The New Kidney Allocation System (KAS) Frequently Asked Questions

Contents

General: The Need for the New System and Key Implementation Details	4
Why was the newly revised KAS necessary?	4
What were the major changes in the new allocation system that became effective on December 4, 2014?	4
When did the new rules for KAS go into effect?	4
What do transplant programs need to do for KAS?	5
Waiting Time	5
How is waiting time calculated in KAS?	5
Does a candidate need to meet waiting time criteria (GFR or dialysis) to be listed?	6
Does policy require that the most recent GFR be used when listing a candidate?	6
Is waiting time for patients having GFR ≤20 ml/min prior to being registered back-dated similar to dialysis start date?	6
Now that waiting time includes all pre-registration dialysis time, is there any need for early referral and listing?	6
If a patient accumulated waiting time based on pre-registration dialysis time and is subsequently removed from the waitlist, how will the original waiting time count if the patier later added to the waitlist?	
How do the changes to waiting time affect multiply listed candidates? Will candidates still be able to (or have any need to) transfer primary waiting time?	
If a patient is not on dialysis at the time of listing, but they meet the GFR criterion, is there a requirement to enter the dialysis start date on the waitlist record if/when the patient starts dialysis after listing?	
Dialysis start date	7
If a candidate begins dialysis and then stops for a period of time, should I list a dialysis star date?	
On May 27, 2014, UNet began displaying the CMS Medical Evidence Form 2728 dialysis s date for programs to reference (if a reliable match could be found based on the candidate's social security number) for patients registered prior to May 1, 2014. If I selected a dialysis start date that matches the CMS date displayed in UNet [™] , do I need to obtain additional documentation for the purpose of UNOS site visits?	S
Diabetes Status	8
Can you elaborate on the definition of 'current diagnosis of diabetes'?	8

If the EPTS score is only influenced according to whether there is a diagnosis of diabe (yes/no), why does the question in UNet™ ask for the type of diabetes?	
(idney Donor Profile Index (KDPI)	
What is KDPI?	
What is KDRI?	
How does the previous ECD status differ from the KDPI score?	
Can transplant programs select a different maximum acceptable KDPI for all the patier their list? Can the criteria be different for local vs. import offers? What about for zero-a mismatch offers?	nts on Intigen
How does donor offer screening based on maximum KDPI work, given that transplant can also screen offers based on maximum donor age and other factors?	
Do transplant programs need to obtain written, informed consent from every candidate their list for the KDPI criteria that each candidate is willing to accept?	
If a candidate is listed as only accepting KDPI of 85% or less, but receives a kidney plate of the liver (or any other organ) list who has a KDPI over 85%, is there any requirement the transplant hospital to obtain consent from that candidate?	nt for
How does dual kidney allocation work in the new system?	11
PTS	11
What is an EPTS score?	11
How is the EPTS score used?	11
Sensitized Candidates, CPRA Approvals, Desensitization	11
How does the system increase access for sensitized candidates?	11
Why does the policy require the candidate's physician or surgeon and the HLA laborat director to review and sign a written approval of the unacceptable antigens for candidate CPRA greater than 98%?	ites with
What is the process for obtaining written approval for candidates with CPRA greater the in order to receive regional or national prioritization? Can the candidate's physician or surgeon and the HLA laboratory director assign a designee to provide approvals?	
Are the written approvals required every time the unacceptable antigens change? What candidate's CPRA fluctuates below and above 98%?	
What happens if one or both signatures are missing for a patient with CPRA above 98	%?13
Are there any changes to CPRA prioritization for patients undergoing desensitization?	13
Are OPOs able to report donor HLA information for DQA1 or DPB1 for deceased kidned donors?	•
Why are my patients not getting CPRA points when I run the Kidney Points Report?	13
ncreased Access for Blood Type B Candidates (A2/A2B eligibility)	13
Candidates with blood type B who meet eligibility criteria determined by their transplant program will receive offers from donors with blood type A2 (A, non-A1) or A2B (AB, now What do transplant programs need to do to in order to receive these offers?	n-A1B).

Pediatric Candidates1	4
What is the priority for candidates under 18? Is there priority for pediatric candidates?1	4
What is the priority for adult candidates who were listed prior to turning 18 but have since turned 18?1	4
If a candidate is listed after their 18th birthday, but their dialysis start date is before their 18th birthday, does the candidate still receive pediatric priority?1	
Additional priority for prior living organ donors1	4
Do prior living donors receive additional priority under KAS?1	4
Local, State, and National Variances1	5
When will the Kidney Committee consider new allocation policy variances?1	5
Geography1	5
Is the new allocation system expected to have any impact on reducing geographic disparities?1	5
Organ Allocation1	5
What is the order of allocation when an OPO ships a kidney but the intended recipient cannot be transplanted?1	
Multi-Organ Allocation1	5
What is the organ allocation order when there are other organs available in addition to kidney(s)?1	15
Are there any efforts to clarify multi-organ allocation policies?1	
Updating Data1	
What data, if any, are members responsible for updating after listing a kidney candidate (i.e. diabetes, wait time qualifier, CPRA, etc.)?1	
Shipping Logistics1	6
What are the minimum tissue typing materials the OPO must send?1	6
Can the OPO require the results of the crossmatch prior to shipping the kidney if the transplant program doesn't agree to this?1	
Is the OPO required to ship the blood in advance of the kidney if the transplant program requests this?1	6
Is there added value to asking the intended recipient's transplant center to perform a virtual crossmatch in advance of acceptance?1	7
Is the Kidney Committee going to monitor how this change is working and whether there are unintended consequences associated with it?	

General: The Need for the New System and Key Implementation Details

Why was the newly revised KAS necessary?

The new kidney allocation system (KAS) was developed in response to higher than necessary discard rates of kidneys, variability in access to transplants for candidates who are harder to match due to biologic reasons, inequities resulting from the way waiting time was calculated, and a matching system that results in unrealized life years and high re-transplant rates.

The OPTN Kidney Transplantation Committee (Kidney Committee) spent nearly ten years finalizing the changes, taking into consideration feedback from numerous patient groups, professional transplant societies, individual transplant programs, the 11 OPTN regions, and individuals. Simulation modeling predicts that the new KAS will result in over 9,000¹ additional life years achieved annually from the current pool of deceased donor kidneys.

What were the major changes in the new allocation system that became effective on December 4, 2014?

The new KAS is made of up several major components:

- The previous kidney donor quality metric (Standard Criteria Donors or SCD, and Expanded Criteria Donors or ECD) was replaced with a more refined, continuous metric known as the Kidney Donor Profile Index (KDPI).
- All adult kidney candidates now receive an Expected Post Transplant Survival
 (EPTS) score. The score is based on four medical factors: age, time on dialysis, current
 diabetes status, and whether the candidate had a previous solid organ transplant.
- The allocation rules use the KDPI for donors and the EPTS score for longevity matching between a portion of donors and recipients. Those donor kidneys with KDPI 20% or less are first offered to adult candidates with the top 20% of EPTS scores, followed by candidates with EPTS outside the top 20%.
- Sensitized candidates receive increased priority through a sliding scale points system for CPRA and regional and national priority for very highly sensitized candidates (those that have CPRA greater than 98%).
- Pre-registration dialysis time is now included in a candidate's waiting time.
- There are new rules designed to provide greater access to blood type B candidates who can safely accept a kidney from an A₂ (A, non-A₁) or A₂B (AB, non-A₁B) blood type donor.
- In the new system, pediatric priority ("Share 35") is based on KDPI less than 35%, instead of donors age less than 35 years.
- The payback system has been eliminated, including paybacks for multi-organ offers.
- All variances, other than two that have been incorporated into the national policy (increased access for blood type B candidates and including pre-registration dialysis time in candidates' waiting time calculation), were eliminated December 4, 2014.

When did the new rules for KAS go into effect?

The new allocation rules became effective December 4, 2014.

¹ Israni, Ajay K., et al. "New National Allocation Policy for Deceased Donor Kidneys in the United States and Possible Effect on Patient Outcomes." Journal of the American Society of Nephrology (2014): ASN-2013070784.

What do transplant programs need to do for KAS?

There are several key components that kidney transplant programs should follow:

- 1. Communicate to other professionals that early referral for transplantation is still important under the system.
- 2. Review patient data elements and confirm, update, or newly report the data. Specifically, if programs have not already done so, they need to review and/or update candidates' dialysis start date. The UNOS computer system now requires programs to enter the candidate's current diabetes status and number of prior solid organ transplants if the candidate is being added to the list or a change is being made to an existing candidate record. Programs are also encouraged to verify the unacceptable antigens listed for each candidate, as well as whether they are listed as having been a prior living organ donor. Additional information about calculating and interpreting EPTS can be found in the "Guide to Calculating and Interpreting the Estimated Post-Transplant (EPTS) Score Used in the Kidney Allocation System (KAS)" document.
- Review and update candidates' donor acceptance criteria (including the maximum acceptable KDPI and other donor factors each patient will accept). Programs should understand that selecting a very low maximum KDPI score will greatly limit the number of offers a candidate will receive.
- 4. Follow transplant program processes and protocols to:
 - Obtain informed written consent from candidates willing to accept kidneys with KDPI greater than 85% (including pediatric candidates, whose priority is limited in this category to 0-ABDR mismatch offers only);
 - Establish titer levels and report eligibility for blood type B candidates who may consent to accept a kidney from an A₂ or A₂B donor and obtain informed written consent from candidates who are willing to accept these offers;
 - Obtain written approval of unacceptable antigens from the candidate's physician or surgeon and the HLA laboratory director when a candidate's CPRA is greater than 98%, document the approval in candidate's medical record and enter approver names into UNet.

A number of resources and educational materials are available to assist programs with these key components. Refer to the OPTN website (https://optn.transplant.hrsa.gov) and TransplantPro (https://transplantpro.org/kidney-allocation-system/) often to access these resources. UNet™ also now contains help documentation on all of the data elements.

Waiting Time

How is waiting time calculated in KAS?

Waiting time for adult and pediatric patients now includes time spent after starting dialysis (for the treatment of ESRD) prior to being registered on the waitlist. Candidates that haven't started dialysis at time of registration begin to accrue waiting time once they are registered on the waiting list and have a glomerular filtration rate (GFR) or creatinine clearance (CrCl) value less than or equal to 20 ml/min, or have begun dialysis.

Pediatric candidates immediately begin to accrue waiting time upon listing and receive additional waiting time if dialysis was started prior to listing.

For candidates that have had prior transplants, the dialysis start date after the most recent transplant should be used unless the candidate experienced immediate and permanent non-

function from the transplant. OPTN Policy 3.6.B.i defines immediate and permanent non-function of a transplanted kidney as:

- Kidney graft removal within the first 90 days of transplant
- Kidney graft failure within the first 90 days of transplant with documentation that the candidate is either on dialysis or has CrCl or GFR less than or equal to 20 mL/min

Programs must submit a *Renal Waiting Time Reinstatement Form* and supporting documentation to the OPTN/UNOS in order for waiting time to be reinstated.

Does a candidate need to meet waiting time criteria (GFR or dialysis) to be listed?

No. There are no medical criteria requirements for a patient to be listed on the kidney waiting list. GFR and dialysis criteria are only used for accruing waiting time and not for listing requirements. Candidates without any waiting time points will still receive other allocation points (e.g., for CPRA) and are eligible to receive match offers, including zero-ABDR mismatches, even if the candidate is not accruing waiting time.

Does policy require that the most recent GFR be used when listing a candidate?

No. As long as a patient has had a documented GFR less than or equal to 20 ml/min at some point in time, this value can be entered to qualify for accruing waiting time starting at time of registration. However, if a candidate has had a previous kidney transplant, the documented GFR value must be after the most recent transplant.

Is waiting time for patients having GFR ≤20 ml/min prior to being registered back-dated similar to dialysis start date?

No. Waiting time begins for candidates on or after the date of listing with a GFR or CrCl of less than or equal to 20 ml/min.

Now that waiting time includes all pre-registration dialysis time, is there any need for early referral and listing?

Early referral and listing are still very important and the best practice under the new allocation system, since patients with a shorter duration on dialysis prior to transplant tend to have better outcomes. While waiting time is calculated to include pre-registration dialysis time, the GFR criterion remains the same. Patients can accrue waiting time points based on this criteria alone. KAS prioritizes zero HLA-ABDR mismatches and patients who are listed early will have access to such offers, even prior to accumulating significant time on dialysis. It's also important to remember that candidates must be listed prior to their 18th birthday in order to receive pediatric priority.

If a patient accumulated waiting time based on pre-registration dialysis time and is subsequently removed from the waitlist, how will the original waiting time count if the patient is later added to the waitlist?

The patient will still have the same waiting time as long as the same dialysis start date is entered for the subsequent kidney registration. However, if the patient is re-listed due to having received a transplant that is no longer functioning, the dialysis start date entered for the new registration cannot be prior to the kidney transplant date, unless the recipient qualifies for

reinstatement of waiting time according to *Policy 3.6.B.i Non-function of a Transplanted Kidney* and the graft failure has been reported in TIEDI. This policy allows waiting time to be reinstated (i.e., the original, pre-transplant dialysis start date to be entered) if the recipient is re-registered on the waiting list as a candidate for the same organ and experiences immediate and permanent non-function of a transplanted kidney within the first 90 days of transplant. Otherwise, the candidate will qualify for waiting time for the new registration based on clinical information (GFR, CrCl, or start of dialysis) *after* the most recent kidney transplant.

How do the changes to waiting time affect multiply listed candidates? Will candidates still be able to (or have any need to) transfer primary waiting time?

Primary waiting time transfers are still permissible. If a candidate began to accrue waiting time based on a GFR/CrCl value prior to starting dialysis, the transfer is especially relevant.

If the candidate began to accrue waiting time based on start of dialysis, then the waiting time is the same at each center (assuming that each center enters the same dialysis start date for the candidate) and a waiting time transfer is less relevant. However, a candidate may still transfer their primary registration date, which will be used in the event of a tie.

If a patient is not on dialysis at the time of listing, but they meet the GFR criterion, is there any requirement to enter the dialysis start date on the waitlist record if/when the patient starts dialysis after listing?

A candidate's dialysis start date is used in two ways in allocation: 1) to calculate waiting time points; and 2) as one of four factors of the EPTS score. A candidate's EPTS score will be updated anytime the transplant hospital reports changes to any EPTS factor for a candidate. Although there is no OPTN policy requirement to enter the dialysis start date, one of the EPTS score factors is the candidate's time on dialysis and each candidate should have the dialysis date entered so that the EPTS score is accurately calculated.

Dialysis start date

If a candidate begins dialysis and then stops for a period of time, should I list a dialysis start date?

According to OPTN policy, waiting time points begin to accrue on the date that the candidate began regularly administered dialysis for ESRD. So, if the dialysis was administered for ESRD, the program can list this dialysis start date, even if the patient subsequently stopped receiving dialysis for a period of time (programs are required to maintain documentation of the dialysis start date in the candidate's medical record). If the dialysis was administered to handle an acute renal issue, that date cannot be used as a dialysis start date.

On May 27, 2014, UNet began displaying the CMS Medical Evidence Form 2728 dialysis start date for programs to reference (if a reliable match could be found based on the candidate's social security number) for patients registered prior to May 1, 2014. If I selected a dialysis start date that matches the CMS date displayed in UNet^{5M}, do I need to obtain additional documentation for the purpose of UNOS site visits?

No. Site surveyors will not request documentation if the dialysis start date selected matches the CMS date displayed in UNetsM.

If the program selects a different date or enters one when no CMS reference date is provided, the program will need to provide documentation supporting this date in the candidate's medical record (the list of acceptable documents is the same as those in the current OPTN Evaluation Plan).

Diabetes Status

Can you elaborate on the definition of 'current diagnosis of diabetes'?

UNetsM allows you to select Type I, Type II, or Other Type of Diabetes. If the candidate has drug-induced diabetes or both Type I and Type II diabetes, you should choose Other Type of Diabetes. If the candidate was previously diagnosed with diabetes but the condition was reversed by significant weight loss, gastric bypass surgery, etc., you should choose Does Not Have Diabetes. However, if the candidate was previously diagnosed with diabetes and no longer requires insulin or other diabetic medications (i.e. due to the reduced need for insulin after starting dialysis), you should still indicate a diabetes diagnosis since the diabetes has not been reversed. Gestational diabetes should not be considered a current diagnosis of diabetes.

The Help Documentation in UNetsM offers further guidance.

If the EPTS score is only influenced according to whether there is a diagnosis of diabetes (yes/no), why does the question in UNet[™] ask for the type of diabetes?

The Kidney Committee would like to review the data in the future to determine whether the EPTS score should be influenced by the type of diabetes (not simply yes/no). Collecting the data in this way is also consistent with how diabetes status is collected on the Transplant Candidate Registration (TCR) form in TIEDI.

Kidney Donor Profile Index (KDPI)

What is KDPI?

The kidney donor profile index (KDPI) combines 10 donor factors into a single number that summarizes the potential risk of graft failure after kidney transplant. KDPI can help predict how long a particular kidney is expected to function relative to other kidneys recovered during the previous calendar year. The KDPI is intended to be a more granular and predictive measure of organ quality compared to the binary ECD/SCD indicator. Physicians and surgeons should use KDPI in evaluating kidney offers, while also considering other donor characteristics. The KDPI is not intended to serve as the only metric for determining donor suitability. The KDPI Guide for Clinicians has more information on how to interpret and discuss KDPI with patients.

The KDPI ranges from 0% to 100%. Lower KDPI values are associated with higher expected post-transplant longevity, and higher KDPI values are associated with lower expected post-transplant longevity. KDPI is derived by first calculating the Kidney Donor Risk Index (KDRI) for a deceased donor.

What is KDRI?

The Kidney Donor Risk Index (KDRI) is an estimate of the relative risk of post-transplant kidney graft failure (in an average, adult recipient) from a particular deceased donor compared to a reference donor. In DonorNet, the median (50th percentile) donor is used as the reference donor. A donor with a KDRI of 1.28, for example, confers an estimated risk of kidney graft failure that is 1.28 times that of an "average" donor. Lower KDRI values are associated with a lower inherent risk of graft failure while higher KDRI values are associated with a higher inherent risk of graft failure. Multiple donor characteristics are used to calculate the KDRI:

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

A donor with a KDRI greater than 20% of last year's recovered kidney donors has a KDPI of 20%.

How does the previous ECD status differ from the KDPI score?

KDPI is a more refined metric for assessing how long a kidney is expected to function, since it takes into account 10 donor factors, compared to ECD which only considers four (age, creatinine, history of hypertension, and cause of death). In addition, the ECD criterion is limited since it is a binary assessment of donor quality, while KDPI estimates donor quality on a continuous scale. Some ECD donors actually have better estimated longevity (per KDPI) than some SCD donors, and vice versa.

Can transplant programs select a different maximum acceptable KDPI for all the patients on their list? Can the criteria be different for local vs. import offers? What about for zero-antigen mismatch offers?

Yes, yes, and yes. Transplant programs have the ability to set a different maximum KDPI score for each candidate on their list.

Programs also have the ability to set the maximum KDPI differently for local vs. import offers as well as zero-mismatch vs. non-zero mismatch offers. Programs are required to provide 4 different maximum acceptable KDPI values for each candidate: (local, non-0MM), (local, 0MM), (non-local, non-0MM), (non-local, 0MM). For example, a program might choose to set the maximum acceptable KDPI for local, zero-antigen mismatch offers to 100%, but set a lower

threshold (e.g., 85%) for receiving non-local, non-zero mismatch offers. Programs can choose maximum KDPI values anywhere along the spectrum from 0% to 100%.

How does donor offer screening based on maximum KDPI work, given that transplant centers can also screen offers based on maximum donor age and other factors?

The system screens donor offers (prevent a candidate from appearing on the match) if *any* of the donor parameters do not match the donor criteria selected for the candidate.

For example, if a candidate is listed as willing to accept a kidney with a maximum KDPI of 85% and the maximum age is set to 60, the candidate will be screened off of all match runs for donors with KDPI above 85% *or* age above 60. This candidate would be screened off the match if the donor was 61 years old even if the donor's KDPI was less than 85%.

Since the KDPI incorporates factors such as donor age, DCD status, serum creatinine, history of diabetes, and history of hypertension that can also be used for offer screening, if a transplant program desires to screen kidney offers for expected longevity by primarily using the KDPI, the program should consider relaxing some or all of the screening parameters that are components of the KDPI. For example, if a candidate has a maximum age value set to 60, but the center is interested in receiving offers from KDPI≤85% donors as long as donor age does not exceed 70, the center may choose to set the maximum KDPI to 85% but increase the maximum age to 70.

It is important to recognize that HCV serostatus is only included in the KDPI due to its effect on graft longevity, not due to the potential risk of disease transmission. An HCV positive donor, for example, may still have a low KDPI. Transplant programs must ensure that "Accept an HCV positive donor?" and other acceptance parameters related to donor serologies are set appropriately for each candidate.

Do transplant programs need to obtain written, informed consent from every candidate on their list for the KDPI criteria that each candidate is willing to accept?

No. Transplant programs are only required to obtain written, informed consent for candidates willing to receive offers for kidneys with a KDPI score greater than 85%. If the program previously obtained consent for ECD kidney offers from a candidate listed prior to December 4th, 2014, the program does not need to obtain a new consent. However, transplant programs' consent forms must now reference KDPI greater than 85%.

If a candidate is listed as only accepting KDPI of 85% or less, but receives a kidney placed off of the liver (or any other organ) list who has a KDPI over 85%, is there any requirement for the transplant hospital to obtain consent from that candidate?

Transplant programs must obtain written, informed consent from each multi-organ candidate prior to transplant for kidneys with a KDPI score greater than 85%. That change will not prohibit a transplant program from obtaining consent earlier (e.g., at the time of listing). Kidney-alone candidates will still need to provide informed consent *prior to receiving offers* for kidneys with a KDPI greater than 85%.

How does dual kidney allocation work in the new system?

The same kidneys that are eligible for dual allocation under the old system are eligible under the new KAS. Kidneys from donors that meet *at least* two of the following donor criteria are eligible to be allocated to the same patient:

- age>60
- eCrCl<65 ml/min based on admission creatinine (Cr)
- rising Cr (>2.5mg/dl)
- long-standing hypertension or diabetes
- 15%<qlomerulosclerosis<50%

The dual usage of kidneys has been shown to confer a survival advantage compared to single kidney transplantation. However, in both the old system and new KAS, transplant programs do not have the ability to differentiate donor criteria between dual versus single offers. Consequently, if a candidate is willing to accept a single kidney with KDPI up to 85%, but is interested in receiving dual kidney offers from a donor with KDPI up to 100%, the transplant program should enter 100% as the maximum acceptable KDPI for that candidate.

EPTS

What is an EPTS score?

The Estimated Post Transplant Survival (EPTS) score is a numerical measure used in the kidney allocation system to allocate about 20% of kidneys. Every adult patient on the kidney waitlist receives an EPTS score.

EPTS scores are percentages that range from 0% to 100%. Candidates with a lower EPTS score are expected to experience more years of graft function from a transplanted kidney compared to candidates with higher EPTS scores.

EPTS values are derived by comparing each candidate's raw EPTS score to percentiles from a reference population consisting of all adult kidney patients on the (national) waitlist as of a recent date. More information about EPTS scores can be found in the "Guide to Calculating and Interpreting EPTS."

How is the EPTS score used?

Beginning on December 4, 2014, the EPTS score was assigned to all adult kidney candidates on the waiting list for whom all four required data fields had been entered. The score is based on four factors: candidate age, length of time on dialysis, prior transplant of any solid organ, and current diabetes status. The EPTS score is designed to achieve better longevity matching. The candidates with the top 20% EPTS scores will 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. Candidates will not be prioritized based on EPTS for allocation of kidneys from donors with KDPI scores greater than 20%.

Sensitized Candidates, CPRA Approvals, Desensitization

How does the system increase access for sensitized candidates?

Kidney candidates are assigned a Calculated Panel Reactive Antibody (CPRA) score that is based on the unacceptable antigens (HLA-A, B, DR, DQ, and C) listed for each candidate. In

the old system, candidates received four additional prioritization points if their CPRA score was equal to or above 80%. In the current allocation system, prioritization points are assigned based on a sliding scale, beginning with a CPRA score of 20%. Candidates with CPRA of 20% receive 0.08 points, which is equivalent to about a month of waiting time. Candidates with CPRA of 75-79% receive 1.58 points, and those with CPRA 80-84% receive 2.46 points, equivalent to about one and a half and two and a half years of waiting time, respectively. Candidates with CPRA of 98%, 99%, or 100% receive 24.4, 50.09, and 202.10 points, respectively.

The Kidney Committee determined through statistical simulation modeling that points alone were insufficient for increasing access to candidates that are extremely difficult to match. Consequently, candidates with CPRA of 98%, 99%, or 100% also receive local, regional, and national priority, respectively, in additional to the large number of priority points according to the sliding scale.

In addition to improving access for sensitized candidates, these changes are intended to incentivize programs to enter <u>all</u> unacceptable antigens for their candidates. The Kidney Committee anticipates that these changes will help decrease the likelihood of unexpected positive crossmatches on kidneys shared regionally and nationally and, therefore, increase efficiency in the overall allocation system.

Programs should review the unacceptable antigens reported for sensitized candidates to determine whether all unacceptable antigens have been reported. This ensures that candidates receive their full prioritization points and will decrease the chance that candidates receive incompatible offers that will result in a positive cross-match.

Why does the policy require the candidate's physician or surgeon and the HLA laboratory director to review and sign a written approval of the unacceptable antigens for candidates with CPRA greater than 98%?

The review is a way to ensure accuracy in the unacceptable antigens listed for these candidates and reduce the chances of a positive cross-match, since they have access to kidneys shipped regionally and nationally.

What is the process for obtaining written approval for candidates with CPRA greater than 98% in order to receive regional or national prioritization? Can the candidate's physician or surgeon and the HLA laboratory director assign a designee to provide approvals?

This is a multiple step process:

- 1. The candidate's physician or surgeon and the HLA laboratory director must review the unacceptable antigens listed.
- 2. Written approval from both individuals must be documented in the candidate's medical record along with the unacceptable antigens that are approved. Electronic signatures are permissible as long as they are provided consistent with the hospital's internal policies for electronic signatures.
- 3. The approver names must be manually entered into UNetSM so that the system recognizes that the candidate is eligible for regional or national sharing.

Approval must be given by the physician or surgeon and HLA laboratory directory and cannot be given by a designee. However, once both approvers have reviewed and provided signatures in the candidate's medical record, the transplant program can designate other individuals to enter the names of the approvers into UNetSM.

Are the written approvals required every time the unacceptable antigens change? What if a candidate's CPRA fluctuates below and above 98%?

No. The approval process outlined above is only required once.

Once both names are entered, the system recognizes the additional sharing priority even if the CPRA fluctuates to 98% or below and then above 98% again. The system will not prompt you to enter the names a second time.

What happens if one or both signatures are missing for a patient with CPRA above 98%?

If one or both approver names are missing, the candidate will still be eligible for offers and will still receive prioritization points based on the sliding scale CPRA.

However, the system will not provide the candidate with regional or national priority.

Are there any changes to CPRA prioritization for patients undergoing desensitization?

No, not at this time. However, the OPTN/UNOS Kidney Transplantation and Histocompatibility Committees are discussing the issue and considering whether to recommend a policy change that would allow patients undergoing desensitization to keep their CPRA prioritization points (even while some unacceptable antigens are removed) for a period of time.

Are OPOs able to report donor HLA information for DQA1 or DPB1 for deceased kidney donors?

Yes, DonorNet® fields to report HLA-DQA1 or HLA-DPB1 have been available since January 21, 2016. These fields are required for making offers.

Why are my patients not getting CPRA points when I run the Kidney Points Report?

Table 8-1: Kidney Points and Table 8-2 Points for CPRA show that sensitized candidates (CPRA of at least 20%) only receive CPRA points under the 8.5.H (donors with KDPI 0-20%), 8.5.I (21-34%), or 8.5.J (35-85%) allocation sequences. Sensitized patients do not receive CPRA points for the 8.5.K allocation sequence, which is for deceased donors with KDPI scores greater than 85%. Therefore, sensitized candidates would not receive CPRA points for deceased donor kidneys with a KDPI of 85% or more reflected in the Kidney Points Report.

Increased Access for Blood Type B Candidates (A2/A2B eligibility)

Candidates with blood type B who meet eligibility criteria determined by their transplant program will receive offers from donors with blood type A2 (A, non-A1) or A2B (AB, non-A1B). What do transplant programs need to do to in order to receive these offers?

Blood type B candidates who meet their program's clinical criteria for titer levels are eligible to accept kidneys from donors with blood type A2 or A2B. Programs need to develop a written protocol for patient eligibility, selecting a maximum titer level for candidates in this category.

Programs need to obtain written informed consent from each blood type B candidate willing to accept a blood type A2 or A2B kidney before reporting the candidate as eligible in the system. Programs are required to confirm in UNetSM every 90 days that the candidate is still eligible

according to the program's protocol to accept these offers. However, the only confirmation needed is a "yes" or "no" for eligibility; there is no requirement to report the titer values in the new system. UNetSM displays the number of days remaining before the next confirmation is needed as a reminder to transplant programs.

Pediatric Candidates

What is the priority for candidates under 18? Is there priority for pediatric candidates?

There are three types of pediatric priority if the patient is registered on the deceased donor waitlist prior to turning 18:

- 1. pediatric "points" (OPTN Policy 8, Table 8.1)
- 2. match classification priority for zero-ABDR mismatches.
- 3. match classification priority for donor kidneys at the local, regional, and national levels

For kidneys with KDPI scores greater than 85%, candidates under the age of 18 are screened from the match with the exception of zero mismatches with the donor (if the required consent for KDPI>85% kidneys is in place).

What is the priority for adult candidates who were listed prior to turning 18 but have since turned 18?

After turning 18, candidates will still receive match classification priority for donor kidneys at the local, regional, and national levels for registering prior to turning 18. This priority is included in Table 8-5 Allocation of Kidneys from Deceased Donors with KDPI Less Than or Equal to 20% (see lines 41, 61, 66) and Table 8-6: Allocation of Kidneys from Deceased Donors with KDPI Scores Greater Than 20% but Less Than 35% (see lines 41 and 44). This patient will no longer receive pediatric points or pediatric match classification priority for zero-ABDR mismatches.

If a candidate is listed after their 18th birthday, but their dialysis start date is before their 18th birthday, does the candidate still receive pediatric priority?

No. The dialysis start date is used for assessing waiting time points and as a factor for the EPTS score. The policy 8.4.B specifies that the candidate must have been listed prior to their 18th birthday to receive pediatric priority.

Additional priority for prior living organ donors

Do prior living donors receive additional priority under KAS?

Yes. As in the old system, prior living donors continue to receive four additional prioritization points as well as local match classification priority with every listing (i.e. for second or additional transplants).

If a patient has donated a kidney, liver segment, lung segment, partial pancreas, or small bowel within the U.S. or its territories, he or she is qualified to receive priority. The name and hospital of the recipient and date of organ procurement must first be reported to the OPTN Contractor before this priority is awarded.

Local, State, and National Variances

When will the Kidney Committee consider new allocation policy variances?

The Committee needs to allow some time to pass after the policy is fully operational in order to establish a baseline from which to assess any new variance. The Committee has decided that no variances will be considered until the policy has been operational for at least one year.

Geography

Is the new allocation system expected to have any impact on reducing geographic disparities?

Some of the changes are expected to have an impact on geographic disparities. For example, kidneys are expected to be allocated outside of the local DSA more frequently due to regional and national priority for very high CPRA patients, as well as the use of a combined local/regional list for allocation of KDPI>85% kidneys.

However, the Committee recognizes that substantial geographic disparities will continue to exist, since addressing this issue was not a primary goal of the new system. The Committee anticipates further discussion on potential allocation changes to address geographic disparity.

Organ Allocation

What is the order of allocation when an OPO ships a kidney but the intended recipient cannot be transplanted?

Per OPTN Policy 5.9 Released Organs, the transplant program must release the organ back to the host (originating) OPO. The host OPO must allocate the kidney according to its own match, delegate allocation to the receiving OPO (often called "granting local back up"), or delegate allocation to the UNOS Organ Center. Similarly, the host OPO can backup the organ offer according to its match list prior to shipping the kidney or allow the importing OPO to back up the offer according to its match sequence. The decision lies with the host OPO.

The Kidney Committee recommends that the host OPO make the decision in advance of shipping whether they want to be responsible for the alternative allocation or not. The Committee also recommends that the host OPO allow the receiving OPO/transplant center to back up the kidney locally in the event that not doing so would greatly increase cold ischemia time and, therefore, the likelihood that the kidney will be discarded.

Multi-Organ Allocation

What is the organ allocation order when there are other organs available in addition to kidney(s)?

When a kidney is available with a heart, lung, liver, or pancreas, the OPO must first offer the kidney to local candidates listed for these combinations. The host OPO has the discretion to choose any of the following:

- Allocate the kidney to local candidates on the heart match run
- Allocate the kidney to local candidates using the lung match run
- Allocate the kidney to local candidates using the liver match run

• Allocate the kidney to candidates using 1-5 classifications on the kidney-pancreas match run (see *Policy 11.4.A Kidney-Pancreas Allocation Order*)

OPOs are not required to allocate a kidney as part of a multi-organ combination beyond the local level (except for those specified in 1-5 classification on the kidney-pancreas match run). However, OPO's do have the discretion to allocate the kidney beyond the local level.

If the kidney is offered and accepted as part of a multi-organ combination but cannot be transplanted into the intended multi-organ recipient, the OPO must then offer the kidney using the kidney alone match run.

Are there any efforts to clarify multi-organ allocation policies?

Yes. UNOS staff are aware of the concerns regarding lack of clarity in multi-organ allocation policies and the Policy Oversight Committee recently discussed a plan to work on substantive changes to the policy. This is one of the key objectives in the 2015-2018 OPTN strategic plan.

Updating Data

What data, if any, are members responsible for updating after listing a kidney candidate (i.e. diabetes, wait time qualifier, CPRA, etc.)?

Members should update candidate data whenever there are changes to the candidate's clinical information; however, there is no policy requirement to do so with the exception of blood type B candidates. Allocation of kidney by blood type requires that kidneys from donors with blood types A, non-A₁ and AB₁, and non-A₁B are allocated to candidates with blood type B. Transplant programs must confirm the blood type B's eligibility every 90 days (+/- 20 days).

Shipping Logistics

What are the minimum tissue typing materials the OPO must send?

Policy 2.15.D Required Tissue Typing and Blood Type Verification Materials specifies the minimum materials that must be provided by organ. OPOs are not required to provide materials beyond this minimum number. If the OPO is able to provide the additional materials requested, it is recommended that you do so. It's in the interest of all parties to be able to perform the crossmatch as early as possible.

Can the OPO require the results of the crossmatch prior to shipping the kidney if the transplant program doesn't agree to this?

No. According to *Policy 5.6.C Effect of Acceptance*, if the transplant hospital accepts the kidney, the offer is binding and the OPO cannot make shipping contingent upon other conditions.

Is the OPO required to ship the blood in advance of the kidney if the transplant program requests this?

No, however, the Kidney Committee suggests sending the blood in advance when possible because it is in the best interest of all parties. Otherwise, there is an increased chance that the crossmatch will come back positive after the kidney has already been shipped.

Is there added value to asking the intended recipient's transplant center to perform a virtual crossmatch in advance of acceptance?

Yes. Because the match run avoids candidates with unacceptable antigens listed to the donor's HLA type, the match run essentially performs a virtual crossmatch prior to allocation. However, this virtual crossmatch is somewhat limited as it does not take into account multiple, moderate-level donor specific antibody sensitivities that may produce a positive crossmatch but were not entered as individually unacceptable antigens. Also, UNet currently does not collect donor HLA-DPA1 that some sensitized candidates have been shown to be making antibodies against. However, histocompatibility labs that test for -DPA1 antibodies could perform a virtual crossmatch today to account for this information if the OPO lab can also provide the donor's DPA1 type to ensure an accurate virtual crossmatch. Therefore, there can still be some benefit for histocompatibility labs to perform virtual crossmatch due to multiple moderate-level DSAs or antibodies to DPA1.

Is the Kidney Committee going to monitor how this change is working and whether there are unintended consequences associated with it?

Yes, the Kidney Committee has been monitoring numerous data elements to determine how the changes are working and this particular aspect of the new policy very closely through monthly "Out of the Gate" monitoring reports for the first six months post-KAS implementation as well as a more comprehensive six-month analysis. Going forward, the UNOS research department will also provide 1 year and 2 year comprehensive reports.