At-a-Glance

Proposal to Substantially Revise The National Kidney Allocation System

Click here to view a video summary of this proposal. Part 1 (17:40 minutes) *
Click here to view a video summary of this proposal. Part 2 (10:39 minutes) *

***Note:** To view the video files, you will need an .mp4 player installed on your computer. QuickTime is available free as a download at: http://support.apple.com/downloads/#quicktime

- **Affected/Proposed Policy:** 3.5 Allocation of Deceased Donor Kidneys

- **Kidney Transplantation Committee**

- This proposal seeks to substantially revise the national kidney allocation system to enhance post-transplant survival benefit, increase utilization of donated kidneys and increase transplant access for biologically disadvantaged candidates. The proposal incorporates new features such as an expanded definition of waiting time, a sliding scale for assigning points to sensitized patients, expanded access for blood type B candidates who can accept kidneys from subtypes of blood type A donors, broader sharing for extremely highly sensitized candidates, longevity matching of some kidneys, and regional sharing for kidneys with the highest risk of discard. The proposed changes are estimated to result in an additional 8,380 life years achieved annually from the current pool of deceased donor kidneys while improving access for sensitized candidates and minority candidates.

- **Affected Groups**
  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  PR/Public Education Staff
  Transplant Program Directors
  Transplant Social Workers
  Organ Candidates
  Donor Family Members
  General Public

- **Number of Potential Candidates Affected**
  As of July 19, 2012, there were 92,696 candidates listed for a kidney or kidney-pancreas transplant. All of these candidates will be affected in some way by the proposed changes.

- **Compliance with OPTN Strategic Goals and Final Rule**
  This proposal is expected to meet the OPTN Key Goals of increasing access to transplant and improving post-transplant survival for recipients. Additionally, this proposal will reset kidney allocation variances to comply with the requirements set forth in the OPTN Final Rule.

Proposal to Substantially Revise the National Kidney Allocation System

Affected/Proposed Policy: 3.5 Allocation of Deceased Donor Kidneys

Kidney Transplantation Committee

Public Comment Response Period: September 21, 2012-December 14, 2012

Summary and Goals of the Proposal:

This proposal seeks to substantially revise the national kidney allocation system to enhance post-transplant survival benefit, increase utilization of donated kidneys and increase transplant access for biologically disadvantaged candidates. The proposal incorporates new features such as an expanded definition of waiting time, a sliding scale for assigning points to sensitized patients, expanded access for blood type B candidates who can accept kidneys from subtypes of blood type A donors, broader sharing for extremely highly sensitized candidates, longevity matching of some kidneys, and regional sharing for kidneys with the highest risk of discard. The proposed changes are estimated to result in an additional 8,380 life years achieved annually from the current pool of deceased donor kidneys while improving access for sensitized candidates and minority candidates. Additionally, the proposed changes are believed to reduce the discard rate, thereby making more kidneys available for transplantation. Finally, the proposed changes are expected to streamline the kidney allocation system and improve efficiency.

Background and Significance of the Proposal:

These revisions to kidney allocation policy were developed in response to feedback provided by transplant professionals, patients, donor family members, and the general republic regarding organ allocation and limitations of the current kidney allocation system. Such limitations include:

- higher than necessary discard rates of kidneys that could benefit candidates on the waiting list,
- variability in access to transplantation by candidate blood type and geographic location, and
- many kidneys with long potential longevity being allocated to candidates with significantly shorter potential longevity and vice versa. This results in unrealized graft years and unnecessarily high retransplant rates.

The Organ Procurement and Transplantation Network (OPTN) Kidney Transplantation Committee worked with the OPTN and Scientific Registry of Transplant Recipients (SRTR) contractors since 2003 to design a kidney allocation system which addresses the above limitations and meets the following objectives:

- More accurately estimate graft longevity and recipient longevity to maximize the potential survival of every transplanted kidney within biological reason and to provide acceptable levels of access for those on the waiting list.
- Promote post-transplant kidney function for candidates with the longest estimated post-transplant survival and who are likely to require additional transplants due to early age of end stage renal disease (ESRD).
- Minimize loss of potential functioning years of deceased donor kidney grafts through improved matching.

- Improve offer system efficiency and organ utilization through the introduction of a new scale for kidney quality, called the kidney donor profile index (KDPI).
- Make comprehensive data better available to patients and transplant programs to guide them in their treatment choices.
- Reduce differences in transplant access for populations described in the National Organ Transplant Act (e.g., candidates from racial/ethnic minority groups, pediatric candidates, and sensitized candidates).

The following table lists some of the major events undertaken in the formulation of this proposal.

Table 1: Sentinel events in the development of the kidney allocation proposal

Date	Sentinel Event
2003	OPTN Board of Directors instructs the Kidney Allocation Review Subcommittee (KARS) to conduct a 360 degree review of the current kidney allocation system. This review included a series of public hearings to better understand the limitations of the current system and possible approaches for improvement.
2004	OPTN Board of Directors instructs KARS to examine the use of net lifetime survival benefit in a revised allocation system.
2005	KARS merges with the OPTN Kidney Transplantation Committee to begin formal policy development process.
2007	Public Forum held in Dallas, Texas to review the use of life years from transplant (LYFT) in an allocation system.
September 2008	Request for Information (RFI) issued detailing the concepts of life years from transplant (LYFT), kidney donor profile index (KDPI), and changes to the waiting time calculation to include time on dialysis prior to listing.
January 2009	Public forum held in Saint Louis Missouri to review concepts circulated in September 2008. Participants included representatives from the following organizations: • American Association of Kidney Patients • American Society of Histocompatibility and Immunogenetics • American Society of Transplant Surgeons • American Society of Transplantation • National Association of Transplant Coordinators • National Kidney Foundation • Renal Support Network
2009	At the recommendation of forum participants, the Committee considers age matching as a way to address concerns about system complexity.
February 2011	Concept document is released detailing the use of estimated post transplant survival (EPTS), age matching within 15 years of donor and recipient, and kidney donor profile index (KDPI).
August 2011	Committee receives feedback suggesting that age matching does not meet the requirements of the 1979 Age Discrimination Act since it uses age as an arbitrary determinant in allocation.
2011-2012	Committee considers alternatives to age matching.
September 2012	Committee issues a proposal for public comment.

As of July 19, 2012, 92,696 individuals were listed for kidney transplant.[1] The demand for kidney transplant has steadily increased since the OPTN began keeping records. However, the number of kidneys available from deceased donors has not kept pace with the increasing demand. The demand is projected to continue to grow given the increases in the number of Americans with end stage renal disease (ESRD) and chronic kidney disease (CKD) (Figure 1).

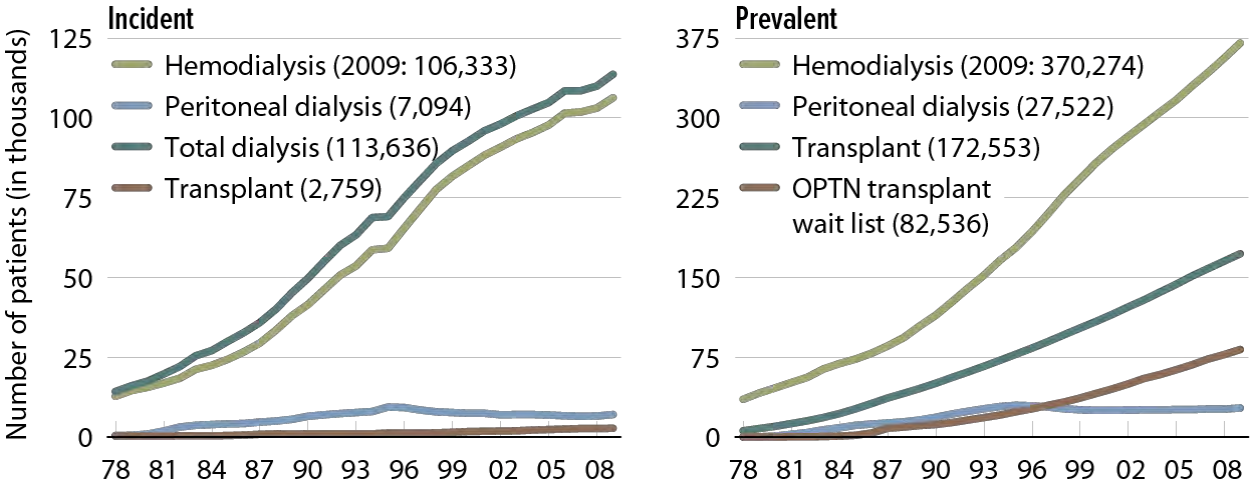


Figure 1: End stage renal disease (ESRD) incident and prevalent patient counts, by modality

In a perfect scenario, all who need a kidney transplant would receive one without delay. However, the shortage of deceased donor organs means that most candidates for kidney transplantation have to wait, oftentimes for years before receiving a transplant. Some transplant candidates do not survive long enough to receive a kidney from a deceased donor and die while on the waiting list. Other candidates are fortunate to receive a kidney from a living donor. While the number of living donor transplants has increased over time, even with these additional kidneys, there is not enough supply to provide a transplant to all who need one.

Organ allocation is the process the OPTN uses to determine which transplant candidates are offered which organs. Each organ allocation system attempts to achieve different goals. For example, livers are allocated based on a candidate's chance of dying while waiting for a transplant. Those candidates at highest risk are transplanted ahead of candidates at lower risk. Lungs are allocated based on the candidate's chance of dying while waiting for a transplant and also on the chance of dying during the first year following transplant. In this way, the liver and lung allocation systems both attempt to minimize death on the waiting list. The lung allocation system is designed also to maximize survival in the first year after transplant. In contrast, kidneys are currently allocated based primarily on how long a candidate has been on the waiting list.

Waiting time's status as the primary determinant in the kidney allocation system has evolved gradually. The kidney allocation system was initially designed so that candidates who were close biological matches with a donated kidney received more priority than candidates who were not as close of a biological match. In the past, closer biological matching was necessary for acceptable patient and graft survival. With improvement in anti-rejection medications, the priority for tissue typing has been

[1] Based on OPTN data as of July 19, 2012. http://optn.transplant.hrsa.gov/data/

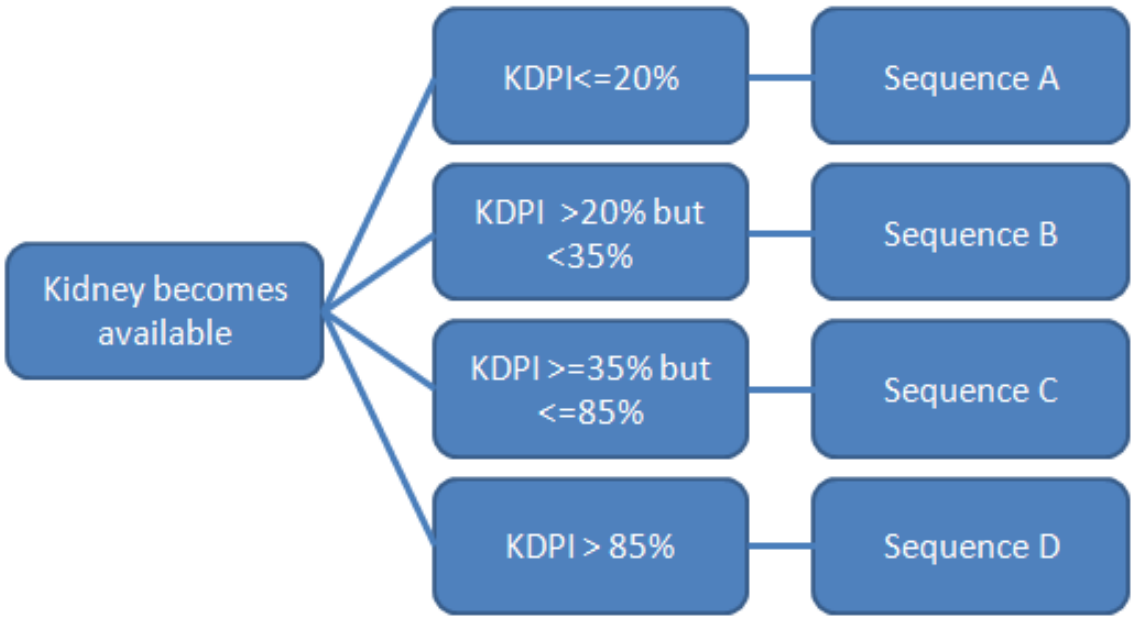
decreased greatly over the last several decades. While the current design of giving most of the priority based on waiting time may be perceived as "fair", it does not strive to minimize death on the waiting list nor maximize survival following transplant. It does not recognize that all candidates do not have the same ability to survive the wait. It does not attempt to match the characteristics of a donor's kidney to the candidate's characteristics to promote a long and healthy survival post-transplant. The system can be designed to achieve more in the way of patient health and longevity, as well as more efficient utilization of a limited resource than it currently does.

With the belief that the system can be improved, the Kidney Transplantation Committee, under direction from the OPTN Board of Directors, set out to design a new kidney allocation system. Over the past nine years, this process has involved hundreds of individuals including transplant professionals, transplant recipients, transplant candidates, donor family members, living donors, and members of the general public.

Brief Description of Proposed System:

Currently, the kidney allocation sequence has four distinct pathways based on the characteristics of the kidney. Kidneys from donors younger than 35 are allocated preferentially to pediatric candidates. Kidneys from expanded criteria donors (ECD) are allocated to candidates who consent to receiving these organs. Kidneys from standard criteria donors (SCD) are allocated to all candidates on the waiting list. Kidneys from donation after cardiac death (DCD) donors are allocated according to a sequence that speeds placement by focusing on local distribution.

Similarly, there are four distinct pathways for kidney allocation within the proposed system. Unlike the current system which uses different criteria for determining the pathways (ECD status, DCD status, donor age), the proposed system uses the kidney donor profile index (KDPI). The diagram below demonstrates the four different pathways based on KDPI. For example, if a kidney becomes available with a KDPI score greater than 20% but less than 35%, then the kidney would follow allocation sequence B. For reference, kidneys with higher estimated quality have lower KDPI scores.



The following table provides a summary of the allocation categories for each of the sequences. Detailed allocation sequences may be found in section 3.5.6 of the proposed policy language.

Sequence A **KDPI <=20%**	**Sequence B** **KDPI >20% but <35%**	**Sequence C** **KDPI >=35% but <=85%**	**Sequence D** **KDPI>85%**
Local CPRA 100	Local CPRA 100	Local CPRA 100	Local CPRA 100
Regional CPRA 100	Regional CPRA 100	Regional CPRA 100	Regional CPRA 100
National CPRA 100	National CPRA 100	National CPRA 100	National CPRA 100
Local CPRA 99	Local CPRA 99	Local CPRA 99	Local CPRA 99
Regional CPRA 99	Regional CPRA 99	Regional CPRA 99	Regional CPRA 99
Local CPRA 98	Local CPRA 98	Local CPRA 98	Local CPRA 98
Zero mismatch (top 20% EPTS)	Zero mismatch	Zero mismatch	Zero mismatch
Prior living organ donor	Prior living organ donor	Prior living organ donor	Local + Regional
Local pediatrics	Local pediatrics	Local	National
Local top 20% EPTS	Local adults	Regional	
Zero mismatch (all)	Regional pediatrics	National	**all categories in Sequence D are limited to adult candidates*
Local (all)	Regional adults		
Regional pediatrics	National pediatrics		
Regional (top 20%)	National adults		
Regional (all)			
National pediatrics			
National (top 20%)			
National (all)			

Within each category, candidates are rank-ordered according to points. Briefly, the proposed point system is as follows:

- 1 point per year (awarded as 1/365 points per day) for *qualified* time spent waiting
- 0-202 points based on degree of sensitization (as determined by CPRA)
- 0-2 points for degree of HLA-DR matching
- 4 points for prior living organ donors
- 1 point for pediatric candidates if donor is less than 35 years old
- 4 points for pediatric candidates (aged 0-10 at time of match) when offered a zero antigen mismatch
- 3 points for pediatric candidates (aged 11-17 at time of match) when offered a zero antigen mismatch

Once candidates are rank-ordered within the appropriate categories of an allocation sequence, the organ procurement organization (OPO) can begin to make offers. These offers are made for specific candidates in the order they appear on the OPTN Match Run. Just as they are now, OPOs would be required to follow the Match Run and administrative policies when placing kidneys under the proposed system.

Alternatives Considered:

The Committee evaluated several different approaches to kidney allocation during this process. Over 50 simulation runs were conducted with the majority falling into the following themes or combinations of themes:

- *Life years from transplant (LYFT)*: All candidates would be ranked according to their likelihood of realizing the full survival potential of a given organ. Feedback on this approach indicated that it was too complex as candidate priority could fluctuate greatly from one offer to the next. Transplant programs expressed concern that they would not be able to adequately maintain workups for all candidates on their waiting lists to accommodate such a system.
- *Age matching*: Candidates within 15 years (older/younger) of the donor would be prioritized ahead of candidates outside of the age band. This approach was found to be problematic because it used candidate age as a hard demarcation in the allocation system. After consultation with legal experts, the Committee decided not to pursue this approach as it may be perceived as age discrimination.
- *Matching of candidates and donors within quality bands*: The waiting list would be divided into five categories based on life years from transplant (LYFT) scores. Kidneys would also be divided into five categories based on kidney donor profile index (KDPI) scores. Kidneys would be allocated first to candidates in the same category before being allocated outside of the category. The Committee found that this approach resulted in substantial differences in waiting times for candidates in different categories.

Ultimately, the Committee found that the current system could be modified slightly to provide better outcomes for 80% of candidates on the list. For the remaining 20% of candidates, the Committee also recommends more substantial changes. The Committee decided to recommend that the 20% of candidates with the longest estimated post transplant survival (EPTS) have priority for the top 20% of kidneys in terms of estimated donor quality, as measured by the kidney donor profile index (KDPI). When coupled with refinements in the way candidates are rank-ordered, the Committee found that longevity matching (Top 20% of kidneys prioritized to Top 20% of candidates) is projected to achieve significantly more life years and graft years than the current kidney allocation system, without substantially diminishing access to any one group of candidates.

Table 2 outlines the current and proposed systems. Additional details are provided in later sections.

Table 2: Brief overview of proposed changes by policy section

Brief Overview of Proposed Changes to the Waiting Time Calculation	
Current	*Proposed*
Adult candidates begin accruing waiting time when listed once on dialysis or with a glomerular filtration rate [GFR] of less than or equal to 20 ml/min. Pediatric candidates begin to accrue time immediately upon listing	Adult candidates would begin to accrue waiting time when listed once on dialysis or with a GFR less than or equal to 20 ml/min. Candidates would also receive a credit for time spent on dialysis prior to listing. Pediatric candidates will still immediately begin to accrue time upon listing or will receive credit for prior dialysis if applicable
Brief Overview of Proposed Changes to Priority for Sensitized Candidates	
Current	*Proposed*

Candidates with a calculated panel reactive antibody [CPRA] score over 80% receive 4 points. Local candidates with extremely high CPRA (80%) and high total scores are categorized ahead of local candidates with lower scores.	Candidates with CPRA scores of 20% or above would receive points based on a sliding scale commensurate with CPRA. Local, regional and national candidates with CPRA =100%, regional and national candidates with CPRA =99%, and local candidates with CPRA =98% will appear before candidates with zero-antigen mismatches.
Brief Overview of Proposed Changes to Blood Type Eligibility	
Current	*Proposed*
Kidneys are allocated to candidates who are blood type identical to the donor when the donor has blood type O or blood type B.	Candidates with blood type B who meet defined clinical criteria will be eligible to accept kidneys from donors with blood type A_2 or A_2B. Otherwise, kidneys allocated to candidates who are blood type identical to the donor when the donor has blood type O or blood type B.
Brief Overview of Proposed Changes to Candidate Classification	
Current	*Proposed*
Adult candidates are not prioritized based on estimated patient survival.	The 20% of adult candidates who have the longest estimated post transplant survival (based on candidate age, prior transplant, diabetes status and dialysis time) will receive priority for kidneys from donors with KDPI scores in the top 20%.

Brief Overview of Proposed Change to Pediatric Kidney Allocation	
Current	*Proposed*
Pediatric candidates receive additional priority for kidneys from donors age of 35 or younger.	Pediatric candidates would receive additional priority for kidneys from donors with a kidney donor profile index [KDPI] score of less than 35%.
Brief Overview of Proposed Change to Kidney Classifications	
Current	*Proposed*
Kidneys are classified as either coming from standard criteria donors (SCD) or expanded criteria donors (ECD) based on donor age, history of hypertension, creatinine, and cerebrovascular accident as cause of death.	Kidneys would be classified along a continuous scale known as the kidney donor profile index (KDPI). KDPI is based on donor age, height, weight, ethnicity, history of hypertension, history of diabetes, cause of death, serum creatinine, hepatitis C virus (HCV) status, and donation after circulatory death (DCD) status.
Brief Overview of Proposed Change to Kidney Payback Policy	

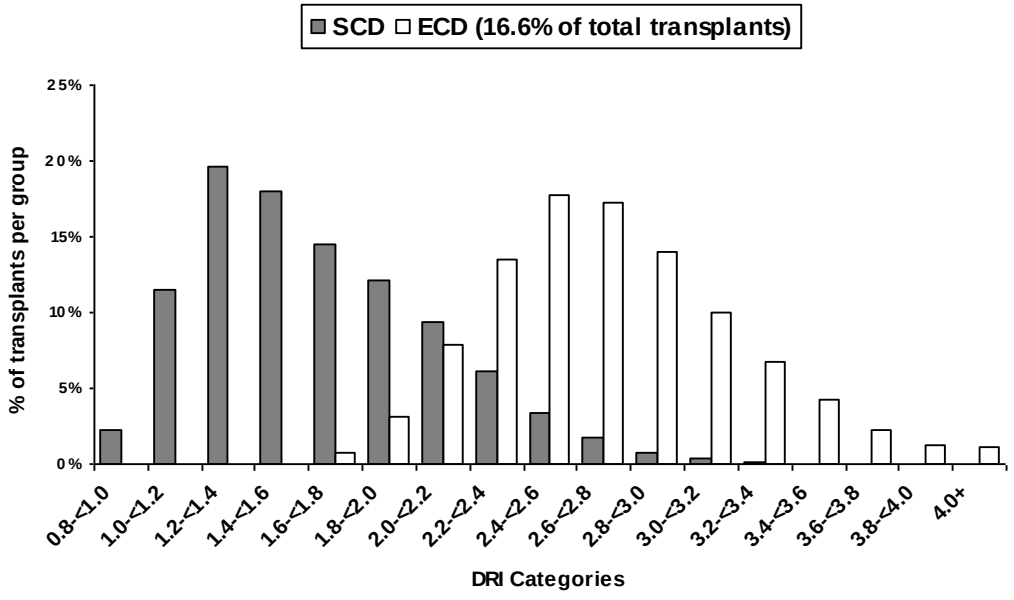
Current	*Proposed*
When a kidney is transplanted outside of the procuring donation service area (DSA), the receiving DSA is required to pay back a kidney. Kidneys are most likely to be shared as zero antigen mismatches, or as kidney/extra-renal transplants.	Paying back a kidney would no longer be required or allowed.
Brief Overview of Changes to Kidney Variances	
Current	*Proposed*
There are currently several regional and local variances to national kidney allocation policy. These include variances to geographic distribution units, allocation points, and allocation categories.	The Committee-sponsored alternative allocation systems for A_2/A_2B kidneys for B recipients and the system for allowing dialysis time to commence from the start of dialysis will be incorporated into national policy. All other variances will be eliminated at the time a new national kidney allocation system is implemented.

a. Proposed Changes to Kidney Classifications

In the current kidney allocation system, kidneys are classified as either coming from a standard criteria donor (SCD) or an expanded criteria donor (ECD). These classifications result in different allocation sequences and transplant programs are required to obtain additional consent from candidates who elect to receive ECD kidneys. The ECD classification was implemented in 2002 and is based on combinations of the following criteria: death from cerebrovascular accident, hypertension, creatinine greater than 1.5 mg/dL, and donor age. Kidneys from donors over age 60, or kidneys from donors between 50 and 59 with two of the following (hypertension, creatinine > 1.5 mg/dL, death from cerebral vascular accident) are classified as ECD.

Unfortunately, these two classifications have resulted in the labeling of kidneys as either "good" or "bad". In analyses of the KDRI, some ECD kidneys have been found to have better function than some SCD kidneys, as represented by the overlapping histograms in Figure 2.

Figure 2: Overlapping kidney donor risk index (DRI) of SCD and ECD kidneys



The Committee proposes that the dichotomous labeling system be replaced with a continuous scale, the kidney donor profile index (KDPI). The KDPI is a numerical measure that combines ten dimensions of information about a donor, including clinical parameters and demographics, to express the quality of the donor kidneys relative to other donors. The KDPI is derived by first calculating the Kidney Donor Risk Index (KDRI), using strictly donor factors, for a deceased donor.[2]

A donor with a KDPI of 90%, for example, has an estimated risk of graft failure (as per the KDRI) greater than 90% of donors in the chosen reference population. In this way, the KDPI is simply a mapping of the KDRI from a relative risk scale to a cumulative percentage scale. The reference population of donors is all donors in the U.S. from whom a kidney was recovered during the prior year. Lower KDPI values are associated with increased donor quality; higher KDPI values are associated with lower donor quality.

The following donor factors are used to calculate KDPI:

- Age
- Height
- Weight
- Ethnicity
- History of Hypertension
- History of Diabetes
- Cause of Death
- Serum Creatinine
- Hepatitis C Virus (HCV) Status
- Donation after Circulatory Death (DCD) Status

The association between these donor factors and graft survival was determined by estimating a multivariable Cox proportional hazards regression model using graft outcomes from nearly 70,000 adult, solitary, first-time deceased donor kidney recipients in the U.S. from 1995-2005. The estimated coefficients derived from this model are shown in Table 3.

Table 3: KDRI Donor Factors and Model Coefficients

Donor Characteristic	Applies to:	KDRI Coefficient ("Beta")	KDRI "XBeta" Component
Age (integer years)	All donors	0.0128	0.0128*(age-40)
	Donors with age < 18	-0.0194	-0.0194*(age-18)
	Donors with age > 50	0.0107	0.0107*(age-50)
Height (cm)	All donors	-0.0464	-0.0464*(hgt-170)/10

[2] Rao PS, Schaubel DE, Guidinger MK, Andreoni KA, Wolfe RA, Merion RM, Port FK, Sung RS. A comprehensive risk quantification score for deceased donor kidneys: the kidney donor risk index. Transplantation. 2009 Jul 27;88(2):231-6.

Weight (kg)	Donors with weight < 80kg	-0.0199	-0.0199*(wgt-80)/5
Ethnicity	African American donors	0.1790	0.1790
History of Hypertension	Hypertensive donors	0.1260	0.1260
History of Diabetes	Diabetic donors	0.1300	0.1300
Cause of Death	Donors with cerebrovascular accident as cause of death	0.0881	0.0881
Serum Creatinine	All donors	0.2200	0.2200*(creat-1)
	Donors with creatinine > 1.5 mg/dL	-0.2090	-0.2090*(creat-1.5)
HCV status	HCV positive donors	0.2400	0.2400
DCD Status	DCD donors	0.1330	0.1330

KDPI provides more information about donated kidneys than the current SCD/ECD classifications. In March 2012, the KDPI value began being displayed in DonorNet®. The purpose of this display is to help inform clinicians when making offer acceptance decisions, as well as to provide clinicians practical experience with the calculation before any possible use in an allocation system. Whereas the ECD classification indicates that a kidney has a risk of graft failure estimated to be 1.7 times greater than the average SCD kidney, the KDPI provides a continuous scale that is highly correlated with graft and patient survival (Figure 3).

	Estimated Kidney Graft Survival Rates				
KDPI	1 Year	2 Years	3 Years	5 Years	8 Years
1%	94.0%	90.8%	87.8%	80.6%	68.8%
5%	93.5%	90.1%	86.8%	79.1%	66.6%
10%	93.1%	89.4%	85.9%	77.8%	64.7%
20%	92.4%	88.4%	84.5%	75.7%	61.7%
30%	91.6%	87.3%	83.1%	73.6%	58.8%
40%	90.7%	86.0%	81.5%	71.2%	55.5%
50%	89.8%	84.6%	79.7%	68.7%	52.2%
60%	88.8%	83.2%	77.9%	66.1%	48.7%
70%	87.7%	81.5%	75.7%	63.1%	45.0%
80%	86.2%	79.4%	73.1%	59.5%	40.6%
90%	84.0%	76.3%	69.2%	54.4%	34.7%
95%	82.1%	73.6%	65.9%	50.1%	30.2%
99%	78.7%	69.0%	60.4%	43.4%	23.5%

Based on OPTN data **as of April 13, 2012** including primary, solitary, adult kidney transplants from 2000-2007. These survival rates are for SINGLE kidney-alone transplants; survival rates are generally higher for en bloc or double kidney transplants. These rates were not adjusted for recipient characteristics, but instead reflect the expected survival averaged across the broad spectrum of adult recipients. The survival rates for any particular recipient will depend on specific characteristics of that recipient. Survival rates were estimated using a Cox regression model with log(KDRI) as the sole independent variable and graft failure defined as loss of graft or patient death. **Donor reference population: all kidney donors recovered in 2011.**

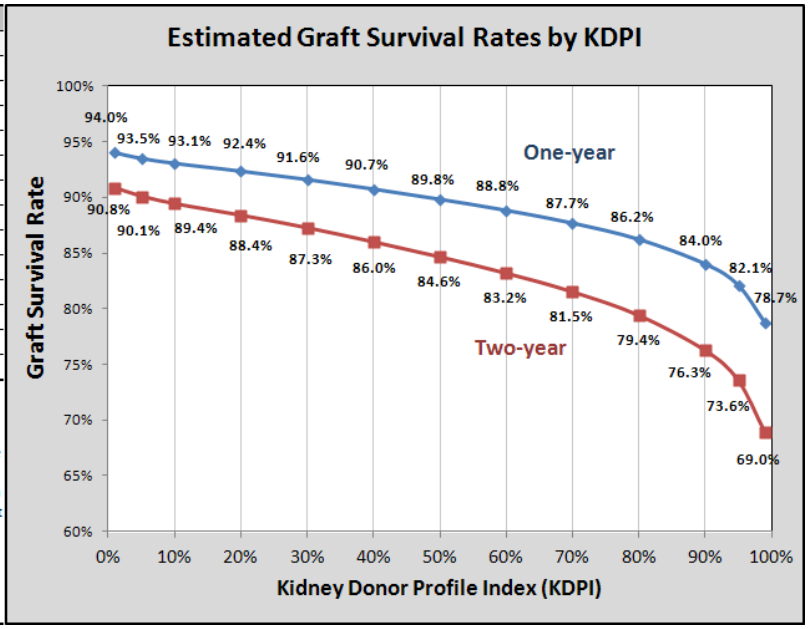


Figure 3: Estimated Graft Survival Rates by KDPI

The Committee recognizes the need for efficient placement of kidneys with higher KDPI scores which have lower expected longevity and are often less likely to be accepted for transplant. Therefore, it recommends allocating kidneys with KDPI scores greater than or equal to 85% to a combined local and

regional list of candidates, and according to a simpler algorithm based only on waiting time. Unlike the current ECD/SCD classifications, an expedited system for higher risk kidneys based on KDPI can be modified over time. In the future, the line of demarcation could be moved to 75% or 90% to include more or fewer kidneys in this pathway of the allocation algorithm in response to changing waiting list dynamics.

b. Proposed Addition to Candidate Classifications; Longevity Matching

In the current kidney allocation system, candidates are classified according to pediatric or adult, sensitized (CPRA >=80%, or CPRA between 21% and 79%) or unsensitized, and blood type. Unlike the liver allocation system or the lung allocation system, the current kidney allocation system does not have a candidate classification based risk of death while on the waiting list or estimated post-transplant survival. Incorporating a metric like estimated post-transplant survival would allow for better matching of candidates and donated grafts so that individuals with very long estimated post transplant survival do not receive kidneys with very short survival (necessitating a second or third transplant from an already limited donor pool) and vice versa.

The Committee investigated several approaches to matching graft and patient survival. Among these, life years from transplant, or LYFT, was debated in two public forums. The feedback received on LYFT was that it was made up of too many variables and that an allocation system which attempted to match each kidney and patient was too complicated and unpredictable to be feasible. Based on this feedback, the Committee revised its approach and decided to use a simplified, four-variable metric, (estimated post-transplant survival (EPTS)), instead of a "net-benefit" approach like LYFT, which also takes into account a candidate's estimated survival on dialysis. The Committee further decided to limit the use of EPTS in an allocation system to only 20% of donated kidneys. If longevity matching proves to be a successful approach for kidney allocation, future policy iterations could expand the number of kidneys and candidates which participate.

EPTS is based on the following four factors: candidate age, length of time on dialysis, prior transplant (any organ) and diabetes status. These factors were selected for the metric because they are available in the OPTN database, are clinically relevant, statistically significant, and are objective. While other factors, such as cardiovascular health, affect survival, an objective metric is not currently available in the OPTN database. As the field of transplantation advances, study of additional factors could lead to their incorporation into the dataset and ultimately into allocation policy. The formula for EPTS was derived using a Cox proportional hazards model to estimate survival of kidney transplant recipients and is shown below. Higher EPTS scores are associated with lower expected patient survival.

EPTS SCORE =
0.047 * MAX(Age - 25, 0) +
-0.015 * Diabetes * MAX(Age - 25, 0) +
0.398 * Prior Organ Transplant +
-0.237 * Diabetes * Prior Organ Transplant +
0.315 * log(Years on Dialysis + 1) +
-0.099 * Diabetes * log(Years on Dialysis + 1) +
0.130 * (Years on Dialysis = 0) +
-0.348 * Diabetes * (Years on Dialysis = 0) +
1.262 * Diabetes

The Committee determined that introducing longevity matching for all candidates at this time is not a viable policy option. In the proposed system, only 20% of candidates who have the longest EPTS would receive offers for kidneys from donors with KDPI scores of 20% or less before other candidates at the local, regional, and national levels of distribution. Kidneys from donors with KDPI scores greater than 20% would be allocated to all candidates based on allocation points.

The Committee examined the distribution of KDPI and EPTS across donation service areas (DSAs). The majority of DSAs had between 15% and 25% of donors with a KDPI score of 20% or less (Figure 4). The majority of DSAs also had between 15% and 25% of candidates with an EPTS score of 20% or less (Figure 5). The relationship between the percent of donors and candidates in the top 20% of KDPI and EPTS, respectively, is shown in Figure 6 and Figure 7. These figures show that the majority of DSAs have donor and candidate populations with KDPI and EPTS scores respectively that both fall within +/-5% of the 20% threshold. The percentage of donors within the 20% KDPI threshold appears to be only weakly correlated with the percentage of candidates within the 20% EPTS threshold.

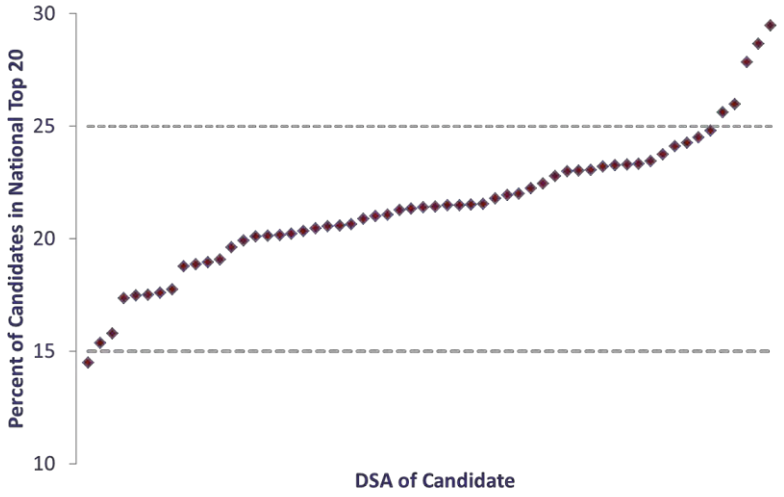


Figure 4: Percent of candidates in national top 20% by EPTS, by donation service area of candidate's listing center

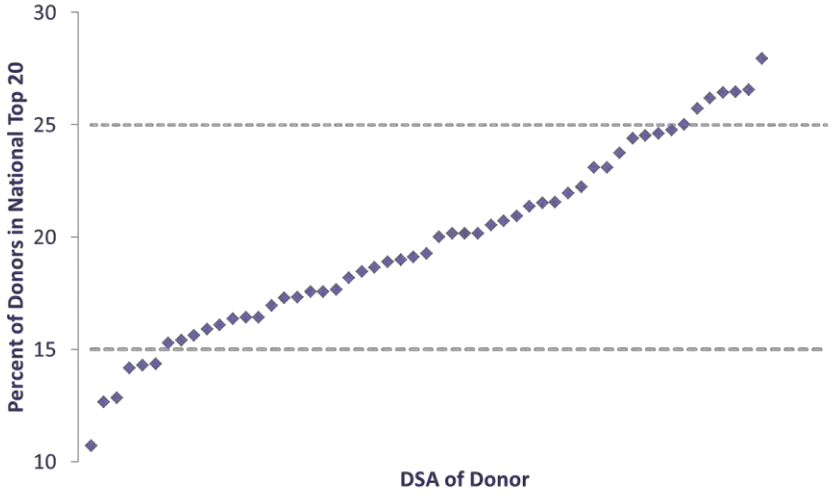


Figure 5: Percent of kidney donors in national top 20% by KDPI, by donation service area of donor

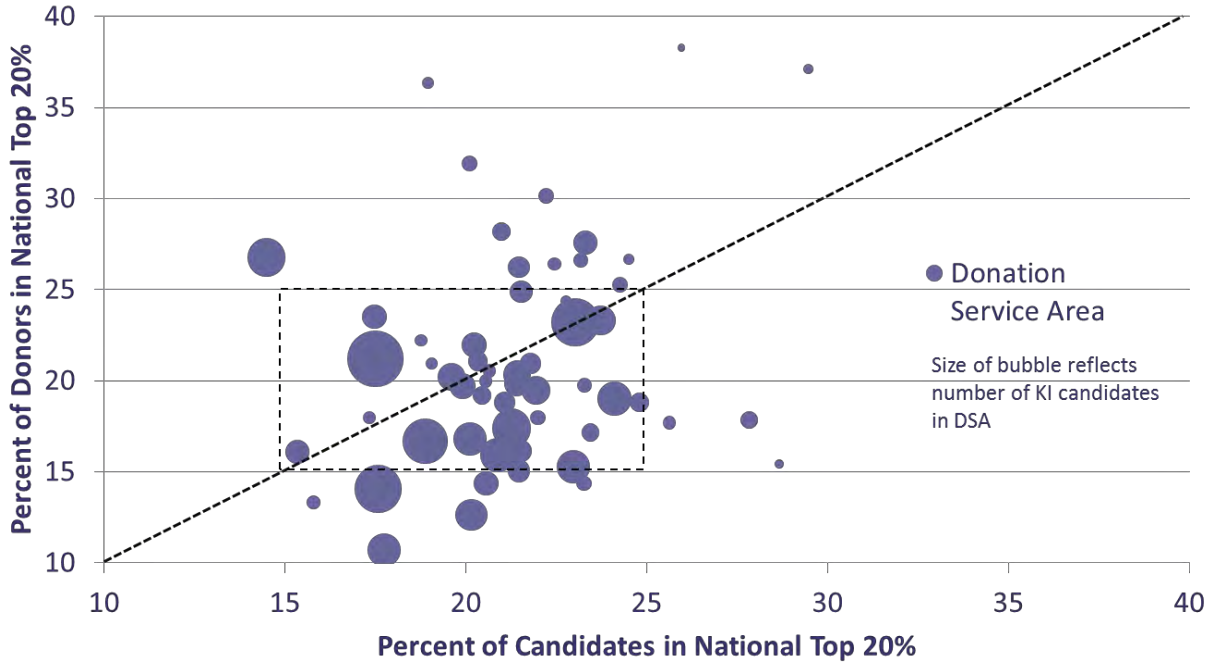


Figure 6: Percent of Top 20 candidates and Top 20 donors within DSA: by candidate volume

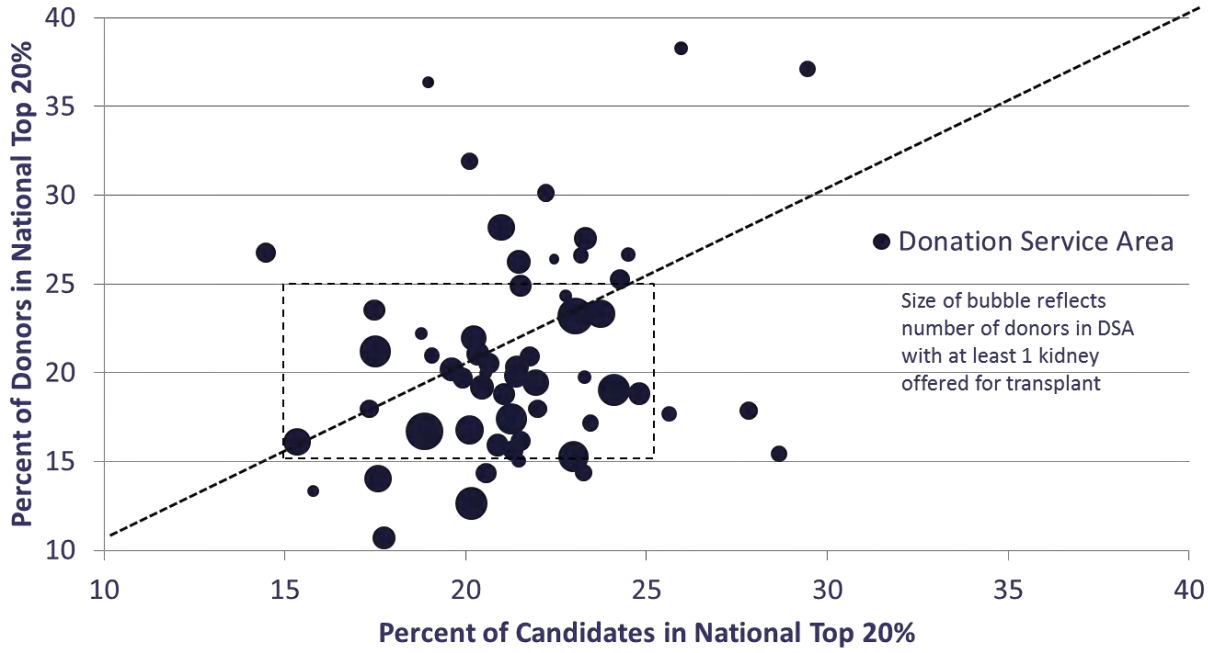


Figure 7: Percent of Top 20 candidates and Top 20 donors within DSA: by donor volume

During this process, questions have arisen regarding an allocation system in which waiting time, though still a key factor, is not the single most dominant factor driving the prioritization of candidates. Many transplant programs today rely on the "predictability" of the current allocation system and, due to the

size of their waiting list, may only maintain current workups on candidates who are most likely to receive a transplant within the next year, for example. Feedback from the transplant community indicated that some kidney programs would have difficulty maintaining workups in candidates who fluctuated into and out of the top 20% category. However, due to the nature of the factors used in the calculation, expected post transplant survival tends to decline over time and only rarely will a candidate's EPTS score improve with time. Age, time on dialysis, and prior transplant are all negative factors in the score. The only opportunity for improvement would be reversal of diabetes, but even that would not lead to a substantial improvement. Furthermore, individual candidate EPTS scores are proposed to be updated quarterly, as opposed to daily, further reducing EPTS fluctuations. Consequently, the Committee does not expect candidates to frequently fluctuate into and out of the top 20% in terms of EPTS.

The Committee considered the predictive accuracy of the EPTS calculation, or how well it can rank order candidates according to estimated longevity. The index of concordance or c-statistic for the EPTS calculation is estimated to be 0.693 (SE=0.002). For comparison, the c-statistic for another allocation model, the Model for End Stage Liver Disease (MELD), is estimated to be 0.867. The predictive ability for the EPTS calculation is not as high as for MELD; however, EPTS is not being considered as a tool for rank-ordering candidates in the same way as MELD does. Whereas liver transplant candidates are rank-ordered according to their MELD scores, the kidney allocation system would only use EPTS to categorize candidates into two broad groups: the top 20% longevity group, and the bottom 80% group. Candidates would then be rank-ordered within these groups according to allocation points.

Though a c-statistic of nearly 0.70 is considered reasonably good for a predictive model, the EPTS score does not always accurately predict which of two clinically similar candidates will actually survive longer. This difficulty is caused by sources of variability not included in the EPTS model, such as donor characteristics, recipient compliance with treatment, transplant program effects, and other measured as well as unmeasured factors. Even in a "full" model including all measured and available factors predictive of kidney transplant outcomes, the c-statistic for distinguishing recipient longevity tops out at around 0.71. This suggests that the simplified, 4-factor EPTS model has not lost significant predictive power compared to the maximum predictive capability possible given the currently available data. Though EPTS may have some difficulty distinguishing between clinically similar candidates, the expected longevity of recipients at opposite ends of the EPTS spectrum is very different.

c. Proposed Changes to the Waiting Time Calculation

As waiting time remains a core component of the proposed allocation system, this proposal seeks to refine the definition of waiting time to include the time that a patient with ESRD spent on dialysis prior to being listed for transplant. For candidates who have received a prior kidney transplant, only dialysis time since the most recent transplant applies. This proposed change is expected to increase the transplant rate for underserved (often ethnic minority) populations who may not receive adequate information to pursue transplant at the time of dialysis initiation and thus may be added to the waitlist long after their ESRD diagnosis. Current policy permits waiting time to start at registration if a candidate is either on dialysis or with a GFR<=20 ml/min.

In November 2004, the OPTN Board of Directors approved a voluntary pilot study regarding alternative kidney waiting time calculations. The study assessed the impact on kidney allocation from permitting kidney waiting time accrual to commence from the time of initiation of chronic maintenance dialysis, even if this time pre-dated the date of listing. The study did not change current policy allowing waiting time (1) for adult candidates who have not yet initiated chronic maintenance dialysis to accrue upon

attaining a minimum creatinine clearance level or calculated GFR, with no time accrued based upon these criteria prior to the date of the candidate's listing, and (2) for pediatric candidates who have not yet initiated chronic maintenance dialysis to accrue upon date of wait listing. The intent of the study was to test the effect of a change in the definition of waiting time on access to transplantation within participating DSAs. Since implementation in 2006, three OPOs have elected to participate in the study: OneLegacy in California, Iowa Donor Network, and Gift of Life Michigan.

d. Proposed Changes to Priority for Sensitized Candidates

The National Organ Transplant Act (NOTA) of 1984 called for additional consideration to be given to candidates who face biological difficulties in obtaining a transplant. Candidates who are immunologically sensitized through events such as prior transplant, blood transfusion, or prior pregnancy, are unable to receive transplants from some or most organ donors due to immunologic incompatibility. The current kidney allocation system recognizes and attempts to address these barriers by awarding four points to candidates who have a calculated panel reactive antibody greater than or equal to 80% and by prioritizing highly sensitized candidates who have been waiting longer than unsensitized candidates at the local level of distribution.

The Committee examined the performance of these policies and found that they did not adequately address the needs of sensitized candidates on the waiting list. As of the end of 2010, nearly two-thirds of kidney candidates were reported as being non-sensitized (CPRA=0%), but about 11% were "very highly sensitized," with a CPRA of 95% or higher. Though about 5% of candidates had CPRA of 100%, these extremely difficult to match candidates accounted for less than 1% of the transplants. Demographically, candidates who were younger, female, and African American tended to have a higher likelihood of being very highly sensitized (CPRA>=95%). There was only a weak relationship between blood type and CPRA, with types O and B having a slightly higher chance of being highly sensitized.

Sensitized candidates were found to wait substantially longer than unsensitized candidates, suggesting that more needs to be done to equalize waiting times between these two groups. On average, non-sensitized patients received about 17 compatible offers per year, while fully sensitized (CPRA=100%) patients received only 0.09 compatible offers per year, a 187-fold difference, in spite of the four-point advantage (Figure 8). If not for the additional priority given to sensitized candidates for zero-antigen mismatches, the decrease in offer rates would be even more dramatic for those with CPRA approaching and equal to 100%.

Additionally, candidates with CPRA greater than 95% see a marked decline in the number of compatible offers received (Figure 9). Finally, the Committee observed that the current policy may assign too much priority for candidates with CPRA scores of 80-84%, as indicated by the artificial increase in offers for this group and the substantial increase in transplants for this group (Figure 10).

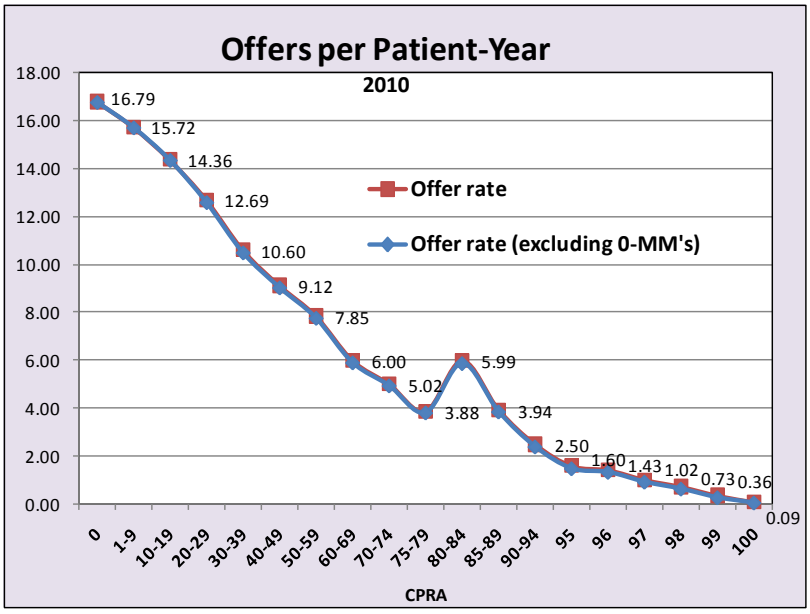


Figure 8: Offers per patient-year by candidate CPRA

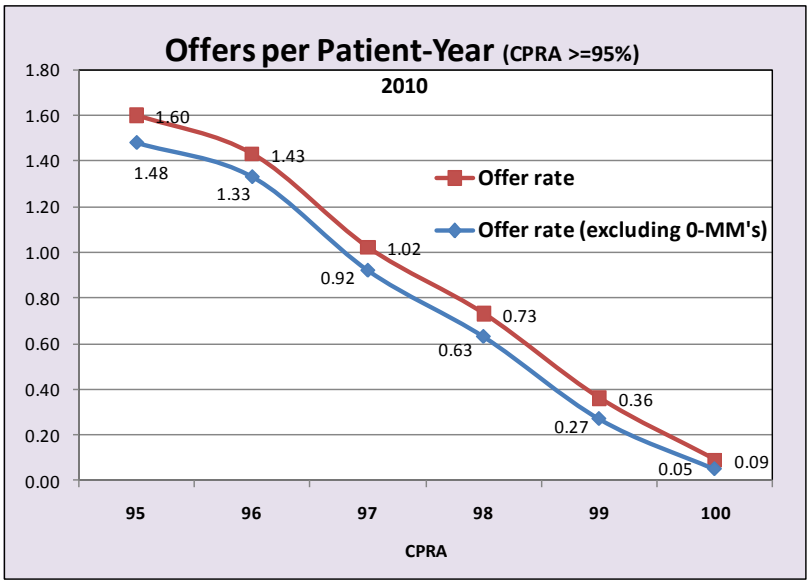


Figure 9: Offers per patient-year for candidates with CPRA scores greater than or equal to 95%

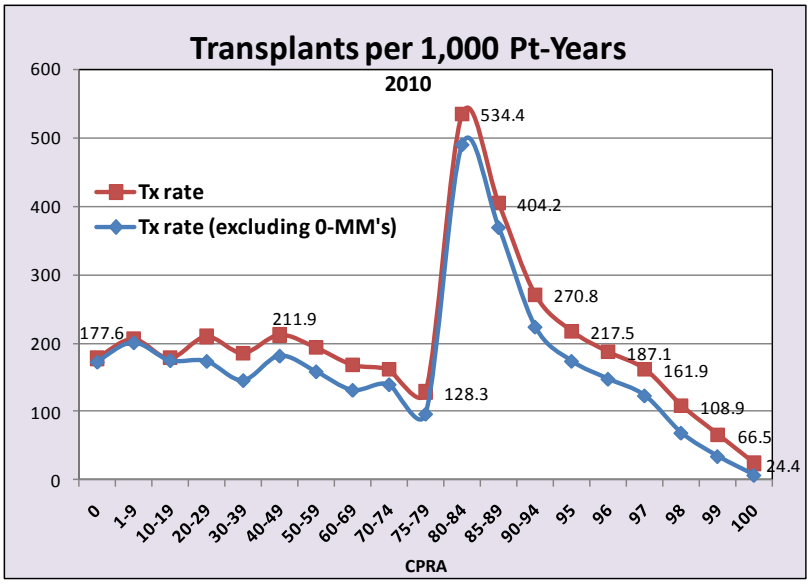


Figure 10: Transplants per 1,000 patient years by candidate CPRA

In consultation with the OPTN/UNOS Histocompatibility Committee, the following interventions were proposed as policy options to address the above problems:

1. Assign points for sensitization at a lower CPRA and scale these points to the level of difficulty that these candidates have in obtaining a compatible transplant.
2. Prioritize candidates who are extremely unlikely to receive a transplant due to sensitization ahead of zero-antigen mismatch transplants. The Committees determined that candidates with CPRA scores greater than or equal to 98% face far greater difficulty in obtaining a transplant and require exposure to a larger donor pool to have any chance of receiving a transplant at roughly the same time as similar unsensitized candidates.

The Committee reviewed data analyses to determine where to begin assigning points for sensitization and how to scale these points (see Appendix 1 uploaded as a separate .pdf attachment on the OPTN public comment website). Though there are some similarities, transplant rates (Figure 10) showed a somewhat different pattern as a function of CPRA than did offer rates (Figure 8 and Figure 9). As CPRA increased from 0% to around 60%, transplant rates held constant at around 200 transplants per 1,000 patient-years, in spite of the steady decline in the offer rate. As CPRA increased beyond 60%, transplant rates decreased moderately up to a CPRA of 79%. When CPRA reached 80%, the transplant rate increased dramatically, more than doubling the rate of non-sensitized or moderately sensitized candidates, in spite of the fact that the offer rates for the 80-84% CPRA group increased only moderately. This disconnect between the transplant rate and offer rate patterns by CPRA is thought to be due to differences in transplant center offer acceptance practices.

Based on a time-to-offer analysis, the Committee found that that candidates began to experience barriers to transplant starting at a CPRA score of 20% which gradually increased with increasing sensitization until an inflection point at about 95%. Above 95%, waiting time increases more substantially due to the decreasing offer and transplant rate for these candidates. In response to these observations, the following point system, a “sliding scale” based on candidate CPRA was derived via a mathematical transformation of the offer rate patterns shown in Figure 8 and Figure 9.

If the candidate's CPRA score is…	Then the candidate receives this many points…
x=0	0.00
0<x<10	0.00
10<=x<20	0.00
20<=x<30	0.08
30<=x<40	0.21
40<=x<50	0.34
50<=x<60	0.48
60<=x<70	0.81
70<=x<75	1.09
75<=x<80	1.58
80<=x<85	2.46
85<=x<90	4.05
90<=x<95	6.71
95<=x<96	10.82
96<=x<97	12.17
97<=x<98	17.30
98<=x<99	24.40
99<=x<100	50.09
100	202.10

Even with such a substantial increase in points (24.40 points for CPRA of 98; 50.09 points for CPRA of 99, 202.10 points for CPRA of 100), candidates with CPRA scores greater than or equal to 98% still cannot hope to achieve a transplant rate similar to unsensitized candidates based on an increased number of points alone. If there are few local, compatible donors available for these candidates, awarding a large number of points to put them at the top of their local list will have very little impact. Due to their level of sensitization, these candidates require access to a larger donor pool in addition to priority within their donation service area.

The Committee also investigated two approaches for broader sharing for candidates with CPRA scores greater than or equal to 98% (Table 4). Option 1 prioritized all candidates with CPRA scores greater than or equal to 98% ahead of zero-antigen mismatch transplants at the local, regional and national levels. Option 2 took a tiered approach to broader sharing, recognizing that candidates with CPRA scores of 100% are much less likely to receive a compatible offer than lesser sensitized candidates. Additionally, Option 2 broadened the geographic donor pool incrementally so that candidates with CPRA scores of 99% received regional priority while candidates with CPRA scores of 100% received national priority. Under Option 2, candidates with CPRA scores of 98% received local priority ahead of zero-antigen mismatch offers. Based on the findings from KPSAM (see Supporting Evidence section), the Committee selected Option 2 for this policy proposal.

Table 4: Allocation sequences considered for broader sharing for very highly sensitized candidates

Option 1	Option 2
• Local CPRA 98-100 • Regional CPRA 98-100 • National CPRA 98-100 • Zero mismatch classifications • […]	• Local CPRA 100 • Regional CPRA 100 • National CPRA 100 • Local CPRA 99 • Regional CPRA 99 • Local CPRA 98 • Zero mismatch classifications • [...]

As with any policy that requires sharing especially for highly sensitized candidates, concerns were raised about unforeseen positive crossmatches. Under the current allocation system, for every one offer refusal due to positive crossmatch, (among non-local offers in 2010 to candidates with CPRA of greater than or equal to 98%), there were 3.5 successful transplants for these very highly sensitized candidates. However, since the rate of offer refusal due to positive crossmatch is higher for highly sensitized candidates, the proposed policy includes additional requirements to reduce these events. Specifically, in order for a candidate with a CPRA score of 99% or 100% to receive regional or national offers, the candidate's transplant physician and the transplant program's HLA laboratory director would be required to review and approve the unacceptable antigens listed for the candidate.

e. Proposed Changes to Pediatric Allocation

Currently, pediatric candidates receive priority in several ways for kidneys from donors generally considered of higher quality. Specifically, candidates who are younger than 18 years *at the time of the match* and who have a 0-ABDR mismatch with the donor receive priority in the form of points (4 points for 0-10 years old and 3 points for 11 to 17 years old) and also categorical priority. Candidates who were younger than 18 at *the time of registration* receive priority ahead of all other local candidates for kidneys from donors younger than 35. This system was designed to expedite transplant for pediatric candidates by providing increased access to organs with longer estimated post-transplant function. The system has been working well and achieving its stated objectives.

As the Kidney Transplantation Committee began working to design a kidney allocation system based on KDPI, it asked the Pediatric Transplantation Committee to consider whether the donor age threshold could be converted to KDPI, a more refined measure of donor quality compared to age alone. The purpose of this change would be to maximize system flexibility. As the composition of the waiting list or the donor population changes, having the entire system based on KDPI could allow for easier changes to accommodate the changing needs of the pediatric population. After modeling various thresholds, the Pediatric Transplantation Committee recommended that the KDPI threshold be set at 0.35. With this threshold, SRTR simulation modeling has forecasted that pediatric candidates would maintain the same level of access that is experienced under the current system.

Additionally, in the proposed system, pediatric candidates would no longer receive offers for kidneys from donors with KDPI scores greater than 85%. An analysis of OPTN data determined there have been zero transplants of solitary ECD kidneys into pediatric candidates since 2007. Removing pediatric

candidates from this allocation sequence would streamline system efficiency without harming access for this patient population.

f. Proposed Changes to Blood Type Eligibility

Currently, the kidney allocation system limits the blood types that may be transplanted into each candidate as a means of maintaining equity. Blood type B kidneys must be transplanted into blood type B recipients and blood type O kidneys must be transplanted into blood type O recipients. Exceptions are made only in the case of zero antigen mismatched transplants.

In 2001, the OPTN Board of Directors approved a variance to enable the transplantation of blood type A_2 (technically, "non-A_1") and A_2B (technically, "non-A_1B") deceased donor kidneys into blood type B candidates. The goal of this variance was to increase the rate of transplantation in blood type B candidates by allocating these kidneys to them without negatively impacting post-transplant outcomes. Since the national median waiting time for deceased donor kidney transplantation is highest for blood type B candidates, this variance was expected to decrease an access barrier to transplantation for blood type B candidates.

Since implementation, nine OPOs have participated in this variance. Published studies have found A_2 and A_2B kidneys transplanted into blood type B recipients have comparable survival rates and that this practice has shortened waiting times for this blood type.[3,4]

To be eligible to receive an A_2 or A_2B kidney, a blood type B candidate would need to have two consecutive quarterly anti-A titers performed demonstrating low isoagglutinin titers (anti-AIgG titer<1:8); any candidates with a titer value of 1:8 or higher will be excluded.

g. Proposed Changes to Kidney Payback Policy

Currently, the kidney allocation system requires an OPO that receives a kidney from another OPO for zero-antigen mismatch or for a combined organ transplant to payback a kidney to the originating OPO from the same blood type. Policy sets requirements for which types of kidneys must be offered as paybacks.

From an administrative perspective, the kidney payback system has been fraught with challenges since its implementation. Penalties for exceeding debt thresholds are levied against all transplant programs served by an OPO, even if only one program is responsible for accruing the debt. Several OPOs have reported difficulty in paying down debt because credited OPOs do not accept payback offers. The Kidney Transplantation Committee has spent considerable time hearing complaints about the payback system and has, over the years, adjusted the system to no apparent benefit. Furthermore, the benefit of shipping kidneys purely for administrative purposes is not clear. Payback kidneys tend to have more cold ischemic time than kidneys transplanted locally. For these reasons, the Committee proposes eliminating the kidney payback system entirely. Kidneys that are shared for zero antigen mismatches,

[3] Bryan CF, Winklhofer FT, Murillo D, Ross G, Nelson PW, Shield CF 3rd, Warady BA. Improving access to kidney transplantation without decreasing graft survival: long-term outcomes of blood group A2/A2B deceased donor kidneys in B recipients. Transplantation. 2005 Jul 15;80(1):75-80.

[4] Bryan CF, Nelson PW, Shield CF 3rd, Ross G, Warady B, Murillo D, Winklhofer FT. Transplantation of A2 and A2B kidneys from deceased donors into B waiting list candidates increases their transplantation rate. Clin Transpl. 2004:127-33.

for extremely highly sensitized candidates, and for combined organ transplant would no longer incur a payback debt.

h. Proposed Regional Allocation for Higher KDPI Kidneys

Currently, kidneys from expanded criteria donors are offered first locally and candidates who elect to receive ECD kidneys are rank ordered only according to waiting time. The goal is to expedite placement of these kidneys. Unfortunately, discard rates for ECD kidneys are high and also vary widely across OPOs. Generally, OPOs with longer waiting times tend to procure and transplant more ECD kidneys than OPOs with shorter waiting times. This suggests that demand drives decision making on whether to utilize these kidneys more so than clinical utility.

The Committee investigated ways to improve procurement and transplantation rates for kidneys at a high risk of discard. Among the options considered was expanding the distribution area for these kidneys so that these kidneys are offered first to a combined regional and local unit. This proposed approach would make available with less cold ischemic time those kidneys that would be discarded in one OPO due to shorter candidate waiting times but utilized in a neighboring OPO with longer waiting times.

i. Proposed Changes to Kidney Allocation Variances

Many OPOs have variances in place that allow for kidney allocation according to rules or distribution units that are different from the national policy. These variances were reviewed by the Kidney Transplantation Committee and approved by the OPTN Board of Directors over a period of over two decades. Many of these variances pre-date the OPTN Final Rule which sets requirements for variances (Figure 11).[5] Briefly, the OPTN Final Rule describes variances as experimental policies designed to test allocation methods. As such, variances are to have a research design with data collection and analysis plans and an end date. Additionally, variances must adhere to the principles of policy development including being based on medical judgment, achieve best use of organs, be designed to avoid wasting organs/futile transplants, promote access, and shall not be based on a patient's place of residence except as required under Final Rule provisions.

Section 121.8: Allocation of Organs

(g) Variances. The OPTN may develop, in accordance with § 121.4, experimental policies that test methods of improving allocation. All such experimental policies shall be accompanied by a research design and include data collection and analysis plans. Such variances shall be time limited. Entities or individuals objecting to variances may appeal to the Secretary under the procedures of § 121.4.

(a) Policy development. The Board of Directors established under § 121.3 shall develop, in accordance with the policy development process described in § 121.4, policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:
(1) Shall be based on sound medical judgment;
(2) Shall seek to achieve the best use of donated organs;
(3) Shall preserve the ability of a transplant program to decline an offer of an organ or

[5] 42 C.F.R. §121.8

not to use the organ for the potential recipient in accordance with § 121.7(b)(4)(d) and (e) ;
(4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;
(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;
(6) Shall be reviewed periodically and revised as appropriate;
(7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program; and
(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.

Section 121.4: OPTN policies: Secretarial review and appeals
(a) The OPTN Board of Directors shall be responsible for developing, with the advice of the OPTN membership and other interested parties, policies within the mission of the OPTN as set forth in section 372 of the Act [Public Health Service Act] and the Secretary's contract for the operation of the OPTN, including:

Policies for the equitable allocation of cadaveric organs in accordance with 121.8

Figure 11: Excerpt from the OPTN Final Rule regarding variances

The Committee engaged in a review process of all of the existing kidney allocation variances. As with other major allocation system revisions (e.g., lung allocation, and heart allocation), the Committee decided not to carry existing variances into the new kidney allocation system with two exceptions. The Committee-sponsored alternative allocation systems to initiate waiting time from the start of dialysis and to allocate organs from A_2 and A_2B donors to blood type B candidates are being proposed as a national policy. All other variances would sunset with the implementation of a new kidney allocation system. Transplant programs may apply for new variances according to the Final Rule requirements and OPTN policies governing variances.

Transplant programs in OPOs that requested continuation of a variance were invited to submit a proposal for a transition plan which would be implemented prior to the implementation of a new kidney allocation system. As some of these variances have been in place for over 20 years, the purpose of these transition plans would be to lessen severe effects of switching from the current allocation system to the proposed allocation system. The Committee received two requests for transition plans, one from the transplant programs in Region 1, and one from the transplant programs served by Southwest Transplant Alliance in Texas.

Proposed Transition Plan for Candidates Listed in Region 1
Region 1 uses the standard distribution and allocation system with the following exceptions. For distribution, the region combines kidney waiting lists for its two OPOs - New England Organ Bank (MAOB) and LifeChoice Donor Services (CTOP) - into a single list. There are no "OPO KI" classifications on Region 1 kidney matches. Region 1 renal candidates cannot be listed at multiple programs within Region 1.

Region 1 waiting time is based upon the time a candidate has been on dialysis. This requirement to be on dialysis applies to both pediatric and adult candidates, but time cannot be accrued prior to the listing date in UNet^{SM}. Anniversary year points are not awarded to Region 1 candidates. Instead, for allocation of standard criteria donor kidneys, a maximum of eight points are assigned for time waiting if one of the following criteria is met:

- candidates 0-5 years old who have been waiting six months or more,
- candidates 6-10 years old who have been waiting 12 months or more,
- candidates 11-17 years old who have been waiting 18 months or more, and
- candidates 18 years old or older who have been waiting three years or more.

For candidates that do not meet the above criteria, waiting time points are based on the following formulas:

- 0-17 years old at the time the match is run:
  - ABS [(√((1 - ((days waiting)^2/(threshold)^2)) * 64.0) + 8.0) - 16.0]
    threshold = 180, 365, or 545 days as defined above by candidate age
- 18 years old or older at the time the match is run:
  - (8.0/3.0)*(days waiting/365.0)

Additionally, seven points are assigned if there are no B or DR mismatches between the patients' and donors' antigens. Potential recipients in Region 1 can also accrue up to a maximum of 10 "population distance points." Population distance points are distributed according to a linear curve which is based upon population between donor hospital and the candidate's transplant center.

The transplant programs in Region 1 propose a single stage transition plan that would reduce the maximum number of population distance points from the current of 10 points down to 6 points. Other aspects of the variance would remain in place until the transition to the new national system. Population distance points are unique to Region 1 and have significant influence on the allocation of kidneys. Reducing these points from 10 to 6 is expected to be less disruptive than a sudden, total elimination of points as would occur if no transition plan were put into place.

Proposed Transition Plan for Candidates Listed at Programs Served by Southwest Transplant Alliance
Southwest Transplant Alliance (TXSB) uses the standard distribution and allocation system with the following exception. For distribution of standard and expanded criteria donors, the system divides the OPO into four sub-units – Dallas area, Tyler area, El Paso area, and Galveston area. Kidneys recovered within each sub-unit are distributed, first, according to a single waiting list for the sub-unit, and then to patients within the entire OPO according to a single OPO-wide list. Candidates appear in the "Local KI" classifications if they are listed at a transplant center in the same subunit as the donor hospital.

TXSB proposes that the subunits be combined into a single local unit based on the donation service area. Potential recipients who are in the same subunit as the donor hospital would then receive three additional points during the transition period. The transition period would last until the implementation of a new national kidney allocation system.

Supporting Evidence:

The Scientific Registry of Transplant Recipients (SRTR) used the Kidney-Pancreas Simulated Allocation Model (KPSAM) to evaluate the effect of policy changes described above. The complete technical analysis is provided as Appendix 2.[6]

To better determine the individual effects of the proposed policy changes, four separate simulation runs were conducted. These are referred to as N1, N2, N3, and N4 for reference purposes. Simulation run N1 represents the current kidney allocation system with results that closely mimic those actually observed in 2010. Simulation run N2 included the following proposed changes to the current allocation system: the revised definition of waiting time, allocation of A_2 and A_2B kidneys to B candidates, etc. (per Table 5). Simulation run N3 includes those enhancements from N2 and also longevity matching, national priority for candidates with CPRA greater than or equal to 98%, regional sharing for kidneys with KDPI scores greater than 85%. Simulation run N4 is identical to simulation run N3 but alters the priority for candidates with CPRA greater than or equal to 98% to provide national priority for candidates with CPRA scores of 100%, regional priority for candidates with CPRA scores of 99%, and local priority for candidates with CPRA scores of 98%. The following tables summarize the proposed changes evaluated in each simulation run.

Table 5: Kidney transplant recipients by recipient CPRA, with waitlist prevalence

Proposed Change	N1	N2	N3	N4
SCD allocation (defined as KDPI <=0.85 for N3 and N4)	X	X	X	X
DCD allocation	X	X		
ECD allocation (defined as KDPI >=0.85 for N3 and N4)	X	X	X	X
Eliminate kidney payback system		X	X	X
Enhanced definition of waiting time to include pre-listing time since initiation of dialysis		X	X	X
Waiting time based on fractional years		X	X	X
A_2/A_2B donor to B candidates priority (local, regional, national)		X	X	X
Pediatrics cannot receive non zero mismatched ECD offers (defined as KDPI >=0.85 for N3 and N4)		X	X	X
Longevity matching (based on KDPI and EPTS)			X	X
Share KDPI 0.35 pediatric priority (donor <35 years for N1, N2)	X	X	X	X
CPRA sliding scale point assignment			X	X
National Priority for CPRA>=98%			X	
Tiered Priority for CPRA>=98%				X
Regional sharing for kidneys with KDPI scores >=85%			X	X

Summary of Findings

Simulation run N4 represents the combination of proposed changes the Committee proposes to best address the limitations of the current system and achieve the objectives of reducing discards, reducing

[6] The Committee has reviewed over 50 separate simulation runs since 2004 including simulation modeling of the LYFT and age matching concepts which are no longer under consideration. To learn more about prior modeling, you may review the Committee's reports at http://optn.transplant.hrsa.gov/members/committeesDetail.asp?ID=89.

variability in access, and improving outcomes for all kidney transplant candidates. Overall, the system results in a projected total of 144,676 "life years" from the approximately 11,000 annual deceased donor kidney transplants. By comparison, the current system (N1) results in a simulated 136,296 life years, reflecting an estimated increase of 8,380 life years achieved annually for the proposed system (N4) compared to the current system. This increased is based on a projected 7.7% increase in the median life years per transplant, from 11.82 to 12.73. The new system is also expected to increase the median life years of benefit (relative to staying on the waitlist) per transplant from 5.01 to 5.27, a 5.2% increase (Table 6). In addition, the proposed system results in an increase in the number of sensitized candidates receiving transplants, especially those with very high levels of sensitization. This system also results in an increased transplant rate for African American and Hispanic candidates. These results are obtainable with a minimal increase in the rate of shipping kidneys.

Table 6: Summary Table for Simulation Runs N1-N4

Average for 10 iterations	N1	N2	N3	N4
Number of candidates (on waitlist at start or joining during run)	122,669	122,669	122,669	122,669
Average number of primary KI+KP transplant recipients (min, max of runs)	11,531 (11,463-11,586)	11,595 (11,526-11,655)	11,386 (11,359-11,429)	11,365 (11,324-11,409)
Average median lifespan post-transplant (min, max of runs)	11.82 (11.75 - 11.85)	11.72 (11.68-11.83)	12.63 (12.3-12.45)	12.73 (12.65-12.79)
Average median graft years of life (min, max of runs)	8.82 (8.80-8.84)	8.8 (8.77-8.82)	8.99 (8.97-9.02)	9.1 (9.08-9.12)
Average median extra life-years for tx recipient versus waitlist candidate (min, max of runs)	5.01 (4.99-5.03)	4.95 (4.93-4.99)	5.24 (5.20-5.27)	5.27 (5.24-5.29)
Average median LYFT per transplant (min, max of runs)	5.7 (5.68-5.72)	5.65 (5.63-5.69)	5.93 (5.89-5.96)	5.97 (5.95-6.0)

Results by Recipient Demographics

The following graphs depict the percent of candidates on the waiting list as well as the recipients under simulation runs N1-N4 by blood type, ethnicity, age, degree of zero antigen mismatches, and degree of sensitization. In these graphs, "Waitlist" indicates the percentage of the total kidney candidates on the waitlist in 2010 by each characteristic; "2010" indicates the actual, observed percentage of transplants that occurred in 2010 by each characteristic; and N1-N4 display the simulated output from KPSAM under each of the four allocation systems.

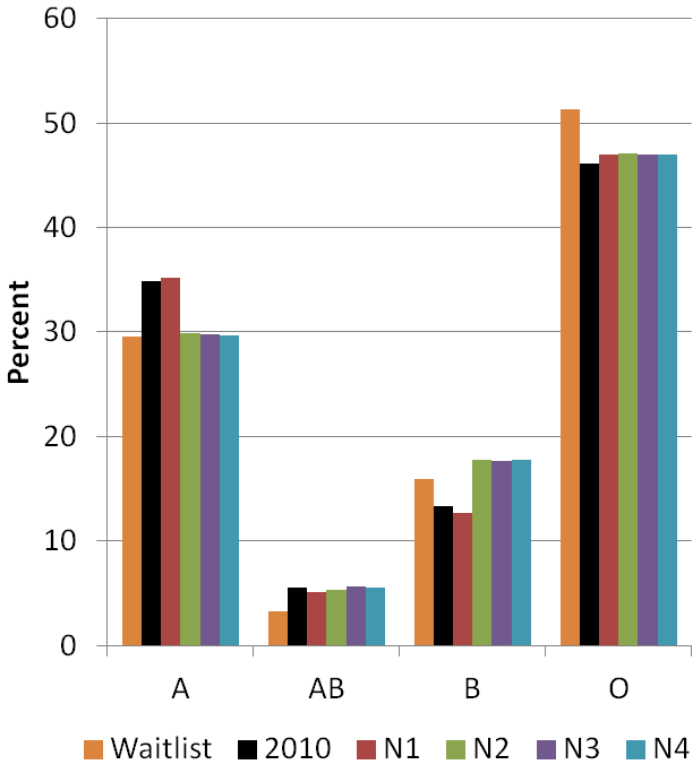


Figure 12: Kidney candidates and kidney transplant recipients by blood type

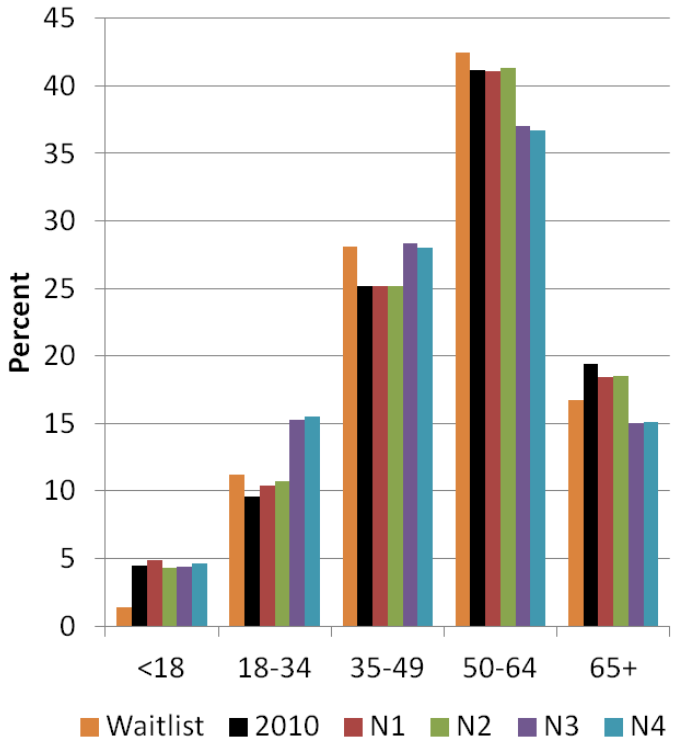


Figure 13: Kidney candidates and kidney transplant recipients by age

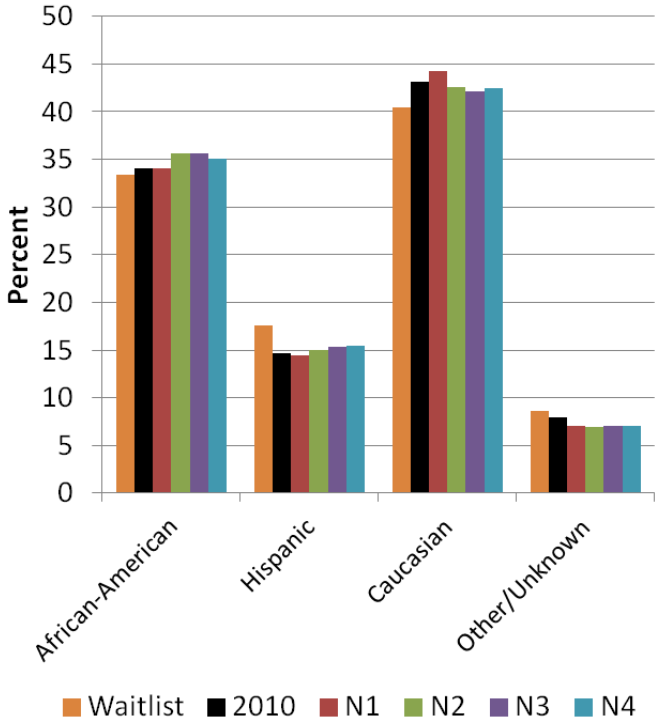


Figure 124: Kidney candidates and kidney transplant recipients by ethnicity

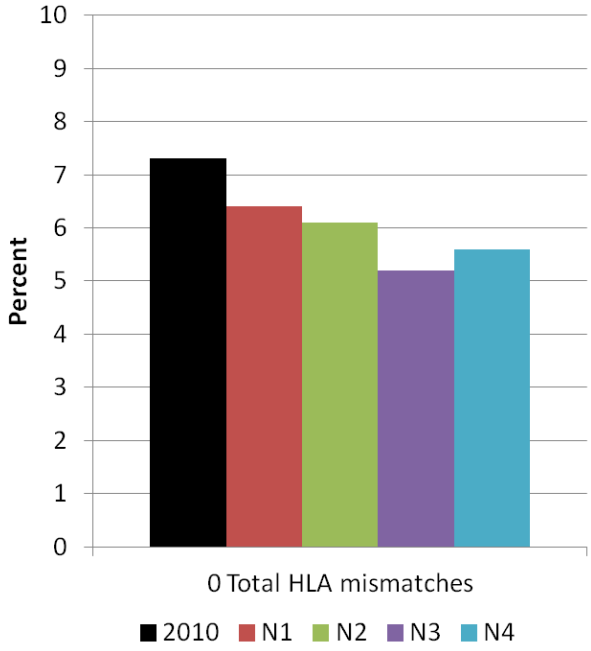


Figure 15: Kidney transplant recipients by zero antigen mismatches

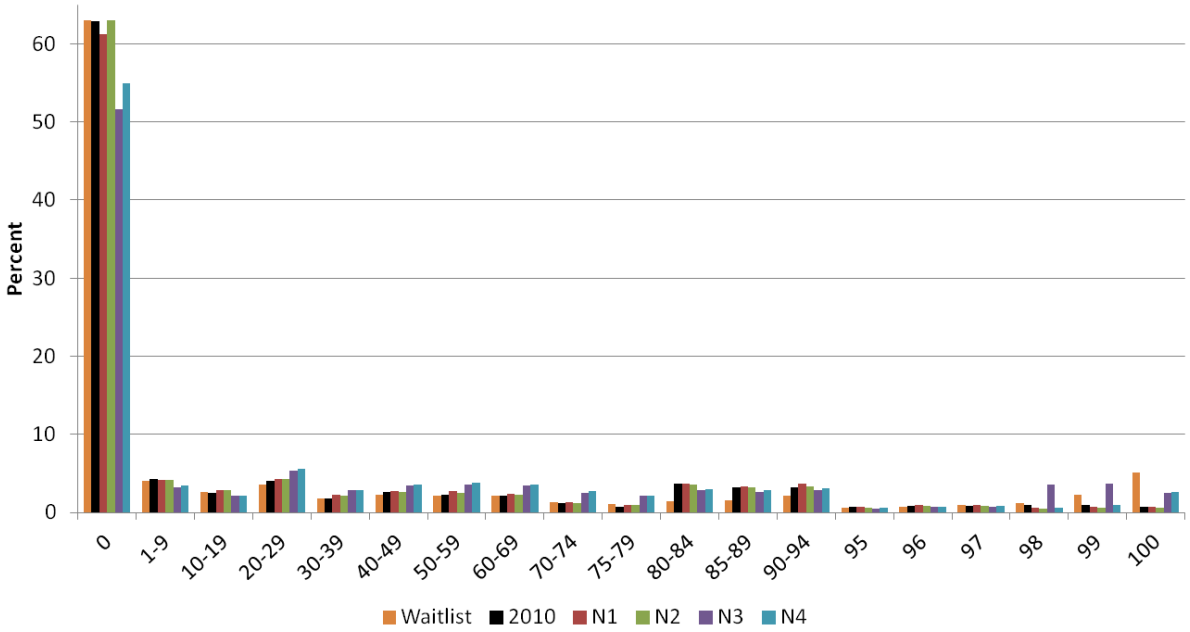


Figure 16: Kidney candidates and kidney transplant recipients by CPRA

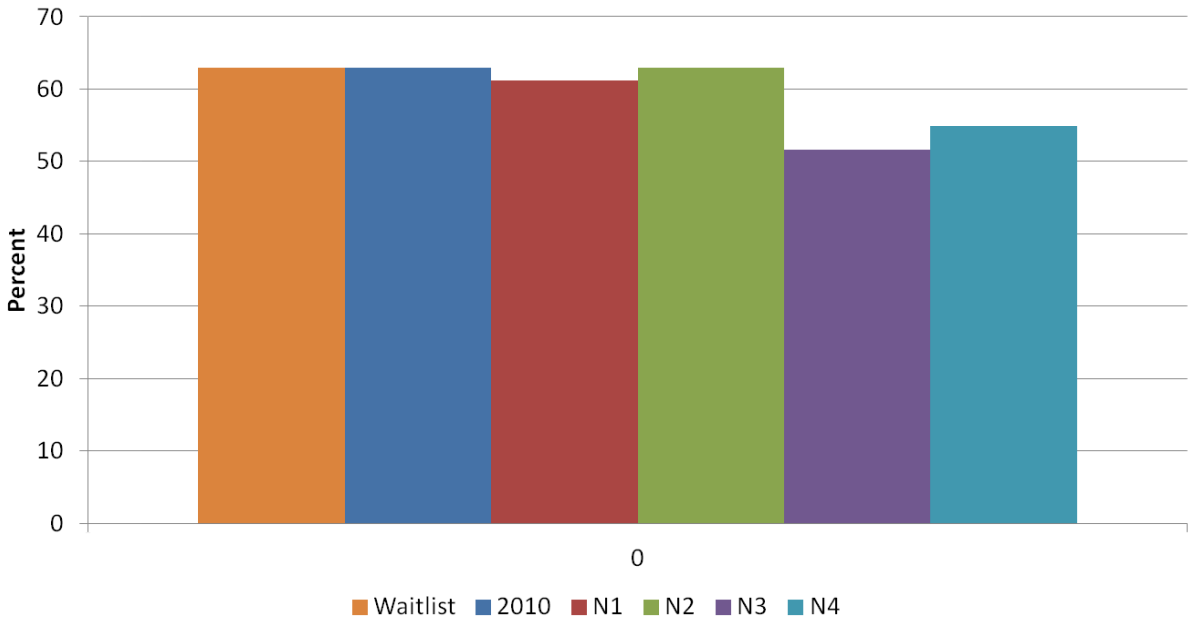


Figure 17: Kidney candidates and kidney transplant recipients where CPRA equals zero

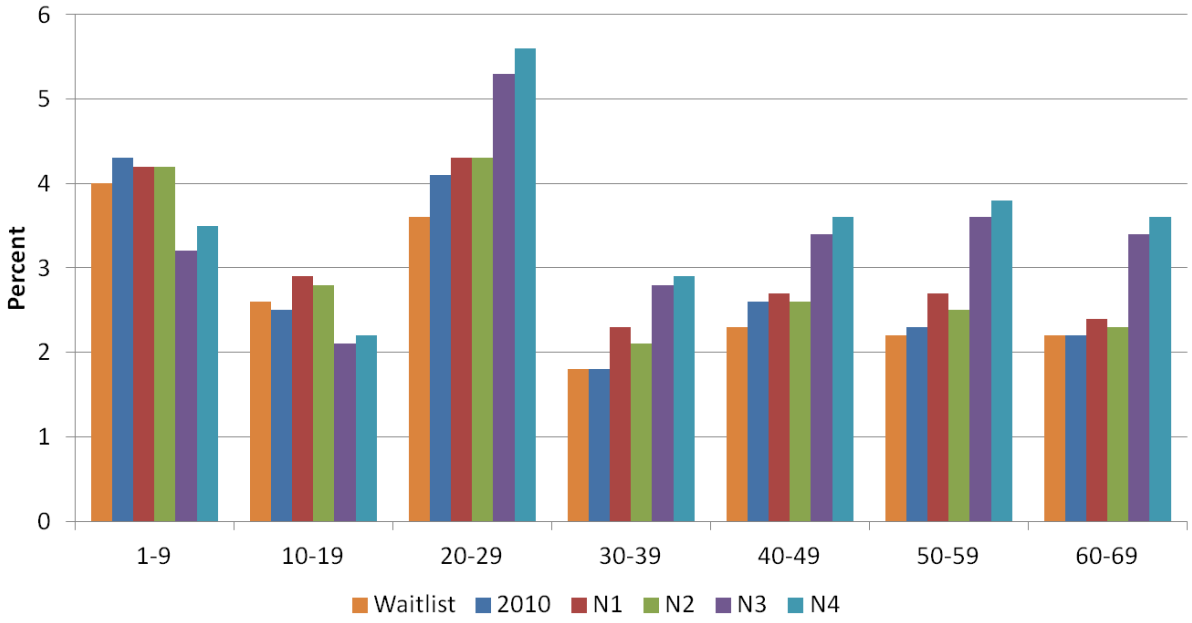


Figure 18: Kidney candidates and kidney transplant recipients by CPRA, where CPRA is between 1% and 69%

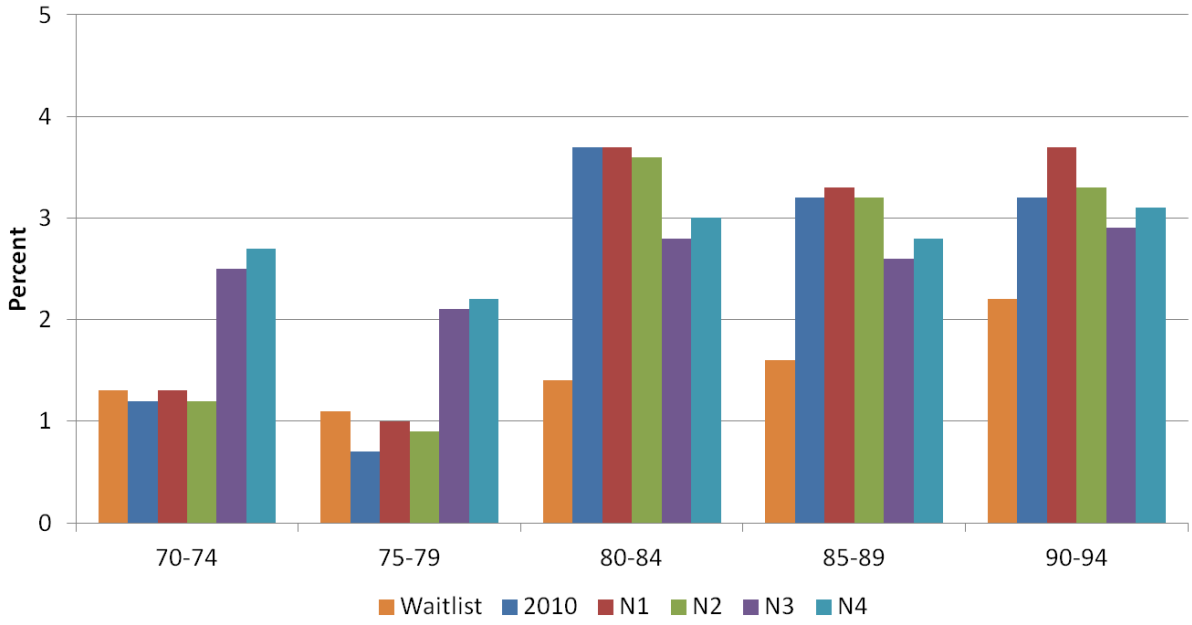


Figure 19: Kidney candidates and kidney transplant recipients by CPRA, where CPRA is between 70% and 94%

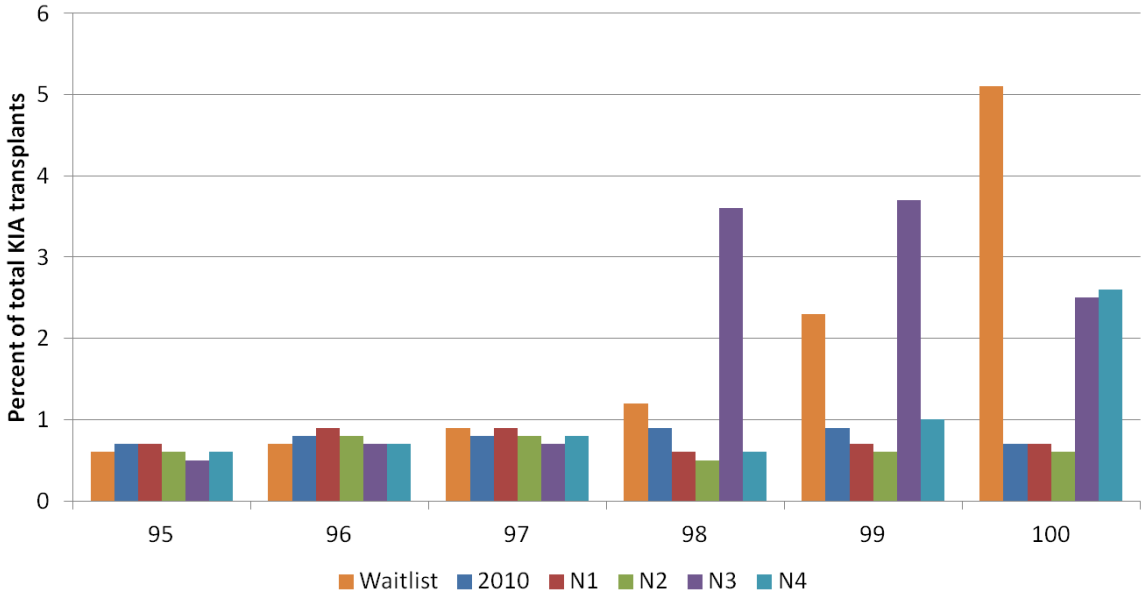


Figure 20: Kidney candidates and kidney transplant recipients by CPRA, where CPRA is between 95% and 100%

System Effects

The percent of kidney sharing, or kidneys being transplanted in a DSA other than the DSA of procurement, is expected to increase under the proposed policy. This was anticipated, as the policy specifically adds new rules for sharing for candidates with CPRA scores of 99% or 100% and also combines local and regional allocation for kidneys with KDPI scores greater than 85%. However, the level of sharing for the proposed policy was found to be less than the level of sharing under simulation run N3.

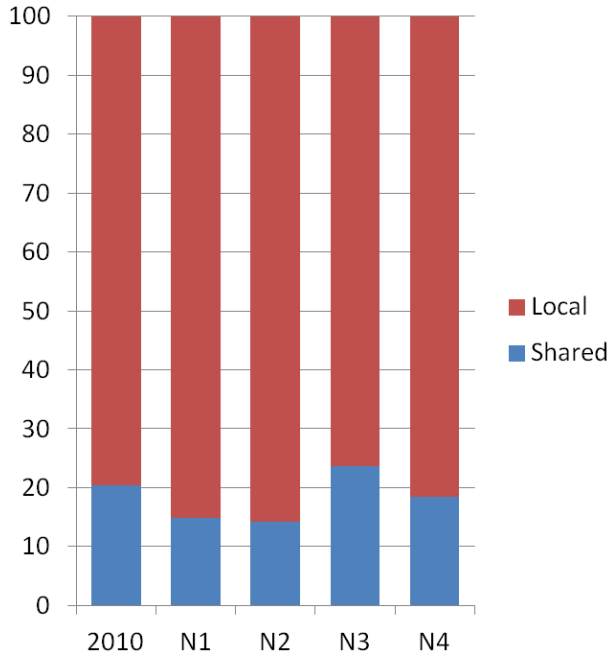


Figure 21: Kidney transplants by organ sharing

Expected Impact on Living Donors or Living Donation:

This proposal updates the prior living organ donor policy to specify that the date of procurement, not the date of transplant, is necessary to certify a candidate as a prior living organ donor. The current policy is vague on situations where an organ is procured from a living donor but not transplanted into a recipient. These occurrences are infrequent but may be due to a change in the recipient's health status, the discovery of disease or trauma in the donated organ, or other factors outside of the donor's control. The proposed policy language clarifies that a candidate will be considered a prior living organ donor if they donated an organ, even if that organ did not ultimately result in a transplant.

As to effects on living donation, during the course of policy development, some professional groups raised concerns that longevity matching would lead to a substantial drop in living kidney donation for young adult candidates. The concerns cited a decline in living donor transplants shortly after implementation of the pediatric policy to give pediatric candidates priority for kidneys from donors younger than 35. The Committee reviewed this phenomenon and found that the decline in living donor transplants during this time frame was not limited to pediatric candidates and may have been partially due in part to highly publicized donor deaths and not entirely due to the implementation of the Share 35 policy.[7]

Some people reasoned that if candidates with EPTS scores less than or equal to 20% are able to receive a high quality kidney transplant with little waiting time, then they will be less likely to seek out a living donor. The Committee reviewed the distribution of candidates and donors and found that in every OPO, the number of candidates with EPTS scores less than or equal to 20% greatly exceeds the number of donors with KDPI scores less than or equal to 20%. This means it is highly unlikely that a candidate with no waiting time and an EPTS score less than or equal to 20% would immediately receive a kidney transplant because the demand still greatly exceeds the supply. All candidates, with the exception of those fortunate enough to receive a zero antigen mismatch transplant, will still need to wait for a deceased donor kidney transplant regardless of their EPTS score. Consequently, the Committee believes that incentives for seeking a living donor, whose kidneys are also generally of significantly higher quality than deceased donor kidneys, will not be appreciably changed by this proposal.

Expected Impact on Specific Patient Populations:

Please see the section entitled Supporting Evidence for a detailed description of expected impact by patient demographics.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

This proposal is expected to meet the OPTN Key Goals of increasing access to transplant and improving post-transplant survival for recipients. Through the CPRA sliding scale, the enhanced definition of waiting time and incorporation of the A_2/A_2B kidneys for B candidates, access for minority candidates and highly sensitized candidates is expected to improve. The addition of longevity matching through KDPI and EPTS is expected to improve post-transplant survival by adding an additional 8,380 life years

[7] Wainwright JL, M Cooper, DL Bolton, CL Davis. The changing landscape of living kidney donors in the US. Presented to the American Transplant Congress. June 2, 2009.

obtainable annually from the proposed allocation system. Finally, this proposal will reset kidney allocation variances to comply with the requirements set forth in the OPTN Final Rule.

Plan for Evaluating the Proposal:

The policy will be formally evaluated approximately 6 months post-implementation, 1 year post-implementation, and annually thereafter, or until no longer needed, as per the direction of the OPTN Kidney Transplantation Committee.

The following hypotheses, and any others subsequently requested by the Committee, will be evaluated to compare performance before versus after the implementation of the new system.

1. Is the new kidney allocation system resulting in fewer transplants considered to be severe mismatches in terms of donor and recipient age or expected longevity?
2. Has the implementation of a system incorporating longevity-matching resulted in changes in the kidney utilization patterns for candidates of different ages and/or EPTS?
3. How have offer acceptance and organ utilization rates changed after the implementation of KDPI in DonorNet® and for allocation?
4. Has the new system increased equity in access to opportunities (offers) for transplant, as well as actual transplants, for candidates with differing demographic and medical characteristics: age, ethnicity, blood type, and sensitization level (CPRA)?
5. Has access to pediatric candidates, and the quality of kidneys used in pediatric transplants, changed significantly?
6. How has the new system changed the geographic distribution of kidney transplants (local vs. regional vs. national)?
7. Has there been a significant increase in cases where kidneys are shipped but ultimately discarded or redirected due to an unexpected positive crossmatch?
8. Has the new system resulted in any (positive or negative) unintended consequences for particular patient subpopulations, or in other areas such as the rates of living kidney donation, the rates of adding candidates to the list, or the percent of candidates in inactive status?

The following metrics, and any others subsequently requested by the committee, will be evaluated to compare performance before vs. after the implementation of the new system:

- The distribution of transplants by recipient age, ethnicity, ABO, CPRA, HLA-mismatch level, diagnosis, EPTS score (after only).
- Rates of receiving kidney offers per patient-year by recipient age, waiting time, ethnicity, ABO, CPRA, HLA-mismatch level, diagnosis, EPTS score (after only).
- Transplant rates per patient-year by recipient age, ethnicity, waiting time, ABO, CPRA, HLA-mismatch level, diagnosis, EPTS score (after only).
- Organ offer acceptance rates by recipient age, ethnicity, waiting time, ABO, CPRA, EPTS score (after only).
- Time to transplant by recipient age, ethnicity, ABO, CPRA, EPTS (after only).
- Organ offer acceptance rates by KDPI and DCD/ECD/SCD
- Kidney utilization and discard rates by KDPI and DCD/ECD/SCD
- Organ offer refusal rates, refusal reasons, and utilization rates for candidates with CPRA exceeding 98%

- Distribution of transplants jointly by recipient and donor age groups
- Distribution of transplants jointly by recipient age and donor KDPI groups
- Frequency of donor blood type A_2 and A_2B transplants into B candidates
- Geographic distribution of transplants: % local, regional, national
- Distribution of cold ischemic times for kidney transplants, in particular for high KDPI kidneys
- Estimated median post-transplant survival, and rates at 1 year post-transplant
- Rates of kidney recipients needing a retransplant, by recipient age
- Rates of kidney recipients dying with functioning grafts, by recipient age
- For cases of death with functioning graft, the average "expected remaining life years" for each transplanted kidney (e.g., projected graft half-life, per KDPI, minus actual graft usage time)

Since external factors, such as the changing donor pool, improving graft survival rates over time, and other changes in transplant policy or practice, can influence the pre and post-implementation periods differently, interpreting the apparent impact of a policy change based on a "before vs. after" analysis must be done with caution.

Additional Data Collection:

The following data fields would be added as a result of these policy changes.

- Verification that the HLA Laboratory Director and Transplant Physician approve of the listed unacceptable antigens for candidates with CPRA scores greater than or equal to 98%.
- Titer fields will be added for blood type B candidates who wish to be considered for kidneys from blood type A_2 or blood type A_2B donors. These fields will be required to be updated between 70 and 110 days and remain below 1:8 for a candidate to remain eligible to receive incompatible blood type offers. Additionally, a field indicating that the candidate consents to receive a blood type incompatible organ would be added.
- Whether a candidate has had a prior solid organ transplant (organ type(s) and date(s)) will also need to be collected for calculating EPTS.
- The acceptable upper and lower threshold values for KDPI for each candidate will be collected.

The following data are currently collected, however the proposed policies may change how data are entered into the system.

- Unacceptable Antigens. Currently, candidates with CPRA scores greater than or equal to 80% receive 4 points, with no further distinction in points based on differing CPRA values. Some programs only enter enough unacceptable antigens to receive this priority. The proposed policy utilizes a sliding scale, assigning incrementally increasing points as CPRA increases, starting with CPRA of 20%. This may increase the incentive to enter all unacceptable antigens for each candidate.
- Dialysis start date. Current policy does not count time spent on dialysis prior to registration towards waiting time. The proposed policy would count all time spent on dialysis, including any time prior to registration, towards a candidate's waiting time. Candidates with missing dialysis start dates at the implementation of the new system will receive time only back to registration with a GFR<=20. In particular, transplant centers will be requested to provide this historical data to ensure that such candidates receive the full waiting time credit to which they are entitled under the expanded definition of waiting time.

- Diabetes status is currently collected on the Transplant Candidate Registration (TCR) form and would now also be collected on the Waitlist. If a candidate's diabetes status changes, it will need to be updated on Waitlist only. Transplant programs will not be able to enter "unknown" for diabetes status.

All fields necessary to calculate the donor's KDPI are already required to run a kidney match, so this proposal does not result in additional data collection requirements for OPO's.

Expected Implementation Plan:

This proposal will be considered by the Board of Directors in June 2013. If approved, the changes will be effective upon programming and notice to members.

Transplant programs should review its processes and how they may need to change to align with the new policy. Specifically, changes will likely be necessary in the following areas:

- Develop a procedure for obtaining consent for the types of kidneys (defined by upper and lower KDPI values) a newly listed candidate would be willing to accept. Existing candidates listed as unwilling to accept ECD kidneys would receive a minimum donor acceptance value for KDPI of 0% and a maximum donor acceptance value for KDPI value of 85%. Existing candidates listed as willing to accept ECD kidneys would receive a minimum donor acceptance value for KDPI of 0% and a maximum donor acceptance value for KDPI of 100%. Existing candidates listed for both ECD and SCD kidneys would receive a minimum donor acceptance value for KDPI of 0% and a maximum donor acceptance value for KDPI of 100%. Transplant programs will be able to alter these values for existing candidates.
- Create an approval and documentation process to obtain approval of unacceptable antigens from the HLA Laboratory Director and Transplant Physician or Transplant Surgeon for candidates with CPRA scores of 99% and 100%.
- Begin reviewing candidate records to ensure that all components for the EPTS score are correctly listed in UNet^{sm} (i.e., correct dialysis start date, diabetes status, prior organ transplant and date of birth).

Transplant program staff and OPO staff should avail themselves of relevant educational opportunities offered through the OPTN Contractor. Webinars will be made available to explain the changes associated with this proposal. Additionally, staff should review available educational materials related to kidney donor profile index (KDPI) including a calculator and guidance document available here: http://optn.transplant.hrsa.gov/resources/allocationcalculators.asp?index=80

In the future, the Committee plans to provide a calculator that would help patients and providers understand outcomes associated with different treatment modalities. For example, this calculator is expected to provide estimated post transplant survival for dialysis, transplant from a living donor, and transplant from a deceased donor based on the donor's KDPI.

Compliance Monitoring:

UNOS Department of Evaluation and Quality (DEQ) staff reviews all deceased donor kidney match runs daily to determine if the organs were allocated according to the match run sequence as established by

kidney allocation policy and programmed into the UNet^{SM} system. DEQ staff examines any instance where the match run was not followed to determine if the allocation was a violation of policy.

During on-site reviews of kidney transplant programs, DEQ staff selects a sample of transplant recipient records and reviews the recipient file documentation. DEQ staff determines if the organs have been allocated in accordance with the match runs, and verifies the accuracy of data entered in UNet^{SM} against the recipient's medical record. DEQ staff investigates any reports of noncompliance. DEQ requests a corrective action plan if a hospital does not comply with the requirements of Policy 3.5 and forwards the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review in a blinded fashion.

This proposal would require the following additional monitoring:

- DEQ staff will verify that records for candidates who received regional or national offers while they had CPRA scores of 99% or 100% contain documentation of approval for any unacceptable antigens.
- DEQ staff will verify that records for blood type B candidates who received blood type non-A1 or non-A1B kidneys include documentation of consent to receive the incompatible blood type kidney.
- During on-site reviews, DEQ staff will select a sample of transplant recipient records, and review the documentation to verify that each contains a KPDI score consent, that contains all of the following for candidates registered after the implementation date of the allocation system:
    - The recipient's signature
    - The date the recipient signed
    - The KDPI scores the recipient would be willing to consider
- For candidates registered prior to the implementation date of the allocation system:
    - If there is documented consent to receive an ECD kidney, the candidate will be considered to have consented to receive kidneys with KDPI scores of 0-100
    - If there is no documented consent for ECD or specific KDPI scores, the candidate will be assumed to consent to a kidney with a KDPI score of 0-85

In Recognition:

The development of this proposal is the result of nine years of collaborative effort. The OPTN wishes to thank the following individuals who contributed to this proposal by serving on either the Kidney Allocation Review Subcommittee or the Kidney Transplantation Committee during this time.

Mark Aeder, MD; Margo Akerman, MS; Denise Alveranga, MD, FACP, FASN; Sandra Amaral, MD; Kenneth Andreoni, MD; Clyde Barker, MD; Bryan Becker, MD; Adam Bingaman, MD, PhD; Kenneth Brayman, MD, PhD, FACS; Eileen Brewer, MD; William Bry, MD; David Burgio, MPA, LFACHE; Stephan Busque, MD, FRCSC; Michael Cecka, PhD; Blanche Chavers, MD; Dolph Chianchiano, JD, MPA; Laura Christensen, MS; Ari Cohen, MD; Fernando Cosio, MD; Gabriel Danovitch, MD, MB, LRCP, MRCS; Richard DeSanto; Noelle Dimitri, LICSW; Dale Distant, MD; Viken Douzdjian, MD; Pang-Yen Fan, MD; Harold Fassnacht, JD; Erik Finger, MD, PhD; Richard Formica, Jr., MD; Mark Fox, MD, PhD, MPH; Adam Frank, MD; Jonathan Fridell, MD; John Friedewald, MD; Michael Gallichio, MD; Elisa Gladstone, MPH; Nathan Goodrich, MS; Paul Gores, MD; Oscar Grandas, MD; Stuart Greenstein, MD, FACS; Albin Gritsch, MD; Rainer Gruessner, MD; Sundaram Hariharan, MD; Erica Hartmann, MD; Daniel Hayes, MD; Randall Heyn-Lamb, RN, BSN, CPTC; John Hodges, MA; Marjorie Hunter, Esq.; Ajay Israni, MD, MS; Devon John, MD;

Michelle Josephson, MD; Jack Kalbfleisch, PhD; Bertram Kasiske, MD; Dixon Kaufman, MD, PhD; Douglas Keith, MD; Karen Kennedy, RN, CPTC; David Klassen, MD; Dicken Ko, MD; Rob Kochik, RN, BSN; Christian Kuhr, MD; Nicolae Leca, MD; Mary Leffell, PhD; Alan Leichtman, MD; Robert Madden, MD; Ruth McDonald, MD; Patricia McDonough, RN, CPTC, CCTC; Marla Jill McMaster, MA, CAPT-USNR(Ret); Clifford Miles, MD; Shamkant Mulgaonkar, MD; Silas Norman, MD; Kevin O'Connor, MS, PA; Janis Orlowski, MD; Thomas Pearson, MD, Dphil; Ronald Perrone, MD; Todd Pesavento, MD; Tammie Peterson, BSN; Mikel Prieto, MD; Jeffrey Punch, MD; Lloyd Ratner, MD; Stephen Rayhill, MD, FACS; Kunam Reddy, MD; Peter Reese, MD; Nancy Reinsmoen, PhD, D(ABHI); Marla Jill Rodgers, MBA; Jeffrey Rogers, MD; Paolo Salvalaggio, MD; Milton (Sandy) Sander, III, RN, CCTC; Velma Scantlebury, MD, FACS; Mark Schnitzler, PhD; Dorry Segev, MD; Teresa Shafer, RN, MSN; Michael Shapiro, MD; Anton Skaro, MD, PhD; John Smith, MD; Jonathan Snyder, PhD, MS; Rodney Spangler, RN, CPTC; Mark Stegall, MD; Peter Stock, MD, PhD; Deborah Surlas, AEE; Sharon Swofford, MA, RN, CNN, CCTC; Henkie Tan, MD, PhD, FACS; Ron Taubman; Patricia Tencza, RN, BS, CPTC; Christie Thomas, MB, FRCP, FASN, FAHA; Jennifer Thompson, RN, MSN; Trent Tipple, MD; Nicole Turgeon, MD; Charles Van Buren, MD; Sean Van Slyck, MPS/HAS, CPTC; Winfred Williams, MD; Alexander Wiseman, MD; Rachael Wong, DrPH; Francis Wright, Jr., MD; James Wynn, MD

Policy Proposal:

At the time of this proposal, the OPTN had just completed a major initiative to rewrite the OPTN policies in plain language and to organize them logically. Because of the breadth of this proposal, the policy language for this proposal is written in the new format. The following policies were moved to other sections during the plain language policy rewrite and therefore do not appear in this proposal 3.5.3.1, 3.5.3.3, 3.5.4, 3.5.9, 3.5.9.1, 3.5.9.2, 3.5.11.2, 3.5.14, 3.5.15, 3.5.16, and 3.5.17. For more information, the plain language policy rewrite is available at http://optn.transplant.hrsa.gov/plainlanguage.asp.

Additionally, the following sections were rewritten as part of the plain language rewrite and do not represent substantive changes as part of this proposal: 3.5.1 and 3.5.2, 3.5.6(E), 3.5.7(A), and 3.5.7(B).

Policy 3.5: Allocation of Kidneys

3.5.1 Calculated Panel Reactive Antibody 1

3.5.2 Exceptions 1

3.5.3 Points 2

3.5.4 Waiting Time 3

3.5.5 Classification Notes 4

3.5.6 Kidney Allocation Classifications and Rankings 8

3.5.7 Administrative Rules 21

3.5.8 Variances 21

Introduction

This Policy contains requirements for the allocation of kidneys and certain rules regarding kidney candidate registrations.

Policy Statement

3.5.1 Calculated Panel Reactive Antibody

Calculated Panel Reactive Antibody (CPRA) is the percentage of donors expected to have one or more of the unacceptable antigens indicated on the Waiting List for the candidate. In order list an unacceptable antigen, the Transplant Hospital must do at least one of the following:

- Define the criteria for unacceptable antigens that are considered as contraindications for transplantation. This may include clarification of unacceptable antigens based on solid phase testing, consideration of prior donor antigens or non-self antigens involved in pregnancies, as well as considerations for unexpected positive crossmatches and other circumstances.
- Base unacceptable antigens on laboratory detection of HLA specific antibodies using at least one solid phase immunoassay with purified HLA molecules.

Transplant Hospitals may establish criteria for additional unacceptable antigens including, but not limited to, multiple unexpected positive crossmatches. CPRA will be calculated automatically when a Transplant Hospital reports unacceptable antigens to the OPTN Contractor. CPRA will be derived from HLA antigen/allele group and haplotype frequencies for the different racial and ethnic groups in proportion to their representation in the national deceased donor population. CPRA values will be rounded to the nearest one hundredth percentage.

3.5.2 Exceptions

After receiving an organ offer from a donor in the same local unit, a candidate's physician may use his medical judgment to transplant a candidate out of sequence due to medical urgency.

If there is more than one kidney transplant program in the local unit, then the candidate's physician must receive agreement from the other kidney transplant programs in the local unit and must maintain documentation of this decision in the candidate's medical record.

3.5.3 Points

Candidates receive points according to Table 3.5-1: *Kidney Points*.

Table 3.5-1: Kidney Points

If the candidate is…	And the following allocation sequence is used...	Then the candidate receives this many points…
Listed for transplant and meets the qualifying criteria described in Policy 3.5.4 *Waiting Time*	3.5.6.1, 3.5.6.2, 3.5.6.3, or 3.5.6.4	1/365 points for each day since the qualifying criteria in Policy 3.5.4 *Waiting Time*
Aged 0-10 at time of match and a 0-ABDR mismatch with the donor	3.5.6.1, 3.5.6.2, or 3.5.6.3	4 points
Aged 11-17 at time of match and a 0-ABDR mismatch with the donor	3.5.6.1, 3.5.6.2, or 3.5.6.3	3 points
Aged 0-10 at time of match and donor has a KDPI score <35%	3.5.6.1 or 3.5.6.2	1 point
A prior living donor	3.5.6.1, 3.5.6.2, or 3.5.6.3	4 points
Sensitized (CPRA at least 20%)	3.5.6.1, 3.5.6.2, or 3.5.6.3	*See* Table 3.5-2: *Points for CPRA*
Share a single HLA-DR mismatch with the donor*	3.5.6.1, 3.5.6.2, or 3.5.6.3	1 point
Share a zero HLA-DR mismatch with the donor*	3.5.6.1, 3.5.6.2, or 3.5.6.3	2 points

**Donors with only one antigen identified at an HLA locus (A, B, and DR) are presumed "homozygous" at that locus.*

Table 3.5-2: Points for CPRA

If the candidate's CPRA score is…	Then the candidate receives this many points…
0	0.00
1-9	0.00
10-19	0.00
20-29	0.08
30-39	0.21
40-49	0.34
50-59	0.48
60-69	0.81
70-74	1.09
75-79	1.58
80-84	2.46
85-89	4.05
90-94	6.71
95	10.82
96	12.17
97	17.30
98	24.40
99	50.09
100	202.10

3.5.4 Waiting Time

3.5.4.1 Waiting Time for Candidates Listed After Age 18

If a candidate is 18 years of age or older on the date he is registered for a kidney, then the candidate's waiting time is based on the earlier of the following:

1. The candidate's registration date with a measured or calculated creatinine clearance or glomerular filtration rate (GFR), less than or equal to 20 ml/min.
2. The date after registration that a candidate's measured or calculated creatinine clearance or GFR becomes less than or equal to 20 ml/min.
3. The date that the candidate began dialysis that is regularly administered to an End Stage Renal Disease (ESRD) patient in a hospital based, independent non-hospital based, or home setting.

For candidates who have received a previous kidney transplant, only post-transplant dates for the above qualifying criteria (#1-3 above) apply.

3.5.4.2 Waiting Time for Candidates Listed Prior to Age 18

If a candidate is younger than 18 years of age on the date he is registered for a kidney, the candidate's waiting time is based on the earlier of the following:

1. The date that the candidate registered regardless of clinical criteria.

2. The date that the candidate began dialysis that is regularly administered to an ESRD patient in a hospital based, independent non-hospital based or home setting.

For candidates who have received a previous kidney transplant, only post-transplant dates for the above qualifying criteria (#1-2 above) apply.

3.5.5 Classification Notes

3.5.5.1 Candidate Classifications

Each candidate registered on the kidney waiting list receives an Estimated Post Transplant Survival (EPTS) score. EPTS is based on four factors: candidate time on dialysis since the last transplant, diabetes status (either Type 1 or Type 2), any prior solid organ transplant, and candidate age. Each candidate's EPTS score is calculated at time of registration. All candidate EPTS scores are updated every 13 weeks. The reference population used to determine the top 20% EPTS threshold is reviewed annually by the Kidney Transplantation Committee and updated by the OPTN Contractor on or before June 1 of each calendar year.

A candidate's EPTS score is equal to:

0.047 * MAX(Age - 25, 0) +

-0.015 * Diabetes * MAX(Age - 25, 0) +

0.398 * Prior Organ Transplant +

-0.237 * Diabetes * Prior Organ Transplant +

0.315 * log(Years on Dialysis + 1) +

-0.099 * Diabetes * log(Years on Dialysis + 1) +

0.130 * (Years on Dialysis = 0) +

-0.348 * Diabetes * (Years on Dialysis = 0) +

1.262 * Diabetes

The following factors in the EPTS calculation are binary indicators: diabetes, prior organ transplant, years on dialysis=0. If a binary indicator is true, then it is replaced by a value of 1.0 in the calculation; otherwise, it is replaced by 0. Fractional calendar years are used for candidate's age and years on dialysis.

3.5.5.2 Donor Classifications

Kidneys from deceased donors are classified according to the Kidney Donor Profile Index (KDPI). The KDPI score is derived directly from the Kidney Donor Risk Index (KDRI) score. The donor characteristics used to calculate KDRI are provided in Table 3.5-3: *KDRI Factors*.

Table 3.5-3: KDRI Factors

This donor Characteristic…	Applies to…	KDRI score component
Age (integer years)	All donors	0.0128*(age-40)
	Donors with age < 18	-0.0194*(age-18)
	Donors with age > 50	0.0107*(age-50)
Ethnicity	African American donors	0.1790
Creatinine (mg/dl)	All donors	0.2200*(creatinine - 1)
	Donors with creatinine > 1.5	-0.2090*(creatinine - 1.5)
History of Hypertension	Hypertensive donors	0.1260
History of Diabetes	Diabetic donors	0.1300
Cause of Death	Donors with cerebrovascular accident as cause of death	0.0881
Height (cm)	All donors	-0.0464*(height -170) / 10
Weight (kg)	All donors with weight < 80 kg	-0.0199*(weight - 80) / 5
Donor type	DCD donors	0.1330
HCV status	HCV positive donors	0.2400

To calculate KDRI, sum each of the applicable KDRI score components in Table 3.5-3, and then apply the antilog (base e) function to this sum. Divide the KDRI by the median KDRI value of the most recent donor reference population, and determine the KDPI using the KDRI-to-KDPI mapping table made available by the OPTN Contractor.

The KDPI used for allocation is based on the most recent values of donor characteristics (e.g., the latest serum creatinine) reported to the OPTN Contractor prior to running a match.

The reference population used to determine the KDRI-to-KDPI mapping is reviewed annually by the Kidney Transplantation Committee and updated by the OPTN Contractor on or before June 1 of each calendar year.

The KDPI is the percentage of donors in the reference population that have a KDRI less than or equal to this donor's KDRI. This percentage is rounded to the nearest integer .

3.5.5.3 Consent for Kidneys Based on KDPI

Prior to receiving offers, transplant programs must obtain consent from each kidney candidate regarding the KDPI scores he or she would be willing to consider.

3.5.5.4 Sorting Within Each Classification

Within each classification, candidates are sorted in the following order:

1. Total points (highest to lowest)
2. Date and time of the candidate's registration (oldest to most recent)

3.5.5.5 Blood Type Permissibility

Transplants are restricted by blood type in certain circumstances.

- Blood type O kidneys must be transplanted only into blood group O candidates.
    - Exception: In cases of offers made to candidates in 0-ABDR mismatch categories, blood type O kidneys may be transplanted into candidates who have blood types other than O.
- Blood type B kidneys must be transplanted only into blood type B candidates
    - Exception: In cases of offers made to candidates in 0-ABDR mismatch categories, blood type B kidneys may be transplanted into candidates who have blood types other than B.
- Blood type non-A_1 (i.e., A_2) and non-A_1B (i.e., A_2B) kidneys may be transplanted into candidates with blood type B who meet the following criteria.
    - Indication that the candidate consents to accept a blood type incompatible kidney
    - At least two anti-A titer values must have been entered for the candidate's titer history at least 70 days apart but no more than 110 days apart with the most recent value within the last 110 days or the candidate becomes ineligible.
    - No anti-A titer value(s) of 1:8 or greater in the candidate's titer history. Candidates with titer value(s) of 1:8 or greater will become permanently ineligible.

Kidney candidate and donor blood types are matched according to *Table 3.5-4: Blood Typing for Kidney Allocation*. Fields with a "●" indicate identical blood type matches. Fields with a "◑" indicate non-identical blood type matches. Fields with a "○" indicate incompatible (and

therefore, impermissible) blood type matches. Fields with a "*" indicate permissible blood type matches only if the candidate is 0 ABDR mismatch, otherwise the match is not permissible. Fields with a "**" indicate compatible blood type matches only if the candidate is non-A_1/non-A_1B eligible, otherwise the match is not permissible.

Table 3.5-4: Blood Typing for Kidney Allocation

Donor's Blood Type	Candidate is O	Candidate is A	Candidate is B	Candidate is AB
O	●	◑*	◑*	◑*
A	○	●	○	◑
A, Non-A_1	○	●	◑**	◑
B	○	○	●	◑*
AB	○	○	○	●
AB, Non-A_1B	○	○	◑**	●

3.5.5.6 Prior Living Organ Donors

A candidate will be classified as a prior living donor and receive priority for each kidney registration if *all* of the following conditions are met:

1. The candidate donated at least one of the following for transplantation within the United States or its territories:
    - Kidney
    - Liver segment
    - Lung segment
    - Partial pancreas
    - Small bowel segment.

2. The candidate's physician reports all of the following information to the OPTN Contractor:
    - The name of the recipient or intended recipient of the donated organ or organ segment
    - The recipient's or intended recipient's Transplant Hospital
    - The date the donated organ was procured

3.5.5.7 Highly Sensitized Candidates

Before a candidate with a CPRA score of 99% or 100% may receive offers in allocation classifications 1-5 in allocation sequences 3.5.6.1 - 3.5.6.4, the transplant program's HLA laboratory director and the candidate's transplant physician must review and sign a written approval of the unacceptable antigens listed for the candidate. The Transplant Hospital must document this approval in the candidate's medical record.

3.5.6 Kidney Allocation Classifications and Rankings

3.5.6.1 Allocation of Kidneys from Donors with KDPI less than or equal to 20%

Kidneys from donors with a kidney donor profile index (KDPI) score of less than or equal to 20% are allocated to candidates in the following order:

Table 3.5-5: Allocation of Kidneys from Donors with KDPI less than or equal to 20%

Classification	Candidates that are within the…	And are…	When the donor is this blood type...
1	Donor hospital's local unit	CPRA equal to 100%, blood type identical or permissible	Any
2	Donor hospital's region	CPRA equal to 100%, blood type identical or permissible	Any
3	Nation	CPRA equal to 100%, blood type identical or permissible	Any
4	Donor hospital's local unit	CPRA equal to 99%, blood type identical or permissible	Any
5	Donor hospital's region	CPRA equal to 99%, blood type identical or permissible	Any
6	Donor hospital's local unit	CPRA equal to 98%, blood type identical or permissible	Any
7	Donor hospital's local unit	Top 20% EPTS, 0-ABDR mismatch, and blood type identical	Any
8	Donor hospital's region	Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
9	Nation	Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
10	Donor hospital's region	Top 20% EPTS, 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 identical	Any
11	Nation	Top 20% EPTS, 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 identical	Any
12	Donor hospital's region	Top 20% EPTS, 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 identical	Any
13	Nation	Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 years old at time	Any

Classification	Candidates that are within the…	And are…	When the donor is this blood type...
		of match, and blood type identical	
14	Donor hospital's region	Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
15	Nation	Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
16	Donor hospital's local unit	Top 20% EPTS, 0-ABDR mismatch, and blood type B	O
17	Donor hospital's region	Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
18	Nation	Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
19	Donor hospital's region	Top 20% EPTS, 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
20	Nation	Top 20% EPTS, 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
21	Donor hospital's region	Top 20% EPTS, 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
22	Nation	Top 20% EPTS, 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
23	Donor hospital's region	Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
24	Nation	Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
25	Donor hospital's local unit	Top 20% EPTS, 0-ABDR mismatch, and blood type permissible	Any
26	Donor hospital's region	Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any

Classification	Candidates that are within the…	And are…	When the donor is this blood type...
27	Nation	Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
28	Donor hospital's region	Top 20% EPTS, 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 permissible	Any
29	Nation	Top 20% EPTS, 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 permissible	Any
30	Donor hospital's region	Top 20% EPTS, 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 permissible	Any
31	Nation	Top 20% EPTS, 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 permissible	Any
32	Donor hospital's region	Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
33	Nation	Top 20% EPTS, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
34	Donor hospital's local unit	Prior living donor, blood type permissible or identical	Any
35	Donor hospital's local unit	Registered prior to 18 years old, blood type permissible or identical	Any
36	Donor hospital's local unit	Top 20% EPTS, blood type B	A2 or A2B
37	Donor hospital's local unit	Top 20% EPTS, blood type permissible or identical	Any
38	Donor hospital's local unit	EPTS greater than 20%, 0-ABDR mismatch, blood type identical	Any
39	Donor hospital's region	EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
40	Nation	EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
41	Donor hospital's region	EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, less than 18 at time of	Any

Classification	Candidates that are within the…	And are…	When the donor is this blood type...
		match, and blood type identical	
42	Nation	EPTS greater than 20%, 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
43	Donor hospital's region	EPTS greater than 20%, 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
44	Nation	EPTS greater than 20%, 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
45	Donor hospital's region	EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
46	Nation	EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
47	Donor hospital's local unit	EPTS greater than 20%, 0-ABDR mismatch, and blood type B	O
48	Donor hospital's region	EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
49	Nation	EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
50	Donor hospital's region	EPTS greater than 20%, 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
51	Nation	EPTS greater than 20%, 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
52	Donor hospital's region	EPTS greater than 20%, 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
53	Nation	EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 0% but less than or equal to 20%, less than 18 at time	O

Classification	Candidates that are within the…	And are…	When the donor is this blood type...
		of match, and blood type B	
54	Donor hospital's region	EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
55	Nation	EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
56	Donor hospital's local unit	EPTS greater than 20%, 0-ABDR mismatch, and blood type permissible	Any
57	Donor hospital's region	EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
58	Nation	EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
59	Donor hospital's region	EPTS greater than 20%, 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 permissible	Any
60	Nation	EPTS greater than 20%, 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 permissible	Any
61	Donor hospital's region	EPTS greater than 20%, 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 permissible	Any
62	Nation	EPTS greater than 20%, 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 permissible	Any
63	Donor hospital's region	EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
64	Nation	EPTS greater than 20%, 0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any

Classification	Candidates that are within the…	And are…	When the donor is this blood type...
65	Donor hospital's local unit	EPTS greater than 20%, blood type B	A2 or A2B
66	Donor hospital's local unit	All remaining candidates, blood type permissible or identical	Any
67	Donor hospital's region	Registered prior to 18 years old, blood type permissible or identical	Any
68	Donor hospital's region	Top 20% EPTS, blood type B	A2 or A2B
69	Donor hospital's region	Top 20% EPTS, blood type permissible or identical	Any
70	Donor hospital's region	EPTS greater than 20%, blood type B	A2 or A2B
71	Donor hospital's region	All remaining candidates, blood type permissible or identical	Any
72	Nation	Registered prior to 18 years old, blood type permissible or identical	Any
73	Nation	Top 20% EPTS, blood type B	A2 or A2B
74	Nation	Top 20% EPTS, blood type permissible or identical	Any
75	Nation	All remaining candidates, blood type permissible or identical	Any

3.5.6.2 Allocation of Kidneys from Donors with KDPI Scores Greater than 20% but less 35%

Kidneys from donors with KDPI scores greater than 20% but less than 35% are allocated to candidates in the following order:

Table 3.5-6: Allocation of Kidneys from Donors with KDPI Scores Greater than 20% but Less than 35%

Classification	Candidates that are within the…	And are…	When the donor is this blood type…
1	Donor hospital's local unit	CPRA equal to 100%, blood type permissible or identical	Any
2	Donor hospital's region	CPRA equal to 100%, blood type permissible or identical	Any
3	Nation	CPRA equal to 100%, blood type permissible or identical	Any
4	Donor hospital's local unit	CPRA equal to 99%, blood type permissible or identical	Any
5	Donor hospital's region	CPRA equal to 99%, blood type permissible or identical	Any
6	Donor hospital's local unit	CPRA equal to 98%, blood type permissible or identical	Any

Classification	Candidates that are within the…	And are…	When the donor is this blood type…
7	Donor hospital's local unit	0-ABDR mismatch, blood type identical	Any
8	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
9	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
10	Donor hospital'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
11	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
12	Donor hospital'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
13	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
14	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
16	Donor hospital's local unit	0-ABDR mismatch, blood type B	O
17	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
18	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
19	Donor hospital'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
20	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

Classification	Candidates that are within the…	And are…	When the donor is this blood type…
21	Donor hospital'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
22	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
23	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
24	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
25	Donor hospital's local unit	0-ABDR mismatch, blood type permissible	Any
26	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
27	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
28	Donor hospital'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 permissible	Any
29	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 permissible	Any
30	Donor hospital'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 permissible	Any
31	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 permissible	Any
32	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
34	Donor hospital's local unit	Prior living donor, blood type permissible or	Any

Classification	Candidates that are within the…	And are…	When the donor is this blood type…
		identical	
35	Donor hospital's local unit	Registered prior to 18 years old, blood type permissible or identical	Any
36	Donor hospital's local unit	Blood type B	A2 or A2B
37	Donor hospital's local unit	All remaining candidates, blood type permissible or identical	Any
38	Donor hospital's region	Registered prior to 18 years old, blood type permissible or identical	Any
39	Donor hospital's region	Blood type B	A2 or A2B
40	Donor hospital's region	All remaining candidates, blood type permissible or identical	Any
41	Nation	Registered prior to 18 years old, blood type permissible or identical	Any
42	Nation	Blood type B	A2 or A2B
43	Nation	All remaining candidates, blood type permissible or identical	Any

3.5.6.3 Allocation of Kidneys from 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 or equal to 85% are allocated to candidates in the following order:

Table 3.5-7: Allocation of Kidneys from Donors with KDPI >=35% and <=85%

Classification	Candidates that are within the…	And are…	And the donor is this blood type
1	Donor hospital's local unit	CPRA equal to 100%, blood type permissible or identical	Any
2	Donor hospital's region	CPRA equal to 100%, blood type permissible or identical	Any
3	Nation	CPRA equal to 100%, blood type permissible or identical	Any
4	Donor hospital's local unit	CPRA equal to 99%, blood type permissible or identical	Any
5	Donor hospital's region	CPRA equal to 99%, blood type permissible or identical	Any
6	Donor hospital's local unit	CPRA equal to 98%, blood type permissible or identical	Any
7	Donor hospital's local unit	0-ABDR mismatch, blood type identical	Any
8	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%,	Any

Classification	Candidates that are within the…	And are…	And the donor is this blood type
		and blood type identical	
9	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
10	Donor hospital'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
11	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
12	Donor hospital'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
13	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
14	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
15	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
16	Donor hospital's local unit	0-ABDR mismatch, and blood type B	O
17	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
18	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
19	Donor hospital'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
20	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
21	Donor hospital'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

Classification	Candidates that are within the…	And are…	And the donor is this blood type
22	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
23	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
24	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
25	Donor hospital's local unit	0-ABDR mismatch, blood type permissible	Any
26	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
27	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
28	Donor hospital'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 permissible	Any
29	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 permissible	Any
30	Donor hospital'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 permissible	Any
31	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 permissible	Any
32	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
33	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
34	Donor hospital's local unit	Prior living donor, blood type permissible or identical	Any
35	Donor hospital's local unit	Blood type B	A2 or A2B
36	Donor hospital's local unit	All remaining candidates, blood type permissible or identical	Any

Classification	Candidates that are within the…	And are…	And the donor is this blood type
37	Donor hospital's region	Blood type B	A2 or A2B
38	Donor hospital's region	All remaining candidates, blood type permissible or identical	Any
39	Nation	Blood type B	A2 or A2B
40	Nation	All remaining candidates, blood type permissible or identical	Any

3.5.6.4 Allocation of Kidneys from Donors with KDPI Scores Greater than 85%

Kidneys from donors with KDPI scores greater than 85% are allocated to candidates in the following order:

Table 3.5-8: Allocation of Kidneys from Donors with KDPI Scores >85%

Classification	Candidates that are within the…	And are…	And the donor is this blood type…
1	Donor hospital's local unit	CPRA equal to 100%, blood type permissible or identical	Any
2	Donor hospital's region	CPRA equal to 100%, blood type permissible or identical	Any
3	Nation	CPRA equal to 100%, blood type permissible or identical	Any
4	Donor hospital's local unit	CPRA equal to 99%, blood type permissible or identical	Any
5	Donor hospital's region	CPRA equal to 99%, blood type permissible or identical	Any
6	Donor hospital's local unit	CPRA equal to 98%, blood type permissible or identical	Any
7	Donor hospital's local unit	0-ABDR mismatch, blood type permissible or identical	Any
8	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
9	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type identical	Any
10	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any
11	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type identical	Any

Classification	Candidates that are within the…	And are…	And the donor is this blood type…
12	Donor hospital's local unit	0-ABDR mismatch, blood type B	O
13	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
14	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type B	O
15	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
16	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type B	O
17	Donor hospital's local unit	0-ABDR mismatch, blood type permissible	Any
18	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
19	Nation	0-ABDR mismatch, CPRA greater than or equal to 80% but no greater than 100%, and blood type permissible	Any
20	Donor hospital's region	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
21	Nation	0-ABDR mismatch, CPRA greater than or equal to 21% but no greater than 79%, and blood type permissible	Any
22	Donor hospital's region	Blood type B	A2 or A2B
23	Donor hospital's region	All remaining candidates, blood type permissible or identical	any
24	Nation	Blood type B	A2 or A2B
25	Nation	All remaining candidates, blood type permissible or identical	any

3.5.6.5 Double Kidney Allocation

An OPO must offer kidneys individually through one of the allocation sequences in Policies 3.5.6.1 *Allocation of Kidneys from Donors with KDPI less than or equal to 20%*- 3.5.6.4 *Allocation of Kidneys from Donors with KDPI Scores Greater than 85%* before offering both kidneys to a single candidate unless the OPO reports to the OPTN Contractor prior to allocation that the 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%.

3.5.7 Administrative Rules

3.5.7.1 Mandatory Sharing

Kidneys shared as 0-ABDR mismatches or for candidates with CPRA greater than or equal to 99% in classifications 1-5 in allocation sequences 3.5.6.1 through 3.5.6.4 must be offered within the following time limits:

Table 3.5-9: Organ Offer Limit

If the donor is…	And must make at least this many offers to identified 0-ABDR mismatch candidates…	Then the OPO must offer the kidneys within this many hours of procurement…
KDPI < 85%	10	8 hours
KDPI ≥ 85%	5	3 hours

3.5.7.2 Choice of Right versus Left Donor Kidney

If both kidneys from a donor are transplantable, the Transplant Hospital that is offered a kidney for a candidate may select which of the two kidneys it will receive. The Transplant Hospital which received the offer for the candidate with higher priority on the waiting list will have selection preference.

However, when a kidney is offered to a 0-ABDR mismatched candidate, a candidate with a CPRA greater than or equal to 99% in classifications 1-5 in allocation sequences 3.5.6.1 through 3.5.6.4, or to a combined kidney and non-renal organ candidate, the Host OPO determines whether to offer the left or the right kidney.

3.5.7.3 Regional and National Kidney Offers

If a non 0-ABDR mismatched kidney is not placed in the donor hospital's local unit, the OPO must contact the OPTN Contractor to assist with regional or national placement.

3.5.8 Variances

Reserved

History

Notes

- For membership and personnel requirements for kidney programs, see the OPTN Bylaws, Appendix E.