The UNOS ‘preferential allocation’ concept proposal for the allocation of deceased donor kidney transplants: implications for patients with diabetes

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Introduction

Kidney transplantation is highly cost-effective [1] and remains the preferred treatment for end-stage renal disease (ESRD), a condition affecting over half of a million Americans with annual costs exceeding US $25 billion [2]. Transplantation offers a clear survival advantage for qualifying patients compared to dialysis [3]. Unfortunately, the disparity between supply and demand for transplantable kidneys continues to increase. The current waiting list for a kidney transplant now includes over 93,000 patients [4]. In the Scientific Registry of Transplant Recipients 2009 report, there were 10,101 deceased donor kidney transplants and 5,966 live donor transplants in 2008, leaving an estimated 76,089 patients still waiting for a transplant [5].

Two patient cohorts, those with diabetes and the elderly, disproportionately contribute to the disease burden of ESRD in the USA. Diabetes causes 44% of new cases of ESRD, >200,000 patients are currently on dialysis or living with a kidney transplant as a result of diabetic nephropathy [2]. The proportion of incident elderly dialysis patients who have diabetes also continues to rise. Between 2000 and 2030, the estimated number of people with diabetes in age groups 45–64 and >65 years will likely double [6].

There is substantial evidence to support kidney transplantation for patients with diabetes. The proportion of diabetic recipients has increased >10-fold since 1970 [7] due to improved care of uremic diabetic patients and higher transplant success rates, particularly early graft survival. Curves of graft survival comparing non-diabetic and diabetic recipients begin to diverge only after ~3 years [7]. Most importantly, as Wolfe et al. [3] demonstrated that the long-term mortality for deceased donor transplant recipients was 48–82% lower compared to patients on the waiting list, with young diabetics experiencing even greater benefit than non-diabetics. In summary, kidney transplantation remains the treatment of choice for diabetic patients with ESRD. Nonetheless, evidence indicates that, for patients with diabetes, the likelihood of being listed for transplant as well as for actually receiving one is less than for other individuals [8, 9]. The result is that patients with diabetes are more likely to die before receiving a deceased donor kidney transplant.

The current allocation system for deceased donor kidneys uses a point system determined by waiting time, patient sensitization (anti-HLA antibodies) and tissue matching. Of these factors, the main determinant for allocation is the candidate’s waiting time. In 2011, the Organ Procurement and Transplantation Network proposed a major change to the current 20-year-old kidney allocation policy [10]. The new policy of ‘preferential allocation’ to achieve better survival matching between the donated kidney and its recipient introduces two new metrics to allocation. The first is a kidney donor profile index (KDPI) aimed at identifying the highest quality kidneys [11]. This is coupled with an estimated post-transplant score (EPTS), a measure of a recipient’s predicted life expectancy after transplantation. The EPTS calculation is based on four factors felt to provide a ‘reasonable estimate’ of identifying candidates with the longest post-transplant survival: length of time on dialysis, any prior organ transplant, diabetic status and age. Together, the KDPI and EPTS will be used to match the best 20% of donor kidneys to candidates with the longest expected post-transplantation survival. Afterward, a 30-year age range will be used to allocate the remaining 80% of organs.
Remarkably, the United Network for Organ Sharing (UNOS) kidney allocation document circulated for public input contains little justification for the addition of three new factors to the waiting time, which is used in the current allocation system, acknowledging under ‘supporting evidence’ that ‘data available to estimate post-transplant survival (time on dialysis, candidate age, prior transplant and diabetes status) are limited’ [10].

The Scientific Registry of Transplant Recipients performed simulations to predict changes in transplantation trends with the new proposal. The results show that the proposed system increases the total life span of patients following kidney transplant and total graft years of life. Although there was a slight decrease in the total number of transplants, this was not considered statistically significant. Most notably, UNOS calculations suggest that the life span benefit per transplanted organ would rise from 4.9 to 5.4 years under the new proposal. However, the simulation also demonstrated that diabetic patients would see a sizable decrease in kidney transplantation from 31 to 26% (Figure 1).

**Implications of the policy proposal for diabetics on the transplant list**

According to the most recent data reports from UNOS, there were 16,151 kidney transplants performed in 2010 for patients aged ≥18 years [12]. Three thousand two hundred and ninety-one (20%) of the total transplants were performed for patients with a diagnosis of diabetes. This proportion has been relatively stable over the last decade. The simulation for the newly proposed policy suggests a 16% decrease in kidney transplants for patients with diabetes. This equates to ~600 fewer diabetic patients receiving a kidney transplant each year.

**Discussion**

As noted in their proposal, UNOS aims to ‘better approximate graft longevity and recipient longevity so that the potential survival of every transplanted organ can be realized within biological reason and acceptable levels of access for those on the waiting list’ [10]. The new policy attempts to match the best quality organs (using the KDPI score) to the patients with longest expected post-transplantation life (using the EPTS score); in short, it aims to increase aggregate graft survival. This objective is laudable and the simulations suggest the goal could successfully be met. However, some experts have called into question the inherent validity of the KDPI and EPTS scores in driving organ allocation decisions [13]. Unavoidably, a shift in policy will lead to net gains for certain patient groups and net losses for other patient groups in terms of the number and quality of organs offered. As the simulations indicate, patients with diabetes are among those negatively affected.

UNOS has conceded that the four variables proposed for the EPTS score are not completely predictive. Unfortunately, the committee does not explain in detail the decision to incorporate only these four criteria: age, time on dialysis, prior organ transplantation and diabetes status. According to UNOS, including other calculations such as life years from transplant do not add significant predictive power to the EPTS score and adding other factors would ‘increase the complexity of the system to the point of confusion’ [10].

The advantages of a simplistic model are self-evident. However, by including diabetes in the scoring system, it automatically selects against a group representing a large proportion of possible recipients. If this concept proposal is accepted, patients with diabetes will see a decrease in kidney allocation despite the fact that young diabetics gain the most life years of any group evaluated in the seminal paper of Wolfe [3]. And while diabetes status is a proven determinant of post-transplantation life expectancy, other conditions have also shown to contribute to lower life expectancy. For instance, older age and cardiovascular disease are important comorbid conditions, which contribute to post-transplant survival. Neither is independent of diabetes [14] and cardiovascular disease is the major driver of post-transplant mortality [15]. It is unclear what the specific rationale is for including diabetes but not other disease states such as cardiovascular disease from the EPTS score.

In addition, the proposal does not clearly distinguish between the causes of diabetes, the severity or duration of the condition or the presence of absence of complications from diabetes in determining a patient’s EPTS. One of the specific objectives outlined by UNOS for the revised kidney allocation system is to reduce the transplantation access disparity between populations from certain racial/ethnic minority groups or sensitized candidates. However, little is discussed on how this objective is met by the implementation of the KDPI and EPTS scores. The implications of this proposal on equity for diabetics of different ethnic groups and kidney transplantation are unknown. The simulation results did not demonstrate shifts in kidney transplantation based on race [10]. Some racial/ethnic minorities suffer disproportionately from diabetes [16] and by extension an increased risk for ESRD [17]. Furthermore, access disparities based on race have been established previously for kidney transplantation [18]. This new proposal...
could potentially exacerbate existing racial disparities for those with diabetes.

In summary, UNOS in effect is proposing a concept of deceased donor kidney allocation in which diabetic patients will be offered fewer kidneys. From the information provided, it is difficult to discern whether the new policy disfavors diabetic patients as collateral for favoring the young or as a direct result of the EPTS scoring system. Although this new allocation system may extend the average life per graft, there is no clear explanation for the focus on diabetic status over other conditions for the EPTS score or how to deal with the nuanced degrees of this condition. It is our view that the current ‘preferential allocation’ proposal requires reconsideration. We do not support an overhaul in policy, which crudely lumps all diabetic wait-listed patients together. When compared to those who remain wait-listed on dialysis, patients with diabetic nephropathy derive at least the same projected increase in life-span from renal transplantation as non-diabetics [3]. Evidence suggests that poorer survival outcomes in diabetic recipients may be related more to patients’ age than to the presence or absence of diabetes. Should the new policy be accepted, all physicians caring for patients with diabetes and chronic kidney disease should be vigilant regarding the new proposal for kidney allocation and be aware of the possible reduction in access to deceased donor kidney transplants for their patients.

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References


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