OPTN/UNOS Kidney Transplantation Committee
Report to the Board of Directors
June 25-26, 2012
Richmond, Virginia

Summary

I. Action Items for Board Consideration

- Request from Fingerlakes Donor Recovery Network to Remove Alternative System from Programming Queue, (Item 1, Page 2)
- Revisions to Policy 3.2.1.8 (Waiting Time Modification) (Post Public Comment), (Item 2, Page 2)

II. Other Significant Items

- Progress to Develop a Revised National Kidney Allocation System, (Item 3, Page 6)
- Report of the Variance Review Subcommittee, (Item 4, Page 15)
- Response to Region 4 Concerns about Dialysis Waiting Time, (Item 5, Page 20)
- Proposed Revisions to the Prior Living Donor Priority Policy, (Item 6, Page 21)
- Kidney Paired Donation Policy Language Proposal, (Item 7, Page 22)
- Kidney Paired Donation Bridge Donor Proposal, (Item 8, Page 22)
- Proposed revisions to Waiting Time Point Accrual in the OPTN Kidney Paired Donation Pilot Program, (Item 9, Page 22)
- Revisions to Renal Minimum Acceptance Criteria, (Item 10, Page 24)

OPTN/UNOS Kidney Transplantation Committee
Report to the Board of Directors
June 25-26, 2012
Richmond, Virginia

John J. Friedewald, MD, Chair
Richard N. Formica, Jr., Vice Chair

This report details the discussions had and decisions made by the Kidney Transplantation Committee during the teleconference meeting on December 12, 2011, in person meeting on February 6, 2012, conference call on May 23, 2012 and electronic discussions since the November 2011 Board of Directors meeting.

1. **Request from Fingerlakes Donor Recovery Network to Remove Alternative System from Programming Queue**

In March, the Committee reviewed a request from the Fingerlakes Donor Recovery Network (NYFL) (**Exhibit A**). NYFL currently has a variance for intended candidate priority in the programming queue, which it has requested to be removed. NYFL no longer wishes to have this variance programmed. The Committee agreed with NYFL's request and unanimously voted to send the following resolution for consideration by the Board of Directors (22 in favor, 0 opposed, 0 abstentions):

> ****RESOLVED that the intended candidate variance for NYFL currently in the programming queue be removed as soon as is feasible as requested by NYFL.**

2. **Revisions to the Waiting Time Modification Policy (Post Public Comment)**

Ciara Samana, liaison to the Committee, shared feedback received from other OPTN Committees, the OPTN Regions and the general public on a proposal the Committee circulated for public comment in September 2011 (**Exhibit B**). Briefly, the proposal was to clarify the requirements for submitting waiting time modification requests. Current OPTN policies regarding submission of waiting time modification requests are not clear, leading to wasted time for the transplant centers that submit requests, for OPTN contractor staff who process requests, and for the Committees that review requests. Required documentation is often missing and results in delays for transplant candidates to receive the waiting time that they may be entitled to receive under OPTN policy.

The proposal was supported by all regions as well as the Pancreas Transplantation, Patient Affairs, and Transplant Coordinators Committees. The Thoracic Organ Transplantation and Transplant Administrators Committees also supported the proposal with comments. Public support was strong with 38 public responses, 87% in favor and 13% with no opinion.

Ms. Samana shared some additional modifications that were recommended through public comment. The first was to clarify that requests for waiting time modification must meet the requirements set forth in the organ-specific allocation policies. Additionally, the proposal inadvertently left out the current requirement for all kidney transplant programs in the allocation unit to sign off on the request. With these two modifications, the Committee agreed to send the following resolution for consideration by the Board of Directors with a vote of 18 in favor, 0 opposed and 0 abstaining:

> ****RESOLVED that the modifications to Policy 3.2.1.8 (Waiting Time Modification) set forth below be implemented following notice to OPTN membership.**

3.2.1.8 Waiting Time Modification

3.2.1.8.1 Permissible Modifications

Applications for waiting time modifications that meet *any* of the following qualifications must follow the procedures for expedited modifications of waiting time in Policy 3.2.1.8.3 below.

- An error occurred in modifying, removing, or renewing the candidate's waiting list record and the Transplant Program requests a modified waiting time to include time accrued under the previous registration, in addition to any time lost by the error.
- The candidate was removed from the waiting list for medical reasons, other than receiving a transplant, was subsequently relisted for the same organ with the same diagnosis, and the Transplant Program requests a modified waiting time to only include the time accrued under the previous registration without the time interval when the candidate was removed from the waiting list.
- The candidate is waiting for a heart, liver, or lung, needs a second organ, and the Transplant Program requests a modified waiting time for the second organ that includes the waiting time accrued for the first organ.

Applications to modify a candidate's registration date and all other applications for waiting time modifications must follow the procedures for modifications of waiting time in Policy 3.2.1.8.4 below. Additionally, applications must meet any additional requirements stipulated in the organ-specific allocation policies. If an application does not comply with the requirements of Policy 3.2.1.8, then the OPTN Contractor will neither implement the requested waiting time modifications nor forward the application for review.

3.2.1.8.2 Application

To apply for a waiting time modification, a candidate's Transplant Program must submit an application to the OPTN Contractor with *all* of the following information:

1. The requested listing date and documentation showing an intent to register the candidate at the requested listing date.
2. That the candidate met applicable waiting time qualifying criteria in the organ specific policies (Policy 3.0 *et seq.*).
3. A corrective action plan, if the application is due to an error.
4. The name and signature of the candidate's physician or surgeon.
5. Signatures indicating agreement from all applicable transplant programs in the OPO. If a signature cannot be obtained from a transplant program, the submitting program must explain the efforts it made to obtain a signature and include any stated reasons for disagreement with the request.

3.2.1.8.3 Expedited Modifications of Waiting Time

Applications eligible for expedited modifications of waiting time must use the following process:

1. Upon receipt of a complete application, the OPTN Contractor will implement the waiting time modification.
2. The OPTN Contractor will report the modification, without person-identified data, to the relevant

organ specific Committee.

3. The Committee will report the modification, without person-identified data, to the Board of Directors.

3.2.1.8.4 Modifications of Waiting Time

All other applications for waiting time modifications must use the following process:

1. Upon receipt of a complete application and approval or explanation of disagreements from all applicable Transplant Programs within the local unit where the candidate is registered, the OPTN Contractor will forward the application, without person-identified data, as follows:

If the candidate requests a modification on the following organ waiting list:	Then the application will be reviewed by the:
Kidney	Kidney Waiting Time Modifications Subcommittee
Liver	A subcommittee of the Liver and Intestinal Organ Transplantation Committee, appointed by the Chair of the Liver and Intestinal Organ Transplantation Committee
Thoracic	A subcommittee of the Thoracic Transplantation Committee, appointed by the Chair of the Thoracic Transplantation Committee
Pancreas	Pancreas Waiting Time Modifications Subcommittee
Intestine	A subcommittee of the Liver and Intestinal Organ Transplantation Committee, appointed by the Chair of the Liver and Intestinal Organ Transplantation Committee

Review of Waiting List Modification Applications

2. The reviewer will determine if it is appropriate to modify the candidate's waiting time as requested in the application and notify the OPTN Contractor of the decision.
3. Upon notice, the OPTN Contractor will implement the waiting time modification.
4. The reviewer will report the modification, without person-identified data, to the relevant organ specific Committee.
5. The Committee will report the modification, without person-identified data, to the Board of

Directors.

3.2.1.8 Waiting Time Modification. Transplant candidates on the Waiting List may have waiting time accrued under a previous Waiting List registration reinstated under the following circumstances:

i. The candidate was incorrectly removed from the Waiting List, as a result of errors and/or miscommunication between clinical/clerical personnel. The reinstated waiting time shall include time accrued under the previous registration, in addition to the time interval during which the candidate was removed from the Waiting List.

ii. The candidate was removed from the Waiting List for medical reasons other than having received a transplant and subsequently was relisted for the same organ with the same diagnosis. The reinstated waiting time only shall include time accrued under the previous registration and not the time interval during which the candidate was removed from the Waiting List.

Upon receipt by the Organ Center of a completed Waiting Time Modification Form (with all required information) and verification of the information through review of the candidate's history, Organ Center staff may reinstate the candidate's waiting time. All other requests for waiting time reinstatement that are not specified under Policy 3.2.3.2 (Waiting Time Reinstatement for Kidney Recipients), or other policies which describe permissible waiting time adjustments, shall be first approved by unanimous agreement among the hospitals (with transplant programs for the applicable organ) within the local area in which the candidate is listed, and then submitted to the appropriate organ-specific committees and Board of Directors for review with appropriate supporting documentation. Notwithstanding the above, however, upon demonstration to the appropriate organ-specific committee that unanimous agreement among the relevant parties cannot be obtained despite efforts to do so, such a request may be submitted with appropriate supporting documentation, including without limitation, reasons provided by the dissenting party(ies) for any disagreement, for consideration despite the lack of unanimous approval. Modification requests for isolated kidney and combined kidney/pancreas waiting time shall indicate and substantiate with supporting documentation that the candidate met waiting time criteria as defined in Policy 3.5.11.1 (Time of Waiting), or Policy 3.5.12.1 (Time of Waiting), or Policy 3.8.4.3 (Waiting time) as of the listing date requested. Under the circumstances described in this paragraph, waiting time modifications will be made, in the case of requests for modifying kidney or pancreas waiting time, after consideration and approval by the Kidney Transplantation Committee (for kidney and kidney/pancrease candidates) or& Pancreas Transplantation Committee (for kidney/pancreas and pancreas candidates),, or, in the case of pediatric (*i.e.*, less than 18 years old) kidney candidates, with approval from the Chair of the Kidney & Pancreas Transplantation Committee to proceed to a subcommittee of the full Committee followed by consideration and unanimous approval by this subcommittee. Pediatric candidate cases addressed by a subcommittee of the Kidney & Pancreas Transplantation Committee will subsequently be referred to the full Committee for consideration of final action as determined appropriate by the Committee and in the case of requests for modifying waiting time for organs other than kidney, kidney-pancreas, and pancreas (except as provided in Policy 3.2.1.8.1 (Waiting Time Modification for Urgent Status Candidates)) only upon approval by the Board of Directors, or by the Executive Committee subject to ratification by the

~~Board of Directors. Requests for modifying kidney or pancreas waiting time, along with decisions of the Kidney Transplantation Committee & Pancreas Transplantation Committee or subcommittee in the case of pediatric candidates and Pancreas Transplantation Committee, shall be reported to the Board of Directors retrospectively.~~

~~**3.2.1.8.1 Waiting Time Modification for Urgent Status Candidates**. Adjustments will be permitted to the waiting time of Status 1 liver transplant candidates, Status 1A heart transplant candidates, and Priority 1 pediatric lung candidates registered on the Waiting List if an error or miscommunication occurred in listing, modification, or accidental removal of the candidate, or in renewing the candidate's status. Supporting documentation must be submitted, including a written request from the physician/surgeon in charge of the candidate's care explaining the circumstance along with the appropriate status justification form and Wait Time Modification Form. Upon receipt of completed documentation, the requested modification will be made. Each case will be reported retrospectively to the appropriate regional review board for consideration.~~

~~**3.2.10**~~**7** ~~**Waiting Time Adjustment for Candidates Needing a Life-Saving Organ Transplant When the Need for a Second Organ Transplant Arises.** Waiting time accrued by a candidate for a transplant of a life-saving organ while waiting on the Waiting List may also be accrued for a second organ, when it is determined that the candidate requires a multiple-organ transplant. For purposes of this policy, a life-saving organ shall be defined as the heart, lung or liver. Kidney, pancreas or intestine may qualify as life-saving organs if routine alternative therapies are not possible and demonstrable and after all transplant centers and programs within those centers, the other transplant programs within the OPO and the OPO itself agree to the waiting time adjustment.~~

3. Progress to Develop a Revised National Kidney Allocation System

In December 2011, the Committee met by conference call to review progress on the data request submitted following its August 2011 meeting (**Exhibit C**). The Committee Chair, asked the Committee to consider both the trends and directionality of the simulation modeling results so that it could discuss how to address any unintended consequences.

Sally Gustafson, MS, of the Scientific Registry of Transplant Recipients (SRTR) presented the findings from the data analysis. This work built on the work of the prior SRTR Contractor, which had generated over 40 simulation runs using the kidney pancreas simulated allocation model (KPSAM). Specifically, this data analysis built upon the previously completed Run #37, which included the longevity-matching of kidneys and recipients (top 20% of kidneys to top 20% of candidates). The SRTR used Run 37 as the starting point for its work and added allocation elements such as the CPRA sliding scale, national priority for very highly sensitized candidates (those with CPRA scores greater than 97%), and regional sharing of kidneys with a higher risk of graft failure (those with KDPI scores greater than 85%).

The SRTR structured its work into three distinct simulation runs:

- **N1**. Baseline (old Run 35): current ‘as is’ system

- **N2**. Baseline + extras (e.g., dialysis waiting time, A2/A2B kidneys for B candidates) (old Run 36)
- **N3**. New allocation system including longevity matching

A complete set of rules for the three simulation runs is provided below.

Concepts	N1	N2	N3
SCD allocation (defined as KDPI ≤ .85 for N3)	X	X	X
DCD allocation	X	X	
ECD allocation (defined as KDPI > .85 for N3)	X	X	X
Payback system	X		
Waiting time since listing	X		
Back-dating dialysis time		X	X
Waiting time points based on fractional years		X	X
A2/A2B donor to B candidates priority(local, regional, and national)		X	X
Highest scoring high CPRA classification	X		
Pediatrics cannot receive non-0 mm ECD offers		X	X
Longevity Matching (top 20% survivors get first chance at top 20% kidneys)			X
"Share 0.35" pediatric priority (Donor < 35 yrs for N1, N2)	X	X	X
CPRA sliding scale			X
National priority for CPRA ≥ 98% candidates			X
Regional sharing for marginal kidneys (KDPI>.85)			X
KP/PA System: current	X		
KP/PA system: future		X	X

The Committee focused most of its discussion on the results from N3. The allocation sequences for this simulation run, based on KDPI scores are shown below.

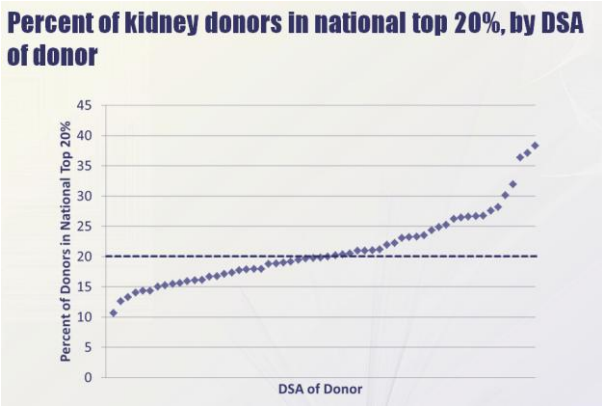
KDPI ≤0.20	KDPI 0.21-0.34	KDPI 0.35-0.85	KDPI >0.85
Local CPRA 98+ Regional CPRA 98+ National CPRA 98+ 0mm top 20 Local pediatrics Local top 20 0mm bottom 80 Local bottom 80 Regional pediatrics Regional top 20 Regional bottom 80 National pediatrics National top 20 National bottom 80	Local CPRA 98+ Regional CPRA 98+ National CPRA 98+ 0mm Local pediatrics Local adults Regional pediatrics Regional adults National pediatrics National adults	Local CPRA 98+ Regional CPRA 98+ National CPRA 98+ 0mm Local Regional National	Local CPRA 98+ Regional CPRA 98+ National CPRA 98+ 0mm Local and regional adults National adults

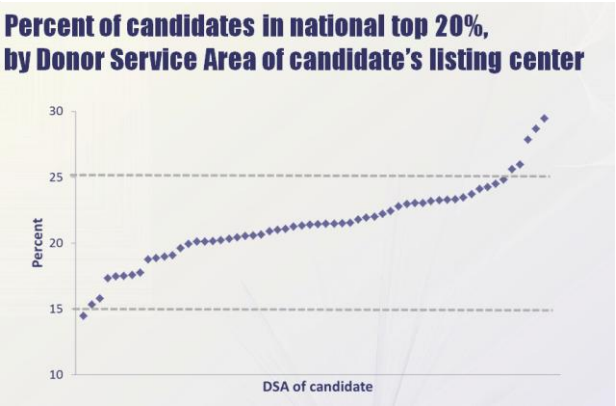
Additionally, N3 included the following allocation elements:

- back-dating for pre-registration time spent on dialysis,
- waiting time points based on fractional years,
- A_2/A_2B donor to B candidates priority at all geographic levels,
- longevity matching,
- kidneys from donors with KDPI less .35 are allocated first to pediatric candidates locally,
- CPRA sliding scale,
- national priority for CPRA>=98%, and
- regional sharing for marginal kidneys (those with KDPI scores >85%).

Some Committee members expressed concerns that regional sharing for kidneys from donors with KDPI scores >0.85 would diminish the incentives that OPOs currently have to procure these organs. Additionally, some members hypothesized that regional sharing for these kidneys would lead to increased organ wastage. For example, centers that are geographically distant from one another may accept a kidney and have it shipped to them only to determine at that point that it is not transplantable. Other members of the Committee argued that regional sharing for these kidneys would lead to increased utilization. OPOs would have more confidence that procured kidneys would be accepted, thereby leading to increased procurement and decreased cold ischemic time. Another member pointed out that this approach may also encourage the use of pulsatile profusion to better preserve procured kidneys.

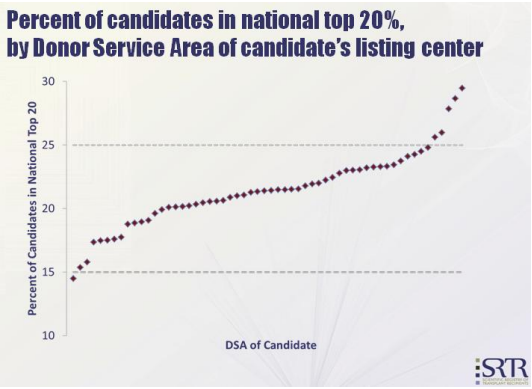
The Committee then examined the distribution of KDPI and Estimated Post Transplant Survival (EPTS) across donation service areas (DSAs). The majority of DSAs had between 15% and 25% of donors with a KDPI score of 20% or less. The percentage of candidates in each DSA with an EPTS score less than 20% ranged from 10% to 40%. The EPTS and KDPI scores were not analyzed to determine correlation.

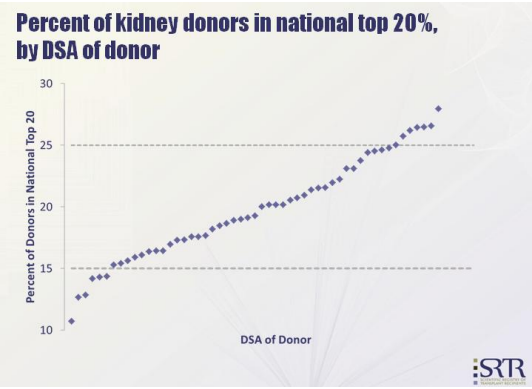




The Committee discussed the above distributions and whether each DSA should have an individualized threshold for determining the top 20%. Some Committee members pointed out the complexity of defining cutoffs differently in each DSA and region. Others expressed concern over having to explain to candidates why different DSAs have different cutoffs and the complexities associated with managing candidates who are multiply listed. The Committee decided to use a national standard for determining the top 20% for EPTS and KDPI. While DSAs will have slightly higher or lower percentages of candidates

and donors in the top 20% categories with this approach, the reduction in programming and system complexity was believed to warrant a national standard.





The Committee also discussed when to recalculate a candidate's EPTS score. Members did not see a need to dynamically recalculate the EPTS similarly to how the model for end stage liver disease (MELD) and lung allocation scores (LAS) are calculated. EPTS is based only on four factors, time on dialysis, candidate age, prior transplant, and diabetes status. A member pointed out that the EPTS score will likely only decline from the point of listing since time on dialysis and age are two factors that become increasingly negative over time. There are really no opportunities for an EPTS score to improve unless a candidate who has diabetes is later found to be rid of the condition. The Committee did believe that updating a candidate's score regularly to maintain top 20% status was important and given the simplicity of the four factors which do not require any clinical laboratory data, members agreed that quarterly would be an appropriate requirement for updating. To formally document these decisions, the Committee voted on the following resolutions.

> Resolved, that the 20% thresholds for donors (by KDPI) and candidates (by EPTS) be calculated and updated annually based on a national cohort. (21 in favor, 0 opposed, 1 abstention)
>
> Resolved that Estimated Post Transplant Survival scores for candidates in the top 20% be updated quarterly. (18 in favor, 4 opposed, 0 abstentions)

Prior to reviewing the results of the simulation models in December, Ms. Gustafson shared some caveats. The acceptance model was based on acceptance practice from 2007 to 2009 and was the same for all 3 runs however, a change in allocation rules would likely cause a change in acceptance behavior. Patient deaths and graft failures were counted at 1 year. Longer term counts (which were not done) would likely show greater differences between the runs. The results of the models were considered to be preliminary when presented in December. In the N2 and N3 results, the payback system affected whether organs from kidney-pancreas donors were offered to kidney-pancreas candidates before kidney and pancreas candidates. Consequently, relatively fewer kidney-pancreas transplants and relatively more kidney transplants were performed. Payback debts and credits did not affect the relative priority of kidney candidates during kidney allocation.

A member asked if the results for distribution were statistically significant. An analyst with the SRTR shared that standard deviations are not available for the results and asked that the Committee instead consider whether the results were clinically significant.

Another member asked for theories about the decline in zero antigen mismatched transplants from N1 to N3. A SRTR analyst shared that the decline (from almost 5% in N1 to just over 3% in N3) may have been due to the acceptance model. Other changes that may have affected the number of zero antigen mismatches included the decision to prioritize sensitized candidates with a CPRA greater than 98% and the decision to prioritize candidates with EPTS scores under 20% for kidneys with KDPI scores under 20%. The Committee asked that the SRTR further investigate possible causes for this decline.

The Committee focused on the dramatic increase in the number of kidneys shared (i.e., kidneys that are procured in one DSA and transplanted in another DSA). The percentage of kidneys shared almost tripled from N2 to N3. Possible causes of this increase included the decision to allocate ECDs first at a combined regional and local level and to share kidneys at the local, regional, and national levels. The Committee asked the SRTR to delineate the number of kidneys shared by reason (e.g., due to zero antigen mismatch, CPRA >98%, or KDPI >85%).

The Committee discussed its prior decision to model sharing for candidates with CPRA scores of at least 98%. Many on the Committee expressed concern that kidneys shared for this population, with current policies for the listing of unacceptable HLA antigens, would result in positive crossmatches. The Committee briefly discussed strategies for decreasing the number of kidneys ultimately turned down due to a positive crossmatch including requiring national PRA trays and requiring the listing of all antigens with a certain median fluorescence intensity (MFI) level. The Committee Chair asked that a subcommittee work on addressing these issues by the end of January 2012 so that solutions could be discussed at the Committee's February 6, 2012 meeting. Following the December 2011 meeting, the SRTR discovered an error in the simulation model which was leading to over-sharing for very highly sensitized candidates. Very highly sensitized candidates were not programmed into the model with corresponding unacceptable antigens. When the SRTR corrected this error, sharing declined to levels seen in the current system. Despite this finding, the Chair remarked that the subcommittee's work to recommend best practices for sharing of kidneys for very highly sensitized candidates is still necessary and important.

The Committee then focused on the additional information it would need to further policy development. The SRTR offered to examine the bolus effect of allocating preferentially to candidates with CPRA of 98% or greater including estimating the waiting times for recipients in these categories and other descriptive statistics. Staff from the UNOS Research Department offered to run descriptive statistics on the number of candidates listed annually with CPRA scores of 98% or greater to determine on-going potential volume. A member asked that the level of kidney sharing be examined to determine if the first year of the allocation system would be substantially different than subsequent years.

In May 2012, the Committee met by conference call to review the latest KPSAM results and determine whether additional information was needed before finalizing a proposal for public comment (**Exhibit D**). Sally Gustafson, biostatistician with the SRTR, then reviewed the findings from the analysis (**Exhibit E**). One member asked why there was variation between the number of transplants obtained with each simulated iteration. Nicholas Salkowski, biostatistician with the SRTR, explained that the simulation models do not perfectly replicate reality. The results of each run are actually averages of 10 iterations. In each iteration, the kidneys become available in a different order, thereby affecting which candidates receive offers at certain points in time.

One member expressed concern that some candidate groups experienced slight declines in the number of transplants received. The Committee was reminded that since additional kidneys are not being made available in the modeling, any change in allocation will result in improved access for some candidates and decreased access for other candidates. The Committee was also reminded that KPSAM does not take into account changes in acceptance behavior resulting from policy changes. The Committee believes that there are organs which are currently discarded which provide substantial survival advantage. Through the implementation of kidney donor profile index (KDPI), these organs would be better identified and utilized, thereby mitigating the observed drop in transplants for certain candidate groups.

The Committee then examined the 2% decline in 0-ABDR mismatch transplants. Ms. Gustafason explained that runs N2, N3, and N4 utilize the new allocation system for kidney-pancreas and pancreas alone transplants. Additionally, the national sharing for candidates with CPRA of greater than or equal to 98% may contribute to these declines as new allocation categories have been added ahead of the 0-ABDR mismatch categories. The Committee also noted that the change is relatively minor compared to previous analyses which showed a more substantial decline in 0-ABDR mismatch transplants.

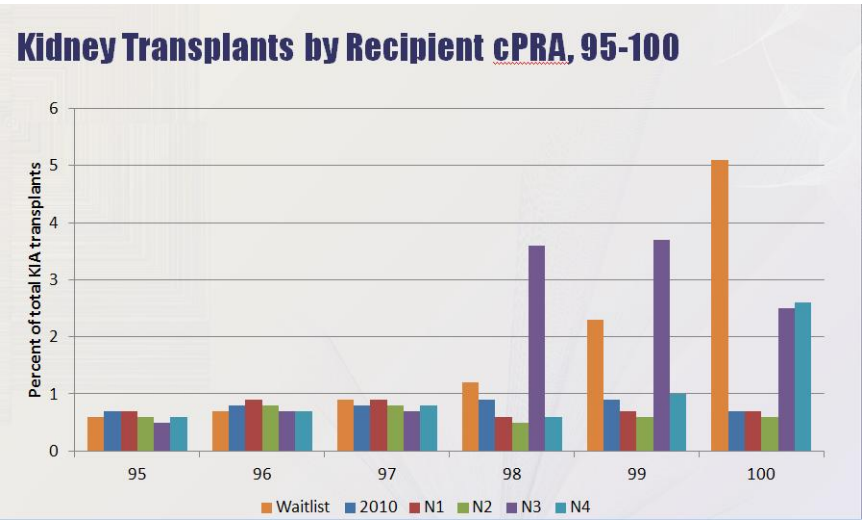
The Committee examined the amount of sharing (defined as kidneys being transplanted outside of the local procurement area) in each of the simulation runs. Run N4 resulted in less sharing than N3 by design. In N4, only candidates with CPRA=100% receive national priority for 0-ABDR mismatch offers whereas in N3, any candidate with a CPRA >=98% would receive national priority for these offers. The Committee believed that the improved access for very highly sensitized candidates was balanced by more moderate levels of sharing in N4. The degree of sharing in N3 was thought to be too high, especially since the Committee has not yet formulated policies to reduce chances of positive crossmatches resulting in transplants to back-up candidates or discarded kidneys. The Committee learned that the degree of sharing was equally distributed across all donation service areas (DSAs). This means that no one DSA would be a primary exporter of kidneys to other DSAs.

The Committee then reviewed the simulated effects of each run on sensitized candidates. Runs N3 and N4 both utilized the same sliding scale for awarding CPRA points. N3 and N4 differed in their categorical approaches to allocation for candidates with CPRA scores greater than or equal to 98%.

Run N3	Run N4
OPO KI, Candidates with CPRA≥ 98% Regional KI, Candidates with CPRA ≥ 98% National KI, Candidates with CPRA≥ 98%	OPO KI, Candidates with CPRA≥ 100% Regional KI, Candidates with CPRA≥ 100% National KI, Candidates with CPRA≥ 100% OPO KI, Candidates with CPRA≥ 99% Regional KI, Candidates with CPRA≥ 99% OPO KI, Candidates with CPRA≥ 98%

The Committee noted that the sliding scale appeared to be operating as intended. Transplants increased for the moderately sensitized candidates (defined as candidates with CPRA scores between 20% and 80%) and declined slightly right at 80%. These results align with previous analyses reviewed by the Committee which suggest that candidates with CPRA scores of 80% in the current system receive too much priority to overcome barriers in access.

The Committee then turned its attention to how the categorical priorities for highly sensitized candidates differed between N3 and N4. The Committee noted that the rules simulated in Run N3 provided too much priority for candidates with CPRA scores of 98% and 99% as their transplant rate greatly exceeded their waitlist rate. The Committee noted that Run N4 corrected for this imbalance somewhat but may have over corrected. The candidates with CPRA scores of 100% appeared to fare slightly better under Run N4 but neither run provided a transplant rate similar to the waitlist rate.
The Committee determined that the rules simulated in Run N4 accomplished the intended goal of providing access to transplant for candidates who are unlikely to match with many donors.



A member asked for additional time to review the simulation modeling report and presentation provided by the SRTR. The Committee agreed and decided to post the following poll on its SharePoint site which was closed on May 30, 2011.

Resolved, that the allocation rules from Run N4 of the Kidney Pancreas Simulated Allocation Model (KPSAM) be circulated for public comment.

(22 in favor, 0 opposed, 0 abstentions)

Report of the Histocompatibility Working Group
In February, Nancy Reinsmoen, PhD, ABHI, presented the work of the Histocompatibility Working Group, which was formed to identify best practices to reduce the positive crossmatch rate for highly sensitized candidates. She cautioned the Committee against setting a common mean fluorescence intensity (MFI) cutoff for use by all transplant centers and histocompatibility labs. Those on the working group did not agree that this was a particularly strong option. Currently, centers are able to set their own thresholds based on their own practice experiences. To set a common cutoff would over-simplify the process for identifying and classifying unacceptable antigens. The working group also debated whether to require that candidate sera be shipped so that a positive crossmatch could be identified prior to shipment of a kidney. While potentially effective at identifying unexpected positive crossmatches, the working group did not recommend this approach as it found it to be overly simplistic and not an efficient strategy for organ sharing.

For additional context, Darren Stewart, MS, UNOS biostatistician, presented the findings from an analysis regarding very highly sensitized candidates (**Exhibit F**). During a prior meeting, the Committee had requested a tabulation of the number of candidates on the list with a CPRA >=98% by number of years on the waitlist as well as the number of candidates with a CPRA >=98% added to the list annually in 2010 and 2011. The purpose of these requests was to assess how strong the bolus effect might be if candidates with a CPRA>=98% were given national priority.

Of the 174 pediatric registrations currently on the waitlist, Mr. Stewart shared that, 119 (68%) were waiting in active status, and 55 (32%) were waiting in inactive status. Among the 9,094 adult registrations currently on the waitlist, 6,336 (70%) were waiting in active status, and 2,758 (30%) were waiting in inactive status. About 65% of pediatric registrations with a CPRA of 98%+ had been on the waitlist for less than 5 years, and 71% of adult registrations with a CPRA of 98%+ had been on the waitlist for less than 5 years. For pediatric candidates, there are 171 pediatric candidates currently on the waitlist, 117 (68%) were waiting in active status, and 54 (32%) were waiting in inactive status. There were 8,288 unique adult candidates currently waiting, of which 5,790 (70%) were active, and 2,676 (32%) were inactive. About 67% of pediatric candidates with a CPRA of 98%+ had been on the waitlist for less than 5 years, and 76% of adult candidates with a CPRA of 98%+ had been on the waitlist for less than 5 years. Eighteen (1.0%) pediatric registrations were added to the waitlist during 2010-2011 with an initial CPRA of 98%+, whereas 847 (1.3%) of adult registrations were added with a CPRA of 98%+.

Mr. Stewart also shared the results from an analysis regarding positive crossmatch refusals by degree of sensitization (**Exhibit G**). The purpose of this analysis was to determine if positive crossmatches occur too frequently for highly sensitized candidates (CPRA>=95%) to award national priority. Overall, 0.7% of offers were refused due to a positive crossmatch, resulting in 5,106 positive crossmatch refusals over the study period. However, as CPRA increased, the positive crossmatch refusal rate increased as well. Though zero-mismatch offers had a higher rate of refusal due to positive crossmatch (3.6%), they only accounted for 73 (1.6%) of the 5,106 +XM refusals. The rate of refusal due to positive crossmatch was higher for local offers (1.5%) than non-local offers (0.2%).

The working group decided that it was not attempting to prevent positive crossmatches, as there are some positive crossmatches which can be transplanted across. Rather, the working group focused on how to prevent kidneys being allocated and shipped to one candidate and then ultimately turned down and transplanted into another candidate due to a positive crossmatch. The working group determined that the rate of offer turn downs due to positive crossmatch is actually very low for highly sensitized candidates (CPRA>=96%), approximately 3-4%. While the incidence is low, when kidneys are shipped and then

found not to be compatible with the intended recipient, there is additional cold ischemic time accrued while a new match is run or the kidney is shipped back to the offering OPO.

A member of the working group shared that there are some common reasons for unexpected positive crossmatches. Among these, a positive crossmatch due to HLA-DP and HLA-DQA antigens is possible, especially since the current allocation system does not take these into account. The future allocation system could be designed to require HLA-DP and DQA for all candidates or just for those highly sensitized candidates who wish to participate in national sharing. A member suggested that HLA-DP typing is currently not conducted for all donors due to expense. Other members indicated that the cost of the test is approximately $50 to $100 and that HLA-DP typing is required when requested for thoracic organs.

The working group devised some basic requirements and options to facilitate an efficient sharing program for highly sensitized candidates. These included:

- Requiring both the HLA lab director and the clinician sign off the unacceptable antigens listed for candidates with a CPRA>=98%. This requirement would set a tone of accountability for acceptance of national shares.
- Requiring that candidates must have HLA-DP typing in order to participate in the highly sensitized sharing program.
- Allowing centers to list two sets of unacceptable antigens for highly sensitized candidates. In this approach, centers could list additional unacceptable antigens for imported organs to reduce the chance of a positive crossmatch requiring reallocation.

Dr. Reinsmoen also presented the working group's recommendations for assisting centers that repeatedly accept a kidney and then have to turn it down due to an unexpected positive crossmatch. For example, centers with one or two positive crossmatch turn downs for a specific candidate could be required to send the HLA information on the candidate to a third party (e.g., the Histocompatibility Committee or a regional review board) for blinded review and recommendations. Centers would then be required to alter a candidate's unacceptable antigens based on the third party's recommendations in order for the candidate to remain eligible to participate in the sharing program. While the option of temporarily disqualifying candidates from national high CPRA priority after organs are accepted and then turned down due to a positive cross match, the working group decided that this approach would unfairly disadvantage candidates, and the idea was not further pursued.

The Chair thanked Dr. Reinsmoen and the working group for the recommendations.

In May 2012, Darren Stewart, MS, biostatistician from the UNOS Research Department, reviewed an analysis he prepared in response to a request from the February 6, 2012 meeting (**Exhibit H**). After seeing positive crossmatch refusals counts and rates for non-local offers made to CPRA>=95% candidates, the committee asked that these numbers be put into context – to show the "successes" (transplants) side-by-side with the "failures" (positive crossmatch refusals) by determining the number of actual transplants that occurred among these highly sensitized patients that received shared kidneys.

Though there were 13 non-local offers to CPRA=98% candidates that ended up in a positive crossmatch refusal, 63 transplants occurred among the CPRA=98% recipients in 2010. For CPRA=98%, 99%, and 100% together, there were 38 positive crossmatch refusals, but 206 transplants – more than 5 transplants for every positive crossmatch refusal, for non-locally offered kidneys.

Mr. Stewart then reviewed a table of the total number of local and non-local transplants across all CPRA groups, by zero-ABDR mismatch status. For non-local recipients with CPRA>95%, the majority of transplants were zero-ABDR mismatches.

4. Report of the Variance Review Subcommittee

Mark Aeder, MD, chair of the Variance Review Subcommittee, explained that the subcommittee was charged with determining, for each variance, whether to incorporate into the revised national system or to discontinue with the implementation of a new system. Dr. Aeder presented some background on the subcommittee's work and then explained the subcommittee's recommendations regarding each of the kidney allocation variances in existence.

In Fall 2011, the Committee sent a letter to each OPO with a kidney allocation variance explaining whether or not the variance would be recommended for incorporation into the new national kidney allocation system. OPOs whose variances were not selected for incorporation were invited to submit a response explaining the necessity of their variance. Four OPOs submitted responses agreeing with dissolution, six submitted responses asking to maintain their variances, and one OPO requested an extension (Table 1).

Table 1: Responses received from OPOs with variances initially recommended for dissolution

OPO Code	OPO Name	Description of variance	Date OPO instituted a variance
submitted letter agreeing with dissolution			
LAOP	Louisiana Organ Procurement Agency		
CTOP	LifeChoice		
CADN	California Transplant Donor Network		
NYFL	FingerLakes DonorRecovery Network		
requests to maintain variance/ALU			
TXSB	Southwest Transplant Alliance	OPO is divided into two subunits; kidneys are allocated first within the subunit of procurement before being offered out to the remaining OPO candidates.	9/1/1993
PATF	Center for Organ Recovery and Education	OPO is divided into two subunits; kidneys are allocated first within the subunit of procurement before being offered out to the remaining OPO candidates.	2/5/1996
PADV	Gift of Life	OPO is divided into two subunits; kidneys are allocated first within the subunit of procurement before being offered out to the remaining OPO candidates.	2/5/1996
TXGC	LifeGift	1) OPO is divided into three subunits; kidneys are allocated first within the subunit of procurement before being offered out to the remaining OPO candidates. 2) no points for HLA matching 3) .5 points for each year of waiting time 4) intended candidate system	11/1/1991
OKOP	LifeShare	1) OPO is divided into two subunits; kidneys are allocated first within the subunit of procurement before being offered out to the remaining OPO candidates. 2)candidates from the other subunit may appear in the procuring subunit when they have a CPRA>=60%, are listed for KP, or are <18 years old	10/20/1997
VATB	LifeNet Health	Intended Candidate	8/6/2003
requests an extension to reply			
MAOB	New England Organ Bank	1) CTOP and MAOB form single Region 1 list 2) wt awarded based on dialysis only (no GFR) 3) wt points calculation based on different formula than national 4) 7 points for 0 HLA-B or HLA-DR mismatches 5) intended candidate 6) up to 10 "population points"	6/12/1989

James Bowman, MD, Medical Officer for the Department of Health and Human Service's Division of Transplantation, reminded the Committee to keep in mind the OPTN Final Rule requirements for variances while considering each request. Specifically, Dr. Bowman pointed out sections 121.8 (Allocation of Organs) subsection (g) (Variances) and subsection (a) (Policy Development). Briefly, these sections describe variances as experimental policies designed to test allocation methods. As such, variances are to have a research design with data collection and analysis plans and an end date. Additionally, variances must adhere to the principles of policy development including being based on medical judgment, achieve best use of organs, be designed to avoid wasting organs/futile transplants, promote access, and shall not be based on a patient's place of residence except as required under Final Rule provisions.

Excerpt from the OPTN Final Rule

Section 121.8: Allocation of Organs

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

(a) Policy development. The Board of Directors established under § 121.3 shall develop, in accordance with the policy development process described in § 121.4, policies for the equitable allocation of cadaveric organs among potential recipients. Such allocation policies:
(1) Shall be based on sound medical judgment;
(2) Shall seek to achieve the best use of donated organs;
(3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with § 121.7(b)(4)(d) and (e) ;
(4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate;
(5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;
(6) Shall be reviewed periodically and revised as appropriate;
(7) Shall include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program; and
(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section.

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

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

Based on the Committee's prior work to develop a new, national kidney allocation system, some OPOs received letters stating that their variances were likely to be incorporated into the new system. Dr. Aeder explained that the Committee was asked to consider two recommendations from the subcommittee regarding these variances:

- Recommendation #1: Incorporate the dialysis waiting time study as currently operated by CAOP, IAOP, and MIOP into the national kidney allocation system.
- Recommendation #2: Incorporate the A_2/A_2B kidneys into B candidates system currently operated by MWOB, TXSA, GALL, CORS, ILIP, OHLB and WALC, according to the requirements in the A_2/A_2B committee sponsored allocation system.

As these recommendations align with prior Committee recommendations, no discussion was had, but the following resolution was made. Dr. Aeder asked that any member with a conflict of interest on any of the resolutions abstain from voting.

> Resolved that, the Kidney Transplantation Committee recommend to the Board of Directors that the dialysis waiting time study as currently operated by CAOP, IAOP, and MIOP as well as the A2/A2B kidneys into B candidates system currently operated by MWOB, TXSA, WALC, GALL, CORS, ILIP, and OHLB according to the requirements in the A_2/A_2B committee sponsored allocation system be incorporated into the new national kidney allocation system at the time of its implementation. (22 in favor, 0 opposed, 0 abstentions)

Dr. Aeder explained that OPOs whose variances were recommended for discontinuation were given the option of disagreeing or expressing either tacit or explicit agreement. Those that expressed tacit agreement by not submitting a response included OHOV, DCTC, FLWC, MOMA, NCCM, NYWN, TNDS, TNMS, UTOP, and NYAP. Based on these responses the subcommittee made the following recommendation.

- Recommendation #4: Discontinue the variances operated by OHOV, CADN, CTOP, DCTC, FLWC, LAOP, MOMA, NCCM, NYWN, TNDS, TNMS, UTOP, NYAP.

The Committee again agreed with the subcommittee's recommendations and voted on the following resolution.

> Resolved that, the Kidney Transplantation Committee recommend to the Board of Directors that the variances operated by OHOV, CADN, CTOP, DCTC, FLWC, LAOP, MOMA, NCCM, NYWN, TNDS, TNMS, UTOP, and NYAP be discontinued at the time of implementation of a new national kidney allocation system. (22 in favor, 0 opposed, 0 abstentions)

Dr. Aeder explained that the subcommittee had received a request from Life Net Health (VATB) to maintain its intended candidate variance. This variance was implemented in 2003 prior to the implementation of a robust kidney paired donation systems. The Committee reviewed the data provided by VATB which showed 40 transplants facilitated by this variance since its implementation. Of these 40 transplants from deceased donors allocated to intended candidates, 29 were from blood type O donors. Several on the Committee argued that this variance disadvantaged blood type O candidates on the waiting list by funneling kidneys from blood type O donors to intended candidates. Therefore, the subcommittee put forth the following recommendation.

- Recommendation #5: Discontinue the intended candidate variance operated by Life Net Health (VATB).

Following discussion, the Committee ultimately decided that the candidates currently served though the intended candidate system would be better served through kidney paired donation (KPD) especially now

that KPD is better established. Additionally, the current disadvantage to blood type O candidates awaiting deceased donor transplantation would be eliminated.

> ****Resolved that, the Kidney Transplantation Committee recommend to the Board of Directors that the intended candidate variance operated by VATB be discontinued at the time of implementation of a new national kidney allocation system. (22 in favor, 0 opposed, 1 abstaining)**

The Committee then turned its attention to those variances which divide donation service areas (DSA) into subunits for allocation purposes. Five OPOs (TXSB, PATF, PADV, TXGC, OKOP) submitted requests for continuation of this variance type.

The Committee reviewed these variances as a block since they have the same theoretical basis. Some OPOs offered the need for continuation because waiting times would increase for candidates in one of the subunits. The Committee did not find this to be a compelling argument. While waiting times for one subunit may increase, the waiting times for the other subunit would decrease, thereby equalizing waiting times throughout the DSA.

Committee members shared that transplant centers in some of these OPOs have suggested that they would seek a transfer to a different OPO if the variance is not continued. The OPTN does not assign transplant centers to OPOs; transplant center assignment is the responsibility of the Centers for Medicare and Medicaid Services (CMS). The burden of proof to transfer from one OPO to a different OPO would be on the transplant center and it would need to make a compelling argument for CMS to grant the request. Additionally, any changes in reassignment are not automatically granted. These requests are required to be circulated for public comment through the Federal Register.

The Committee understood the political pressure to continue these variances but did not find compelling arguments in the responses. Geographically, it does not appear that there are substantial impediments to transporting the organs throughout the DSAs. The Committee did not find that cold ischemic times would substantially increase with the removal of the subunit variances. Conversely, in some instances, cold ischemic times may decrease as geographically contiguous areas that are currently in different subunits would be in the same level of allocation.

Several on the Committee recognized the political pressures associated with these variances. Many agreed that if the OPOs wish to reapply for their variances by submitting a time-limited study as described by the OPTN Final Rule, the Committee would seriously consider the applications.

The Committee discussed whether these OPOs should be offered the option of implementing a transition plan. The purpose of the transition plan would be to equalize waiting times between subunits gradually before implementation of a new system. The Committee agreed to offer to appealing OPOs the opportunity to apply for a transition plan with the following limitations: any transition plan would be limited to a single step to reduce programming complexity and would be timed to end with the implementation of a new system. The Committee will review submitted transition plans over the summer of 2012 and circulate for public comment with the kidney allocation system proposal in fall 2012.

- Recommendation #6: Discontinue the variances operated by TXSB, PATF, PADV, TXGC, and OKOP.

  Resolved that the Kidney Transplantation Committee recommend to the Board of Directors that the kidney allocation variances operated by TXSB, PATF, PADV, TXGC, and OKOP be discontinued with the implementation of a new system. (21 in favor, 0 opposed, 0 abstentions)

Further Resolved that these OPOs, be offered the opportunity to submit for consideration a single stage transition plan. (21 in favor, 1 opposed, 1 abstention)

Dr. Aeder explained that New England Organ Bank (MAOB) had requested an extension and had submitted a response to the Committee after the subcommittee meeting (b). The Committee noted that the variance was operated regionally by MAOB and CTOP. CTOP also submitted a response indicating that it no longer wanted to participate in the variance.

- Recommendation #7: discontinue the variance operated by Region 1

  Resolved that the Kidney Transplantation Committee recommend to the Board of Directors that the kidney allocation variance operated by Region 1 (MAOB and CTOP) be discontinued with the implementation of a new system. (20 in favor, 0 opposed, 3 abstentions)

  Further Resolved that these OPOs, be offered the opportunity to submit for consideration a single stage transition plan. (21 in favor, 1 opposed, 1 abstention)

In March, the Committee considered whether to continue its committee sponsored alternative system for intended candidates once Chrysalis is implemented. In 2006, the Board of Directors passed a committee-sponsored alternative allocation system for intended candidates. Essentially, any OPO could decide to participate in this system. In participating OPOs, an incompatible donor could donate to a candidate on the deceased donor waiting list and the intended candidate could receive the next suitable deceased donor kidney. The Committee was advised that four OPOs currently operate this system (MOMA, NYAP, NYWN, and UTOP). Since the system was implemented in 2006, 89 transplants of intended candidates have resulted.

The Committee was then asked to decide whether to have this committee-sponsored system programmed into Chrysalis (the new waitlist software). The Committee had previously decided not to include this committee-sponsored system in the new kidney allocation system so the programming would only be effective from November 2013 (the expected date of Chrysalis) and the implementation of the new kidney system (estimated 2014).

When the Committee was making decisions about continuing or discontinuing variances during its February meeting, it chose to discontinue this variance with the implementation of a new kidney allocation system. The Committee was asked to consider whether the system should even be programmed into the new waitlist software (Chrysalis). Since this is a Committee-sponsored system, the Committee is responsible for determining the timing of dissolution. By electing, to program the variance into Chrysalis (expected late 2013), it would only be effective until implementation of the new kidney allocation system (likely 2014). Resources spent programming this system cannot be used for other Committee projects.

Following discussion, the Committee reviewed and voted unanimously on the following resolution (16 in favor, 0 opposed, 0 abstentions). Notice will be sent to the affected OPOs.

Resolved that the Committee-sponsored alternative allocation system for intended candidates, currently operated by MOMA, NYAP, NYWN, and UTOP be discontinued upon the implementation of Chrysalis.

5. Response to Region 4 Concerns about Dialysis Waiting Time

Eileen Brewer, MD, Region 4 Representative, shared a letter sent from her region to the Committee regarding plans to use Dialysis Waiting Time in the new kidney allocation system. The letter explained

that using dialysis time would disincentivize early referrals and that CMS requires patient education regarding transplantation. The Committee did not agree with these assertions. Several members pointed out that the CMS requirements are vague and variably applied across the country. Additionally, the Committee emphasized that by implementing dialysis time in addition to waiting time it was basing the allocation system on more objective clinical criteria (i.e., the time when a patient was classified as having end stage renal disease). Some on the Committee wondered if Region 4 did not understand that waiting time as it is currently defined (time accrual from listing with a GFR<=20 ml/min) would remain in effect. The Committee agreed that a letter should be sent back to Region 4 explaining the Committee's viewpoints on this matter.

6. Proposed Revisions to the Prior Living Donor Priority Policy

Ms. Samana explained that Policy 3.5.11.6 currently awards 4 points to prior living organ donors who are later listed for a kidney transplant. The language is unclear, however, as to whether these points are to be granted for one kidney transplant only. In rare circumstances, prior living organ donors have required more than one kidney transplant. This policy was created with the intent to increase awareness of and focus upon the need for organ donation, while acknowledging the personal health risks undertaken by those who served as actual living organ donors.

In 2006, the Kidney Transplantation Committee reviewed this policy in light of a situation where a prior living organ donor required more than one kidney transplant. During the discussion, many on the Committee expressed that the policy was developed to expedite kidney transplant for prior living donors. However, once the transplant has taken place, this goal has been met and the priority should not be re-assigned if the candidate requires another kidney transplant at a later date. At that time, others on the Committee expressed concern for those prior living donors, in particular, who receive a transplant and experience primary graft non-function. In these cases, OPTN/UNOS Policy 3.2.4.2 (Waiting Time Reinstatement for Kidney Recipients) allows a patient to be re-listed without losing waiting time, however, it does not specifically address re-assignment of priority for prior living donors. Committee members agreed that, in the case of graft failure within the first 90 days post transplant as defined in Policy 3.2.4.2, prior living donors should receive not only their waiting time, but also their priority for being a prior living donor.

In 2006, it was expected that the national kidney allocation system would be substantially revised in the near future and the Committee decided to incorporate these policy clarifications into the revised system. In 2011, however, the major changes to the system had not yet been implemented and a subcommittee of the Living Donor Committee met to discuss whether previous living donors should always receive priority when listed for kidney transplant. The subcommittee was in unanimous agreement that the priority should always be available to prior living organ donors.

The Committee was asked to consider whether priority is to be are to be applied each time a prior living organ donor requires a kidney transplant, regardless of the number of previous kidney transplants the prior living organ donor has received. The Committee unanimously agreed that the policy should be revised and circulated for public comment.

> Resolved, that the policies regarding priority for prior living organ donors be revised to clearly state that the priority applies to each and every kidney registration a prior living organ donor may have and these revisions circulated for public comment. (18 in favor, 0 opposed, 0 abstentions)

7. Kidney Paired Donation Policy Language Proposal

Ken Andreoni, MD, Chair of the Kidney Paired Donation Work Group presented a proposal to convert the existing Kidney Paired Donation (KPD) Pilot Program rules, housed in the KPD Pilot Program Operational Guidelines, into OPTN policy. With this proposal, the full range of adverse actions would be available to the MPSC for violations of KPD policy, up to and including member not in good standing. The policy also includes additional elements of potential donor informed consent that are specific to KPD and requirements for how the matching will be conducted in the KPD Program.

Dr. Andreoni shared with the Committee that the KPD Pilot Program had enrolled its 100th center on February 6, 2012 and that interest in the program is very strong. The Committee voted to circulate the proposed policy language with the following resolution.

> Resolved that, the proposal for converting existing Kidney Paired Donation Pilot Program rules into OPTN policy be circulated for public comment. (18 in favor, 0 opposed, 0 abstentions)
>
> Further resolved that the KPD Work Group be charged with finalizing the proposal. (18 in favor, 0 opposed, 0 abstentions)

8. Kidney Paired Donation Bridge Donor Proposal

Ken Andreoni, MD, Chair of the KPD Work Group introduced a proposal to increase matching opportunities in the KPD Program by allowing bridge donors (a donor who does not have a match identified during the same match run as his paired candidate) in the KPD Program. Currently, the KPD Pilot Program requires that donor chains end with a donation to a candidate on the deceased donor waiting list. As a result, donor chains could end when there may be the potential to extend the chain and transplant more candidates. Additionally, many transplant hospitals have expressed a desire for the KPD Program to include bridge donors. A secondary goal of this proposal is to increase participation in the KPD Program by providing more options for participating transplant hospitals.

Many on the Committee agreed that the time had come to include bridge donors. A few stated that without bridge donors, programs may choose to participate in other KPD programs that provide this option. After discussion, the Committee voted to circulate this proposal for public comment.

> Resolved that, the proposal for including bridge donors in the KPD Pilot Program be circulated for public comment. (18 in favor, 0 opposed, 0 abstentions)
>
> Further resolved that the KPD Working Group be charged with finalizing the proposal. (18 in favor, 0 opposed, 0 abstentions)

9. Proposed revisions to Waiting Time Point Accrual in the OPTN Kidney Paired Donation Pilot Program

In April 2012, the Committee was asked to consider revisions proposed by the KPD Working Group regarding the accrual of waiting time points. Currently, KPD waiting time accrues by match run, with 2 points per match run. Match runs typically occur once a month. The KPD Work Group and participating centers would prefer for the match to be run more frequently. However, with the current method of assigning waiting time points, which is based on the number of match runs and not calendar time, KPD waiting time will not accrue consistently across candidates if the match run schedule changes (e.g., from monthly to semi-monthly) or becomes dynamic (e.g., matches are rerun when X new pairs have been added).

Background

In the original KPD proposal, the plan was to have a set monthly match run schedule, and waiting time would be tied to the match run. However, experience with KPD has shown that there is a benefit to having greater flexibility in when a match can be run. For example, if all the exchanges identified in a match run are refused within a week of the match run, it would be preferable to be able to run the match again in case those candidates could be matched in other exchanges rather than waiting until the next scheduled match run.

However, if the match run schedule changes, then rationale for tying KPD waiting time points to the match run may no longer be the appropriate approach. Some candidates may receive more waiting time points because they were entered in the KPD system in a month that had more match runs than another. The KPD Work Group's goal is to tie waiting time points to a more consistent marker, such as the number of days a patient has waited since being added to the KPD system. This consistent marker – the patient's "add date" in the KPD system – would be used both for patients already in KPD and new patients added after the change. All candidates would then have waiting time points based on their add date to the OPTN KPD Program.

Currently, if candidates are ineligible for a match run because they are in a pending exchange, they do not accrue waiting time points simply because they were involved in a pending match, even if that match falls through. This new method would allow candidates who have been in a pending match status to receive waiting time points so that candidates are not penalized for being part of a match that does not proceed to transplant.

Proposed Solution

The Committee considered whether to change the KPD waiting time points from 2 points per match run to 0.07 points per day (approximately 2 points per 30 days) in order to keep the relative value of points the same if the match is run more often than once a month.

KPD waiting time will begin when a candidate is added to the KPD system and accrues whether a candidate is active or inactive. The change in KPD waiting time points and accrual will be effective pending programming. The Committee was reminded that it had previously discussed and approved this concept as part of the Proposal for KPD Policy that was concurrently out for public comment. This proposal would make this change to the KPD Operational Guidelines so that the match can be run more often at an earlier date. Additionally, it would allow IT staff to plan to only program one method for calculating waiting time in the KPD Automated Solution.

Other Alternatives Considered

The KPD Work Group also considered continuing to have the KPD waiting time points to accrue by match run. However, the KPD Work Group thought this method was more arbitrary and not consistent with how waiting time accrues for deceased donor transplants.

Following consideration and discussion, the Kidney Transplantation Committee voted to approve the following resolution with a vote of 22 in favor, 0 opposed, 0 abstentions.

> Resolved, that KPD waiting time points accrue by 0.07 points per day beginning on the date the candidate is added to the KPD system and the KPD Operational Guidelines be revised as set forth in Attachment A, effective pending programming.

10. Revisions to Renal Minimum Acceptance Criteria

The Renal Minimum Acceptance Criteria (MAC) is a donor questionnaire, exclusive to the Organ Center (OC) that allows for additional screening for regional and national kidney shares that are offered through the OC. Transplant centers enter information about what donor characteristics they would consider for non-local kidney offers (excluding zero antigen mismatch offers), and prior to any OC offer of a regional or national share, OC staff complete the relevant sections of the MAC, to screen out unwanted organ offers. Over the course of using the MAC for several years, OC management has developed clarifications for staff in an effort to ensure the intent of the screening criteria. The Committee was asked to review and approve the clarifications on the following questions to determine if they make clear the intent of the MAC question for the purpose of screening candidates off the match run.

Ultimately, the entire MAC will need to be evaluated in conjunction with the current kidney screening tools in DonorNet®. This would include an analysis of the usefulness and frequency of the criteria in the donor population of each question. Much of this analysis has been completed by OC management in conjunction with UNOS Research staff, but that project will require programming to the UNet^{sm} system, which is on hold due to the Chrysalis re-write. Another long term goal would be to have the wording on each MAC question modified to eliminate the need for any additional clarification, but those types of changes would also involve programming.

The Committee reviewed current OC interpretations (<u>single underline below</u>) on the MAC and offered guidance (<u>double underlines</u> and ~~strikethroughs~~).

MAC Question	Clarification for Staff
A history of cancer (other than a primary brain tumor): Less than one year? 1 to 5 years? 6 to 10 years? More than 10 years?	This would include any history of cancer, including skin cancer, other than a primary brain tumor. <u>This would exclude a benign tumor.</u> The number of years would be how long ago the cancer was initially diagnosed.
A primary brain tumor that is: • Malignant (i.e. Glioblastoma, Astrocytoma, Medulloblastoma)? • Non-malignant (i.e. Meningioma, Ependymoma, Nueroblastoma)?	Make sure that it is clearly documented whether the brain tumor is malignant or not. <u>If a cancer type has not been determined, this question cannot be answered</u>. The donor must have a current brain tumor.
The donor: Has evidence of current injection of non-prescription drugs?	"Current injection" is evidence or history of injection within the <u>last month.</u>

The donor Has been an inmate of a correctional system?	Defined as anyone who has been incarcerated greater than 72 hours within the past 12 months. If you can't determine a time-frame based on the information in the medical/social history, you must have OPO clarification prior answering this question. (This clarification is taken from the AOPO standardized medical/social history questionnaire.)
The donor has any of the following positive serologies: • (1) Hepatitis B Core Antibody with no IGG/IGM testing? • (2) Hepatitis B Core Antibody with IGM testing.	The Hepatitis B Core Antibody serology result must be positive to answer either of these two questions. If the IGM testing is pending but the result is not back by the time the Organ Center begins placement, or no testing will be performed, staff may answer "Yes" to question number one. If IGM testing that was pending does come back (either – or +) after placement has begun, then update the MAC (change question number one to "No" and answer question number two as "Yes.")
What is the warm ischemic time for this donor?	If the OPO is one that does not perform a calculation of WIT for DCD recovery, staff may calculate a WIT from cardiac arrest until initiation of flush. Note that initiation of flush is not the same as cross clamp time.
What is the donor's creatinine clearance level either measured or estimated based on the serum creatinine upon donor's admission?	If the OPO does not provide a CrCl, the following Cockcroft Gault calculation can be used; Est. Creatinine Clearance = [[140 - age(yr)]*weight(kg)]/[72*serum Cr(mg/dL)] (multiply by 0.85 for women). Admission creatinine will be defined as the first creatinine value in the lab panel section of data that's entered into DonorNet.

What is the cold ischemic time on cold storage?	"~~Cold storage" is defined as static preservation. Do not use this question for kidneys that are on pulsatile preservation (pumps.)~~ Add together pulsatile preservation (pumps) and static preservation to determine cold ischemic time on cold storage.
Does the kidney have soft plaque in the renal artery described as: • mild? • moderate? • severe? Does the kidney have hard plaque in the renal artery described as? • mild? • moderate? • severe? • ulcerative?	If placing both kidneys, staff may answer the arterial plaque question with whichever kidney has the worst arterial plaque. If staff is placing only 1 kidney, then arterial plaque for that kidney must be used. This clarification is based on a similar OPTN/UNOS Kidney Committee decision in March 2008 on biopsy results (using the poorer of the two biopsy results when offering both kidneys, or if a single kidney is being offered using the biopsy result from that kidney.)

Attendance
OPTN/UNOS Kidney Transplantation Committee Meeting
Chicago, IL
February 6, 2012

John Friedewald, MD	Chair
Richard Formica, Jr., MD	Vice Chair
Richard Formica, Jr., MD	Region 1 Representative
Sundaram Hariharan, MD	Region 2 Representative
Shamkant Mulgaonkar, MD	Region 3 Representative
Ari Cohen, MD	Region 4 Representative
Adam Bingaman, MD, PhD	Region 5 Representative
William Bry, MD	Region 6 Representative
Viken Douzdjian, MD	Region 7 Representative
Alexander Wiseman, MD	Region 8 Representative
Lloyd Ratner, MD	Region 9 Representative
Jeffrey Punch, MD	Region 10 Representative
Jeffrey Rogers, MD	Region 11 Representative
Mark Aeder, MD	At Large
Eileen Brewer, MD	At Large
Blanche Chavers, MD	At Large
Pang-Yen Fan, MD	At Large
Erica Hartmann, MD	At Large
Michelle Josephson, MD	At Large
Patricia McDonough, RN, CPTC, CCTC	At Large
Peter Reese, MD	At Large
Nancy Reinsmoen, PhD, D(ABHI)	At Large
Teresa Shafer, RN, MSN	At Large
Sharon Swofford, MA, RN, CNN, CCTC	At Large
Ron Taubman,	At Large
Rachael Wong, DrPH	At Large
Marla Jill McMaster, MA, CAPT-USNR(Ret)	Visiting Board Member
Kenneth Andreoni, MD	Ex. Officio
James Bowman, III, MD	Ex. Officio
Sally Gustafson	SRTR Liaison
Ajay Israni, MD, MS	SRTR Liaison
Nicholas Salkowski,	SRTR Liaison
Ciara Samana, MSPH	Committee Liaison
Wida Cherikh, Ph.D	Biostatistician
Darren Stewart, MS	Biostatistician
Elizabeth Sleeman, MHA	UNOS Assistant Director
James Alcorn	UNOS Director
Brian Shepard	UNOS Assistant Executive Director