

Public Comment Proposal

Improving Dual Kidney Allocation

OPTN/UNOS Kidney Transplantation Committee

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Improving Dual Kidney Allocation

Affected Policies: Policy 8.6 Double Kidney Allocation
Sponsoring Committee: Kidney Transplantation
Public Comment Period: July 31, 2017 – October 2, 2017

Executive Summary

By the conclusion of 2016, a record-setting 12,245 deceased donor kidneys transplants were performed nationwide.¹ However, there were still 98,962 candidates waiting for a kidney transplant.² One strategy to increase the number of kidney transplants is to reduce the number of discards of high Kidney Donor Profile Index (KDPI) kidneys through double kidney transplantation. The OPTN/UNOS Kidney Transplantation Committee (“the Committee”) is proposing amendments to OPTN policy to improve dual kidney allocation. 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 Amending current OPTN policy and enhancing programming could increase usage of high KDPI kidneys that are currently at increased risk for discard.

Members say that current policy is ambiguous, out-of-date, and does not enable them to identify and allocate dual kidneys in a timely manner. As a result, dual kidneys are often offered only after the wait list has been exhausted, leading to longer cold ischemia. Transplant programs, especially those with high dual transplantation volume, say that they would prefer to receive dual kidney offers earlier (ideally before organ recovery), to allow time for logistical planning and to minimize cold ischemia. Likewise, OPOs tell us that they favor pre-recovery criteria to facilitate allocation more efficiently.

The Committee distributed a concept paper during the spring 2017 public comment period in order to seek public input on three proposed concepts that aim to address the above problems. This initial round of public comment revealed support for a modification to the allocation tables that incorporate dual kidney allocation to centers that have opted in to receive these offers. The Committee now seeks additional community feedback on the selected policy solution.

¹ “Data – OPTN,” United Network for Organ Sharing, <https://optn.transplant.hrsa.gov/data/>. Accessed December 14, 2016.

² *Ibid*

³ Stewart, Darren E. & A. Kucheryavaya, Beck, J. *One Year Evaluation of the New National Kidney Allocation System (KAS)*. OPTN/UNOS Monitoring Plan Final report. Prepared for the OPTN KAS Implementation Committee of the Kidney Transplantation Committee, April 18, 2016.

What problem will this proposal solve?

Among kidneys recovered for the purpose of transplantation, kidneys with a KDPI above 85% have particularly high discard rates, approaching and even exceeding 50%.⁴ Between 2010 and 2015, approximately 3% of the total donor population met 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 kidneys tend to be discarded due to biopsy findings, reaching maximum cold ischemia, or list exhaustion.⁶

Dual transplantation of high KDPI deceased donor kidneys has been shown to provide a substantial patient survival advantage over single high KDPI kidney transplantation.⁷ Post-KAS, however, double kidney transplant has declined, from 0.9% of deceased donor kidney transplants in 1 year pre-KAS to 0.5% in 2nd year post-KAS.⁸

One strategy to increase the number of kidney transplants is to reduce the number of discards via dual kidney transplantation. 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 of candidates 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 of high KDPI kidneys.

Current policy 8.6: *Dual Kidney Allocation* does not provide sufficient direction for OPOs on how 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 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 within a given time period, or when a candidate with acute kidney injuries indicated clearance rates not indicative of their steady state. The policy also predates KDPI and does not incorporate KDPI into the candidate profile.

⁴ Stewart, Darren E. *Double and En Bloc Kidney Data*. OPTN/UNOS Descriptive Data Analyses. Prepared for Double and En Bloc Kidney Workgroup Conference Call, February 19, 2016.

⁵ Stewart, Darren. *Analysis of Deceased Kidney Donors, Donor Meets Double Kidney Criteria, 2010-2015*. OPTN/UNOS Descriptive Data Analyses. Prepared for Double Kidney Workgroup Conference Call, April 15, 2016.

⁶ Stewart, Darren E. & A. Kucheryavaya, Beck, J. *One Year Evaluation of the New National Kidney Allocation System (KAS)*. OPTN/UNOS Monitoring Plan Final report. Prepared for the OPTN KAS Implementation Committee of the Kidney Transplantation Committee, April 18, 2016.

⁷ *Ibid.*

⁸ Wilk, Amber R., John Beck, Anna Kucheryavaya. *Two Year Evaluation of the New, National Kidney Allocation System (KAS)*. OPTN/UNOS Descriptive Data Analyses. Prepared for OPTN Kidney Transplantation Committee Teleconference, April 19, 2017.

UNOS has also received concerns from members about candidates being screened off 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 collects data on whether the donor qualifies for dual kidney allocation, but it has no impact on the match run. Thus, the calculated KDPI of each kidney singly may not accurately reflect survival outcomes when transplanted dually

This policy is also designed to streamline and speed the double kidney allocation process. Prior to implementation of the KAS, OPOs had the ability to run a “Standard Criteria Match” for a dual-eligible extended-criteria donor, shortening the match run. This question and functionality, however, were removed with KAS. Transplant programs, especially those with expertise in double kidney transplantation, find that double kidneys are now often allocated with extended cold ischemia as OPOs near the end of a given match run without an acceptance on two high-KDPI kidneys. Likewise, OPOs expressed a strong preference for more explicit direction on when to allocate kidneys as doubles in a given match run. Policy does not currently indicate when an OPO must alternate to double allocation criteria with a given set of kidneys. Practically applied, this means OPOs often alternate between double and single allocation for the same pair while they search for a recipient on a match run. Current policy is insufficient as it includes double kidney eligibility criteria but does not include allocation instruction.

The Committee’s proposed solution is intended to address the goal of increasing the overall number of organ transplants with updated double kidney allocation criteria, allocation instruction, and enhanced programming.

Why should you support this proposal?

This proposal addresses the concerns described above by offering explicit direction on which kidneys must be offered as duals; when an OPO is permitted to offer dual kidneys; and how to place dual kidneys with willing centers most efficiently. A designated allocation pathway for dual kidneys will allow OPOs to make offers pre-recovery more often given a match run with self-identified centers willing to accept dual kidneys for their patients. As such, transplant hospitals may opt to decline a single kidney for a recipient but indicate interest for dual kidneys further down the match.

A KDPI-Driven Allocation Policy Solution

The Committee opted for an allocation-based policy solution based on feedback from the community, which included significant input from OPO stakeholders, who requested that any solution provide explicit direction for allocation of these kidneys. This solution adds dual kidney allocation classifications to Sequences C (kidneys with KDPI scores between 35 and 84%) and D (kidneys with KDPI scores 85% and above). This method allows for OPOs to quickly identify transplant hospitals willing to accept dual kidneys, as hospitals will be required to “opt in” to receive offers, which in turn should minimize cold ischemia times. Current policy only provides clinical criteria that may be used to determine which kidneys may be offered as duals. OPOs report they are often left to place dual kidneys only after they’ve exhausted a match run, leading to longer cold ischemia time and increasing likelihood of discard and discouraging recovery of very high KDPI kidneys.

In the proposed policy language, Sequence D now includes dual opt-in candidates in classifications 31, 33 and 36 in Table 8-8 under Policy 8.5.K: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85% and Sequence C includes classifications 48-50 as dual opt-in classifications. The Committee also voted to split the combined Local and Regional list in Sequence D so as to accommodate for a single and double allocation at the local and regional levels. The Committee chose to include dual opt-in classifications at the end of Sequence C to accommodate the rare cases in which Sequence C kidneys would be best transplanted as doubles.

Table 1: Illustration of current allocation sequences

Sequence A KDPI ≤ 20%	Sequence B KDPI >20% but <35%	Sequence C KDPI 35-84%	Sequence D KDPI ≥ 85%
Highly Sensitized	Highly Sensitized	Highly Sensitized	Highly Sensitized
0-ABDR mm (top 20% EPTS)	0-ABDR mm	0-ABDRmm	0-ABDRmm
Prior Living Donor	Prior living donor	Prior living donor	Local safety net
Local Pediatrics	Local pediatrics	Local safety net	Local + Regional
Local top 20% EPTS	Local safety net	Local	National
0-ABDR mm (all)	Local adults	Regional	
Local (all)	Regional pediatrics	National	
Regional Pediatrics	Regional adults		
Regional (top 20%)	National pediatrics		
Regional (all)	National adults		
National Pediatrics			
National (top 20%)			
National (all)			

Table 2: Illustration of proposed changes to allocation sequences

Sequence A KDPI ≤ 20%	Sequence B KDPI >20% but <35%	Sequence C KDPI 35-84%	Sequence D KDPI ≥ 85%
Highly Sensitized	Highly Sensitized	Highly Sensitized	Highly Sensitized
0-ABDR mm (top 20% EPTS)	0-ABDR mm	0-ABDRmm	0-ABDRmm
Prior Living Donor	Prior living donor	Prior living donor	Local safety net
Local Pediatrics	Local pediatrics	Local safety net	Local*
Local top 20% EPTS	Local safety net	Local	Local (Dual Opt-In)*
0-ABDR mm (all)	Local adults	Regional	Regional*
Local (all)	Regional pediatrics	National	Regional (Dual Opt-In)*
Regional Pediatrics	Regional adults	Local (Dual Opt-In)*	National
Regional (top 20%)	National pediatrics	Regional (Dual Opt-In)*	National (Dual Opt-In)*
Regional (all)	National adults	National (Dual Opt-In)*	
National Pediatrics			
National (top 20%)			
National (all)			

*Proposed change

How was this proposal developed?

Since the project’s 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 considered concepts that meet the requirements of the OPTN Final Rule and the *UNOS Statement of Principles and Objectives of Equitable Organ Allocation*.

The Committee first opted to distribute a concept paper during spring 2017 public comment, intended to inform the community of the Committee’s discussions and seek early feedback on three potential policy solutions. The Committee now seeks feedback on the chosen policy solution and related policy language. Public comment and OPTN Board of Directors’ feedback of the en bloc proposal received during the spring 2017 public comment period regarding the specific provisions common to both the dual and en bloc proposals also informed the Committee’s decisions on this proposal.

Donor criteria considered

The workgroup first vetted the criteria in current policy.⁹ The workgroup also considered other criteria not currently in policy that might 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.

Table 3: Summary of current double kidney policy criteria discussion

Current Policy (donor kidney):	Workgroup discussion summary
Age 60+ years	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 it 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. ¹⁰

⁹ OPTN Policy 8.6 *Double Kidney Allocation*.

https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf#nameddest=Policy_08. Accessed January 4, 2017.

¹⁰ Wilk, Amber. *Analysis of Dual (double) and En Bloc Kidney Transplants, 2010-2015*. OPTN/UNOS Descriptive Data Analyses. Prepared for Double and En Bloc Kidney Workgroup Conference Call, August 15, 2016.

Current Policy (donor kidney):	Workgroup discussion summary
Creatinine Clearance (CrCl) >65mL/min based on serum creatinine at admission	<p>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, a workgroup member commented that using creatinine clearance or the GFR is problematic due to the acute kidney injury (AKI) kidneys.¹¹ 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 might not be useful in double kidney allocation.</p> <p>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 was included as a potential criterion for Concept I.</p>
Rising serum creatinine (greater than 2.5 mg/dL) at time of organ recovery	<p>The workgroup felt that rising serum creatinine is 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.</p>
History of longstanding hypertension or diabetes mellitus	<p>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 seeking 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 is captured in the KDPI. Ultimately, this criterion was not used as an individual criterion in any of the concepts released in the concept paper.</p>
Glomerulosclerosis greater than 15% and less than 50%	<p>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 was included as a potential criterion for Concept I.</p>

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.

Considering a Facilitated Placement Policy

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 cold ischemia. The OPO representatives on the workgroup encouraged the group 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 allocated late, increasing their cold ischemia and thus many surgeons find it difficult to accept them with so little time to plan for surgery.

¹¹ *Ibid*

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 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 the potential for added cold ischemia as a component to double kidney allocation. One reason why duals are not done more frequently is because they typically have an increased cold ischemia. One member proposed establishing a time limit on single kidney allocation, at which point the OPO would switch to dual allocation. 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. Not all workgroup members supported this as the decision whether to accept an organ with increased cold ischemia is multifactorial. Ultimately, the group opted to include time as a criterion in one of the concepts described below.

What were the concepts considered?

The Committee submitted three concepts, described below, for consideration during the fall 2017 public comment period. The community was asked to respond to guiding questions specific to each concept and to inform the Committee as to which concept is preferred.

Concept 1: Two-Tier Criteria Scheme

The first concept considered was a two-tiered criteria scheme. This scheme offers pre- and post-recovery criteria to determine which kidneys to offer as duals and to define at what point in time dual kidney placement should begin. The 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 post-recovery criteria, to be utilized in the event the kidney cannot be placed pre-recovery, provides additional criteria available after procurement, including a time parameter (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 sought input on the age, KDPI, and clinical criteria included in the scheme.

Table 4: Two-Tier Criteria Scheme (illustration)

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

When the Offer is...	And the Donor is...	The kidneys are allocated according to...	To...
Pre-Recovery	Age ≥ 70* (or some other value) or KDPI ≥ 92%* (or some other value)	<i>Policy 8.5.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%</i> <i>Policy 8.5.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%</i>	<ul style="list-style-type: none"> • 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.
Post-Recovery	Age ≥ 65* (or some other value) or KDPI ≥ 85%* (or some other value) and 1. One or more clinical criteria (e.g. biopsy results, CrCl, GFR, etc.) or 8* hours post-cross clamp (or some other value)	<i>Policy 8.5.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%</i> <i>Policy 8.5.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%</i>	<ul style="list-style-type: none"> • 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.

*Denotes possible criteria

Concept 2: KDPI-driven Allocation

Concepts 2 and 3 both relied 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 criteria in current double kidney allocation policy, and is how organs are currently classified for allocation.¹² 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 precedent for including a candidate twice on a single run, and is preferable to running a match twice.¹³

¹² Stewart, D., Kucheryavaya, A., Brown, R., Klassen, D., Turgeon, N., & Aeder, M. *Understanding the Initial Rise in Kidney Discard Rates Observed Post-KAS*. American Journal of Transplantation (Vol. 16, pp. 278-278). June 2016.

¹³ 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.

Table 5: Toggled Single/Dual Allocation Concept (illustration)

Concept 2.1	Concept 2.2
Sequence D KDPI ≥ 85%	Sequence D KDPI ≥ 85%
Highly Sensitized 0-ABDRmm Local + Regional Local + Regional (Dual Opt-in) National National (Dual Opt-In)	Highly Sensitized 0-ABDRmm Local Local (Dual Opt-In) Regional Regional (Dual Opt-In) National National (Dual Opt-In)

Concepts 2.1 and 2.2 provide OPOs with concrete direction on how to allocate high KDPI kidneys, allowing them to make offers much more quickly, and allows a transplant program to decline a single kidney but indicate interest for dual kidneys in potential recipients further down the match.

Concept 3: KDPI-driven Allocation Cutoff

Concept 3 utilized 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.

Table 6: KDPI Cutoff Allocation Scheme (illustration)

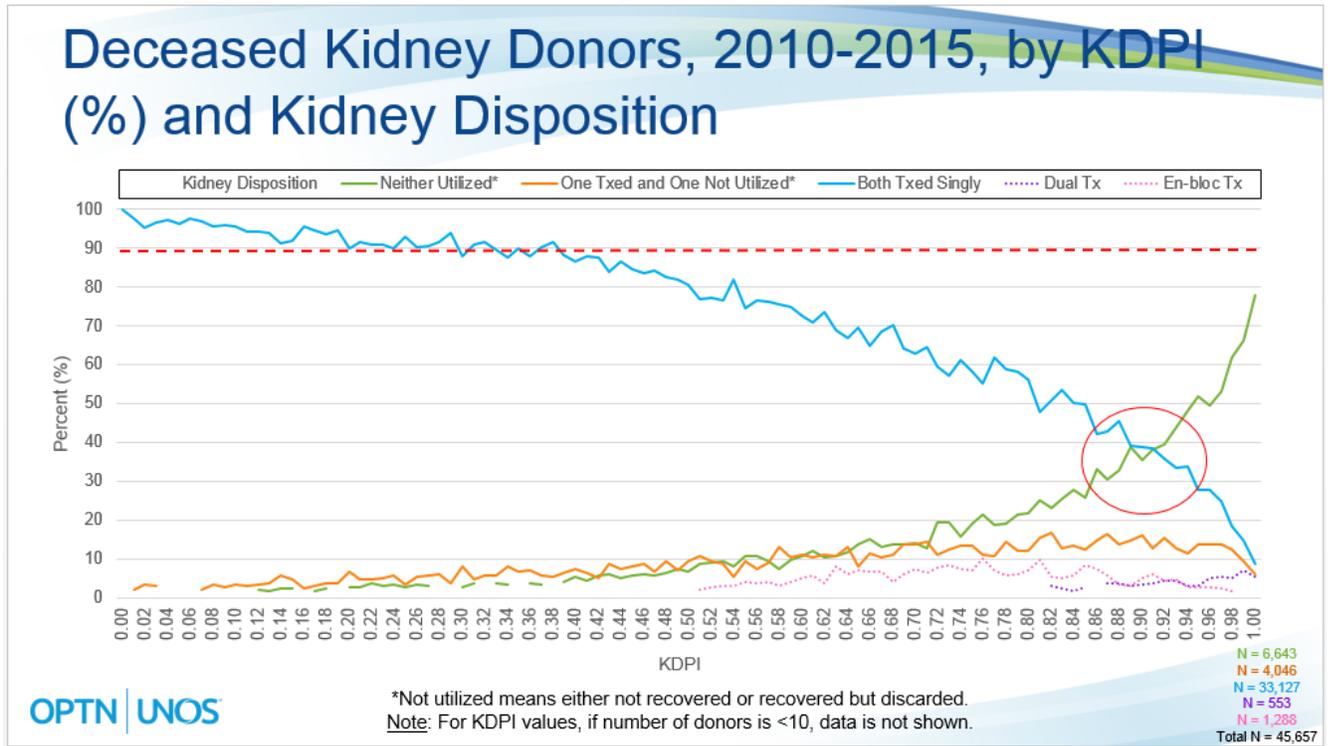
Sequence D KDPI ≥ 85% but < 95%* (or some other value) Allocate as single kidneys	Sequence E KDPI ≥ 95%* (or some other value) Allocate as dual kidneys for opt-in transplant programs
Highly Sensitized 0-ABDRmm Local + Regional National Local + Regional (Dual Opt-in) National (Dual Opt-In)	Highly Sensitized 0-ABDRmm Local + Regional National

*Denotes possible criteria

The workgroup reviewed relevant OPTN data in considering policy solutions, particularly as related to any correlation between dual kidney transplant and KDPI. 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%.¹⁴

¹⁴ Wilk, Amber & T. Baker. *Analysis of Deceased Kidney Donors and Kidney Disposition*. Prepared for the OPTN Kidney Transplantation Committee, August 19, 2016.

Figure 1: Deceased Donor Kidney Disposition by KDPI (2010-2015)¹⁵



As noted above, the workgroup debated whether to include age with KDPI, or just use KDPI alone, as KDPI includes age as a factor. There was some pushback on including age, as some transplant programs may turn down a donor over a particular age, regardless of KDPI.

Discussion of Key Provisions of Selected Policy Solution

- The Committee determined that any policy proposal would incorporate the following key provisions: *A single match run* OPO overwhelmingly preferred a single match run for allocation of dual kidneys. The allocation-based solution allows for this, versus other solutions considered that would require separate match runs for single and dual allocation. *Centers must opt-in to receive dual kidney offers:* In order to expedite placement of these high-KDPI kidneys, the Committee would like to add functionality to DonorNet to allow hospitals to indicate in advance, at *both* the hospital and candidate level, whether they would accept double kidneys. Allocating kidneys can be a time-intensive process, and the OPO members felt that getting these kidneys to the programs most likely to utilize them as quickly as possible would increase the likelihood they would be accepted and transplanted. Workgroup members, including those whose programs do not perform dual transplants, agreed; facilitated sharing to DSAs with more experience may help increase utilization. Therefore, transplant programs will have to indicate that they accept dual kidneys under the proposed policy. *Surgeons may separate kidney pairs if it appears they would be well-suited for single transplant:* It is acknowledged that transplanting two kidneys into a single recipient versus transplanting two kidneys into two recipients may negatively impact the total number of transplants. To mitigate the risk of potentially reducing the number of transplants, the policy includes a provision that allows the transplanting surgeon, based on medical judgment, to separate the kidneys so they may be transplanted into two recipients. In this scenario, the proposal states that the receiving program must do one of the following:

¹⁵ *Ibid.*

- Transplant one of the kidneys into the originally designated recipient and document the reason for not transplanting the kidneys together. The receiving transplant program will decide which of the two kidneys to transplant into the originally designated recipient, and release the other kidney according to *Policy 5.9: Released Organs*
- Release both kidneys according to *Policy 5.9: Released Organs*

Response to Community Feedback Surrounding Released/Split Kidneys Provision

The Committee received substantial feedback on the provision to release the second kidney from a split pair of kidneys. This provision is common between the Dual Kidney and En Bloc Allocation proposals. Several members of the community asked for the Committee to carve out an exception to *OPTN Policy 5.9* in this proposal, expressing a desire for policy to allow them to keep the second kidney automatically. Many of these members were concerned about adding unnecessary cold ischemia time when a recipient may be available at the receiving surgeon's hospital. The Committee discussed these concerns at length, consulting with OPO and UNOS Organ Center staff to gain a clear understanding of what occurs following separation of a pair of kidneys. The Kidney Committee also considered several alternative policy solutions to reallocating the second kidney, including:

- Replacing the split kidneys provision with an exception to current *OPTN Policy 5.9* in the Dual and En Bloc Kidney proposals using new policy language
- Replacing the split kidneys provision with an exception to current *OPTN Policy 5.9* in the Dual and En Bloc Kidney proposals using existing policy as a model.
 - *OPTN Policy 9.6.A Segmental Transplant and Allocation of Liver Segments*
 - *Policy 9.8.A Open Variance for Segmental Liver Transplantation*
- *Policy 14.6.B Placement of Non-directed Living Donor Organs*
- Allowing surgeons to keep the second split kidney for another candidate at their hospital

Ultimately, the Committee reconfirmed its commitment to current policy and practice per *Policy 5.9* for two primary reasons. First, the Committee believes strongly that consistency with the kidney allocation system is the most fair and ethical approach to increasing utilization of this currently-underutilized resource. Second, that creating an exception to *Policy 5.9* for en bloc transplants could increase instances of gaming; an en bloc offer could easily be split to turn one transplant into two at a given center.

While the Committee acknowledged the concern over added cold ischemia on the second kidney, the members agreed that confusion or lack of exposure to the application of *Policy 5.9* in practice may be driving some to oppose its inclusion in this project. *Policy 5.9* is current practice for OPOs and transplant programs. Although the policy does require the importing transplant program to communicate back to the host OPO that they do not intend to use the imported organs for their initial recipient, the policy does allow the host OPO to grant the importing OPO of the transplant program to use those organs locally. As shown in Figure 2, for donors with a KDPI of less than 85%, 1.4% of offers in which both kidneys were accepted between 2010 and 2015 had at least one kidney transported outside of the accepting center. In the end, most host OPOs grant the final rights of the organ to the importing OPO per *Policy 5.9* due to the fact that all local programs have already refused these organs, or that the importing transplant program is geographically distanced from the local DSA. Between 2010 and 2015, there were 645 donors with a KDPI > 85% with at least one offer accepted for both (dual or en bloc) kidneys in the United States. Thirty-one (4.8%) of these offers were transplanted as at least one single kidney (i.e. the kidney unit was split), and of those offers that were split, 5 (16.1%) offers had at least one of the single kidneys physically reallocated to a different hospital for transplant.

Figure 2: Donors KDPI >85% with at Least One Match Acceptance of Both (En Bloc or Dual) Kidneys, 2010-2015

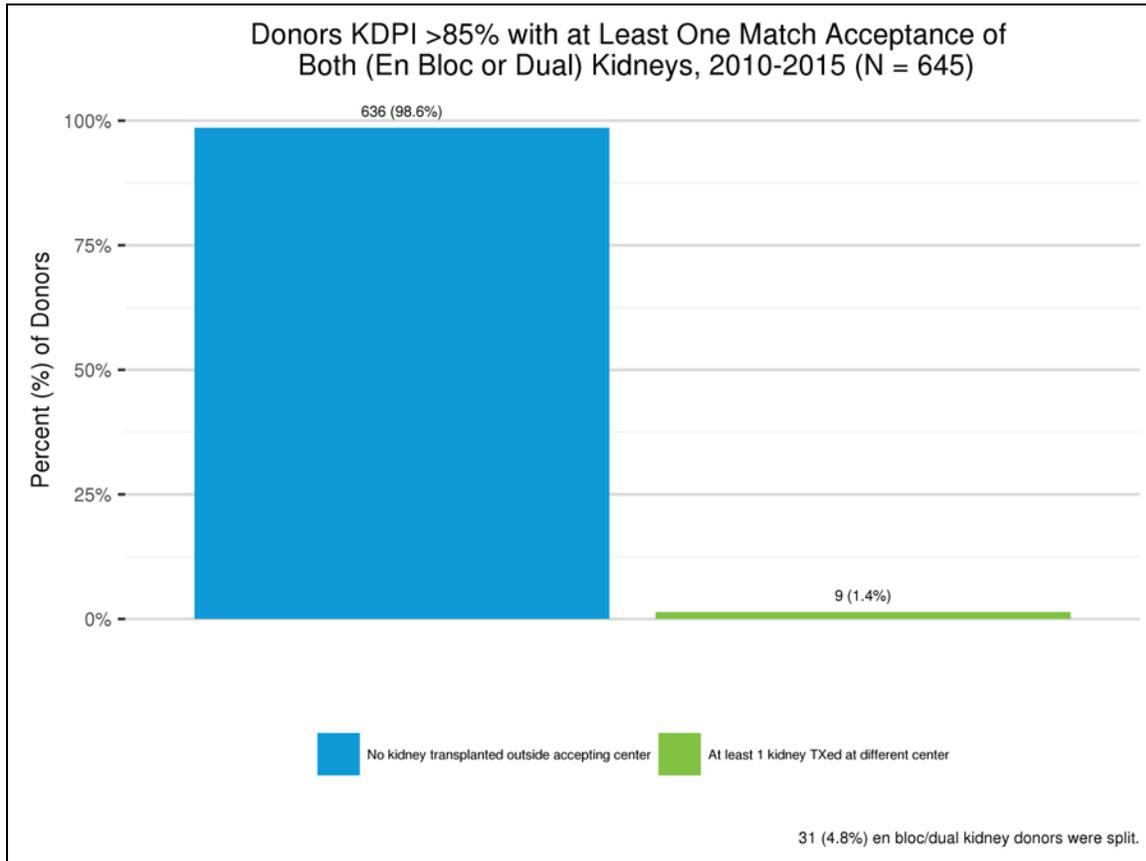
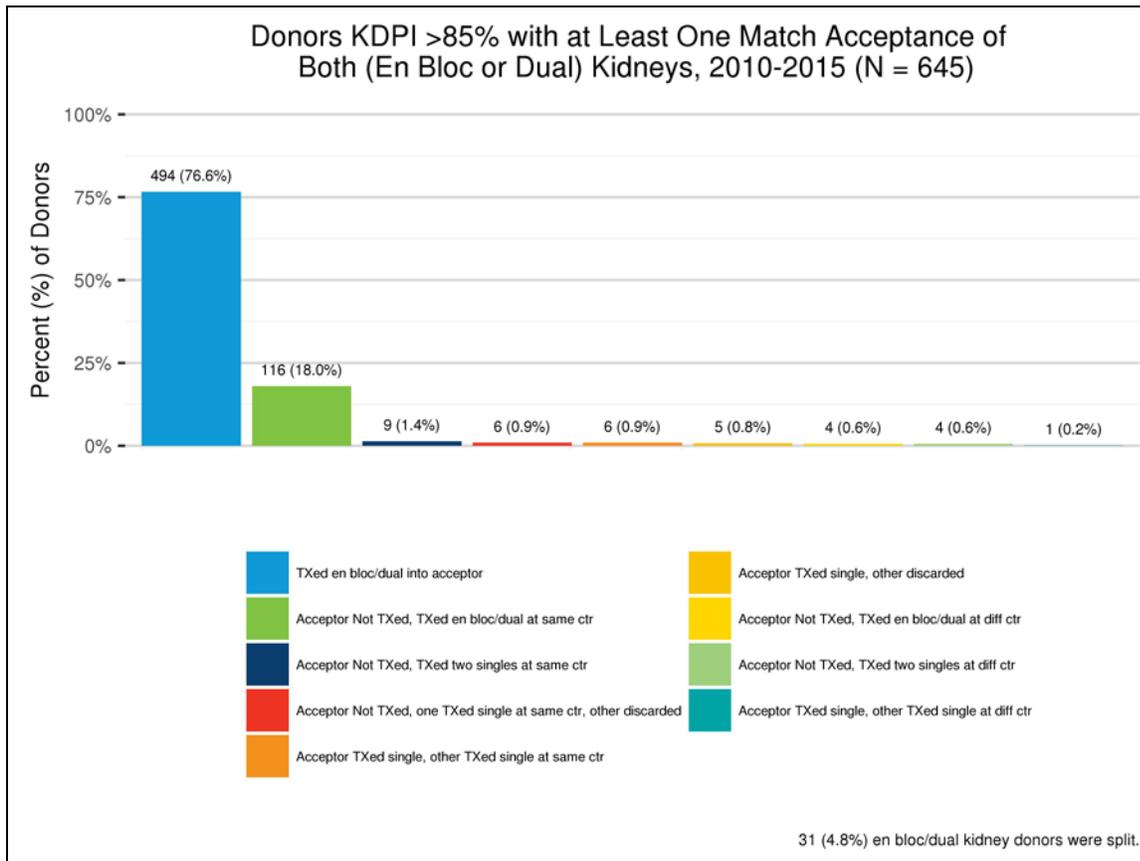


Figure 3: Donors KDPI >85% with at Least One Match Acceptance of Both (En Bloc or Dual) Kidneys, 2010-2015¹⁶



Given that split kidneys so often stay at their receiving hospital, the Committee was asked why the proposed policy does not default to allowing surgeons to keep both kidneys at their center. The Committee felt strongly that a patient-centered policy would ensure that candidates nearby (i.e. those for whom transporting the organ a second time would *not* put it at risk for discard) with higher priority on the Waitlist are first offered the organ. Furthermore, the Committee agreed that implementation of the proposed allocation sequence should reduce the need for importing organs at all. Today's allocation sequences does not incorporate dual kidney allocation, so dual kidneys are often offered nationally post list-exhaustion. The new proposed sequence will incorporate dual kidney allocation early, thus reducing instances of national dual opt-in offers in theory.

The Committee found that alignment with current *OPTN Policy 5.9* is the most transparent and patient-centered method to managing released kidneys, even if rare. The Committee feels that every effort should be made to follow the OPTN's established allocation sequences. Deviating from these sequences without conducting due diligence to the next candidate on a given match run would be in opposition to the core values of the OPTN.

How well does this proposal address the problem statement?

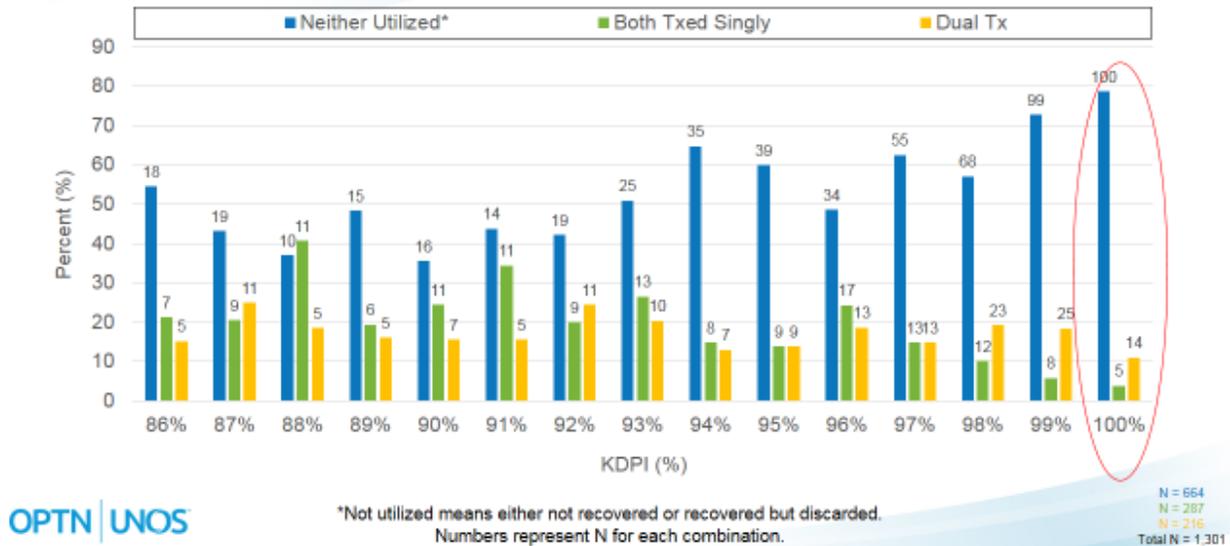
This proposal is informed by OPTN descriptive analyses, current peer-reviewed literature and, in matters of behavior, clinical consensus. The workgroup determined, in conjunction with feedback received via

¹⁶ *Ibid*

public comment in the fall of 2016, that KDPI-driven allocation is a more efficient and explicit policy solution based on OPTN data, previous studies, and clinical practice of Work Group members. As previously mentioned, the workgroup considered discard data stratified by a number of factors – including serum creatinine, estimated glomerular filtration rate, creatinine clearance and age – in order to determine the set of criteria for when to allocate a set of kidneys as doubles.

Figure 4: Dual-Eligible Deceased Kidney Donors, 2015-2015, by KDPI (%) and Kidney Disposition¹⁷

Dual-Eligible Deceased Kidney Donors, 2010-2015, by KDPI (%) and Kidney Disposition



This bar graph shows the percent of all dual-eligible deceased kidney donors recovered between 2010 and 2015 by KDPI (integer percentage) and kidney disposition. As you can see, the percent of donors with both kidneys not utilized for any KDPI unit never reaches 90% for this cohort, but instead maxes out at approximately 79% for donors with higher KDPI. The higher the KDPI, the higher the percentage of neither kidney utilized versus both transplanted singly. For dual eligible deceased kidney donors, the percentage within each KDPI is almost always higher for neither utilized than for both transplanted singly; this may be due to the fact that they are more marginal kidneys, as evident that these are all KDPI > 85% kidney donors. For values with enough data to analyze, for dual eligible deceased kidney donors in the cohort, the only time the percentage of both transplanted singly versus neither utilized within any particular KDPI was 88%. Recall that the curves for neither utilized and both transplanted also intersect at KDPI = 88 for all deceased donors.

With a strong correlation between KDPI and discard rate for dual kidneys, the Work Group felt that an opt-in policy based on our current allocation sequences would best expedite placement to the transplant hospitals that will use them. Given that kidneys with KDPI scores over 85% are at increased risk for discard, transplant hospitals that are willing to accept these marginal organs will be able to indicate their willingness well before a match run, giving OPOs clear direction on where to place the kidneys. Which populations are impacted by this proposal?

¹⁷ Ibid

All kidney transplant candidates could potentially be impacted by this proposal. At the conclusion of 2016, there were 98,962 candidates waiting for a kidney transplant.¹⁸ The proposed policy is expected to impact adult kidney transplant candidates primarily, as dual kidneys are transplanted into adult recipients.

How does this proposal impact 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 post-KAS.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* Transplants involving two high KDPI kidneys are shown to have a significant survival advantage over transplants with one high KDPI kidney.
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.

How will the OPTN implement this proposal?

This proposal will require programming in UNetSM. UNOS IT provides cost estimates for each proposal that will require programming to implement. The estimates can be small (108-419 hours), medium (420-749 hours), large (750-1,649 hours), very large (1,650-3,999 hours), or enterprise (4,000-8,000 hours). This proposal is estimated to be very large project due to changes required in both the Waitlist and DonorNet applications. In Waitlist, an additional data field will be added for transplant programs to opt-in to accept double kidneys on an individual candidate level (both kidney alone and isolated kidney of a kidney-pancreas registration) and be able to manage via listing defaults and Waitlist update utility.

Changes to the DonorNet application will include a new prompt for OPOs to designate that kidneys will be allocated as duals. Changes to both applications will involve thorough testing as well as additional quality monitoring.

UNOS will follow established protocols to inform members and educate them on any policy changes through Policy Notices. This proposal will require an instructional program and will be monitored for specific needs throughout the development and implementation to determine the eligible modality for educating members.

How will members implement this proposal?

This proposal will impact transplant hospitals and OPOs.

Transplant Hospitals

This proposal requires transplant programs to indicate to the OPTN Contractor which patients they would consider accepting dual kidneys. This proposal will allow transplant programs to manage acceptance of dual kidneys at the candidate or center level via listing defaults and Waitlist utilities. This option should

¹⁸ Wilk, Amber. *OPTN Data*. <https://optn.transplant.hrsa.gov/data/>. Accessed Feb. 6 2017.

mitigate administrative burden and more effectively ensure that only those candidates and programs willing to consider accepting a dual kidney offer appear on the match run.

The receiving transplant program must document the reason for not transplanting the kidneys as duals, if the surgeon determined the dual kidneys could be split and transplanted into two recipients.

There may be financial implications to transplant programs. Current practice of charging one acquisition fee for dual kidneys is not expected to change in light of this proposal.

OPOs

As dual kidney transplants are currently practiced nationwide, this proposal increases efficiency in the allocation process. Otherwise, minimal staff training on new policy allows implementation to be effective immediately to one month. Since volume of dual kidney cases is low, there is minimal impact on operations.

Will this proposal require members to submit additional data?

No additional data collection is proposed.

How will members be evaluated for compliance with this proposal?

Members will be expected to comply with requirements in the proposed language. In addition to the monitoring outlined below, all elements required by policy may be subject to OPTN review, and members are required to provide documentation as requested.

UNOS allocations staff will continue to review all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to policy requirements and will continue to investigate potential policy violations.

Allocations staff will review dual kidney allocations resulting in a single kidney being transplanted into the intended recipient. Staff will request the transplant program's documentation about why both kidneys were not transplanted into the intended recipient and will also verify that the second kidney was released back to the host OPO according to policy requirements.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

This policy will be formally evaluated approximately 6 months, 1 year, and 2 years post-implementation.

The following questions, and any others subsequently raised by the Committee, will guide the evaluation of the proposal after implementation:

- Has the number of dual kidney transplants increased?
- Has the number of patients transplanted from high KDPI (85+) donors (single and dual) increased?
- Has efficiency of dual kidney transplants improved given there is now policy in place regarding these transplants?
- Has there been a decrease in kidney discards?
- Has the number of programs performing dual kidney transplants increased?

The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available to compare performance before and after the implementation of this policy:

- The number (and percent) of transplants (single vs. dual), overall, and by select recipient and donor demographics.

- How many kidneys allocated as dual are subsequently split, and if split, what happens to the second kidney (transplanted at same center, different center, or discarded)?
- The number (and percent) of deceased donor kidney transplant programs performing dual transplants.
- Descriptive statistics on cold ischemia of dual kidney transplants pre- and post-policy implementation.
- The number (and percent) of KDPI 85+ kidneys recovered that are utilized (single vs. dual) vs. discarded.
- Survival outcomes (patient and graft) as data become available.

Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

8.5.J Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%

Kidneys from donors with KDPI scores greater than or equal to 35% but less than or equal to 85% are allocated to candidates according to *Table 8-7* below and the following:

- Classifications 1 through 47 for one deceased donor kidney
- Classification 48 through 50 for double kidneys from a single deceased donor

Table 8-7: Allocation of Kidneys from Deceased Donors with KDPI Greater Than or Equal To 35% and Less Than or Equal To 85%

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
1	OPO's DSA	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
2	OPO's DSA	CPRA equal to 100%, blood type permissible or identical	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
4	OPO's region	CPRA equal to 100%, blood type permissible or identical	Any
5	Nation	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
6	Nation	CPRA equal to 100%, blood type permissible or identical	Any
7	OPO's DSA	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
8	OPO's DSA	CPRA equal to 99%, blood type permissible or identical	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
10	OPO's region	CPRA equal to 99%, blood type permissible or identical	Any
11	OPO's DSA	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	Any
12	OPO's DSA	CPRA equal to 98%, blood type permissible or identical	Any
13	OPO's DSA	0-ABDR mismatch, blood type identical	Any
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
16	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any
17	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type identical	Any
18	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Any
19	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type identical	Any
20	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
21	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
22	OPO's DSA	0-ABDR mismatch, and blood type B	O
23	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	O
24	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	O
25	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	O
26	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of match, and blood type B	O
27	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	O
28	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time of match, and blood type B	O
29	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
30	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
31	OPO's DSA	0-ABDR mismatch, blood type permissible	Any

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
32	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any
34	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Any
35	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 years old at time of match, and blood type permissible	Any
36	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Any
37	Nation	0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time of match, and blood type permissible	Any
38	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
39	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
40	OPO's DSA	Prior living donor, blood type permissible or identical	Any
41	OPO's DSA	Prior liver recipients that meet the qualifying criteria according to <i>Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List</i> , blood type permissible or identical	Any
42	OPO's DSA	Blood type B	A2 or A2B
43	OPO's DSA	All remaining candidates, blood type permissible or identical	Any
44	OPO's region	Blood type B	A2 or A2B
45	OPO's region	All remaining candidates, blood type permissible or identical	Any
46	Nation	Blood type B	A2 or A2B
47	Nation	All remaining candidates, blood type permissible or identical	Any
48	<u>OPO's DSA</u>	<u>Candidates who have specified they are willing to accept double kidneys, blood type permissible or identical</u>	<u>Any</u>
49	<u>OPO's region</u>	<u>Candidates who have specified they are willing to accept double kidneys, blood type permissible or identical</u>	<u>Any</u>

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
50	Nation	Candidates who have specified they are willing to accept double kidneys, blood type permissible or identical	Any

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8.5.K Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%

With the exception of 0-ABDR mismatches, kidneys from donors with KDPI scores greater than 85% will be allocated only to adult candidates only according to Table 8-8 below and the following:

- Classifications 1 through 30, 32, 34, and 35 for one deceased donor kidney
- Classifications 31, 33, and 36 for double kidneys from a single deceased donor

Table 8-8: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85%

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
1	OPO's DSA	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
2	OPO's DSA	CPRA equal to 100%, blood type permissible or identical	Any
3	OPO's region	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
4	OPO's region	CPRA equal to 100%, blood type permissible or identical	Any
5	Nation	0-ABDR mismatch, CPRA equal to 100%, blood type permissible or identical	Any
6	Nation	CPRA equal to 100%, blood type permissible or identical	Any
7	OPO's DSA	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
8	OPO's DSA	CPRA equal to 99%, blood type permissible or identical	Any
9	OPO's region	0-ABDR mismatch, CPRA equal to 99%, blood type permissible or identical	Any
10	OPO's region	CPRA equal to 99%, blood type permissible or identical	Any
11	OPO's DSA	0-ABDR mismatch, CPRA equal to 98%, blood type permissible or identical	Any
12	OPO's DSA	CPRA equal to 98%, blood type permissible or identical	Any
13	OPO's DSA	0-ABDR mismatch, blood type permissible or identical	Any
14	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type identical	Any
16	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
17	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
18	OPO's DSA	0-ABDR mismatch, blood type B	O
19	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	O
20	Nation	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type B	O
21	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
22	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
23	OPO's DSA	0-ABDR mismatch, blood type permissible	Any
24	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 80%, and blood type permissible	Any
25	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% , and blood type permissible	Any
26	OPO's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
27	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
28	OPO's DSA	Prior liver recipients that meet the qualifying criteria according to <i>Policy 8.5.G: Prioritization for Liver Recipients on the Kidney Waiting List</i> , blood type permissible or identical	Any
29	OPO's region	Blood type B	A2 or A2B
30	<u>OPO's DSA</u>	<u>Blood type permissible or identical</u>	<u>Any</u>
31	<u>OPO's DSA</u>	<u>Candidates who have specified they are willing to accept double kidneys, blood type permissible or identical</u>	<u>Any</u>
32	<u>OPO's region</u>	<u>All remaining candidates, blood type permissible or identical</u>	<u>Any</u>

Classification	Candidates that are within the:	And are:	And the donor is this blood type:
<u>33</u>	<u>OPO's region</u>	<u>Candidates who have specified they are willing to accept double kidneys, blood type permissible or identical</u>	<u>Any</u>
<u>34</u>	<u>Nation</u>	<u>Blood type B</u>	<u>A2 or A2B</u>
<u>35</u>	<u>Nation</u>	<u>All remaining candidates, blood type permissible or identical</u>	<u>Any</u>
<u>36</u>	<u>Nation</u>	<u>Candidates who have specified they are willing to accept double kidneys, blood type permissible or identical</u>	<u>Any</u>

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8.6 Double Kidney Allocation of Both Kidneys from a Single Deceased Donor to a Single Candidate

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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:

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- 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%

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

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Host OPOs will offer both kidneys from a single deceased donor only to candidates at transplant programs that have specified to the OPTN Contractor that they are willing to accept double kidneys. Double kidneys will be offered to these candidates according to Policy 8.5.J: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85% or Policy 8.5.K: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 85%.

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If the transplanting surgeon determines, based on medical judgment, that double kidneys should be transplanted individually, then the receiving transplant program must do one of the following:

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- Transplant one of the kidneys into the originally designated recipient and document the reason for not transplanting the kidneys together. The receiving transplant program will decide which of the two kidneys to transplant into the originally designated recipient, and release the other kidney according to *Policy 5.9: Released Organs.*
- Release both kidneys according to *Policy 5.9: Released Organs.*

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