Improving Dual Kidney Allocation

Executive Summary

Is the sponsoring Committee requesting specific feedback or input about the proposal? 

What problem will this concept solve?

How was this concept developed?

How does this concept support the OPTN Strategic Plan?
Improving Dual Kidney Allocation

Concept Paper

Executive Summary

By the conclusion of 2016, a record-setting 12,2451 deceased donor kidneys transplants were performed nationwide. However, there were still 98,962 candidates on the kidney waiting list waiting for a kidney transplant.2 One strategy to increase the number of kidney transplants is to reduce the number of discards through dual kidney transplantation. The OPTN/UNOS Kidney Transplantation Committee (“the Committee”) is considering amendments to current OPTN policy in support of optimizing dual kidney allocation. Because dual kidney and high Kidney Donor Profile Index (KDPI) transplants are disproportionately performed more often in older recipients, expanding the use of dual kidney transplantation of high KDPI kidneys may counterbalance the modest decline in access for older patients that was evident after the new kidney allocation system (KAS) was implemented in December 2014. Dual transplants and high KDPI transplants are disproportionately performed more often in older recipients; expanding the use of dual transplantation of high KDPI kidneys could serve to counterbalance the modest decline in access for older patients post-KAS.3 Furthermore, studies and OPTN data analyses have shown that two high KDPI kidneys have a significant survival advantage over one. Amending policy and enhancing programming could increase use of high KDPI kidneys that are currently at increased risk for discard.

Members have indicated current policy is ambiguous, out of date, and does not enable timely identification and allocation of kidneys suitable for dual transplantation. As a result, dual kidneys often endure long cold ischemic times. Transplant programs, especially those with expertise in dual transplantation, would prefer to receive dual kidney offers earlier (ideally pre-organ recovery) to both allow time for planning and to minimize cold ischemic times. Likewise, OPOs favor pre-recovery criteria to facilitate allocation more efficiently.

The Committee seeks public input regarding three concepts that aim to address the above problems. It is important to note that this document is not a policy proposal. This concept paper is intended to inform all interested parties about the status of the Committee’s discussions and seek valuable input for further consideration. The Committee plans to circulate a policy proposal during the public comment cycle in the fall of 2017.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

The Committee seeks community feedback on which of the three concepts, described below, would best improve utilization of high KDPI kidneys through dual kidney transplantation? What are the drawbacks to each concept?

Members are also asked to comment on both the immediate and long term budgetary impact, if applicable, of resources that may be required if their preferred concept is approved. This information assists the Board in considering the proposal and its impact on the community.

2 Ibid
Improving Dual Kidney Allocation

Affected Policies: Policy 8.6 Double Kidney Allocation

Sponsoring Committee: Kidney Transplantation Committee

Public Comment Period: January 23, 2014 – March 24, 2017

What problem will this concept solve?

Among kidneys recovered for the purpose of transplantation, data show that kidneys with KDPI above 85% have particularly high discard rates, approaching and even exceeding 50%.4 Between 2010 and 2015, OPOs reported approximately 3% of the total donor population meet dual allocation eligibility criteria outlined in OPTN policy, but only about 1% of the total donor population were ultimately transplanted dually.5 Discards are seldom due to factors like gross anatomical abnormalities or organ trauma, but rather tend to be discarded due to biopsy findings, reaching maximum ischemic time, or list exhaustion.6 One strategy to increase the number of kidney transplants is to reduce the number of discards via dual kidney transplantation. Dual transplantation of high KDPI deceased donor kidneys has been shown to provide a substantial survival advantage over single high KDPI kidney transplantation.7

While kidney allocation policy includes language pertaining to dual kidney allocation, members have indicated current policy is ambiguous, out of date, and does not enable timely identification and allocation of kidneys suitable for dual transplantation. In light of these issues, and prompted by an emphasis from the OPTN to consider strategies to increase the number of transplants, the Committee opted to revise dual kidney allocation policy with the goal of ultimately increasing the number of transplants by reducing the number of discards.

Current policy 8.6: Dual Kidney Allocation does not provide sufficient direction for OPOs on how and when to allocate kidneys dually:

8.6. Double Kidney Allocation

An OPO must offer kidneys individually through one of the allocation sequences in Policy 8.5: Kidney Allocation Classifications and Rankings before offering both kidneys to a single candidate unless the OPO reports to the OPTN Contractor prior to allocation that the deceased donor meets at least two of the following criteria:

• Age is greater than 60 years
• Estimated creatinine clearance is less than 65 mL/min based upon serum creatinine at admission
• Rising serum creatinine (greater than 2.5 mg/dL) at time of organ recovery
• History of longstanding hypertension or diabetes mellitus
• Glomerulosclerosis greater than 15% and less than 50%

The kidneys will be allocated according to sequence of the deceased donor’s KDPI.

Members have expressed concern that policy is unclear and outdated for several reasons. Current OPTN policy limits kidneys that can be offered as duals to those meeting at least two of these factors: age over 60, creatinine clearance below 65 ml/min, rising creatinine, hypertensive or diabetic donor, or high

7 Ibid.
sclerosis per biopsy findings. It is not clear whether the creatinine clearance must be based on a terminal creatinine value, as well as how precisely to define “rising” creatinine. The policy may also be considered out of date as it does not incorporate KDPI. The policy also does not contain any language limiting cold ischemic time.

UNOS has also received concerns from members about candidates being screened off of match runs for dual kidneys as the version of KDPI implemented in DonorNet® does not incorporate transplant type (single versus dual). DonorNet® lacks the functionality to screen offers based on whether the offer is single versus dual. The OPTN still collects data on whether the donor qualifies for dual kidney allocation, but it has no impact on the match run. KDPI also does not take into account single versus dual usage. Dual transplantation of marginal kidneys confers improved filtration power over single marginal kidney transplants. Thus, the calculated KDPI of each kidney singly does not accurately reflect projected outcomes when transplanted dually.

In addition, when OPOs offer a kidney as a single kidney on a match run, the only way to offer dual kidneys to the same list is to re-run the match, offering to the transplant programs who have already turned the single kidney down. Multiple match runs are not ideal from an operational standpoint and this process extends cold ischemic time. Transplant programs, especially those with expertise in dual transplantation, would prefer to receive dual kidney offers earlier (ideally pre-recovery) so as to allow time for planning and to minimize cold ischemic times. Likewise, OPOs favor pre-recovery criteria to facilitate kidney allocation more efficiently.

The Committee designed three concepts intended to address the goal of increasing the overall number of organ transplants with improved policy language and enhanced programming. The Committee seeks community input on the below proposed concepts.

What are the concepts under consideration?
The Committee is seeking feedback on the three concepts outlined below. The Committee agrees that the final policy solution, regardless of the concept favored by the community, must incorporate these requirements:

1. Determine more quickly which kidneys are eligible to offer as duals
2. Specify when an OPO is required to offer as duals
3. Allocate kidneys using a single match run
4. Require transplant programs to indicate they are willing to accept and transplant dual kidneys for all candidates or for a subset of their candidates
5. Include a provision that allows transplant surgeons to split dual kidneys if they determine they can be transplanted into two recipients
6. Improve utilization of single kidneys most at risk for discard
7. Expedite placement of double kidneys with transplant programs who will use them

The following concepts are supported by OPTN data analyses.

Concept 1: Two-Tier Criteria Scheme
The first concept under consideration is a two-tiered criteria scheme. This scheme offers both pre- and post-recovery criteria to define which kidneys to offer as duals and to determine when dual kidney placement should begin. The first tier, Pre-Recovery Criteria, requires OPOs to allocate kidneys dually along a match run by age or KDPI to potential recipients at transplant programs that have opted in. The second tier, Post-Recovery Criteria, adds additional criteria available after

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procurement plus a time component (i.e. 6 or 8 hours post-cross-clamp) to more quickly identify and place kidneys dually with opted-in transplant programs, also along a match run. The Committee also agreed that a given donor had to meet one of two criteria: age or KDPI greater than 85%, rather than age and KDPI greater than 85.

Within this concept, the Committee also seeks input on the age, KDPI, and clinical criteria included in the scheme. OPTN data indicate that the percent of donors with more kidneys not being utilized or discarded versus being transplanted as singles intersects at a KDPI of 88% and also at donor age of 66. The Committee agreed, however, that policy should strive to be far more conservative than these minimum thresholds so as not to restrict transplant programs that choose to use these kidneys more frequently. The Committee requests input from the community in order to better reach consensus on the clinical criteria for post-recovery allocation that would require an OPO to switch to dual kidney allocation.

Figure 1: Two-Tier Criteria Scheme (illustration)

Concept 1 states that OPOs must allocate kidneys as duals according if the below criteria are met.

<table>
<thead>
<tr>
<th>When the Offer is…</th>
<th>And the Donor is…</th>
<th>The kidneys are allocated according to…</th>
<th>To…</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-Recovery</td>
<td>Age ≥ 70* (or some other value) or KDPI ≥ 92%* (or some other value)</td>
<td>Policy 8.5.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%</td>
<td>• Only candidates at programs that have “opted in” to receive dual kidneys, and • Candidates that have provided written consent to receive offers for high KDPI kidneys.</td>
</tr>
<tr>
<td>Post-Recovery</td>
<td>Age ≥ 65* (or some other value) or KDPI ≥ 85%* (or some other value) and One or more clinical criteria (e.g. biopsy results, CrCl, GFR, etc.) or 8* hours post-cross clamp (or some other value)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Denotes possible criteria

Guiding questions for community input:
1. Is this your preferred allocation scheme? If so, why? If not, why not?
2. At what donor age should policy permit an OPO to begin dual kidney allocation? Should these thresholds be different for pre- or post-recovery?
3. At what KDPI score should policy permit an OPO to begin dual kidney allocation?

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4. Further, what additional clinical criteria would be appropriate to enable an OPO to go to dual kidney allocation post-recovery? Examples include biopsy results, creatinine clearance, glomerular filtration rate etc.

**Concept 2: KDPI-driven Allocation**

The Committee is also considering a concept that would use KDPI as the determining factor for a toggled method of dual kidney allocation.

Concepts 2 and 3 both rely on donor KDPI alone as the basis for switching to dual kidney allocation. Members of the workgroup felt that KDPI is an appropriate measure to use on its own since it incorporates multiple donor factors, encompasses most of the current criteria in current double kidney allocation policy, and is how organs are currently classified for allocation.\(^{10}\) KDPI incorporates age, ethnicity, creatinine clearance, history of hypertension and diabetes, cause of death, height, weight, donor type and HCV status into a single score.

In this concept, allocation could proceed in one of two ways: toggling between single and dual allocation with a combined local/regional list (Concept 2.1), or toggling between single and dual allocation with a split local and regional list (Concept 2.2). In either case, a candidate may appear twice on a single match run if they would accept a dual kidney. While not a typical construct for match runs, there is some precedent for including a candidate twice on a single run, and is preferable to running a match twice.\(^{11}\)

**Figure 2: Toggled Single/Dual Allocation Concept (illustration)**

<table>
<thead>
<tr>
<th>Concept 2.1</th>
<th>Concept 2.2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sequence D</td>
<td>Sequence D</td>
</tr>
<tr>
<td>KDPI &gt; 85%</td>
<td>KDPI &gt; 85%</td>
</tr>
<tr>
<td>Highly Sensitized</td>
<td>Highly Sensitized</td>
</tr>
<tr>
<td>0-ABDRmm</td>
<td>0-ABDRmm</td>
</tr>
<tr>
<td>Local + Regional</td>
<td>Local</td>
</tr>
<tr>
<td>Local + Regional (Dual Opt-in)</td>
<td>Local (Dual Opt-In)</td>
</tr>
<tr>
<td>National</td>
<td>Regional</td>
</tr>
<tr>
<td>National (Dual Opt-In)</td>
<td>National (Dual Opt-In)</td>
</tr>
</tbody>
</table>

Concept 2 provides OPOs with concrete direction on how to allocate high KDPI kidneys, allowing them to make offers much more quickly, and would allow a transplant program to decline a single kidney but indicate interest for dual kidneys in potential recipients further down the match.

The workgroup understands that uncoupling the currently-combined local/regional list, as in Concept 2.2, for kidneys with KDPIs over 85% would be a reversal of KAS policy, but wishes to receive community feedback on both approaches to toggled allocation.

**Guiding questions for community input:**

1. Is this your preferred allocation scheme? If so, why? If not, why not?
2. Do you support maintaining the combined local/regional list (Concept 2.1), or would you support a separate local/regional list for kidneys with a KDPI over 85% (Concept 2.2)?

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\(^{11}\) Organ Procurement and Transplantation Network (OPTN). "Policy 9.6.B: Allocation of Livers for Other Methods of Hepatic Support." OPTN Policies. Accessed Jan. 19, 2017. OPTN Policy 9.6.B allows livers to be offered for use as part of "other methods of hepatic support" after 6 hours of attempts to allocate the liver for standard transplantation. In this scenario, then, candidates may appear twice on the same match run if they have indicated they would accept a liver in both cases.
Concept 3: KDPI-driven Allocation Cutoff

Concept 3 utilizes a KDPI-based cutoff point after which kidneys would be allocated exclusively as duals. Like Concept 2, this concept uses KDPI alone to determine when a kidney should be allocated dually.

The workgroup discussed how to implement this concept so programs who more commonly transplant high KDPI kidneys singly would not see a diminished number of offers. Given that discard rates of kidneys increase at a KDPI of 88%, the workgroup felt that a mandated KDPI cutoff should be much higher in order to not adversely impact single transplants. Several members felt that only the highest KDPI kidneys (e.g. 97%-100%) should qualify for mandated dual-only allocation. Some workgroup members from transplant hospitals that frequently transplant very high KDPI kidneys expressed concern about losing the opportunity to utilize these kidneys singly, though the vast majority of programs do not transplant them. OPTN data show that approximately 12% of programs performed at least one dual kidney transplant one year post-KAS. To mitigate this risk, the workgroup added the provision that a surgeon may split kidneys if, upon receipt, the surgeon deems them suitable for single transplantation. The surgeon would then be required to transplant one of the kidneys into the originally-intended recipient while releasing the other according to Policy 5.9: Released Organs. The Committee seeks community input on an appropriate threshold within these bounds.

Figure 3: KDPI Cutoff Allocation Scheme (illustration)

<table>
<thead>
<tr>
<th>Sequence D</th>
<th>Sequence E</th>
</tr>
</thead>
<tbody>
<tr>
<td>KDPI &gt; 85% but &lt; 95%* (or some other value)</td>
<td>KDPI &gt; 95%* (or some other value)</td>
</tr>
<tr>
<td>Allocate as single kidneys</td>
<td>Allocate as dual kidneys for opt-in transplant programs</td>
</tr>
<tr>
<td>Highly Sensitized</td>
<td>Highly Sensitized</td>
</tr>
<tr>
<td>0-ABDRmm</td>
<td>0-ABDRmm</td>
</tr>
<tr>
<td>Local + Regional National</td>
<td>Local + Regional National</td>
</tr>
<tr>
<td>Local + Regional (Dual opt in) National</td>
<td>Local + Regional (Dual opt-in) National</td>
</tr>
</tbody>
</table>

*Denotes possible criteria

Guiding questions for community input:
1. Is this your preferred allocation scheme? If so, why? If not, why not?
   a. If so, do you support maintaining the combined local/regional list (Concept 2.1), or would you support a separate local/regional list for kidneys with a KDPI over 85% (Concept 2.2)?
   b. If so, at what KDPI should policy require an OPO to begin dual kidney allocation (Sequence E)?

How was this concept developed?

Since its inception in February 2016, the Committee has considered many concepts and approaches to decreasing the discard rate of high KDPI kidneys through dual kidney transplantation under the new KAS allocation system. Throughout its review, the Committee has included concepts that meet the requirements of the OPTN Final Rule and the UNOS Statement of Principles and Objectives of Equitable Organ Allocation.

Criteria discussion

The workgroup first vetted the criteria in current policy.\textsuperscript{14} The workgroup also considered other criteria not currently in policy that would be useful for identifying kidneys well suited for dual transplantation. These discussions later served as a foundation for determining whether a particular criterion would be useful and appropriate in a given solution.

Figure 4: Summary of criteria discussion

<table>
<thead>
<tr>
<th>Criteria (donor kidney):</th>
<th>Workgroup discussion summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age 60+ years</td>
<td>Age serves as a useful criterion in most but not all cases, as some kidneys from young donors can be difficult to place for a variety of reasons. The workgroup noted that age is a variable in KDPI and some advocated not including as an individual criterion. However, other members cited anecdotal evidence that some transplant programs decline kidneys based on donor age alone and felt age should be included as a stand-alone criterion. The group considered raising the age criterion as little as 5 years and as much as 15 years (i.e. to 65-75), though some members representing OPOs warned against raising the age beyond 65 as these donor kidneys are particularly difficult to place. Other members cautioned against an age limit in the 60s as the decision to accept an organ is multi-factorial one. Sometimes it is more appropriate to transplant those kidneys singly based on biopsy results or KDPI. Data presented to the workgroup show that kidneys are more likely to be discarded or not utilized than transplanted singly in donors 66 years of age and older, and that there is a slight increase in dual transplants at this age.\textsuperscript{15}</td>
</tr>
<tr>
<td>Creatinine Clearance (CrCl) &gt;65mL/min based on serum creatinine at admission</td>
<td>The workgroup discussed creatinine clearance criterion thresholds between 60 and 70 mL/min; whether creatinine clearance should be based on a terminal creatinine value; whether it is more or less valuable than starting glomerular filtration rate (GFR); and whether creatinine clearance is widely used when making acceptance decisions. Some members noted creatinine is included in KDPI. Following the August data presentation,\textsuperscript{16} a workgroup member commented that using creatinine clearance or the GFR is problematic due to the acute kidney injury (AKI) kidneys. Donors may show up with normal creatinine on admission, but over the course of time, the creatinine escalates. There was consensus around this statement, and the group felt that these measures may not be useful in double kidney allocation. Workgroup members discussed the challenges in measuring and using creatinine clearance as a criterion. Others felt strongly about its inclusion as there is no national standard for measuring renal function in a potential donor. Creatinine clearance is included as a potential criterion for Concept I.</td>
</tr>
<tr>
<td>Rising serum creatinine (greater than 2.5 mg/dL) at time of organ recovery</td>
<td>The workgroup felt that rising serum creatinine was only relevant if the donor kidney does not meet other criteria, and that it is best considered within the context of age. There were several questions from the workgroup surrounding the correct threshold and how to define “rising” creatinine (e.g. a certain number of increases? A general increasing trend?). Ultimately, rising serum creatinine was not included as a criterion in any of the final concepts under consideration.</td>
</tr>
</tbody>
</table>


\textsuperscript{16} Ibid
<table>
<thead>
<tr>
<th><strong>Current Policy (donor kidney):</strong></th>
<th><strong>Workgroup discussion summary</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>History of longstanding hypertension or diabetes mellitus</td>
<td>Currently, there is wide variation in interpretation of the term “diabetic history” or “longstanding hypertension.” An OPO member noted that five years of hypertension is often used as a standard for OPOs to seek the Organ Center’s assistance for national allocation, though this was not consistent for other OPOs represented on the group. The workgroup conceded that this information in captured in the KDPI. Ultimately, this criterion was not used as an individual criterion in any of the final concepts under consideration.</td>
</tr>
<tr>
<td>Glomerulosclerosis greater than 15% and less than 50%</td>
<td>The group did not reach consensus on an ideal glomerulosclerosis threshold and discussed challenges with using it as a criterion. Is the percent sclerosis for one kidney or two? Should the criterion be for the total sclerosis or the percentage for a single? Glomerulosclerosis is included as a potential criterion for Concept I.</td>
</tr>
</tbody>
</table>

Current policy was implemented nearly two decades ago, prior to the development of the KDPI scoring system. Many of the above criteria – specifically age, creatinine clearance, history of hypertension and diabetes, and serum creatinine – are included in a donor’s KDPI, so the workgroup acknowledged that inclusion of such an exhaustive list in final policy may no longer be necessary.

Current policy also implies that the offer is being made after recovery (e.g. glomerulosclerosis, one of the qualifying criteria for dual kidney allocation, is not known until a biopsy is performed.) By this time, kidneys have often sustained several hours of CIT. The OPO representatives on the workgroup encouraged it to consider including criteria available prior to recovery if they want to expedite placement. Members of the workgroup agreed that dual kidneys are most frequently offered very late in their CIT, and thus many surgeons find it difficult to accept them with so little time to plan.

The workgroup thoroughly considered the possibility of a “facilitated” (or “expedited”) placement policy. The workgroup felt, however, that the first step to improving efficiencies with dual kidney allocations was first to design a policy solution that included offering duals via a match run. The current policy, nearly two decades old, does not indicate a match run of any kind and puts the burden of placement entirely on the OPO. The workgroup agreed that updating current policy to include clear criteria and an allocation scheme is an appropriate first step to addressing the core problem of discards of high KDPI kidneys. The Kidney Committee may opt to take up facilitated or expedited placement as a project in the future as it applies to kidney allocation in general; however, the workgroup did not want to preemptively design a facilitated placement solution for this small subset of kidneys.

The Committee also recognized the Systems Optimizations Workgroup’s discussions surrounding augmenting policy on the use of the “provisional yes” in acceptance of organ offers in an effort to increase efficiency in organ placement. Members agreed that many transplant programs use the provisional yes as a method of buying more time to review an organ offer, thereby slowing the placement process. The Systems Optimization Workgroup’s efforts on updating policy surrounding the provisional yes will no doubt improve efficiency in allocation of double kidneys.

The Workgroup also discussed CIT as a component to double kidney allocation. One reason why duals are not done more frequently is because they typically have a high CIT and therefore members will not accept them. One member proposed coming up with a time limit where a single is no longer driving allocation. In other words, a transplant program would have X hours to decide if they are going to accept a single kidney (or not). Not all members supported this, but discussion was limited as data on this factor is not readily available and multifactorial. The OPO representatives felt that a 6 to 8 hour time cutoff was appropriate as many OPO locations have limited access to commercial air transportation. This discussion was deemed to be somewhat beyond the scope of this project, although the workgroup is proposing a time-based criterion in Concept 1.
Ultimately, the workgroup developed Concept 1 as a multi-factorial criteria solution and Concepts 2 and 3 as a solely KDPI-based allocation solution.

**Data Discussion**

The workgroup received several presentations from UNOS staff and one from the SRTR on data relevant to this project. A high-level summary of key data points and their impact on the development of these concepts follows.

As shown in Figure 4, the curves for “neither kidney utilized” and “both kidneys transplanted” intersect at KDPI 88% and track closely together until KDPI 92%.

**Figure 5: Deceased Donor Kidney Disposition by KDPI (2010-2015)**

In Figure 5, the curves for both kidneys utilized and both transplanted singly cross at a donor age of 66. That is, when a donor is older than 66 years of age, the kidneys are more likely to not be utilized than transplanted singly. This is slightly higher than the current criteria for dual kidney allocation of donor age greater than 60 years. Around this donor age there is a slight increase in dual transplants.

As noted above, there was debate whether to include age with KDPI, or just use KDPI alone, as KDPI includes age as a factor. Those who supported including age with KDPI asked whether there was a certain age at which the KDPI is going to be greater than 85 or 88%. There was some pushback on including age, as some transplant programs may turn down a donor over a particular age, regardless of KDPI.

**Figure 6: Deceased Donor Kidney Disposition by Donor Age (2010-2015)**
How does this concept support the OPTN Strategic Plan?

1. **Increase the number of transplants**: Amending the policy and programming could increase use of high KDPI kidneys that are currently being discarded. Currently only about 1% of kidney transplants are duals and this low rate has further decreased under KAS. With a 50%+ discard rate for high KDPI kidneys, the goal of this proposal would be to increase the number of transplants by using organs that would ordinarily be discarded.

2. **Improve equity in access to transplants**: Dual transplants and high KDPI transplants are disproportionately performed more often in older recipients; expanding the use of dual transplantation of high KDPI kidneys could serve to counterbalance the modest decline in access for older patients due to KAS.

3. **Improve waitlisted patient, living donor, and transplant recipient outcomes**: Two high KDPI kidneys are shown to have a significant survival advantage over one.

4. **Promote living donor and transplant recipient safety**. There is no impact on this goal.

5. **Promote the efficient management of the OPTN**. There is no impact on this goal.