as primary biliary cirrhosis and primary sclerosing cholangitis. Yet many diseases for which LT is readily recommended could also be considered self-inflicted. For example, one could argue that patients with diseases such as nonalcoholic steatohepatitis (NASH) chose to consume excess calories, which leads to metabolic syndrome and NASH cirrhosis. However, less controversy surrounds access of patients with NASH to transplant. Moreover, mounting evidence of a genetic basis for alcoholism [22, 24] suggests that a belief in absolute personal responsibility for ALD might be unfounded.

As a disease, alcoholism requires careful medical treatment, as does any other disease. Clinicians’ focusing on disease causality in treatment decisions violates the principle of beneficence; clinicians have a duty to treat all patients regardless of the cause of the health problem. Decisions not to provide LT based on the presumption that *all* LT recipients with ALD will fare worse than those without ALD unfairly discriminate against ALD patients, as occurred in a study using hypothetical descriptions of kidney transplant candidates [25]. Clinician decision making based on predicting patients’ behaviors undermines patient autonomy by failing to respect particular patients’ individuality and expressions of free choice.

*Public opinion.* Public opinion polls have traditionally reported negative support for LT for patients with ALD. According to a 1991 public opinion survey in Oregon, citizens prioritized LT for nonalcoholics over patients with alcoholism [26]. Studies in the UK (1998) and in Hong Kong (2006) similarly found that public support for LT was higher for naturally occurring diseases rather than for behavior-associated liver diseases such as ALD [26-29].

The transplant community is also concerned that people will be less willing to donate if organs are allocated to patients with ALD or others perceived as “undeserving.” The perception that the public was reluctant to donate is supported by the paucity of LTs for ALD in the 1980s and early 1990s [12]. On the other hand, a recent survey of 503 participants reported that the majority were “at least neutral” (81.5 percent) toward early transplantation for patients with ALD [13]. Thus, public opinion appears to be

shifting toward lending greater support for treatment to all people, regardless of their historically stigmatized disease. Further research should investigate whether and when knowledge of transplantation in patients with ALD impacts people's decisions to donate.

### **The Questionable Value of Abstinence Plans**

Transplant centers have traditionally adhered to a 1997 guideline established in the Consensus Conference on Liver Transplantation, recommending that patients with ALD undergoing evaluation for LT must abstain from alcohol for at least six-months before being waitlisted [30]. The abstinence period is presumed to enable patients to resolve their addictions and reduce the likelihood of relapse and subsequent graft failure. Among patients with recent alcohol consumption or acute alcoholic hepatitis, the abstinence period might enable spontaneous recovery and obviate the need for LT, as well as reduce the risk of alcohol relapse if LT remains unnecessary. Evidence supporting the six-month abstinence period is poor, however; the introduction of the abstinence period emerged from three poorly controlled studies [31-33], and subsequent data failed to show that it affects survival after LT [34]. One study reports that the length of sobriety from alcohol is an insufficient predictor of relapse risk in most patients, and that the optimal abstinence period remains unclear [35]. Moreover, the definition of relapse is inconsistent across studies, ranging from occasional drinking to regressing to alcoholic states [30].

The six-month abstinence rule is also ethically suspect for faster and life-threatening alcohol-induced liver diseases, such as alcoholic hepatitis [30]. The treatment of severe alcoholic hepatitis (defined as a Maddrey's discriminant function of more than 32) will entail initiation of steroids in the absence of signs or symptoms of infection. If patients do not respond to steroids, mortality rates at 28 days are exceedingly high, 40-50 percent, and there are limited medical therapeutic options [36]. Given these high mortality rates, early LT for patients with alcoholic hepatitis is a medically promising option. In a study of steroid nonresponders with severe alcoholic hepatitis, the six-month survival rate was 77 percent with early LT and only 23 percent without LT [37]. In the 26 LT recipients, zero relapses occurred within the first six months, and three relapses occurred more than two years after transplant. No patients suffered from graft failure.

Although insurance companies mandate a six-month period of pretransplant abstinence, few transplant programs require LT recipients to attend substance abuse programs. A study of substance abuse treatment found, however, that relapse rates did not differ among 118 recipients who did or did not receive substance abuse treatment before LT [38]. On the other hand, LT recipients who received substance abuse treatment before *and after* LT had significantly lower relapse rates (16 percent) than those who received no substance abuse treatment (41 percent) or substance treatment only before LT (45

percent). Accordingly, substance abuse treatment after transplant appears to be more clinically beneficial than pre-LT treatment.

In addition to failing to uphold the principle of beneficence, imposing the abstinence period can contradict the principle of nonmaleficence because the ancillary time patients are required to wait before being listed for an LT can exacerbate their disease and thereby cause harm. Moreover, the utilization of the abstinence period discriminates against a patient group based on a class of diseases [30], which violates conceptions of health care justice. Thus, we should provide, but not limit, waitlist access because substance abuse treatment prior to LT and maintained afterward can help prevent relapse. Without solid evidence to support the use of abstinence periods, many support its elimination [30, 39].

### **Live Donor Liver Transplantation**

Many of the aforementioned ethical concerns can be mitigated by considering the option of adult-to-adult living donor liver transplantation (ALDLT), a form of directed donation from one adult to another, for patients with ALD. ALDLT overcomes the commonly held reservation that patients would take a deceased donor organ from another on the waitlist. Indeed, ALDLT upholds ethical values: it supports equity in patients' access to LT (justice), might improve recipient outcomes (beneficence), and increases the number of organs available for LT, a strategic priority of the OPTN/UNOS.

However, ALDLT raises additional ethical issues [40]. Live liver donors undergo considerable risks to themselves, including a 40 percent chance of a medical complication (e.g., infection, hernia, death) or a psychological complication (e.g., anxiety, feeling inadequately prepared for postoperative pain, suicide) [41, 42], but receive no direct medical benefit to themselves [43]. Potential donors must make a decision about donation with little long-term donor outcomes data [41]. These circumstances differ substantially from those of potential living kidney donors, who face a 3 to 6 percent chance of a major perioperative complication [44] and a 0.03 percent chance of death [45] and have comparatively more information about donors' long-term outcomes, as living kidney donation has been performed for more than 60 years [46]. Furthermore, when the potential LT recipient has alcoholic hepatitis, there is limited time to treat, and potential live liver donors might feel pressured to avoid regret or other consequences of refusing. A core element of informed consent is that individuals make treatment decisions voluntarily, without undue pressure on their decision making. However, some potential living donors feel that they have no choice but to donate in order to save the life of their loved one or fulfill culturally valued family obligations [42].

Besides time constraints, the informed consent process itself remains questionable [42, 47] because many potential live liver donors have little understanding of the transplant candidate's liver disease and therefore the likelihood of benefits to recipients gained

from the transplant and of donors' risks. A living person's decision to donate differs ethically from the allocation of deceased-donor organs; one thing that deserves particular attention is the likelihood of risks and benefits to the donor. Accordingly, informing potential live liver donors about the patient's diagnosis of alcoholic cirrhosis, the date of his or her last drink, and the posttransplant substance abuse treatment plan might help them evaluate the likelihood of benefits of LT to the recipient. Greater information might better enable potential live liver donors to weigh whether the risks and potential benefits to recipients of transplantation are worth undertaking in relation to the risks and potential benefits to themselves. In sum, although it might be unjust for transplant centers to consider how a person's liver became diseased in transplant candidacy and allocation decisions, potential living donors should still be told about the candidate's condition to make an informed donation decision.

In sum, despite that we've argued that it's unjust to consider how a person's liver became diseased in allocation and donation decisions and despite that we've clarified that the relationship between abstinence and relapse rates are dubious, we still acknowledge that living persons deserve something that dead donors don't: opportunities to consider what we might call a kind of the "return" on her or his altruistic "investment" in a recipient.

While ALDLT can be justified on the basis of respect for the donor's autonomy and presumed psychological benefit, it is unclear whether these risks should be undertaken in a given case. Regardless of the cause of the patient's liver disease, transplant centers must still determine whether live liver donors should be allowed to undertake the risks of donation. Studies document that individual patients, donors, and transplant centers tolerate different levels of donor risk [48, 49]. Unlike living kidney donation, ALDLT is relatively new (it has been performed in the US since 1998) [50], and relatively few transplant centers perform it because gaining the necessary surgical experience to reach acceptable donor and recipient outcomes requires a large patient volume. Because live donor complication rates remain high [41], the transplant field has not reached consensus about the appropriateness of ALDLT.

### **Conclusion**

As stewards of transplantable organs, transplant centers have a responsibility to ensure that potential recipients are evaluated carefully without the influence of stigma, and that organs are provided to eligible patients. LT for patients with ALD has traditionally been called into question given social and cultural norms and attitudes about personal responsibility for health. Transplant teams should be mindful of assumptions potentially informing their patient evaluations. Decisions about ALD should be based on the most up-to-date empirical data. Given recent evidence calling into question the value of abstinence periods and public opinion increasingly supporting LT for ALD [13], transplant

centers should consider revising protocols to reflect more equitable and beneficial practices for evaluating this patient population for LT.

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