The New Kidney Allocation System: Resources for Protocols and Processes webinar.

Speakers for the webinar are:

Dr. Richard Formica – Associate Professor of Medicine and Surgery, Yale University School of Medicine. He is the current Chairman of the OPTN/UNOS Kidney Transplantation Committee.

Dr. Mark Aeder – Associate Professor of Surgery in the Division of Transplantation, Department of Surgery at the University Hospitals Case Medical Center. Dr. Aeder is the current Vice Chairman of the OPTN/UNOS Kidney Transplantation Committee.

Presenters

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- Leads on-site reviews at deceased donor transplant programs to assess compliance with OPTN/UNOS policies and bylaws
- DEQ representative to the OPTN/UNOS Operations and Safety Committee
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Angela Marquez – Administrative Director of the transplantation programs at Massachusetts General Hospital, and she is the Region 1 representative to the OPTN/UNOS Transplant Administrators Committee.

Leslee Garland – Site Surveyor in the Department of Evaluation and Quality at UNOS. In this role she leads on-site reviews at deceased donor transplant programs to assess compliance with OPTN/UNOS policies and bylaws.

By the end of this presentation, you will be able to:

1. Describe the impact of upcoming policy and system changes related to the new kidney allocation system.

2. Utilize tools and resources provided by the OPTN to prepare for system implementation.

3. Identify methods for compliance with kidney allocation policies.

Background

Current Kidney Allocation System Limitations

| High kidney discard rates	Variability in access to transplant
	o Certain blood types
	o Sensitization levels
	o Geographic location
Unrealized graft years	High re-transplant rates

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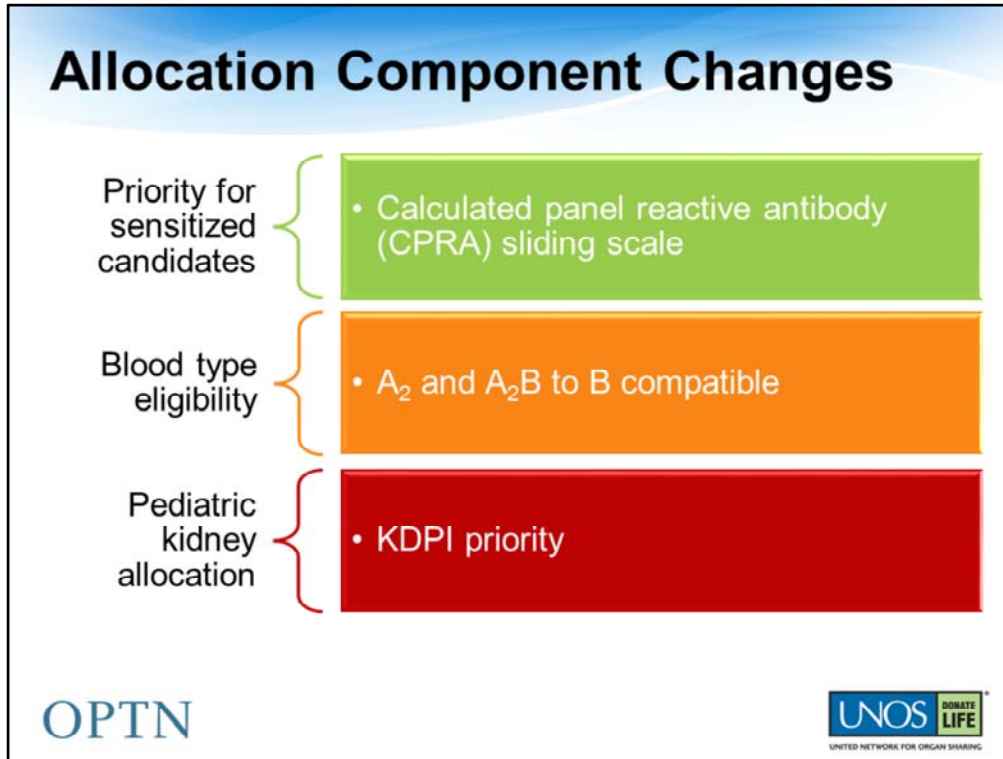Let's start with a brief review of why a new kidney allocation system is needed.

The current kidney allocation system has limitations that include:

- Higher than necessary discard rates of kidneys that could have been transplanted into candidates on the waiting list,

- Variability in access to transplantation by candidate blood type and sensitization level, and

- A matching system that doesn't account for longevity, which means matching the kidneys that are likely to function for many years with the patients most likely to need them for many years. In some cases this means that some recipients end up needing to be re-transplanted, thus lowering the chance for others to get a first-time transplant. The changes to the system are expected to address these limitations.
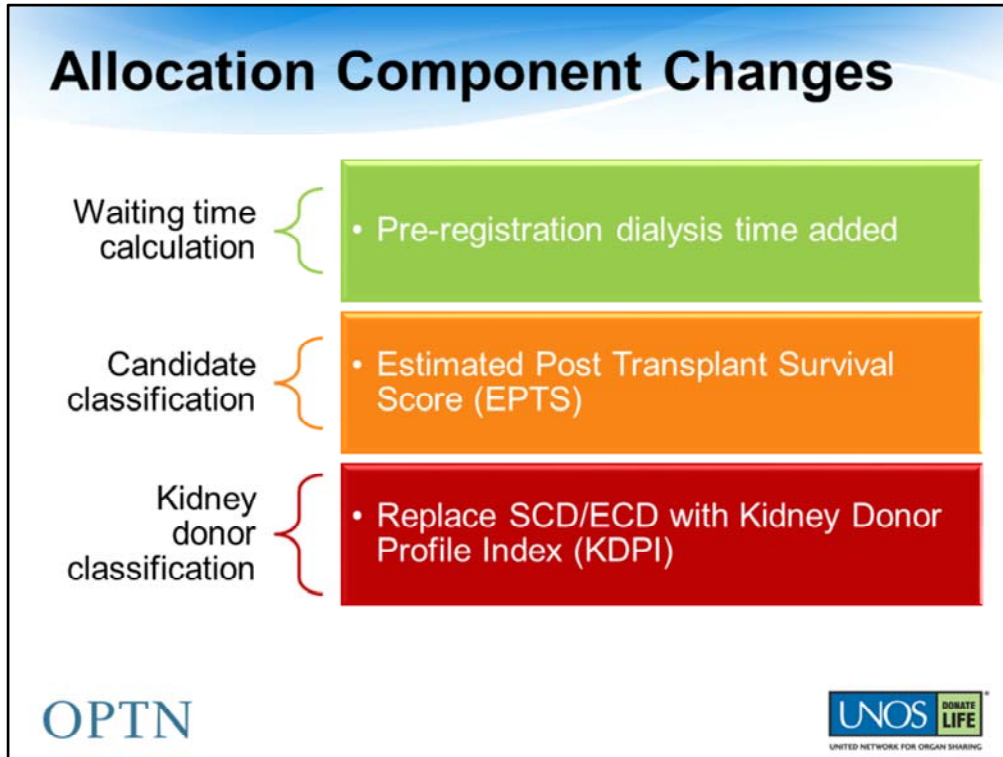
We have previously reviewed the changes in major kidney allocation components. During today's presentation, we will cover the following changes in greater detail:

- Changes to waiting time calculation which will include the addition of pre-registration dialysis time to the candidate's calculated waiting time;

- Today we will expand on the changes in how candidates are classified. The Estimated Post Transplant Survival score, or EPTS, was designed to promote better longevity matching between donor and recipient in order to utilize the maximum amount of graft years post-transplant.

- Kidney donors will also be classified in a new way in the system. Standard Criteria Donors (SCD) and Expanded Criteria Donors (ECD) are being replaced with a more refined metric known as the Kidney Donor Profile Index or KDPI.

Allocation Component Changes

Priority for sensitized candidates
- Calculated panel reactive antibody (CPRA) sliding scale

Blood type eligibility
- A_2 and A_2B to B compatible

Pediatric kidney allocation
- KDPI priority

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- The new system will also change the way highly sensitized candidates get priority for kidneys through additional sharing and a sliding scale points system for calculated panel reactive antibody or CPRA scores.

- There will be greater access to deceased donor kidneys for blood type B candidates who can safely accept a kidney from an A_2 or A_2B blood type donor; and

- For pediatric candidates, priority will be based on the donor's KDPI instead of the donor's age.

In covering these component changes in greater detail, this presentation will aim to help kidney programs develop needed protocols and processes for implementation of the new kidney allocation policies.

Time On Dialysis

Dialysis start date will be used in **two** ways:

1. Waiting time points based on time on dialysis – credit given for dialysis **prior** to registration

2. Dialysis start date is one of four factors to calculate Estimated Post-Transplant Survival (EPTS)

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In the new system, waiting time priority will remain a key factor in allocation. It recognizes that prioritization for transplant is based on a patient's medical need and time on dialysis as an indication of time spent with ESRD. Dialysis start date will be used in the new system in two ways:

1. Both adult and pediatric candidates will be assigned waiting time points to account for time on dialysis prior to registration. Meaning that they receive a credit for time spent on dialysis prior to listing. Of note: the policy that allows a candidate to begin accruing waiting time points at registration for a GFR and CrCl value equal to or less than 20 ml/min remains unchanged.

2. And, the dialysis start date will also be used as one of four factors that calculate each adult patient's estimated post-transplant survival score (EPTS).

Because dialysis start date will be used in these two ways, it is very important that transplant programs collect any missing or undocumented dialysis start dates for their candidates and enter that information into UNet^SM once the fields are available. It is imperative that the dialysis dates entered are correct so that the candidate receives full benefit of waiting time points for time spent on dialysis and a correctly calculated EPTS score.
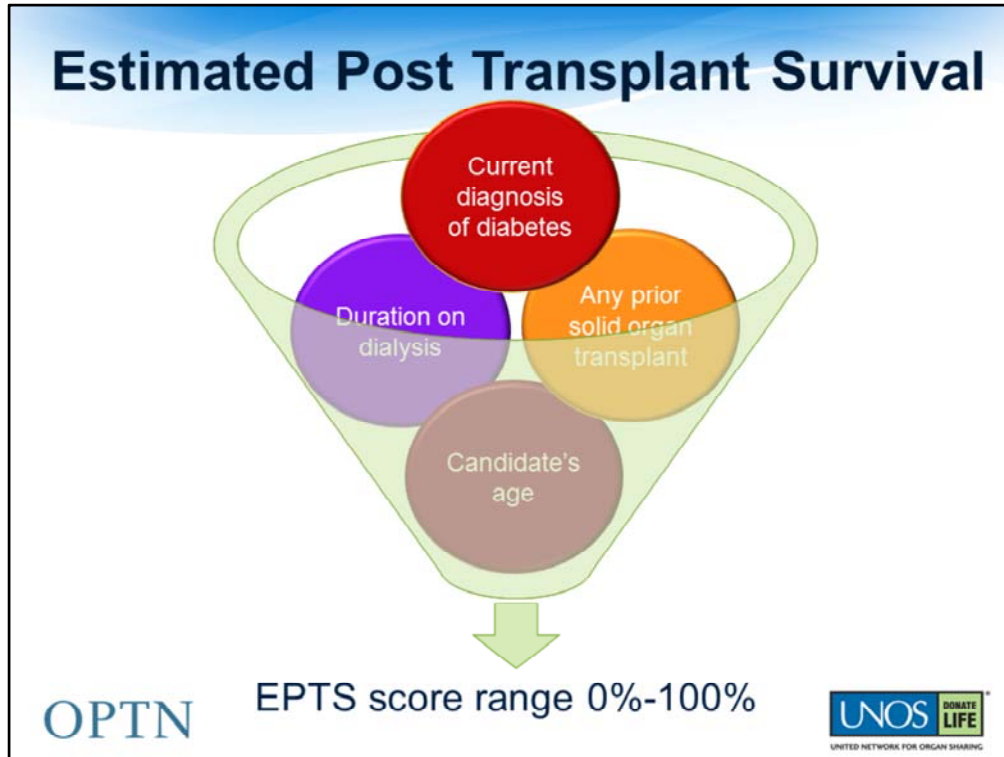
The EPTS score is a numerical measure used in the new kidney allocation system to identify those candidates expected to live the longest after a kidney transplant.

Let's review the factors included in the EPTS formula:
- candidate's age
- duration on dialysis
- whether or not the candidate has a current diagnosis of diabetes
- whether the candidate has had any prior solid organ transplant

EPTS scores range from 0% to 100%.

The EPTS calculator is now available in the Waitlist[SM] application and on the OPTN website. It is intended to help transplant clinicians and patients become more familiar with the EPTS score.

The tool is useful for assessing different combinations of the four candidate factors to evaluate their impact on the score and to generate profiles of patients with varying EPTS scores.

EPTS: Adults vs. Pediatrics

- Every adult candidate will receive an EPTS score
- EPTS scores **will not** be calculated for **pediatrics**
- Programs must still verify dialysis start dates for adult and pediatric candidates

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Every **adult** patient on the kidney waiting list will receive an EPTS score in the new system. An EPTS score will not be calculated for pediatric candidates.

Even though the EPTS score does not apply to pediatric candidates, programs must still verify the dialysis start date for these candidates in order to receive correct waiting time points.

Programs should update all EPTS fields for pediatric candidates, so that these candidates do not have missing scores when they turn 18 years of age and potentially miss out on priority for zero-antigen mismatch offers.

EPTS: Pediatrics

- After a candidate turns 18, an EPTS score will be calculated

- Candidates initially registered as pediatric will maintain priority over adults at local, regional and national levels of distribution

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Once a candidate turns 18, the EPTS score will be calculated. It will be displayed in the Waitlist[SM] application, and used for prioritizing the top 20% of EPTS candidates ahead of the bottom 80% of candidates for zero-antigen mismatch offers.

Even after they turn 18, candidates who were registered while pediatric (age less than 18 years old) will maintain priority over adults at the local, regional, and national levels of distribution, irrespective of the EPTS.

The EPTS score will be calculated based on the national pool of candidates, but it will only be used to identify two broad groups of candidates in that pool:

1. Those with scores of 20% or less, and
2. Those with scores exceeding 20%.

EPTS only identifies these two groups, but not rank order of candidates on the match run.

Candidates with a lower EPTS score are expected to experience more years of graft function from high-longevity kidneys compared to candidates with higher EPTS scores:

- Candidates with lower EPTS scores tend to be of a younger age.
- Analysis has revealed that candidates in their mid-50s can still have EPTS scores in the Top 20%.
- Though candidates with diabetes tend to have higher EPTS scores, the same analysis showed that some younger diabetics have EPTS scores of 20% or less.
- Candidates who have had a prior solid organ transplant, as well as those having spent many years on dialysis, tend to have higher EPTS scores.
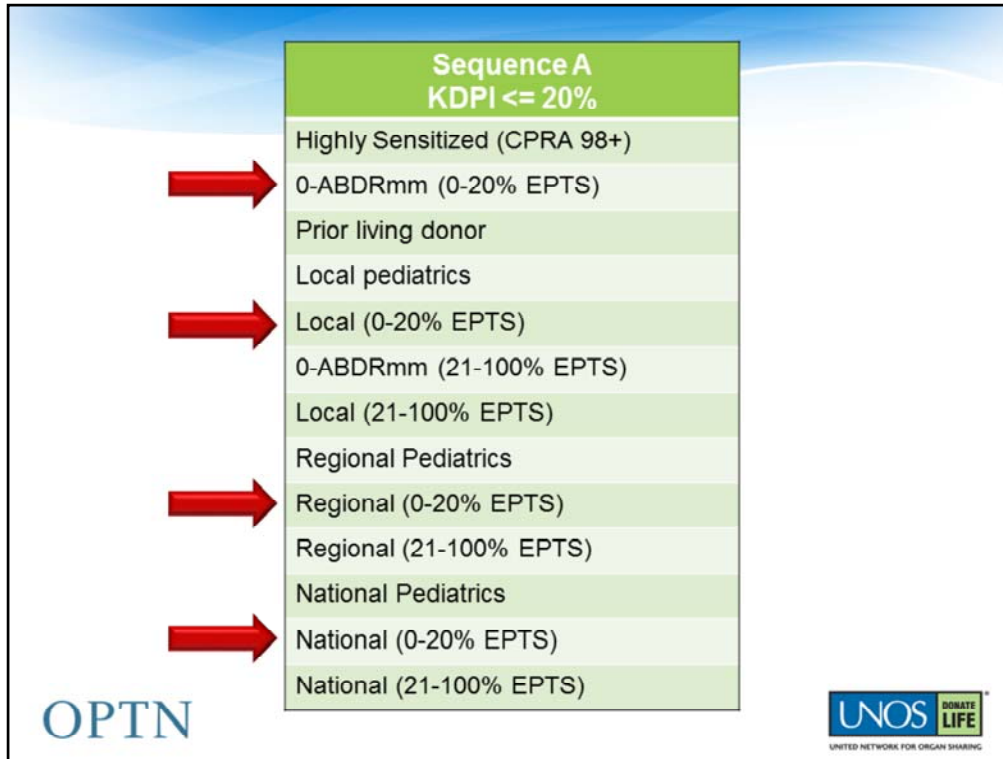
Candidates with EPTS scores of 0-20% will be prioritized ahead of candidates with lower scores, but only for the highest longevity kidneys, which are those kidneys with a KDPI of less than or equal to 20%.

What you see on this slide shows the allocation sequence of KDPI 20% or less kidneys. Patients with an EPTS of 0-20% will receive priority for zero mismatches, local offers, as well as regional and national offers.

Allocation proceeds first to local patients with EPTS of 0-20%, followed by local patients with EPTS exceeding 20%, before offers are made regionally or nationally.

EPTS Calculator Example

For example, a non-diabetic 51 year old candidate that has been on dialysis for a week and has had no prior transplants would have an EPTS score of 15%. Since the EPTS score is 20% or less, this patient would appear in one of the 0-20% EPTS groups in the allocation sequence, as shown in the previous slide.

The calculator can allow you to forecast what that candidate's EPTS score is likely to be at a future date by changing the calculation's 'as of' date at the bottom of the page.

Changing the 'as of' date to a date six months in the future led to an increase in the EPTS score from 15% to 19% for this particular patient.

The increase in EPTS for this patient is due to both increased age as well as increasing time on dialysis. Even though the score increased, it is still below 20%, and the patient would receive priority for being in the EPTS 0-20% group.

Patients who are in the 0-20% EPTS group today may not remain in that group.

Rank-ordering of Candidates

Total points determined by:	
Waiting time	CPRA sliding scale
HLA-DR matching	Pediatric status
Prior living donor status	

- Tiebreaker = date of registration

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Within each of the allocation categories discussed, these two EPTS groups, will be rank-ordered on the match by total allocation points.

Remember that allocation points are determined by:

1. Time on dialysis, or time after meeting eGFR (glomerular filtration rate) or CrCl (creatinine clearance) criteria,
2. The calculated PRA or CPRA sliding scale,
3. HLA-DR matching,
4. Pediatric status, and
5. Prior living donor status.

If a tie-breaker is needed, the date of registration will be used.

EPTS Data Entry

- EPTS data verification report in UNet^{SM}

Existing Fields	New Fields
Age (date of birth)	Number of prior solid organ transplants
Dialysis date (dialysis start date)	Current diabetes status

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In order to help kidney transplant programs transition currently listed candidates to the new allocation system, beginning this summer an EPTS data verification report will be provided in UNet^{SM} to allow entry of the new EPTS factors.

To calculate the EPTS score, only two new data fields for candidates are being added to the waiting list:

- Current diabetes status; and
- The number of any prior solid organ transplants.

Transplant programs must provide this information for all of their waitlisted kidney candidates and verify the dialysis start date to calculate the EPTS score and to determine waiting time points. Electronic data entry tools, including a batch upload utility, will be added to UNet^{SM} to make it easier to update this data. System training this summer will provide instruction to programs on how to use these new online tools. Programs will have six months to update and verify their data prior to the implementation of the new allocation system.

EPTS Score Updates

- EPTS recalculated when one of the four factors change
- EPTS recalculated nightly

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Programs will be responsible for keeping these data fields updated.

For example, if a patient develops diabetes while on the waiting list, the program must update the current diabetes status on the candidate's waiting list record. Likewise, if a patient has a liver transplant while waiting for a kidney, the program must update the number of prior transplants field.

Anytime EPTS data elements are updated or corrected, the EPTS score will automatically be recalculated. In addition, EPTS will be recalculated at midnight each night to take into account each candidate's one day increase in age and time on dialysis (if on dialysis).

Dialysis Start Dates

- **Two** dialysis start date references:
  - Date from CMS database
  - Date from UNet^{SM} database
- Confirm or edit dialysis start date

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As a helpful reference to programs, beginning this summer UNet^{SM} will provide two references to identify an accurate dialysis start date for each candidate:

- The first is the candidate's dialysis start date as indicated in the CMS CrownWeb database, if an associated social security number can be found. If the SSN is not found then the field will not display a date.

- And the dialysis start date the program previously entered into UNet^{SM}, if a date was previously entered. Transplant programs will be responsible for reviewing this data and either confirming that their already-entered date is accurate, or correcting this date if necessary. If the center confirms that their previously entered date as correct, this date does not need to be re-entered.

If the center believes the date previously entered is wrong, they can correct the date to match the displayed CMS date, in which case no further documentation would be required. However, if a different dialysis start date is entered, the center must maintain documentation supporting this alternative date.

It is important to realize that the dialysis date entered or confirmed by the center, not the CMS date that is displayed for reference, will be used by the allocation system for determining EPTS and waiting time.

Candidates with missing or unverified EPTS factors will have a missing EPTS score in the new allocation system. These candidates will appear on the match list, but will be assumed to have an EPTS score greater than 0 – 20%.

Since the dialysis start date is also used to determine waiting time points, candidates without a verified dialysis start date will not receive points for time spent on dialysis prior to being registered on the waiting list.
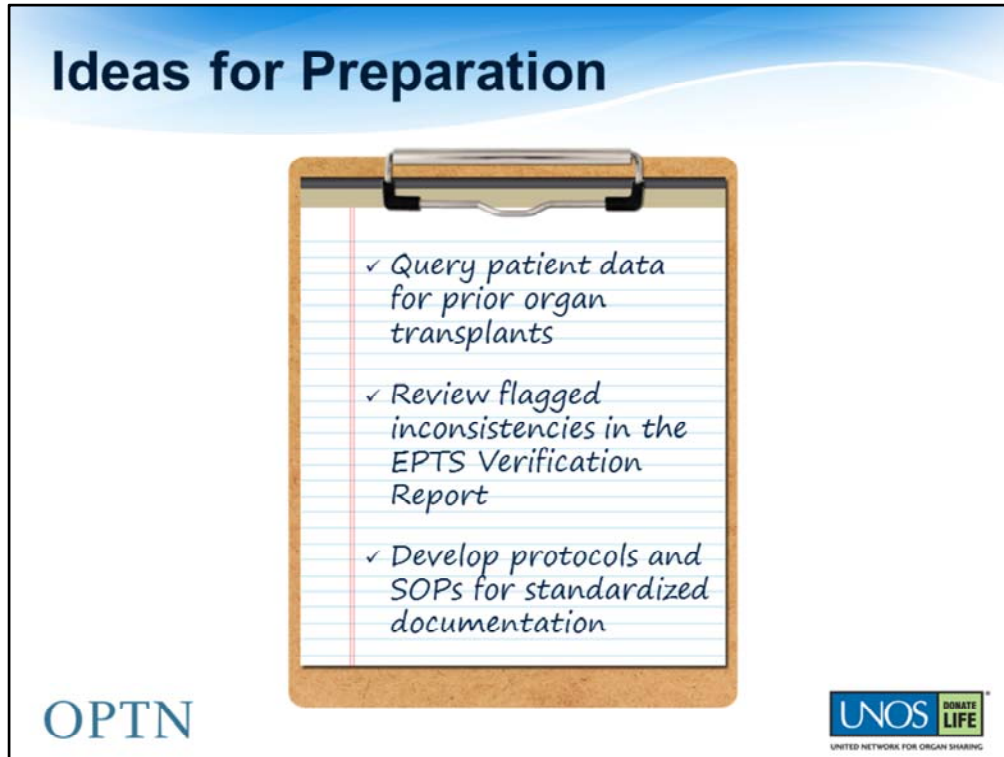
I am Angela Marquez and am the Administrative Director of the transplant programs at the Massachusetts General Hospital (MGH) in Boston. I will share with you ideas for preparing for the upcoming implementation of the new kidney allocation system.

At our Center, we will be querying our internal patient database to assess for candidates with prior organ transplants in preparation of entering this information into UNet^{SM}.

For dialysis start date and diabetes, we will review the flagged inconsistencies from the EPTS data verification report that will be available in the summer. We will look up source documentation to verify or correct the data in the system.

Our team is also currently working on developing protocols and standard operating procedures (SOPs) to standardize criteria and source documentation for diabetes type and prior organ transplants. We are determining how, where and who will document this information in the electronic medical record for all newly listed patients.

We are currently working with our dialysis centers to ensure that we receive important clinical updates so that we can appropriately update patient information in our records, especially as it relates to diabetes status.

Kidney Donor Profile Index

Classified by KDPI based on:
Donor age
Height
Weight
Ethnicity
History of hypertension
History of diabetes
Cause of death
Serum creatinine
Hepatitis C virus status
Donation after circulatory death

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Many of you are familiar with the Kidney Donor Profile Index (KDPI) since it's been available in DonorNet® for a couple of years now. Let's take this opportunity to review KDPI and how it will be used in the new kidney allocation system.

KDPI is a numerical measure that combines ten dimensions of information about a donor, including clinical parameters and demographics, to express the relative longevity of that donor kidney compared to the entire deceased kidney donor pool. The KDPI is derived by first calculating the Kidney Donor Risk Index (KDRI) for a deceased donor.

KDPI is calculated by using the donor variables of:
• Age
• Height
• Weight
• Ethnicity
• History of hypertension
• History of diabetes
• Cause of death
• Serum creatinine
• Hepatitis C status
• Whether the donor donated organ after circulatory death

These factors are used to calculate a percentage score that is associated with how long a kidney offered is likely to function after transplantation based on a historical cohort of similar donated kidneys. The lower the KDPI the greater the likelihood that the kidney will have a longer time of function in the recipient.
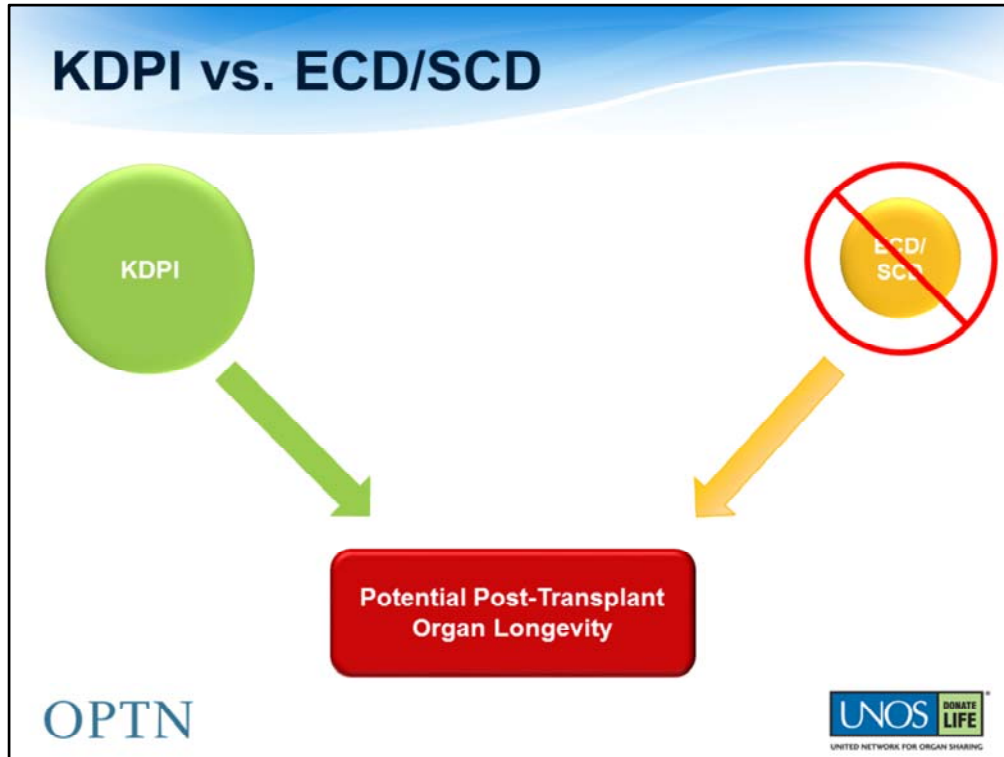
We have previously discussed that in the new kidney allocation system the Expanded Criteria Donor (ECD) and Standard Criteria Donor (SCD) classifications will go away and be replaced with KDPI. Research has shown that the current definitions of ECD and SCD do not precisely estimate the post-transplant kidney function. Kidneys from some donors currently considered "expanded criteria" are expected to function longer than kidneys from some "standard criteria" donors. This is where the KDPI can provide a more detailed estimate of kidney longevity.

KDPI is an improvement over the ECD and SCD in several ways:

1. KDPI explicitly incorporates 10 donor factors (instead of 4 in the ECD definition);
2. It is a continuous "score" instead of a binary (yes/no) indicator; and
3. KDPI illuminates the fact that not all ECDs are alike, for instance:
    o Some ECD kidneys have reasonably good estimated longevity
    o Some SCD kidneys actually have lower estimated longevity than some ECDs
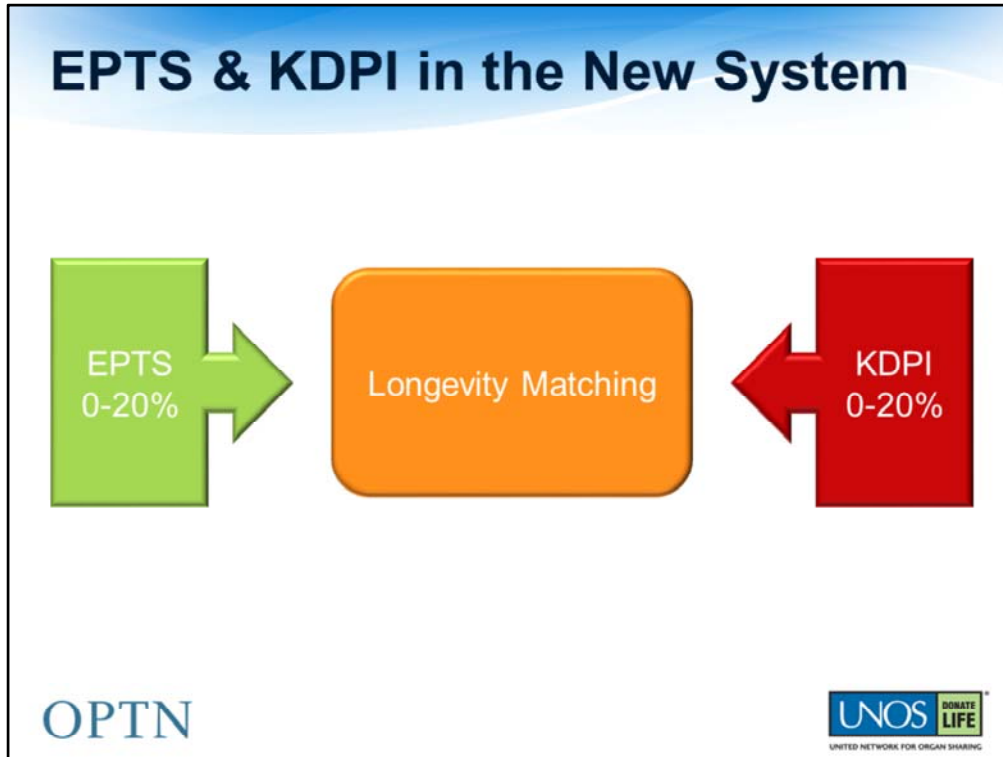
The intent of longevity matching is to ensure that kidneys expected to function the longest are most often transplanted into those candidates expected to live the longest, thereby realizing the greatest benefit from kidney transplantation.

The EPTS will be used in tandem with the KDPI to introduce the concept of longevity matching into the new allocation system. The EPTS score will only be used in kidney allocation when the donor has a KDPI of 0-20%.

In other words, the EPTS will be used to prioritize candidates in only 20% of kidney allocations, while for 80% of allocations EPTS will not be used at all.

EPTS and KDPI in the New System

- Candidates with EPTS < 20% will receive increased priority for offers for kidneys with KDPI scores of < 20%

- Allocation will still proceed by geography

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Candidates with EPTS scores of 20% or less will receive increased priority for offers for kidneys with KDPI scores of 20% or less.

Allocation will still proceed by geography, with local candidates – even those with an EPTS score exceeding 20% – appearing on the match list before candidates listed outside the local donor service area.

KDPI Acceptance Criteria

- Defaults for currently listed candidates

Listed to accept ECD	Not on ECD list
Max KDPI of 100%	Max KDPI of 85%

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Transplant programs will have the ability to set a maximum KDPI score for each candidate on their list.

For those candidates listed prior to implementation of the new system, UNet℠ will be programmed to default to certain maximum KDPI scores for these candidates based on the prior SCD/ECD criteria that the candidate was willing to accept.

For example, for candidates who are currently listed and previously agreed to ECD kidney offers, UNet℠ will default the maximum KDPI to 100% for these candidates. No screening will take place based on KDPI for candidates with a max KDPI of 100%.

For candidates already listed who are only willing to consider SCD offers, the system will default the maximum KDPI to 85%.

These defaults are intended to ease the transition of currently listed candidates into the new system, in particular for centers with large waiting lists.

KDPI Acceptance Criteria

- Ability to change maximum KDPI for all candidates

- Set KDPI for local vs. import offers

- Set maximum KDPI:
  - Local: **non-zero** or **zero** mismatch
  - Non-local: **non-zero** or **zero** mismatch

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Transplant programs will continue to have the ability to change the maximum KDPI for all candidates, whether newly listed or those listed prior to the new system.

Programs should discuss acceptance criteria for local versus import offers, and determine which of their candidates may benefit from a shipped kidney with a KDPI>85%. Also important is that programs will have the ability to set the maximum KDPI differently for local vs. import offers, just as they can today for maximum age and "other" donor acceptance criteria.

In addition, programs will be able to indicate a different maximum acceptable KDPI for zero-mismatch vs. non-zero mismatch offers. Similar to the current ECD offer screening functionality, they will be able to provide different maximum acceptable KDPI values for local, non-zero mismatch and zero mismatch as well as non-local, non-zero mismatch and zero mismatch.

For example, a program might choose to set the maximum acceptable KDPI for local, zero-antigen mismatch offers to 100%, but choose to avoid receiving non-local, non-zero mismatch offers of donors with KDPI>80%. Centers will be able to choose a maximum KDPI value anywhere along the spectrum from 0% to 100%.

KDPI > 85% Consent

- Update consent forms to reference KDPI > 85%

- Obtain informed consent for **newly** listed candidates who agree to kidneys with KDPI > 85%

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Transplant programs will need to update their consent forms to reference KDPI greater than 85% instead of ECD in preparation for implementation of the new system.

At implementation, policy will require transplant programs to obtain informed consent for all candidates who agree to receive kidneys with KDPI scores greater than 85%. These kidneys will be allocated to a combined local/regional list to minimize cold ischemia time.

Transplant programs are only required to obtain informed consent on candidates listed after implementation of the new allocation system when the candidates are willing to receive offers for kidneys with a KDPI score greater than 85%. Candidates on the list prior to implementation with documented consent for an ECD kidney will not need to be consented.

As we previously discussed, candidates who are currently listed and previously agreed to ECD kidney offers, UNet℠ will default to a maximum KDPI of 100%. And candidates currently listed who are only willing to consider SCD offers, the system will default the maximum KDPI to 85%. If these candidates were to agree to receive kidneys from KDPI scores greater than 85%, they will need to be consented.

Other Acceptance Criteria

- Be mindful that **other** independent acceptance criteria may conflict with KDPI

- Any one independent criteria could result in eliminating all donor offers regardless of KDPI

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Review "other" donor acceptance criteria previously entered into the system for your candidates and determine whether updates are needed. Several factors that can be used for offer screening such as donor age, creatinine, and DCD status, are actually taken into account by the KDPI, so screening using both KDPI and these "other" individual factors may be redundant and counter productive.

Centers that want to begin relying more on the KDPI for screening offers might consider relaxing these other criteria, for example, by increasing the maximum acceptable age for some or all candidates.

Acceptance Criteria Examples

- Candidate opts out of DCD but selects KDPI max of 60% = will not see **any** DCD offers, even from KDPI 50% or less donors

- Candidate selects max donor age of 55 and KDPI of 60% = will not see offers from 56 y/o donor with KDPI 36%

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Let's review a few examples of how "other" acceptance criteria can impact screening by KDPI.

In current system: if a candidate is listed as willing to receive a local ECD offer, but the maximum donor age (local) is set to 55, the candidate will not receive any local offers from donors over the age of 55, regardless of whether the kidney is ECD or not.

In the new system: if a candidate is listed as willing to accept a local kidney with a maximum KDPI of 50%, but the maximum age (local) is set to 45, the candidate will be screened off of all local match runs where donor is over the age of 45, regardless of whether the KDPI is 50% or less.

Selecting any one independent criteria could result in eliminating all donor offers in that category regardless of KDPI acceptance criteria that has been set.
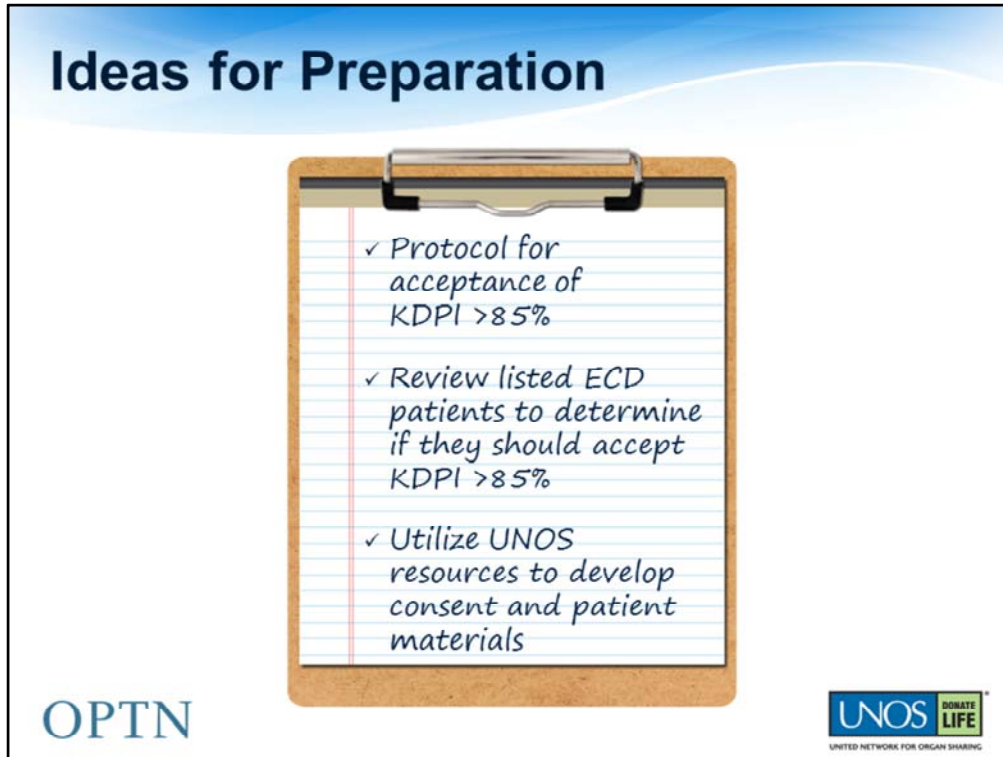
At Massachusetts General, we are developing a protocol for acceptance of kidneys with KDPI >85%. In doing so, we will be mindful that other donor acceptance criteria such as BMI, age, and DCD are taken into account so that the criteria set do not conflict with one another.

Programs are only required to consent candidates listed after implementation of the new allocation system. Any recipient consented for ECD in the system will default to accepting a kidney with >85% KDPI. With this in mind, we are reviewing our ECD-consented patient list to determine whether or not a KDPI of >85% is appropriate for those patients when the system goes live. If not, then we will change the KDPI acceptance criteria for those patients. Likewise if acceptance of KDPI >85% is appropriate for those not already consented for ECD, we will consent the patient and change the acceptance criteria in the system. We will also document any newly listed ECD patients from now until go-live for which we will not accept >85% KDPI. That way we know to change this in the system after the new system goes into effect.

Our team will also be reviewing the patient resources that are planned to be available later this summer to help us develop education materials about KDPI and to develop consents for patients to accept kidneys with >85% KDPI. A patient brochure and e-learning module for patients is planned to be released by UNOS and will be critical to our patient education process. We are considering including the e-learning module in our patient education sessions.

Calculated PRA

- Based on the unacceptable antigens listed for a candidate

- Points will be assigned to a sensitized patient on a CPRA sliding scale beginning at 20%

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CPRA has also been available in UNet^{SM} for some time now. But let's review how it will be used in the new system.

CPRA is based on the unacceptable antigens listed for a candidate and is used to assess the number of incompatible donors for the candidate based on a recent cohort of the deceased donor pool.

In the current allocation system, candidates receive 4 additional points for a CPRA score that is at or above 80%. You may recall that moderately sensitized candidates currently receive no additional points. In the new system, points will be assigned to a sensitized patient based on a CPRA sliding scale, beginning at a CPRA score of 20%.

This change is intended to increase access for sensitized candidates and increase efficiency in the overall allocation system by reducing the unexpected positive crossmatches which may be a result of not entering all of the unacceptable antigens.

Updating Unacceptable Antigens

- Review kidney waiting list

- Enter all unacceptable antigens according to your center's protocol

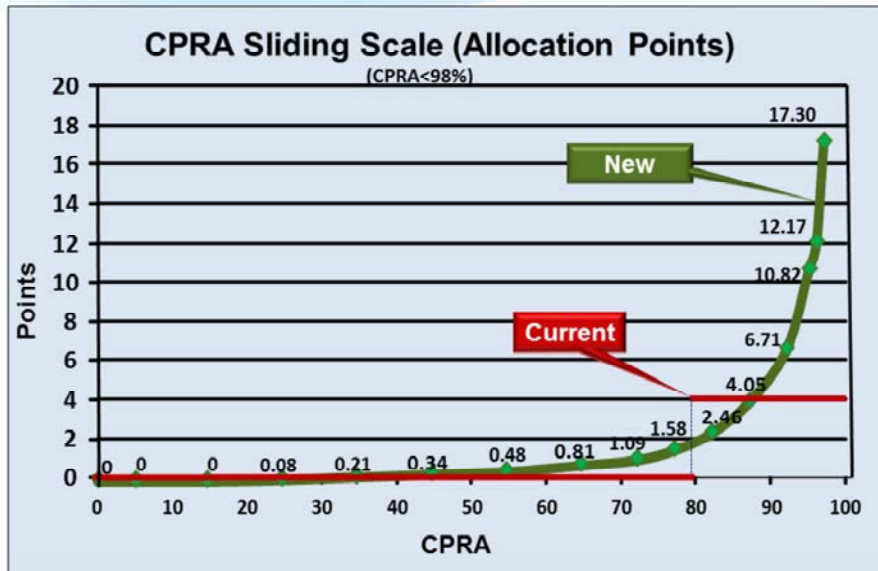- Candidates will receive allocation priority based on unacceptable antigens entered

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Kidney transplant programs should review their kidney waiting list to ensure that all unacceptable antigens are reported for all of their candidates while abiding by their center's protocol for assigning unacceptable antigens.

Prior to implementation of the new system, all unacceptable antigens that may not have previously been entered, must now be entered in order for candidates to receive priority points based on the CPRA sliding scale. Doing this will provide additional access to transplant for candidates even before they reach a CPRA of 80%.

In the new system, candidates will receive additional allocation points based on their sensitization level.

Candidates with a CPRA from 80 to 84 will receive about 2.5 points, while candidates with CPRA of 85 to 89 will receive just over 4 points.

Candidates with CPRA's in the high 90's will receive substantially more points: for example, candidates with CPRA scores of 99% and 100% will receive 50 and 202 points, respectively.

Since no amount of points was found to be sufficient for these extremely hard to match patients, the new system expands their available pool of donors.

CPRA Greater Than 98%

Regional Sharing	National Sharing
CPRA 99%	CPRA 100%

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In the new system, candidates with a CPRA greater than 98% will receive greater sharing priority:

- Regional sharing for CPRA 99%; and
- National sharing for CPRA 100%.

In order to receive this priority the candidate's physician or surgeon and the Histocompatibility (HLA) laboratory director will need to review and approve the unacceptable antigens that will be entered into UNet^{SM} for the candidate.

Sequence A KDPI <=20%	Sequence B KDPI >20% but <35%	Sequence C KDPI >=35% but <=85%	Sequence D KDPI>85%
Highly Sensitized	Highly Sensitized	Highly Sensitized	Highly Sensitized
0-ABDRmm (top 20% EPTS) Prior living donor Local pediatrics Local top 20% EPTS 0-ABDRmm (all) Local (all) Regional pediatrics Regional (top 20%) Regional (all) National pediatrics National (top 20%) National (all)	0-ABDRmm Prior living donor Local pediatrics Local adults Regional pediatrics Regional adults National pediatrics National adults	0-ABDRmm Prior living donor Local Regional National	0-ABDRmm Local + Regional National

Highly sensitized before 0-ABDR

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These very highly sensitized candidates will appear on the match before candidates with zero antigen mismatches.

Local, regional and national offers will go to candidates with CPRA=100%;
then regional offers will go to candidates with CPRA=99%;
then local candidates with CPRA=98%.

CPRA Approval

- Approver signatures indicating approval must be documented in the medical record

- Approver names must be entered into UNet^{SM}

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This summer UNet^{SM} will provide an approver form and a message that will display when a candidate's CPRA score is greater than 98%. The system will also provide a report with a list of candidates that are missing one or both approver names. So to reiterate, two things are required:

1. Signatures of the approvers must be documented in the medical record along with the unacceptable antigens that are approved; and
2. Approver names must be entered into UNet^{SM}.

As long as the approvers have reviewed and provided signatures indicating their approval in the candidate's medical record, the transplant program can designate other individuals to enter the approver names into UNet^{SM}. After entering the required approvals in UNet^{SM}, you will also have the option to print the form so that the documentation can be maintained in the candidate's record.
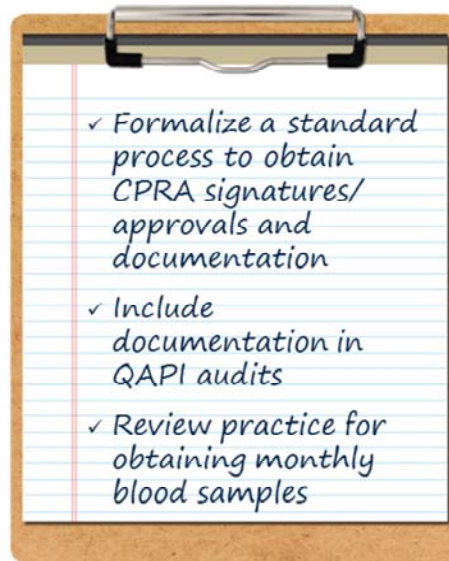
At MGH, we are formalizing a standard process in which we obtain two approvals with signatures for candidates that have a CPRA greater than 98%. We will likely be folding this process into our weekly selection committee meetings and review those patients with CPRA greater than 98%. The HLA Lab Director and Program Director will sign-off on the results and it will be included in the documentation in which we discuss the patient's listing candidacy.

This will provide documentation to support the transplant coordinator adding the approver names in UNet^{SM} once these fields are available. We will also add the documentation requirement to our regular Quality Assessment Performance Improvement (QAPI) audits that we perform for other regulatory requirements.

We are also reviewing our current practice of sending blood kits to listed candidates to ensure we appropriately capture those who have a CPRA greater than 98%.
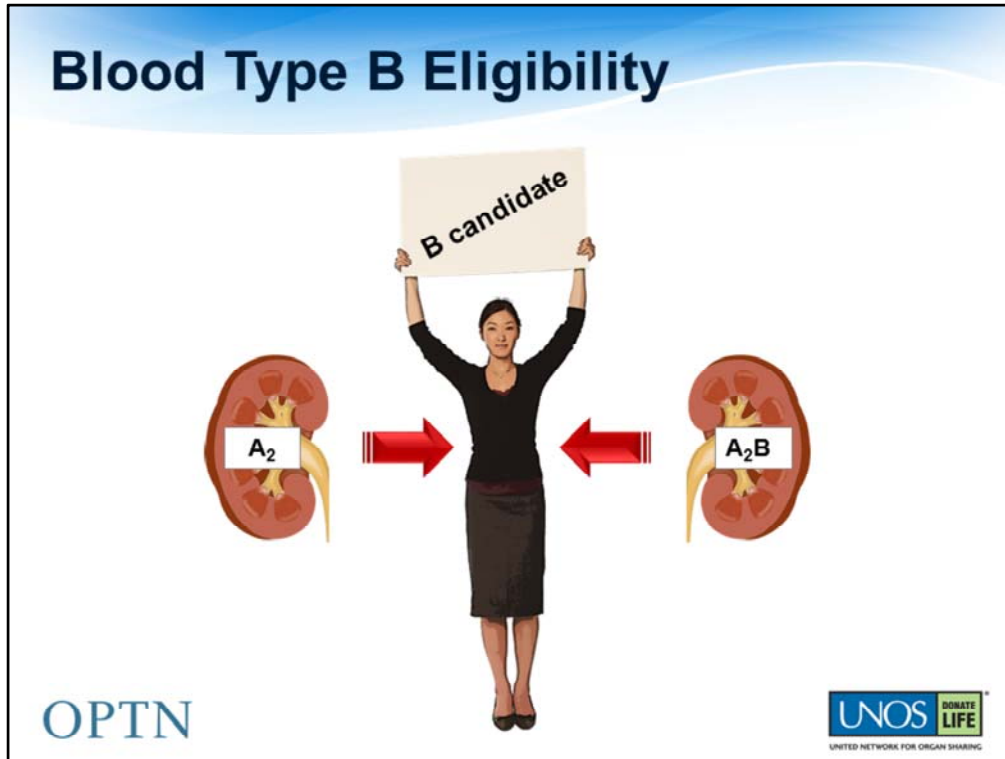
We previously discussed that the new system will provide for greater access to deceased donor kidneys for blood type B candidates who can safely accept a kidney from an A_2 or A_2B blood type donor.

Blood Type B Eligibility

- Set program criteria

- Develop written policy for maximum acceptable titer levels

- Obtain written informed consent

- Report candidate eligibility every 90 days

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To accomplish this, transplant programs will be responsible for setting their own clinical and laboratory criteria to allow their blood type B candidates to receive kidneys from donors with blood type A_2 or A_2B. They will need to develop a written policy that sets a maximum titer level for such candidates to be eligible to accept kidneys from these donors.

Programs will also need to obtain written informed consent from each blood type B candidate regarding their willingness to accept a blood type A_2 or A_2B kidney.

Although programs will not be required to report titer levels in UNet[SM], they will have to indicate whether the candidate is eligible by entering "yes" or no" in the system. They will be required to confirm the candidate's eligibility in the system every 90 days to continue these offers. UNet[SM] will alert programs when a candidate's eligibility is about to expire.
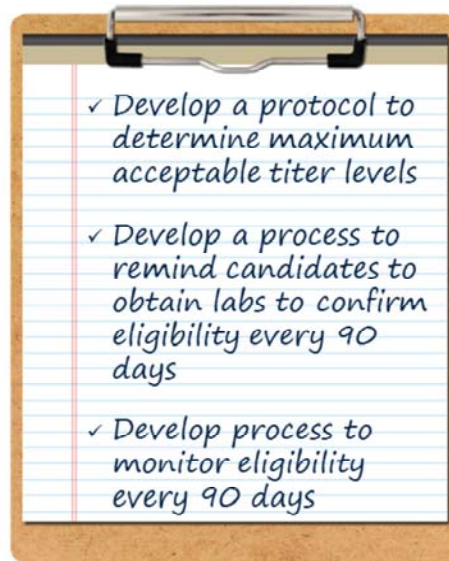
At MGH we are currently developing a protocol to determine the maximum titer levels that are acceptable for our blood type B candidates to accept A_2 or A_2B donors, as well as how we will document the A_2 and A_2B eligibility for these candidates.

Our team has developed a process similar to that for liver candidate MELD score updates so that eligibility is updated appropriately in the system every 90 days once the new system goes live. This will include developing a system of reminder phone calls for patients to obtain labs.

Monitoring of confirmed eligibility every 90 days will be included in our selection committee process or regular QAPI audits.

Pediatric Allocation and KDPI

- Pediatric candidates will receive priority for donors with a KDPI <35%

- Pediatric candidates will receive EPTS score upon turning 18

- Local, regional and national priority remain for pediatric candidates who turn 18

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In the new system, pediatric candidates maintain their current level of access to kidneys, but now they will receive priority for donors with a KDPI less than 35% (instead of from donors less than 35 years old). This priority will be maintained even after the candidate turns 18.

Remember: pediatric candidates will not be given an EPTS score until they turn 18. However, programs will still be required to enter the four critical EPTS data fields for pediatric candidates. Though the candidate will still maintain local, regional, and national priority for offers from donors with a KDPI <35% after turning 18, their EPTS score will be used for prioritizing zero-antigen mismatch offers.

Ideas for Preparation

- ✓ Pediatric team will develop criteria for acceptance of KDPI >85% for pediatrics

- ✓ Develop a consent for parents
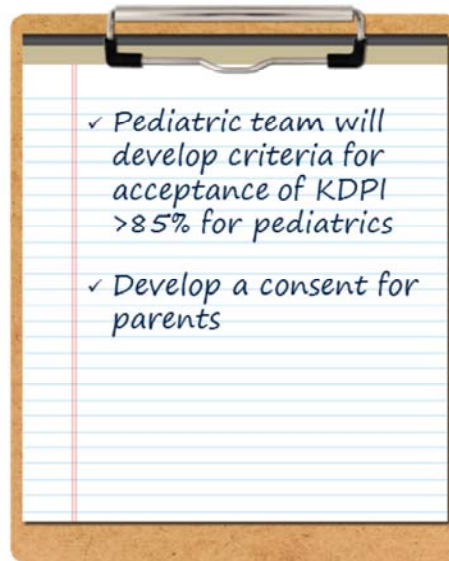
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In preparation for this change with pediatric allocation, MGH is already working with our pediatric team to develop criteria for candidates who may be appropriate to accept KDPI >85% kidneys as well as a consent for parents.
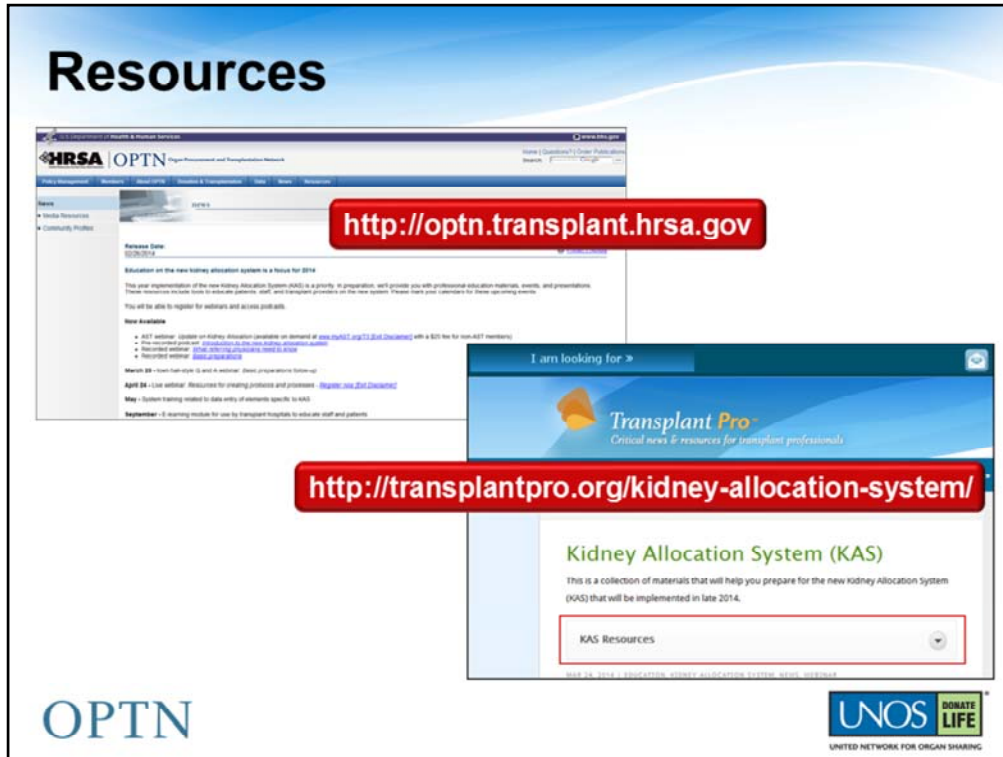
To prepare OPOs, transplant programs, and HLA laboratories for the upcoming changes to the kidney allocation system, a podcast, recorded webinars and a toolkit for professionals has been provided. We hope that you have taken advantage of these resources and shared them with your staff and colleagues. You can find the resources posted on the OPTN website or on Transplant Pro via the links on the screen.

If you have not had the opportunity to review these resources please be sure you make time to do so. Today's webinar is also being recorded and will be added to both websites for reference at your convenience.

Toolkit for Professionals

- FAQs
- Checklist of member responsibilities
- Allocation calculators (KDPI, CPRA, EPTS)
- Clinicians guide to KDPI
- Guidance for early referral considerations

http://optn.transplant.hrsa.gov/resources/professionalResources.asp

http://transplantpro.org/kidney-allocation-system/

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The toolkit of resources for professionals that I mentioned includes:

- A document with frequently asked questions about the new kidney allocation system. This document will be updated along the way to include additional questions that are coming from the community with answers to those questions.
- Also included is a checklist of member responsibilities that can help programs begin to prepare, even now, for implementation of the new system;
- Allocation calculators for KDPI, CPRA, and EPTS with guidance on how to use each are available; along with
- A clinicians guide to KDPI; and
- Guidance for early referral considerations for kidney patients.

This toolkit will continue to grow over the next few months to include patient resources such as:
- A patient brochure explaining the changes in the kidney allocation system;
- Sample language for discussing KDPI with your patients; and
- An e-learning module focused on what patients need to know about the new system.

As these and other resources become available they will be added to the toolkit. Check the OPTN or Transplant Pro sites frequently for updates.

Member Responsibilities

Communicate importance of early referral	Establish protocols for A_2 and A_2B donors to B candidates
Report/update data to calculate EPTS and waiting time	Review candidates to identify prior living organ donors
Establish KDPI acceptance criteria and update consents for KDPI>85%	Review waiting list for unacceptable antigens
Review "other" donor screening criteria	Educate candidates and potential candidates on changes

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Be prepared for a successful transition to the new kidney allocation system:

- Communicate the importance of early patient referral to your nephrologists and referring physicians and share with them the guidance that has been made available along with the recorded presentation on early referral.
- Report and/or update critical patient data elements that will be used to calculate EPTS and waiting time priority once these fields become available in UNet[SM].
- Establish KDPI acceptance criteria and update patient consent forms for accepting a donor kidney with a KDPI greater than 85%.
- Be sure to review "other" donor acceptance criteria to ensure that they do not conflict with KDPI criteria set for your candidates.
- Establish protocols for blood type B candidates who may be eligible to accept a kidney from an A_2 or A_2B donor.
- Identify those candidates that are listed who have previously donated any solid organ, they will receive priority points when the system goes live.
- Review your waiting list to determine that all unacceptable antigens have been entered while abiding by your center's protocol for assigning unacceptable antigens. If unacceptable antigens have not been entered, be sure to enter them so that your candidates receive maximum priority in the new system.
- Also educate your patients about the upcoming changes to the system. Resources for patient education will be available from UNOS this summer.
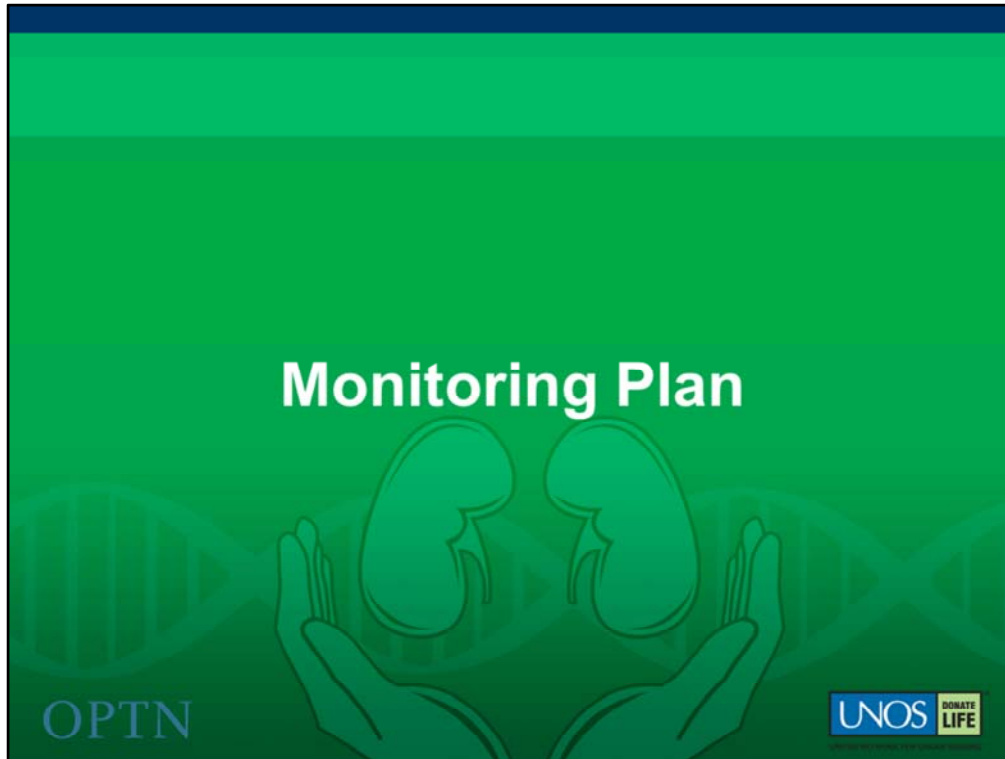
Monitoring Plan

Now let's discuss how UNOS will monitor compliance with the new kidney allocation policies.

Following the implementation of the new kidney allocation policies, transplant hospitals will notice that many of the monitoring activities surrounding policy compliance will remain focused on accurate data entry in UNet^{SM}.

Allocation Analysis

- All deceased donor kidney match runs are reviewed for compliance with policy

- Instances of non-compliance will be reviewed for policy violations

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

Kidney Program Surveys

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Waiting Time

Review a sample of records to verify:

- Dialysis start date
- GFR
- CrCl

- Discrepancies affecting patient waiting time will be considered a clinic error in the kidney survey scorecard

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At the time of your transplant program audit, site surveyors will continue to review a sample of patient medical records to verify accuracy of a candidate's waiting time. This includes the following qualifying criteria: the dialysis start date, GFR, or creatinine clearance as noted in the UNet^{SM} system. Documentation of qualifying criteria must be found in the medical record.

As a result of the implementation of the new kidney policies, you will notice that identified dialysis start date discrepancies will be considered clinical errors for purposes of the compliance review process, and will be reflected as such on the member's compliance summary. Historically, these identified discrepancies would have been considered an administrative error under current policy 8.3B.

For those members choosing to use a dialysis start date different than the CMS dialysis date provided on the EPTS data collection screen in UNet^{SM}, UNOS site surveyors will continue to accept the CMS 2728 form, history and physical notes, and progress notes as documentation for dialysis start dates.

Please understand that if you choose to use the CMS dialysis date that is provided on EPTS data collection screen in UNet^{SM}, you will not be required to provide medical record documentation of this date at the time of your routine audit. However, if you choose to use a date different than the CMS dialysis date or a CMS dialysis date is not provided on the EPTS data collection screen you will be required to provide medical record documentation of the dialysis start date.

In addition, if a candidate was on chronic, maintenance dialysis for a period of time and then regains some kidney function and is no longer on dialysis, the original dialysis start date can still be entered in UNet^{SM}.

EPTS < 20%

Review a sample of records to verify:

- Current diabetes status
- Number of prior organ transplants

- Medical record documentation should reflect the number of prior organ transplants

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For candidates with an EPTS <20%, surveyors will also verify diabetes status and number of prior organ transplants at the time of the EPTS calculation.

Similar to the documentation requirements for dialysis start date, if the number of prior organ transplants in UNet[SM] is different than the actual number of prior organ transplants for the candidate, you will be required to provide medical record documentation reflecting the number of prior transplants entered.

At the time of your transplant program audit, site surveyors will review a sample of medical records for patients with CPRAs >98% in order to verify that there is documentation of an agreement regarding unacceptable antigens between the candidate's physician/surgeon and HLA laboratory director.

Of note, the manual entry of the names of the approvers into the UNet^{SM} system can be delegated. If this role has been delegated to you, please be reminded that UNet^{SM} is not considered part of the candidate's medical record and the field where you will enter the names of the dual approvers does not qualify as an electronic signature of approval. Documentation of the agreement, as evidenced by signatures of the candidate's physician/surgeon and HLA laboratory director at the time of the review and approval, must be maintained by the transplant center in the patient's medical record.

Please understand that for candidates in the new system with a CPRA greater than 98%, a sign off will NOT be required each time the unacceptable antigens fluctuate above and below the 98% threshold. The approval will only be required once and will be maintained for the duration of the candidate's listing.

Site surveyors will also review a sample of medical records of blood type B candidates who are eligible to receive A_2 and A_2B offers. The review will include a verification of the candidate's titer results in order to ensure the candidate's eligibility is confirmed by the transplant center every 90 days.

In addition, site surveyors will verify written, informed consent was obtained from each blood type B candidate regarding their willingness to accept an A2 and A2B blood type kidney.

KDPI > 85% Consent

Review a sample of records to verify:

- Written, informed consent prior to receipt of KPDI > 85% kidney

- Consent is required for candidates after implementation, if willing to accept KDPI > 85%

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In addition, the audit process will include a review of a sample of records for kidney candidates willing to receive kidneys with a KDPI score greater than 85%. We review these candidate records to verify that written, informed consent was obtained prior to offer receipt for kidneys in this category.

As previously explained, transplant programs are required to obtain informed consent on candidates listed after implementation of the new allocation system when they are willing to receive offers for kidneys with a KDPI score greater than 85%. Candidates on the list prior to implementation with documented consent for an ECD kidney will not need to be consented.

Please periodically review the Evaluation Plan on the OPTN website for additional guidance on compliance with the new kidney allocation policies.

If you wish to receive continuing education credit for your attendance on this webinar today, please use the web address on your screen to take the assessment.

Note that you cannot take the assessment as a group; you are required to take the assessment individually to qualify for the credit.

Once you take the assessment, it will take about a week for you to receive your certificate.

This webinar was recorded and will be available soon for those that could not attend. They may also apply for credit after viewing the recording. The assessment will be open until October 23, 2014.

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The UNOS Regional Administrators are your first contact for direct questions about the new kidney allocation policies. Please contact the Administrator for your region with questions.

For questions about educational or training events, contact the UNOS Instructional Innovations department at education@unos.org.