AJKD
Perspective

Debating Organ Procurement Policy Without Illusions

Benjamin Hippen, MD

In this perspective, I review and critique claims that the transplant waiting list overstates the demand for kidneys and correct a few mischaracterizations of some structural barriers to increasing rates of transplantation. The solutions to the shortage of organs proffered by opponents of financial incentives fail to account for a panoply of clinical, regulatory, and financial realities of transplantation centers in the United States in ways that undermine the thesis that a trial of financial incentives for organ procurement is not warranted at this time. I conclude with some personal pessimistic reflections on the progress of this debate.
Am J Kidney Dis. 66(4):577-582. © *2015 by the National Kidney Foundation, Inc.*

INDEX WORDS: Kidney transplantation; end-stage renal disease (ESRD); living donors; transplant waiting list; organ procurement; altruistic organ donation; financial incentives; medical ethics.

The authors of a Perspective in last month's issue of *AJKD* argue that a core premise underlying arguments in favor of financial incentives for organ procurement is false, or at any rate, "rarely challenged by market opponents."[1] Specifically, the authors contend that advocates of financial incentives assume there is an extant and growing organ supply/demand disparity unable to be met by the current system of organ procurement, and that these advocates then exploit this (alleged) disparity and system failure to create a sense of urgency among clinicians and policy makers to permit a trial of financial incentives.

Though not referenced, the authors go on to recapitulate many of the arguments and conclusions of the 2006 Institute of Medicine report on the organ shortage, ratifying its conclusion that a trial of financial incentives was not warranted "at this time" (Recommendation 8.1 from[2]). A decade later, and in the face of 20 years of discussion and concerted efforts, a general sense that the transplantation community has not exhausted conventional organ procurement strategies still remains influential, as does the conclusion that a trial of incentives is (still) not justified. In this article, I argue that the authors misinterpret waitlist data, incompletely account for other evidence of "unseen" demand for organs, and fail to account for extant clinical, regulatory, and financial realities that govern dialysis facilities and transplantation centers in ways that undermine their theses. Regardless of whether a trial of financial incentives is morally defensible or even capable of garnering broad moral support, further debates over the shortage of organs and the success of organ procurement strategies should proceed free of illusions and rooted in current clinical, regulatory, and financial realities.

MEASURING DEMAND

The Waiting List—The Seen

The authors worry that the magnitude of need represented by the waiting list may overstate the true demand for organs, highlighting the observation that one-third of the patients added to the waiting list are listed as inactive (hereafter "status 7") within a week of listing. Historically, candidates were listed as status 7 for a variety of reasons, the salient one being that accrued time on the waiting list was the chief means of achieving priority. In regions where median waiting times to transplantation were more than 5 years for some blood groups, a delay in listing until remediable barriers to candidacy were surmounted put candidates at an unjustifiable disadvantage. This use of status 7 listing is just a feature of how transplantation centers strategically coped with the long waiting times associated with the organ shortage.

In support of their thesis, the authors relate results of a few studies that showed that 50% of status 7 candidates became active within 12 months of listing, one-third remained inactive, and 40% of those who died on the inactive list did so within 2 years of listing, implying that these patients were not candidates to begin with. From these data, they conclude that the waiting list "may therefore result in overstatement of the gap between supply and effective demand for kidneys...."[1]

A closer examination of the data indicates otherwise. Approximately 10,500 candidates were listed as status 7 in 2012, of whom 5,250 became active within 12 months of listing and one-third (~3,100) remained inactive.

From Metrolina Nephrology Associates, PA, and The Carolinas Medical Center, Charlotte, NC.

Received March 21, 2015. Accepted in revised form May 1, 2015. Originally published online June 19, 2015.

Address correspondence to Benjamin Hippen, MD, Metrolina Nephrology Associates, PA, and The Carolinas Medical Center, 2711 Randolph Rd, Bldg 400, Charlotte, NC 28207. E-mail: bhippen@metrolinanephrology.com

0272-6386
http://dx.doi.org/10.1053/j.ajkd.2015.05.013

Which is to say that in 2012, a total of 57,903 candidates were listed as active and another 5,250 candidates listed as status 7 became active within 12 months, a total of about 63,000 candidates. From the observation that 3,100 candidates listed as status 7 in the same time frame remained inactive at 24 months and may not have been viable candidates at all, the authors conclude that the demand for transplantable kidneys "may" be overstated, but the data they cite put that overstatement of demand at a mere 5%. In 2008, the same trend was represented in a respected newspaper of record as a 30% overstatement of organ demand, replete with baseless charges of false advertising leveled against the transplantation community by media-favored bioethicists.[3]

However, there is a different reason why the waiting list will become a less reliable surrogate for demand: A key change in the US kidney allocation system[4] implemented in January 2015 will change when patients are listed for a transplant. The salient change involves shifting how candidate waiting time is calculated from the date of listing (old system) to the date of end-stage renal disease (ESRD) on the Centers for Medicare & Medicaid (CMS) 2728 form. This means that a candidate with 5 years of ESRD who is listed will immediately accrue 5 "points," and so on. This change renders obsolete the old use of status 7 to accrue waiting time. Now, status 7 listing only confers an advantage to those listed pre-ESRD, a small proportion of new referrals. In 2011, only 12.4% of all patients received a deceased donor transplant within 1 year of initiating dialysis therapy.[5]

A key component of sound waitlist management is ensuring that listed candidates are evaluated on a regular basis and that screening tests are up to date. With few exceptions (patients who are young or who have high calculated panel-reactive antibody), candidates who come to the list with very little ESRD time are very unlikely to receive an organ offer from a deceased donor until they accrue enough points (read: waiting time) to near the top of the list. Candidates with less ESRD time will be competing on a rolling basis with newly referred candidates with many years of ESRD, who once listed will immediately jump ahead of those with less ESRD time in the queue. From a transplantation center perspective, if a candidate with little ESRD time does not have an available living donor, it is poor stewardship to expend the time and resources to even evaluate and list the candidate. Because candidates with fewer points will not get offers, listing them early in their ESRD course will mean their testing would have to be repeated over multiple years. Instead, rational centers will likely delay evaluation until the candidate identifies a living donor or accrues enough ESRD time to approach the top of the list, ensuring that testing is current and not unnecessarily redundant. Putting off the evaluation of candidates until they accrue sufficient points will contract the size of the active waiting list, which will appear to show an overall reduction in the demand for kidneys. However, in actuality, there is no overall reduction in demand, only the demand that is *seen* as a number on the waiting list, a false and misleading perception that is just an artifact of the current listing process and allocation system. Many otherwise viable transplant candidates whose evaluations are put off, perhaps for years, will simply join the ranks of the unseen.[6]

Prevalent Kidney Disease and the Unseen

Behind the cohort of listed candidates are legions of patients who appear on no lists, and the benefit they might derive from transplantation and the loss they experience by being deprived of transplantation are largely unappreciated. Schold et al[7] estimated that there are between 80,000 and 130,000 additional patients with ESRD who have an "overlapping risk profile" with listed transplant candidates, but who are never referred, a number that could conceivably double the current waiting list for kidneys. Also, the study by Schold et al[7] did not include the potential transplant candidates among the much larger group of those who are projected to develop chronic kidney disease stage 4 or worse in their lifetimes (9%-11% and 16%-18% of the white and African American US population, respectively).[8] Were even a fraction of the patients in these groups added to the list without proportionate growth in the number of available organs, median waiting times for deceased donor kidneys would exceed the expected life span of all but the heartiest of candidates, and with physiologic toll on the survivors. However, being unseen, these patients do not "count"; if they did, the inadequacies of current organ procurement regimens in the United States would be even more conspicuous, and the need for reforms, even more pressing.

As a moral asterisk to the focus on first-world problems, a recent study published in *Lancet* conservatively estimated that in 2010, more than 2.3 million people worldwide who clinically warranted renal replacement therapy did not receive it,[9] which in countries lacking health care resources amounts to a lack of access to transplantation. Even if meaningful solutions to the organ shortage that can garner broad moral support are lacking, perhaps the least we can do is acknowledge the reality of the plight of the seen and the unseen who bear the true costs of inadequate organ procurement strategies.

STRUCTURAL BARRIERS TO TRANSPLANTATION

In their *AJKD* Perspective, the authors list a series of structural barriers facing these unseen patients, but draw unfounded conclusions. Two are worth examining in detail.