

**Liver Allocation to Non-Citizen Non-Residents:
An Ethical Framework for a Last-In-Line Approach**

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Abbreviations

DDL - Deceased Donor Livers

DDLT - Deceased Donor Liver Transplant/ation

MELD - Model for End-Stage Liver Disease

NCNR - Non-Citizen Non-Resident

NCNRtx - Non-Citizen Non-Resident here solely for purposes of transplantation

NRA - Non-Resident Alien

NOTA - National Organ Transplant Act of 1984

OPTN - Organ Procurement and Transplantation Network

UNOS - United Network for Organ Sharing

Abstract

The incidence of Non-Citizen Non-Resident patients coming to the United States specifically for deceased donor liver transplantation raises compelling ethical questions requiring careful consideration. The inclusion of these often financially and/or socially privileged patients in the pool of potential candidates for an absolutely scarce and life-saving liver transplant may exacerbate disparities already existing in deceased donor liver allocation. Additionally, their inclusion on organ transplant waiting lists conflicts with recognized ethical principles of justice and reciprocity. Moreover, preliminary data suggest that public awareness of this practice could discourage organ donation thereby worsening an already profound supply-demand gulf. Finally, United States organ allocation policies and statutes are out of step with recently promulgated international transplant guidelines which prioritize self-sufficiency of organ programs. This article analyzes each of these ethical conflicts within the context of deceased donor liver transplantation and recommends policy changes that align the United States with international practices that discourage this practice.

Introduction

The practice of providing organ transplant services to patients coming to the US solely for deceased donor liver transplantation raises intriguing and consequential ethical questions. Such patients would often otherwise lack access to transplantation services for reasons ranging from the poverty of their home country, to deeply-held cultural or religious beliefs regarding organ donation. The provision of care to these patients conforms to long-established US norms of international medical relief and accommodation of individual ethnic and religious practices. At the same time, the supply of donor organs in the US, particularly deceased donor livers (DDL) is a mere fraction of that required to meet the needs of US residents awaiting transplantation raising ethical questions about the practice.

The Organ Procurement and Transplantation Network (OPTN) has not ignored this troubling dilemma. In March of 2012, OPTN restructured its citizenship data classifications as part of an effort to better understand those patients coming to the US solely for purposes of transplantation (1), hereafter NCNRtx patients. To do this, OPTN created two new citizenship categories: “Non-Citizen Non-Residents, To US Not for Transplantation” and “Non-Citizen Non-Residents, To US for Transplantation” (1).

This reclassification was followed by the September 2012 revision to former OPTN Policy 6.0 (now Policy 17) on International Organ Transplantation. Policy 17 removes the 5% audit-trigger pertaining to organ transplants performed in patients who are neither citizens nor residents of the US (NCNRs) (2). However, it requires transplant centers to report deceased-donor transplants performed in NCNRs, including NCNRtx patients (1, 2). Although the data are scant, owing to the recent implementation of the policy revisions, the past two years (along with

examinations of the broader data regarding the prior classification of non resident alien patients) have revealed a small, generally socioeconomically advantaged group of individuals traveling to the US solely to obtain organ transplantation (3, 4, 5).

This paper reexamines existing US transplantation policies and law pertaining specifically to the allocation of deceased donor liver transplantation (DDLT) to NCNRtx patients and identifies conflicts with both accepted ethical principles as well as recent international recommendations. The authors limit this discussion primarily to DDLT for three reasons: (1) among NCNR patients who received deceased donor transplantation in the US between 2013 and 2014 (the first two years after the policy revisions), a significantly higher number were here for the sole purpose of obtaining a transplant (6); (2) a higher number and percentage of NCNRtx patients are waiting for DDLT than for other organs (7); and (3) at nearly 20% (8), the 2013 wait-list mortality rate for DDLT candidates is the second highest of any organ wait-listed (9). DDLT, therefore, presents a picture of absolute scarcity of available deceased donor livers such that patients die waiting for organs. Accordingly, while similarities undoubtedly exist across other organ transplant scenarios, an examination of NCNRtx patients seeking DDLT is particularly important.

In this paper, we argue for a last-in-line allocation of DDLT to NCNRtx patients premised on three important considerations. First, the inclusion of NCNRtx patients in the pool of DDLT recipients may augment existing disparities within the US organ transplantation system. Second, ethical principles of reciprocity and justice are not adequately served by current policies and practices. Third, practical considerations, including the potential consequences to the public's willingness to donate organs if it becomes aware of NCNRtx patients receiving life-saving

organs first, weigh against NCNRtx inclusion into the general recipient pool. We will discuss each of these considerations in turn.

Ethical Concerns Arising Out of Inclusion of NCNRs in Deceased Donor Liver Transplantations

Exacerbation of Existing Disparities

As of the end of May 2015, more than 15,000 individuals were waiting for liver transplants in the US (10). Approximately 200-400 individuals obtain living donor livers each year (11). The remaining, an average of over 6000 per year over the past ten years, require DDLT (11). Since 2006, there has been an overall gradual and consistent decrease in the rate of liver transplants performed (12). OPTN attributes this to a worsening donor shortage (12), reflected at least in part by waiting times for adults, which have increased from an average of 12.9 months in 2009 to 18.5 months in 2012 (12).

Despite the apparent and profound shortage, a small number of DDLs are allocated each year to NCNRtx patients. Such patients do not obtain these livers in secret or by illegal means. In fact, many see OPTN Policy 17 as an attempt to increase transparency in the allocation of organs to NCNR patients. Moreover, existing US transplant policy and, arguably, Section 371 of the National Organ Transplant Act of 1984 (which specifies that medical criteria serve as the basis for organ allocation) (13), require that NCNRtx patients be allocated donor organs according to the same criteria as US residents. However, NCNRtx patients appear more easily able to leverage the unintentional inequities in the allocation infrastructure.

Specifically, an unfortunate reality of the US liver allocation system, and one which OPTN and transplant advocates have consistently attempted to remedy, is that patients with

means appear to have increased access to available donor livers. For example, a recent examination of the interplay between geography and socioeconomic disparity in the context of DDLT indicates that patients with financial means experience shorter waiting times and higher transplant rates likely secondary to the ability to Region-shop and travel (3, 5, 14). After controlling for Medicaid status, patients who received transplants in Regions other than their home Region, had significantly higher median incomes than those who died on the wait list (14). Most striking was a direct correlation between income and mortality, with patients having median incomes below \$60,244 more likely to die on the wait list than those with incomes greater than that amount (14).

Accordingly, NCNRtx patients enter a system of liver allocation that, albeit unintentionally, already favors patients with financial means. Further, as noted both in the literature and anecdotally within the transplant community, a portion of the formerly identified NRA transplant population are “highly affluent foreign nationals seeking top of the line care without economic barriers” (3, 4). This is borne out by the sheer number of NRA patients who are self-pay: 38% compared to less than 1% of US citizens (3, 5).

Additionally, not being confined by insurance network distinctions, NCNRtx patients engage in Region-shopping, predominantly traveling to a small, strategic number of transplant centers for transplantation (7). These patients either list in UNOS Regions with low list-to-transplant wait times or list in multiple UNOS Regions, then travel to that Region with the first available liver (5, 7). When combined with their relatively low list-to-transplant wait times (3, 5), low MELD scores (5), and likelihood of receiving exception points (3), it is apparent NCNRtx patients are able to benefit from unintentional existing inequities in the distribution of DDLT.

Aggregate numbers of patients transplanted still favor US residents by a large margin. Still, the possibility that NCNRtx patients receive organs while corresponding US residents die raises significant ethical questions that deserve further careful reflection.

Justice

Justice is demonstrated through avoidance of the allocative inequity and unfairness that can result from factors outside the patient's direct control. Historically, the algorithm used to allocate livers led to serious disparities in wait times and consequently, mortality for reasons that were largely coincidental to where the patient happened to reside. Attempts to ameliorate such inequities were most recently made through the OPTN implementation of the Share-35 policy in 2013. This policy was promulgated with the intent of narrowing the disparity in MELD scores at time of transplantation among Regions (15). Under this new allocation system, DDLs are offered first Regionally to individuals with a MELD score greater than 35, regardless of that patient's local service area, and are only offered locally if there is no Regional match whose MELD score is greater than 35 (15). While Share-35 addresses part of the discrepancy between Regional outcomes, it fails to address the pattern of multi-listing or Region-shopping noted above that favors NCNRtx patients and others who are able to make use of this strategy.

A more equitable approach to DDLT allocation—one which would indirectly discourage the donation of organs to NCNRtx patients—would be adoption of a Survival Benefit-Based Liver Allocation system such as that outlined by Keller, et al. in a recent paper. Under this approach, beyond MELD scoring, patients would be assessed for such things as quality-adjusted life years and age (with higher quality organs going to younger wait-list candidates) (16).

Implicit in Keller's proposal is an examination of which DDL match will maximize the use of the donor liver. While Keller does not advocate for the adoption of "organ stewardship"

as a criteria for receipt of donor livers, his model sets the stage for such considerations by including ethical criteria in the analysis of liver allocation. Further, the authors suggest that the anticipated life of the liver should be factored into allocation determinations and specifically advocate for incorporation of post-transplant outcomes as a part of allocation determinations (16).

At present, OPTN does not maintain data on the individual countries from which NCNRtx patients originate. Nevertheless, it can be surmised that a sizable portion of these individuals come from countries where there is notably inferior domestic transplant infrastructure (5), such as Saudi Arabia, Egypt (17), and Japan (18). Assuming this to be accurate, it would be permissible under a Survival Benefit-Based Model to include considerations of the patient's ability to adhere to accepted post-transplant care and treatment once they have returned to their home country. This would include having access to appropriate medications and medical supervision, as well as physicians available to address post-operative or later complications (e.g. rejection, infection) that may arise after the individual has left the US.

To our knowledge, transplant programs currently have no systematic approach to assessing post-transplant supervisory capacity or long-term outcomes for NCNRtx patients. Where capacity for appropriate organ stewardship cannot be established, such patients should not be placed on the UNOS wait list, since their post-transplant outcomes can neither be surveilled nor assured. This concern was echoed in the 2013 OPTN/UNOS International Relations Committee Report during which several committee members commented that assisting countries in developing their own domestic transplant programs is the "most compassionate way" to address NCNRtx patients in light of the fact they may not have adequate post-transplant care in their country of origin (1).

It is worth reflecting on whether justice is actually served by refusing transplants to patients of wealthy countries such as Japan whose cultural norms are in conflict with organ donation. The Japanese opposition to organ donation stems from centuries old customs and practices that are incompatible with the comparatively new concept of “brain death” (18). Notably, Japanese funeral and “deathbed” customs cannot be adequately preserved if organs are procured from the body, irrespective of a declaration of brain death (18). For people who reside in such countries, whether they share the prevailing beliefs or not, they must look to other countries for access to transplantation.

Conversely, an injustice also occurs when the inclusion of NCNRtx patients as transplant candidates in the US dis-incentivizes the governments of foreign countries from establishing self-sustaining organ donation programs. Moreover, those who may have the most influence and power, who are the most enfranchised, may opt out of activism in their countries of origin in favor of obtaining a transplant abroad. Indeed, it was the result of “external pressures” (namely the recommendations put forth in the Declaration of Istanbul and by the World Health Organization) that led Japan to recognize brain death as legal death and revise existing law to permit organ donation by decedents who had not previously opted out and whose family’s consented to the donation (18).

For the individuals of countries such as Japan or Egypt, who do not have the resources to travel to a country with advanced transplant infrastructure, there is no chance at all of obtaining a life-saving organ. Their only opportunity for access to organ transplantation will result from “external pressures” placed on their governments by the larger international transplant community.

Reciprocity, Investment, and Participation

Reciprocity in the context of DDLT suggests that an ethical allocation of livers would reflect the proportionate participation of the individual patient in the overall transplant infrastructure. For US residents, this translates most obviously to an assumed investment and participation in the donor pool, tax base, or larger organ transplant infrastructure, something arguably lacking from NCNRtx patients.

Admittedly, the question of whether donor registration should determine one's ability to subsequently receive a donated organ presents conflicts for US residents as many US residents are not registered organ donors themselves (19). But the act of registering as a donor is not the only way US residents become organ donors and therefore should not be considered the only indicator of reciprocity among US residents. For example, the US allows the agent of a decedent to donate the organs of their deceased loved one so long as that decedent has not taken steps to expressly prohibit the use of their organs (20). Further, individuals who wish to become donors and have not registered to do so may indicate their desire to be donors in a will or by making certain verbal or written statements before witnesses (20). Although the US does not employ an opt-out framework, affirmative registration as a donor is a facilitator of organ donation, not a prerequisite and therefore, should not be unduly emphasized in evaluating the public's participation in organ donation.

As a final matter, even those individuals who would oppose donation of their own organs indirectly support the US transplant infrastructure through taxes that fund Medicaid and Medicare and/or participation in insurance risk-pools that then provide coverage for others who receive organ transplantation. While paying of taxes certainly does not always translate to feelings of good will towards government programs, it is nevertheless participation in the system on which such an individual may one day draw.

Notwithstanding the indirect participation by US residents, more aggressive measures premised on reciprocity principles have been successfully implemented in other countries. Among such countries is Israel, which instituted policies in 2012 that prioritized registered organ donors ahead of those who had not registered in the event that individual subsequently required an organ transplant (21, 22). These reforms have resulted in a significant increase in donor registrations (22, 23). Still, the success of these policies remains unclear as physicians have reported finding it difficult to overcome the wishes of a decedent's family members who object to donation (22). While similar measures could be used to improve donation rates in the US, some disparity between organ supply and demand would certainly still remain and thus not resolve the critical question of how to prioritize NCNRtx patients.

The access given to NCNRtx patients highlights the additional ethical irony existing for unauthorized immigrants. Unauthorized immigrants have long been barred from receiving a number of publicly-funded services, including publicly financed healthcare (i.e. Medicaid) (24). However, these individuals, who comprise 3.3% of deceased donors (7) (proportional to their overall presence in the US population) (25) are an indisputable part of the donor pool. Further, they are active participants in the larger economy both as taxpayers and consumers.

Current US policy and law result in inclusion of a group of DDLT recipients with little to no potential for direct or indirect reciprocal participation in the US transplant infrastructure while excluding a group with actual, demonstrated participation. It is important to carefully consider the extent to which this disparity respects issues of reciprocity and the equitable treatment of all groups.

To address the issue of individual reciprocity, some have argued for a system of organ allocation that embraces transnational reciprocity (4). In one of the exceedingly few in-depth examinations of ethical conflicts implicated by NCNRtx patients, Cohen acknowledges the precise inherent unfairness we have discussed: allowing a group of persons to draw on a system into which they invest only minimally or not at all (4). Cohen suggests this inequity could be recalibrated if the US allowed for a more international approach to organ sharing in which US residents were listed as transplant candidates in those countries from which NCNRtx patients are traveling (4).

Cohen acknowledges his concept is largely theoretical, but it raises interesting questions of what should count as “reciprocity” and whether true reciprocity is even possible. Taking Cohen’s suggestion of an international transplant reciprocity, while advancements in transplant technology have extended the life of DDLs, as a matter of practical implementation, we are unlikely to create such an international transplantation network (26). Transplant medicine is not yet at a stage where DDLs could make a trans-Atlantic journey without significant risk to the viability of the organ, and therefore to the overall success of the transplant. Rather, the possibility that organs could be shared nationally throughout the US is just beginning to be explored (14, 26).

More compelling is the potential for reciprocity with those very small, poor countries that rely on the US to provide tertiary care. These patients do have at least the potential to serve as organ donors in the US. This would seem to satisfy the reciprocal element missing for many other NCNRtx patients. Unfortunately, the very thing that brings them to the US for medical care (their own small, impoverished country) may hinder their ability to establish access to ap-

appropriate post-transplant care. If so, they would be unable to adequately satisfy their ethical obligation of organ stewardship. When examined closely, it seems there is no avenue for entirely avoiding the ethical obstacles implicit in allocating an absolutely scarce, life-saving liver to an NCNRtx patient.

A Potential for Donor Deterrence

The most effective way to improve organ transplant rates is to increase the rate of voluntary organ donation. However, the task of encouraging individuals to register as donors or willingly donate the organs of a deceased loved one has proven challenging. Extensive debates have swirled around increasing the incentives to potential donors through wide-ranging possibilities from monetary compensation (27, 28), to analogizing donors to firefighters and police officers (29). Conversely, events which undermine public perceptions of fairness and trust in the transplant system clearly can have a negative impact on willingness to donate (30). This public trust is thus a bedrock on which the entire transplant system rests.

There is very little research on whether the public is aware that NCNRtx patients are included in our organ allocation system or what effect their inclusion would have on the public's willingness to donate organs. In the only survey of which we are aware that attempted to quantify public attitudes about NCNRtx patients, nearly one-third of respondents indicated that people should not be allowed to travel to the US for the express purpose of receiving a transplant (31). An additional 28% of respondents indicated the practice should be limited to several select circumstances such as that no US resident could use the organ (exactly the approach endorsed in this paper) or that the transplant was being performed on a NCNR child (31). Importantly, of those individuals who would be willing to donate their own organs, 33% responded they would

or might be less likely to donate if they knew those organs were available to people coming from other countries (31).

Although it seems unlikely the public is aware that NCNRtx patients regularly receive organs in US transplant programs, knowledge of the practice might have a negative effect on donation rates. Additionally, it is possible that anti-foreigner sentiments, which are relatively common in the US (32), may exacerbate any such effect.

Legal and Policy Considerations

Present OPTN policies regarding care to NCNR patients were drafted to avoid inadvertently wading into political waters and ensure that organs were allocated to the sickest patients. Recent discussions regarding policy revisions and the examination of NCNR patients have cautioned that politics should be put aside when considering this issue with focus instead on presenting data that can be easily catalogued and considered (1). Therefore, OPTN policies and US law are not only blind to questions of citizenship and residency, they expressly prohibit such considerations in making determinations of allocation.

The National Organ Transplant Act of 1984 (NOTA) section 371 (b)(2)(E) states that the Organ Procurement Organizations established pursuant to NOTA's authority shall "have a system to allocate donated organs among transplant centers and patients according to established medical criteria" (13). Additionally, OPTN Policy 5.4.A expressly forbids the consideration of either citizenship or residency status (2). In doing so, the policies and law avoid the political minefields of whether to provide access to unauthorized immigrants and whether certain countries that Americans may view unfavorably should be excluded while other countries are provided continued access. Further, the policies allow individual transplant centers to independently decide whether to accept such patients when deciding whether to list them. In short, the policies

encourage autonomy of transplant centers and fairness to patients in the form of equal allocation criteria for any individual wait-listed.

However, the movement towards international collaboration on transplant policies, the worsening of the organ supply-demand gulf in the US (12), and emerging data regarding the connection between socioeconomic status and access to transplantation suggest the implementation of these policies, particularly within the DDLT scenario, does not always result in fairness and conflicts with international policy. The World Health Organization's Guiding Principles on Human Cell, Tissue & Organ Transplantation makes explicitly clear that excessive fees and financial considerations should have no effect on allocation of organs (33). The Declaration of Istanbul, which has been endorsed in the US by UNOS's Board of Directors (34), prioritizes self-sufficiency and states "treatment of patients from outside the country or jurisdiction is only acceptable if it does not undermine a country's ability to provide transplant services for its own population." (35).

The pattern and practice of socioeconomically advantaged patients traveling to the US or other First World countries to obtain organs is uniformly frowned on by the international transplant community, but is indirectly permitted under US policy and law. It is our position that US policy should be revised to align with international norms, particularly where those norms further clearly stated ethical goals such as establishing "self-sufficiency" of organ programs and discouraging potential for exploitative use of organs for financial gain.

Discussion and Recommendations

We wish to acknowledge several of the most compelling arguments against our position: the view that all human beings deserve equal opportunities for life saving treatments irrespective

of artificial boundaries such as geography (a human rights viewpoint); the position that transplants among NCNRtx patients attract funds that might be used for other purposes within transplant programs, such as innovation and research; education and awareness aimed at increasing the rate of organ donation; or to subsidize un- or underfunded patients. We are compelled by each of these arguments. However, in the context of the US transplant system, where literally thousands of US residents die each year waiting for livers, with no dramatic change in the supply of organs anywhere on the near horizon, we currently cannot provide enough DDLs even for those patients already here, to whom we believe we owe our first obligation.

Consequently, and for the reasons outlined above, it is our position NCNRtx patients on the UNOS liver transplant wait list should be reserved to a last-in-line status whereby they may receive a deceased donor liver only to the extent the liver is not acceptable to a US resident (citizen or not) on the list. It is further our position that NOTA and Rule 5.4.A should be repealed or amended, since they, in connection with the newly promulgated Rule 17, not only allow for, but expressly prescribe that NCNRtx patients be accorded equal treatment with residents in organ allocation. Additional revisions to the existing DDLT system of allocation - including the consideration of survival-benefit criteria and movement towards national organ sharing - should also be implemented.

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Disclosures:

None.

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