Why do we have the kidney allocation system we have today? A history of the 2014 kidney allocation system

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ABSTRACT

"*Those who do not know the past are destined to repeat it*".

The current system for the allocation of deceased donor kidneys that was implemented in December 2014 (termed the kidney allocation system (KAS)) was the culmination of a decade-long process. Thus, many people involved in transplantation today may not be aware of the underlying concepts and early debates that resulted in KAS. Others who were involved might not remember the details (or have chosen to forget). The goal of this manuscript is to outline the history of the process in order to shed light on why KAS has its current format.

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1. A Brief history of kidney allocation policies

In the early days of kidney allocation when there were few transplant programs, almost all kidneys were used locally and organ allocation policies were decided mostly by the staff of the transplant center. In 1968, the Southeast Organ Procurement Foundation (SEOPF) was formed to share kidneys in the Southeast region of the US [1]. In 1977, SEOPF implemented the first computer-based organ matching system called "United Network for Organ Sharing" (seven years before Steve Jobs introduced the Macintosh 128k). In 1984, UNOS separated from SEOPF. Also in 1984, Congress passed the National Organ Transplant Act which established the Organ Procurement and Transplantation Network (OPTN) [2]. NOTA also established the Task Force on Organ Procurement and Transplantation to regulate how organ donation was managed and allocated (among other things) [3]. In 1986, the Federal contract to operate the OPTN was awarded to UNOS. Under OPTN/UNOS, organ allocation policies became more stan-

dardized and a more national system began to emerge. By 1999, UNOS launched "UNET", a secure internet-based database system to manage organ allocation.

In 2000, the Federal Government issued the "OPTN Final Rule" that outlined policies "for the equitable allocation of deceased donor organs among potential recipients" [4]. The Final Rule became the roadmap for allocation policy and specified that organ allocation: 1) shall be based on sound medical judgment; 2) shall seek to achieve the best use of donated organs; 3) shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient for access to transplantation. Following this, a new liver allocation system was adopted in 2002. A new lung allocation system was also undertaken. Kidney was next.

2. 2004–2007: A comprehensive review and ideas for a new system

In 2004, the Kidney Transplant Committee of OPTN was charged by HRSA and the OPTN Board with developing a new kidney allocation system based on the Final Rule (see Table 1 for timeline). This charge was delivered to the committee at a meeting coincident with the ATC in Boston in the summer of 2004. Our approach

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Table 1
General timeline for the development of the kidney allocation system.

May 2004	OPTN Board requests review of kidney allocation system
2004–5	Kidney Allocation Review Subcommittee (KARS) hold public hearings and meets with other OPTN Committees
2007	Public Forum held in Dallas; main topic LYFT
2008	RFI released: main topics KDPI/LYFT
2009	Public Forum held in St. Louis; main topics KDPI/LYFT/modeling
2009	Donor/recipient age matching concept developed EPTS is considered as alternative, simpler concept compared to LYFT
2011	Concept document released: main topics EPTS/age matching/KDPI
August 2011	HRSA decides that age can be used in EPTS, but age matching is too arbitrary
2012	Revised proposal is developed and sent for public comment, includes sliding point scale for highly-sensitized patients
2013	Board Approves proposal
December 2014	New Allocation System is implemented

Fig. 1. Kidney allocation policy: Balancing utility and Equity.

from the beginning was to first perform a thorough review of allocation issues and then proceed to develop the new system based on this review. We formed the Kidney Allocation Review Subcommittee (KARS) which held a series of meetings from late 2004 to the middle of 2005. We also sent representative to several other OPTN Committee meetings during that time including the Ethics Committee and the Histocompatibility Committee.
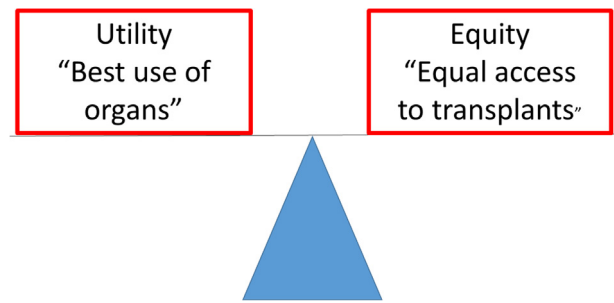
2.1. Kidney is different

From the beginning, it was clear that the issues surrounding kidney allocation were different from those of liver and lung transplantation. For example, preventing wait list mortality and focusing on 1 year post-transplant patient survival were the central guiding principles of liver and lung allocation changes. However, the availability of dialysis therapy for kidney transplant candidates meant that waitlist mortality in this population was primarily related to co-morbid conditions such as heart disease. It was clear that giving kidneys preferentially to patients with the highest waitlist mortality would not result in the "best use of organs".

The fact that in 2004 kidneys transplants were offered to a wide range of patients and that most allocation was based on waiting time meant that the allocation system was heavily weighted to allow equal access to transplantation. Efforts to improve the best use of kidneys (i.e. increased utility) generally were lacking. However, even equal access was not fully achieved. For example, among African Americans, a high percentage of blood group B candidates relative to the low percentage of blood group B donors overall led to longer waiting times for these candidates. Similarly, the fact that some groups including African Americans were less likely to be referred for transplant prior to the start of dialysis meant that these candidates had very long periods of dialysis compared to other groups. Finally, regional variations in organ donation and organ acceptance meant that waiting times varied widely across the US. Thus, the kidney began to explore ways to improve both the equity and utility of allocation.

What emerged as a central concept was that kidney allocation kidney allocation should strike a balance between the best use of kidneys and equal access to organs for all wait-listed patients. In simpler terms, kidney allocation was a balance between utility and equity (Fig. 1). New policies would aim to increase the utility of the existing deceased donor organ pool while still maintaining (or even increasing) access to transplantation.

One area that KARS believed that the best use of organs was not being fulfilled was in the allocation of kidneys from young deceased donors. In 2004, kidneys from very young donors were allocated equally to all candidates including those who were greater than 70 years of age. The committee realized that the longevity of function possible in a young donor kidney was not realized because older recipients had a much higher rate of death with a functioning graft. Conversely, younger recipients were commonly allocated kidneys from older donors. These kidneys tended not to last as long and these younger patients returned to the list for repeat transplants. Thus, a more utilitarian use of kidneys might be to allocate young kidneys to young recipients. The challenge was to develop an objective algorithm to accomplish this.

The first step was to create an improved system of stratifying deceased donor kidneys. In 2004, kidneys were classified as either standard criteria donors or extended criteria donors. This was implemented to expedite placement of hard-to-place kidneys. However, it led to an impression of good/bad kidneys and did not differentiate between very good and merely average kidneys. A continuous scale to estimate the expected survival of deceased donor kidneys, the kidney donor profile index (KDPI) was developed to replace the SCD/ECD classification [5].

2.2. Life-years from Transplant (LYFT)

The debate over how to rank candidates was an ongoing issue for KARS and the Kidney Committee. In 2004, candidates were ranked primarily by waiting time. However, this was felt to be non-compliant with the Final Rules direction that candidates be ranked by medical need.

One of the original ranking proposal stratified patients using their estimated survival benefit from a kidney transplant. Termed Life years from Transplantation (LYFT), this metric sought to show how many more years of life were expected for patients by receiving a transplant versus staying on dialysis. From the very beginning, the calculation of LYFT was confusing to many people. Nonetheless, modeling done by the SRTR using LYFT (and later the related estimated post-transplant survival metric) showed that the number of extra years of life enjoyed by the recipient population could be markedly increased. In the purest form of LYFT with national sharing, the number of incremental life years achieved each year from the existing deceased donor pool could increase by almost 3000 years compared to the national allocation system in place at the time [6,7].

2.3. Matching donors and recipients

Even if agreement could be reached about how to rank donors and recipients, one also had to determine the details of which kidney would be offered to which recipient. Elegant systems were developed in which a continuous scale for both donors and recipients would gradually change from matching kidneys with a low Kidney Donor Profile Index (KDPI, low KDPI kidneys are those with the longest expected function) to those candidates with the highest