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Enhancing the Expanded Criteria Donor Policy as an Intervention to Improve Kidney Allocation: Is It Actually a 'Net-Zero' Model?

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Abstract

In the United States, relatively little progress has been made in recent years to improve the efficiency and effectiveness of deceased donor kidney allocation. Despite enactment of the Expanded Criteria Donor (ECD) Policy in 2002, known inequities and suboptimal utility of donated kidneys persist. In contrast with dialysis patients with shorter predicted life expectancies, those with longer predicted lifetimes can often improve their survival by waiting longer for a Standard Criteria Donor (SCD) kidney. Yet, a substantial fraction of these candidates accept ECD kidneys, often poorly HLA matched. Meanwhile, waitlist mortality continues to rise, particularly among older transplant candidates. Despite required consent processes for candidates to list for ECD kidneys, centers appear to interpret and implement ECD policy differently—some list candidates selectively while others list nearly their entire candidate pool. To ensure more efficient and effective implementation of ECD policy across centers, we advocate for (1) more oversight and guidance in directing patients to the ECD list who stand to benefit the most from receipt of an ECD kidney; and (2) enhanced transparency of center-level ECD consent and listing practices. More uniform implementation of ECD policy could improve efficiency and effectiveness of deceased donor kidney allocation without deleteriously impacting equity.

Keywords

allocation; kidney transplantation; deceased donor kidneys; transplant centers; expanded criteria donors

Despite exhaustive efforts to reform the current system of deceased donor kidney allocation, known inequities and sub-optimal utility of deceased donor kidneys persist (1–5).

Developing a policy which satisfies numerous objective and subjective constraints is an

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extremely daunting task, particularly since the influence of any policy reform will affect patient outcomes for many years. While substantial reform of kidney allocation policy may be necessary, we should also consider the merit of incremental improvements. A primary critique of proposed revisions to kidney allocation policy relates to the concept of a 'net-zero model'. In other words, given limited donor kidneys, any changes that will benefit some patients presumably come at the expense of others. In this viewpoint, we reflect upon the validity of this conventional belief and whether opportunities exist to evolve policy without impacting equity.

In 2002, the concept of expanded criteria donors (ECD) was introduced (6). Among numerous other components, this policy defined a deceased donor kidney at higher risk for graft failure based on donor age and the presence of certain comorbid conditions including reduced kidney function (7). Approximately, 19% of all deceased donor kidneys now originate from ECDs. While not explicitly stated, for many patients an implied benefit of consenting to accept an ECD kidney was the possibility of receiving a transplant sooner. In certain dialysis subgroups, accepting lower quality (i.e. ECD) kidneys may enhance long-term patient survival if coupled with less time on dialysis. For example, among patients waitlisted for kidney transplantation in the United States, annual crude mortality is substantially higher (11–17%) for patients older than 65 compared with those younger than 40 (1–5%) (8).

Subsequent studies, including the sophisticated models incorporating life-years from transplant (LYFT), demonstrated that transplanting SCD kidneys into recipients with limited life expectancy resulted in a significant loss of graft years compared with allocating these kidneys to patients with better predicted long-term survival (9,10). Perhaps the most contentious aspect of an allocation system incorporating LYFT is that the 'net losers' are frequently patients older than 50 who might wait longer, receive lower quality kidneys and die more often on the waiting list (9,11). This 'age bias', along with the imprecision of some variables in calculating LYFT scores, likely contributed to the stalled development of a new LYFT-based allocation policy (11).

Given this apparent stalemate, it is important to consider whether we can improve patient outcomes and use of available kidneys without negatively affecting the survival of transplant candidates with shorter life expectancies. Among the multitude of dynamics to consider in kidney allocation, perhaps the three most influential factors which impact graft and patient survival are recipient age, donor kidney quality and time to receive a transplant (4,12–14). Although many other factors and patient characteristics clearly affect outcomes, some are relatively difficult to codify in a systematic manner (e.g. functional status) while others may be gross indicators of variable health states (e.g. diabetes). There are also important equity considerations that may be difficult to incorporate in an objective manner into any allocation model (e.g. gender, health insurance status or race/ethnicity). Putting aside these additional factors, we consider whether we can make immediate improvements to the current allocation system using these key variables to enhance survival while maintaining equity.

The opportunity to benefit all patients simultaneously through a kidney allocation system may be directly tied to differentiating candidates who have longer (e.g. patients younger

than 40 without diabetes) versus those who have shorter predicted life expectancy (15,16). Restricting considerations to long-term survival (as opposed to quality of life, economics, etc.), patients who have longer predicted life expectancy are often better served by waiting longer on dialysis in order to receive a higher quality (Standard Criteria Donor) kidney (15,17,18). Yet, approximately 10% of recipients younger than 50 accepted an ECD kidney in 2008–09 within 2 years of listing. In addition, more than half of these transplants had 4–6 HLA mismatches, rendering a second transplant (if needed) much less likely due to increased sensitization (19). In contrast, a primary concern for dialysis patients with shorter life expectancies is death on the waiting list (20). Wait list mortality has more than doubled over the past decade and concerns of repeat transplantation are less applicable to many of these patients. Thus, a system in which patients with shorter predicted survival would preferentially receive ECD kidneys (and experience shorter waiting times), while those with longer predicted survival would receive but wait longer for SCD (and perhaps better matched) kidneys would likely benefit all candidates relative to the current system. In fact, this may have been a principal intent of the ECD policy. So what happened?

One of the primary components of the ECD policy included a mandatory consent process for patients to receive an ECD transplant, specifically, ‘The program shall obtain consent from candidates prior to being listed for expanded criteria donor kidney transplantation’ (7). Presumably this policy enhanced transparency of information and promoted patient autonomy and decision-making. However, one early observation regarding policy implementation was that transplant centers (rather than individual patients) interpreted and implemented the policy very differently (21,22). Since 2002, for example, 15% of centers listed the vast majority of their patients (>80%) for an ECD kidney (Figure 1). Meanwhile at other transplant centers, patients were listed more selectively with nearly one-third of centers listing less than 20% of their candidate populations. Not surprisingly, this variable implementation of ECD policy resulted in different outcomes. Patients who were listed for ECDs at more selective centers (i.e. those listing less than 20% of their candidates) were significantly more likely to receive an ECD kidney and receive the transplant earlier after placement on the waiting list compared with those listed at nonselective centers (21,). In contrast, patients who were from centers where the majority of patients were listed for ECDs experienced no change in waiting times. In essence, the ECD policy had no impact on time to transplantation at these ‘nonselective’ centers. A recent study confirmed this center-level ECD practice variability, and in addition, found that patients who were not predicted to benefit but were listed for an ECD kidney experienced worse survival (23). Cumulatively, these results suggest that centers, rather than individual patients, strongly influence ECD listing and that misaligned listings can lead to reduced patient survival and ultimately inefficient kidney allocation.

Given the ramifications and challenges of introducing any new allocation policy, particularly one with so many stakeholders, a viable alternative may be to simply enhance the current ECD policy. Based on prior research and the national experience with the ECD policy to date, we believe that the current allocation policy can be markedly improved. Prior studies suggest that this improvements in allocation efficiency and utility could derive from (a) more selective consenting of candidates with predicted benefit for the ECD list, as illustrated by Merion et al. and Grams et al. and (b) enhanced transparency of center ECD

listing practice (15,23). In other words, more appropriate (selective) listing of patients for ECD kidneys should enhance the benefits of both Standard and Expanded Criteria Donor kidneys by matching donor and patient risks. Furthermore, greater transparency of the ECD policy at the center-level (i.e. what proportions of patients are listed at each center) could enhance patient decision-making, for example whether to list at a particular center and whether to consent for an ECD kidney while preserving patient autonomy.

The important distinction of enhancing current ECD policy as compared to other net-benefit models (such as LYFT) is that all patient groups could ultimately benefit (e.g. patients with shorter predicted lifetimes would receive an ECD kidney more often and earlier while those with longer predicted lifetimes would wait longer for better quality kidneys). Though the overall improvement in graft years may be less than directed allocation of older donors to older candidates (e.g. > 50 year old), improved application of the ECD policy may preserve (or at least not diminish) equity between age groups even with a stable number of available donors. Essentially, we advocate for more effective use of current resources (deceased donor kidneys) through more efficient balancing of the competing risks of donor kidney quality and waiting time based on predicted graft and patient survival. Greater transparency of this information may further guide patients and providers to make more informed decisions, particularly as they consider listing for an ECD kidney. Given that donor risk is much better defined on a continuum (e.g. donor risk profile) rather than dichotomously, further development of such criteria may also enhance decision-making for acceptance of 'higher-risk' SCDs or conversely 'lower-risk' ECDs (14,24). Similarly, a more explicit informed consent process where candidates stipulate an acceptable donor organ risk might also improve the efficiency of ECD listing practice.

So why are candidates not currently listed for the respective type of deceased donor kidney based on predicted benefit? One reason may be poor understanding among patients about the ramifications of consenting for an ECD kidney. Another may relate to incomplete understanding of which criteria to use in selecting patients for ECD listings by providers and how these criteria might change based on the characteristics of patients listed at the respective center. As noted above, substantial data already exists which may inform these decisions, but further work is necessary to better characterize, quantify and refine these concepts. As such, better dissemination and review of center listing practice may be warranted. A caveat to consider is certainly that some patients may 'consent' to receive an ECD kidney based on quality of life, economic or other considerations beyond the predicted survival benefit (25). However, we believe that having access to objective ECD listing data, particularly prior to selecting a specific center could better guide patient decision-making and enhance the efficiency and effectiveness of donor kidneys.

In summary, we believe that more oversight, transparency and guidance are warranted across transplant centers to enhance kidney allocation through the ECD policy. Rather than waiting for further allocation policies to develop, improving the ECD consent process and increasing the transparency of listing information could result in more informed center- and patient-level listing decisions and ultimately improve resource utilization and patient outcomes.

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Abbreviations

ECD	expanded criteria donor
SCD	standard criteria donor
LYFT	life years from transplant

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Figure 1.
Percentage of transplant candidates listed for expanded criteria donors by center (2002–2009).