

OPTN/UNOS Kidney Transplantation Committee
Report to the Board of Directors
June 28-29, 2011
Richmond, VA

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**OPTN/UNOS Kidney Transplantation Committee
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**Kenneth Andreoni, MD, Chair
John Friedewald, MD, Vice Chair**

I. Action Items for Consideration

1. Policy Language Correction to 3.5.5.3 (Kidney Payback Debt Limit)

In December, Ciara Samana, liaison to the Committee, briefed the Committee on a proposed policy language clarification. In 2008, the Board of Directors approved policy changes to eliminate required sharing of zero antigen mismatched kidneys to non-local adult candidates with a CPRA <20%. These changes were implemented on January 21, 2009. Prior to the policy change, if an OPO exceeded the payback debt limits described in policy 3.5.3.3 (Sharing), adult candidates with CPRA <=20% were reprioritized to a lower category until the debt was brought back under the limit. Since the elimination of sharing for adult candidates with CPRA<=20%, this reprioritization no longer occurs because the categories no longer exist. Unfortunately, the policy language in 3.5.5.3 (Kidney Payback Debt Limit) was not simultaneously changed to reflect the removal of these categories. The language continues to refer to reprioritization that no longer occurs. As a solution, the committee was asked to consider updating policy 3.5.5.3 (Kidney Payback Debt Limit) to remove reference to the prioritization adjustment. The following proposal is recommended for consideration by the Board:

****RESOLVED, that effective pending notice to the membership, the language in Policy 3.5.5.3 (Kidney Payback Debt Limit) be amended as set forth below.**

Committee Vote: 16 in favor, 0 opposed, 0 abstentions

3.5.5.3 Kidney Payback Debt Limit. An OPO shall accumulate no more than nine kidney payback debts (all blood groups combined) at any point in time, effective upon implementation of this Policy 3.5.5.3. Debts accumulated prior to the effective date of this Policy 3.5.5.3 by an OPO: (i) shall be considered longterm debt, (ii) shall not apply toward the nine total debt limit effective upon implementation of this policy, and (iii) shall be reduced annually by the volume that is determined pursuant to negotiations with the Kidney and Pancreas Transplantation Committee prior to or around the effective date of this policy. A kidney shared in satisfaction of a payback debt by an OPO owing long-term debt may be applied to the OPO's short-term (*i.e.*, incurred on or after the effective date of this policy) or long-term debt balance, as directed by the OPO. Violation of either of the above provisions shall result in referral to the Membership and Professional Standards Committee as a policy violation by the OPO and all affiliated transplant centers. ~~Additionally, priority for offers of zero antigen mismatched kidneys will be adjusted as detailed in Policy 3.5.3.3.~~

II. Other Significant Issues

2. Progress to Develop a New, National Kidney Allocation System

In 2010, the Committee drafted a document that proposed the use of age matching, survival matching, and a kidney donor profile index for kidney allocation. Prior to the December 2010 meeting, the Committee shared a draft version of the kidney allocation concept document with the American Society of Transplantation, the American Society of Transplant Surgeons, and NATCO. During the December 2010 meeting, Dr. Andreoni shared with the Committee that he had received feedback from the AST, ASTS, and NATCO. The societies found the general framework of the allocation system agreeable (i.e., age matching and survival matching). The societies do want more details about a proposal including rank-ordering. There is remaining confusion about measurement of outcomes and program specific reports. While allocation and outcomes are not the same thing, the Committee will need to carefully consider the effects of one on the other.

During the March 2011 meeting, Dr. Andreoni discussed with the Committee the recent release of the concept document. The document was formally released on February 16, 2011, with a comment period until April 1, 2011. As the meeting took place during the open comment period, the Committee did not discuss individual comments. Instead, it focused on how the document was released to the public. Several members expressed concern that the release was poorly executed, resulting in confusion and a lack of education on the concepts for members of the media and general public. While the transplant community has been exposed to these concepts for several years and has a working familiarity with the approach and process, the general public has not. Some on the committee were dismayed that no press releases, webinars, or other vehicles for educating lay persons were made available and that the Committee was left to “play catch-up” when sensational stories were published in newspapers or aired on national news programs. Dr. Andreoni asked the representatives from the Health Resources and Service Administration (HRSA) to describe whether it would be supportive of a more proactive approach to future proposal releases. Mr. Rich Durbin explained that HRSA has to follow its internal process for the release of information but that it would be supportive of efforts to make future releases smoother. Dr. Andreoni thanked all of the Committee members who had participated in media interviews for their contributions.

The Committee briefly discussed major concerns with the concepts, as garnered from comments to media reports and personal conversations. While age discrimination was cited as the most common concern about the proposed concepts, members of the Committee believed that at least some of these concerns were due to a misunderstanding about how waiting time would be used in a system. A member proposed that the Committee adopt some key points regarding age-matching including one that would emphasize the importance of organ donation from older Americans. Committee members also explained that the concept of age matching may run counter to the outcome measurements utilized by CMS to evaluate transplant programs. Mr. Durbin explained that HRSA and CMS are in discussions to resolve the incongruence between HRSA goals and CMS regulations.

A Committee member asked if the comments received could be classified according to whether the responder was a transplant patient, transplant professional, or member of the general public. Ciara Samana, liaison to the Committee, explained that stratifying the responses would be an imperfect science since commenters did not always provide information as to their profession or relationship to transplant.

A member asked UNOS Staff to describe the timeline to possible Board of Directors consideration of a proposal. Ms. Samana explained that the absolute earliest possibility for consideration by the Board would be June 2012. That timeline was described as ambitious and does not allow for any interruptions to the established policy development process.

Finally, the Committee discussed the immediate need for tools that would help people better understand the concepts. Among these tools is a calculator that will educate patients and physicians about the tradeoffs between waiting for a deceased donor kidney transplant (with varying KDPI values), accepting a living donor transplant, or remaining on dialysis. The Committee will submit a data request to the Scientific Registry of Transplant Recipients to complete this calculator.

The Committee met by teleconference to review comments submitted in responses to the concept document (**Exhibit A**). The concept document was open for comment from February 15, 2011 to April 1, 2011. A total of 264 comments were received. Of these, 52% of comments were opposed to the concepts, 30% were in favor, five percent were of mixed opinion and 13% never clearly stated whether they were for or against. The following professional and patient advocacy organizations also submitted comments. The National Kidney Foundation (NKF), American Society of Transplant Surgeons (ASTS), American Society of Transplantation (AST), National Kidney Registry (NKR), American Society of Nephrology (ASN), Dialysis Patient Citizens (DPC), American Association of Kidney Patients (AAKP), Renal Support Network (RSN), and the American Society of Histocompatibility and Immunogenetics (ASHI). Among these, AST, ASTS, NKF, NKR, ASHI, and ASN expressed support for the concepts. Other organizations, including RSN, DPC and AAKP were supportive of the Committee’s work but had reservations about one or more of the concepts. All of the organizations provided feedback and recommendations regarding the next phase of policy development, specifically for how patients should be rank ordered. Of the opposed comments, concerns over age discrimination were the overwhelming reasons cited. Other cited reasons for opposition included lack of proposed changes to geographical boundaries for kidney distribution and possible effects on the rate of living kidney donation

The following tables further breakdown the comments received by type of responder and specific areas of concern.

	Total	In favor	Opposed	Mixed Opinion	Unknown
General public	26	5	17	0	4
Transplant patient, recipient, family member	85	19	47	5	13
Transplant professional	64	33	14	6	8
Unknown	89	20	57	1	9

For the comments that were found to be opposed, the following reasons were cited (more than one reason may be cited per opposition vote)

Geography	12
Age Discrimination	100
Living Donation	11
Considerations for special populations	8
Inadequate data	8
Social factors	9
Histocompatibility	0
Other	12

The Committee received all of the comments submitted by the deadline (**Exhibit B**) prior to the call. Committee members made general observations about the overall tenor of the comments. For instance, transplant professionals seemed to be more likely to be in favor of the concepts than members of the general public or transplant patients. Some on the Committee believed this may be due, in part, to the way in which the concept document was released. Members expressed frustration that more was not done to release the concepts in a comprehensive fashion and that most of the comment period was spent correcting inaccurate or misleading media articles. Some members remarked that many comments seemed to be mostly in response to news reports and not to the concept document itself. Others were concerned that many of the opposed comments contained factual inaccuracies or misunderstandings about the proposed concepts. The Committee also observed that a number of comments focused on general reaction to the implications of the concepts (for example, age discrimination and effect on living donation). These comments, while heartfelt, did not offer specific guidance regarding the merits of the concepts or potential alternatives for allocation policy. The Committee decided that any future document releases will be accompanied by a comprehensive communication plan and supplemental material written for the lay public.

One member of the Committee remarked that the overwhelming concern seems to be that patients would somehow be excluded from the allocation system. For instance, many of the comments were against excluding patients over a certain age from receiving a transplant. The Committee reiterated strongly that the allocation concepts do not have any exclusion criteria. Listing of candidates for transplant is and would remain the responsibility of transplant centers. Any candidate who is listed by a transplant center would appear on a match run for organ offers.

The Committee discussed other areas of apparent confusion, including concerns that priority for prior living organ donors would be eliminated. It has never been the Committee's intent to eliminate or otherwise modify this priority, which recognizes the risk that living donors undertake to help another individual. Since this priority was not intended to be modified, the Committee did not include it in this concept document.

The Committee discussed the concerns that these concepts would result in a decline in living donation. Some on the Committee observed that a decrease in living donation would not necessarily be a bad thing

and may even be an indication that the deceased donor kidney allocation system is functioning well. The current rate of living donation may, in fact, be due to the perception that the current deceased donor system is inadequate. One Committee member remarked that the observed decline in living donation following changes in the pediatric allocation policy (i.e., Share 35) are not necessarily indicative of what will happen following implementation of the kidney allocation concepts for several reasons:

- 1) the rate of living donation following implementation of Share 35 declined for all kidney recipients, not just for pediatric recipients. This decline may be at least partially attributable to highly publicized adverse events involving living donors that occurred roughly around the same time as the implementation of Share 35, and
- 2) unlike the Share 35 policy where waiting time for pediatric candidates dropped precipitously because they were categorically ranked higher than most other candidates, the proposed concepts would not result in similar declines in waiting times. Under the proposed concepts, all candidates would still have to wait. Therefore, candidates who intend to avoid dialysis entirely would still need to pursue living donation.

Finally, the Committee turned its attention to the issue of geography. The Committee acknowledged that there are wide variations in how kidneys are allocated (due to variances), in waiting times (due to differences in listing practices and demand/supply for kidneys), and in outcomes. The Committee maintains, however, that until one national allocation system is in place and has been operating for a sufficient period of time to evaluate its effects, that changes to geographical boundaries are not feasible. However, the concepts would lay the groundwork for future reforms and enhancements to the kidney allocation system by allowing the public and professional community to become comfortable with incremental changes. Additionally, while the Committee acknowledges that it does not intend to adjust geographical boundaries with a new allocation system, it does plan to propose changes that will directly address geographical inequities. For example, the Committee intends to eliminate the kidney payback system which will likely improve matching through sharing only of phenotypically matched kidneys. This change is likely to improve organ use because it eliminates a potential disincentive for taking an older zero antigen mismatch because it is usually paid back with a kidney from a younger donor. The Committee also believes that utilizing dialysis time as the uniform start of waiting time will at least partially address geographical differences in listing practices. Finally, the Committee believes that the elimination of variances (or incorporation into the national allocation system) will set the groundwork for any alterations that are found to be necessary to geographical boundaries. It is only when disparities within regions are addressed that the Committee can turn its attention to confronting the larger national issues.

The Committee discussed some of the recommendations from the societies and patient advocacy organizations. Many of the recommendations were specific to rank-ordering of candidates. The Committee agreed to incorporate as many of these recommendations as possible when it moves into the next phase of policy development. The Committee discussed the suggestion from the American Society of Nephrology (ASN) that the categorical cut off at 20% for estimated post transplant survival (EPTS) was inappropriate and that a continuous scale should be used. Members agreed that a continuous scale was preferred and had been previously proposed but was changed to a categorical cutoff due to concerns from patients and professionals that a continuous scale was too complex and difficult to explain.

The members on the call unanimously decided to move forward into the next phase of policy development with the concepts forming the framework for a proposed allocation system. As it continues to work, the Committee will focus on developing materials that are easier to understand for the lay public and that highlight some of the potential benefits of a revised allocation system.

Additional Policy Development

In addition to its work on the concepts of age matching, survival matching and KDPI, the Committee continued to evaluate other aspects for a new allocation system. Specifically, the Committee has partnered with the Pediatric Transplantation Committee and the Histocompatibility Committee to evaluate ways to improve allocation to both the pediatric and sensitized patient populations. Additionally, the Committee has begun evaluation of the many kidney allocation variances and has developed a plan to facilitate incorporation or dissolution of each in a new system.

Pediatric Kidney Allocation

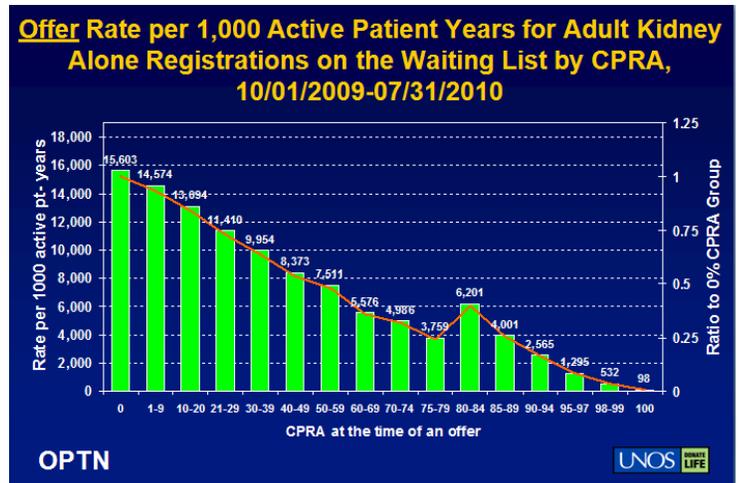
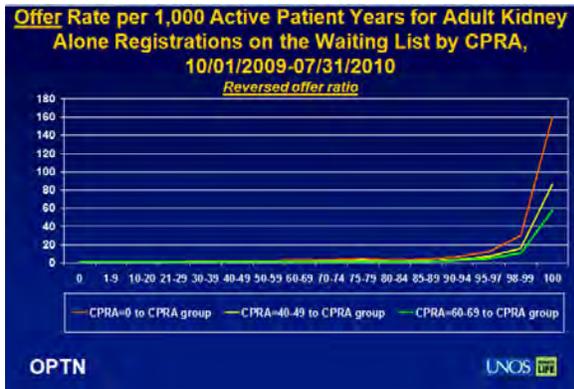
During the December 2010 meeting, Eileen Brewer, MD, presented the work of the Pediatric Committee to determine whether donor age in the current kidney allocation system could be converted to KDPI. The Pediatric Committee asked for a KPSAM run to determine whether there was a KDPI value that would still allow pediatric candidates to be transplanted in a timely fashion. It modeled a KDPI value of .31 and a KDPI value of .39 as possibilities (**Exhibit C**). After looking at the results, the Pediatric Committee decided that the .31 and .39 provided access to transplant for pediatric candidates that is similar to the access experienced under the current system. Therefore, the Pediatric Committee decided to propose that the midpoint of these two values, a KDPI value of .35 be used in the new kidney allocation system. The Kidney Transplantation Committee thanked the Pediatric Committee for its recommendation and agreed to use this value in future simulation modeling.

In March, Dr. Brewer updated the Committee on the Pediatric Committee's work to develop minimum listing criteria for pediatric candidates. In the current kidney allocation system, pediatric candidates accrue time from the point at which they are placed on the waiting list without consideration of disease state. Due to some unique disease processes for pediatric candidates, the group has so far been unsuccessful in determining straightforward criteria for waiting time but will continue to discuss the issue. Additionally, the group has begun discussing ways to increase regional sharing for highly sensitized pediatric patients without adversely causing a rise in cold ischemic time.

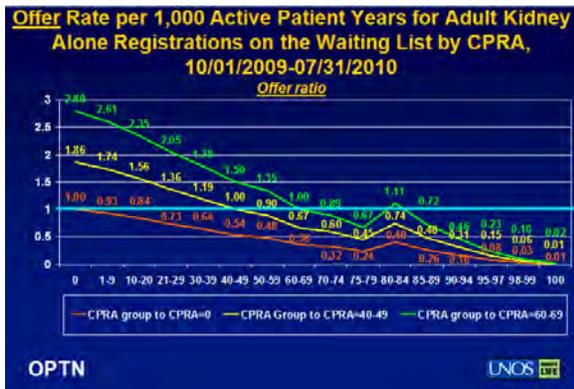
Allocation for Sensitized Candidates

Nancy Reinsmoen, PhD, Chair of the Histocompatibility Committee presented a data analysis on offers for kidney alone candidates by degree of sensitization (**Exhibit D**). For the new allocation system, the Histocompatibility Committee wants the Kidney Committee to think beyond the currently awarded 4 points for CPRA $\geq 80\%$ and consider whether there is a factor that can be used at a DSA specific level to make sure that sensitized patients get transplanted but not ahead of patients who have been waiting for a long time.

As expected, the analysis found that the offer rates declined as CPRA increases. For instance, the offer rate for 80-84% CPRA group is only 40% of the offer rate for 0% CPRA group. The offer rate for 100% CPRA group is only about 1% of the offer rate for 0% CPRA group. Finally, there is a decrease in offer rates from 0 to 79% and from 80 to 100% CPRA. The Histocompatibility Committee believes that the reversed ratio of the offer rate may provide a way to estimate a future sliding scale for sensitization points.



The Committee investigated whether setting a standard for offer rates similar to candidates who are 40% or 60% sensitized would be appropriate for a new kidney allocation system.



The Histocompatibility Committee proposes that significant priority points would need to be awarded for candidates who are sensitized as indicated in the table below. The Committee believes that these points need to be DSA specific. Additionally, the Committee proposes that the priority points should begin at CPRA=60%.

Offer Rate per 1,000 Active Patient Years for Adult Kidney Alone Registrations on the Waiting List by CPRA, 10/01/2009-07/31/2010
Reversed offer ratio

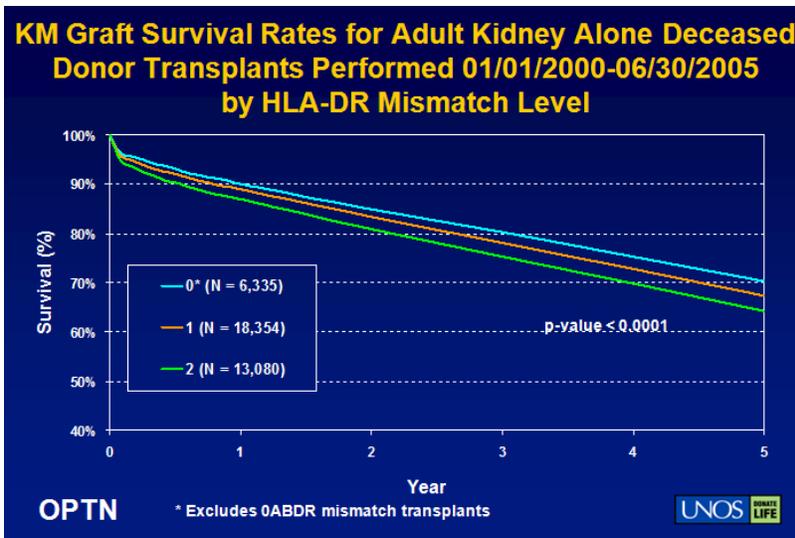
CPRA Group	CPRA=0 to CPRA group	CPRA=40-49 to CPRA group	CPRA=60-69 to CPRA group
0	1.00	0.54	0.36
1-9	1.07	0.57	0.38
10-20	1.19	0.64	0.43
21-29	1.37	0.73	0.49
30-39	1.57	0.84	0.56
40-49	1.86	1.00	0.67
50-59	2.08	1.11	0.74
60-69	2.80	1.50	1.00
70-74	3.13	1.68	1.12
75-79	4.15	2.23	1.48
80-84	2.52	1.35	0.90
85-89	3.90	2.09	1.39
90-94	6.08	3.26	2.17
95-97	12.05	6.47	4.31
98-99	29.36	15.75	10.49
100	159.71	85.70	57.08

OPTN



The Committee then discussed how to most effectively and efficiently facilitate regional sharing for extremely highly sensitized candidates. Currently, many regional shares are not transplanted into the intended candidate due to positive crossmatches. Many on the Committee believed that virtual crossmatches with mandatory uploading of the candidate's unacceptable antigen data would be required for a truly efficient system.

The Committee then reviewed a data analysis of graft survival by HLA-DR mismatches. The survival advantage of receiving a 2 HLA-DR match is about one year. Patients with 2 HLA-DR matches levels have the highest graft survival compared to other groups. Patients with 6 HLA-ABDR mismatch have the lowest survival.



Dr. Cherikh presented some data to help the Committee determine whether 5 or 6 mismatches should be disincentivized in a new allocation system (**Exhibit E**). When looked at by racial/ethnic groups, it was determined that Asian recipients and African American recipients would be harmed. These racial/ethnic groups receive a higher rate of 5 or 6 mismatches than Caucasian recipients.

Kidney Allocation Variances

Mark Aeder, MD, the Chair of the Variance Review Subcommittee presented its work to review all of the existing variances to the national kidney allocation. Based on the review, OPOs were classified as having a variance in place or not. The Subcommittee then examined the existing variances to determine if each would have merit as national policy, or if the variance was in place to deal with a unique geographical challenge within the donation service area (DSA). The Subcommittee has drafted two letters to each OPO. The first letter lets each OPO know about the review and the Subcommittee's findings. The second letter would ask those OPOs with variances not selected for the national system to provide additional information if it believes that the variance would have merit as national policy. These letters are expected to be distributed later in the spring of 2011 and will be shared with the full Committee prior to distribution.

Some members of the Committee expressed concern that OPOs may attempt to transfer between regions or transplant centers may attempt to align with an OPO other than the one serving its DSA. Ms. Samana remarked that the regions are codified in Policy 3.5 and so OPOs could not unilaterally decide to change regions. Similarly, DSAs are codified by CMS and transplant centers could not unilaterally decide to align with an OPO in a different DSA.

3. Discussion of Issues with Existing Variances

During the March 2011 meeting, the regional representative from Region 11, Oscar Grandas, MD, asked the Committee to advise a path forward regarding the kidney allocation variance in Tennessee. Upon review, the transplant programs in Tennessee have discovered an unintended consequence of some modifications they requested to the variance. Sensitized candidates are now receiving transplants at a higher rate than unsensitized candidates. There is not agreement in the state about whether to terminate the variance, to request an additional modification, or to allow it to exist. Dr. Andreoni advised that programming changes are unlikely at this point due to the Chrysalis project. Additionally, Dr. Andreoni shared that UNOS Staff had reviewed the variance modifications and the signoffs obtained from the transplant programs in the state and determined that the programming had been implemented correctly. OPTN/UNOS Policy requires that at least 75% of participating centers request dissolution of a variance. Until such agreement can be achieved in the state, the Kidney Transplantation Committee will not dissolve or otherwise modify the variance.

The regional representative from Region 5, William Bry, MD, asked the Committee to advise a path forward regarding the kidney allocation variance used by the California Donor Network. To expedite placement, the variance distinguishes between sensitized and unsensitized candidates. One kidney from each donor is allocated to sensitized and unsensitized candidates who have been placed on the masterfile. The remaining kidney is allocated only to unsensitized candidates. Due to advances in the testing of sensitized candidates and gains in efficiency regarding kidney placement, the OPO wants to allocate both kidneys to all candidates on the list. As this would constitute a modification to the variance, Dr. Andreoni remarked that policy would require public comment and Board approval. However, upon review of the variance, Dr. Andreoni noted that the definitions for sensitized and unsensitized candidates were left to the discretion of the histocompatibility laboratories. Dr. Andreoni asked the Network to review its practices and determine if there were opportunities to refine its practices within the rules outlined in the existing variances.

4. Kidney Paired Donation Update

In December, Dr. Friedewald, Chair of the OPTN Kidney Paired Donation Work Group, described the latest results from the KPD Pilot Program. Since the Committee's last meeting, two match runs were executed. In October 2010, there were 43 pairs entered into the system. Seven pairs were matched in two two-way matches and one three-way match. The pairs came from six different centers, three different coordinating centers, and four different regions. In December, 62 pairs were entered into the system, there were 12 matched pairs identified in four three-way matches. All four coordinating centers had pairs involved in at least one of the four three way matches. The pairs came from six different regions and four of the matched candidates were highly sensitized. Only one transplant had actually taken place. Reasons for the matches not going forward were not available at the time of the meeting. Dr. Friedewald shared that both the KPD Financial and KPD Coordinating Center subcommittees were actively trying to come up with some generalized agreements that centers can sign so that every time new exchange happens, they do not have to work out legalities de novo. Additionally, these two subcommittees were working to address reimbursement issues for KPD.

In March, Dr. Friedewald shared a comprehensive data analysis (**Exhibit F**) and reported that no matches had been found during the February match cycle and asked the Committee to encourage participating centers to enter pairs to help drive the Pilot Program. Some members reported that they were only entering very highly sensitized or otherwise hard-to-match pairs. This practice is problematic as the

program cannot generate many matches with only hard-to-match pairs participating. The Committee discussed whether more frequent match cycles would result in additional matches, but it was determined that more frequent matches would only exacerbate the problem by skimming off any easy-to-match pairs. One of the hurdles identified to getting additional pairs into the system was the large amount of testing and data submission required just to register pairs. For example, other kidney paired donation systems do not require HLA-DP testing until after a match is identified. This practice reduces expensive testing that may or may not be covered by the candidate's insurance. The Committee agreed to temporarily suspend the KPDPP requirement for HLA-DP testing for a period of six months with the following resolution:

****Resolved that, the Operational Guidelines requirement for submitting results of HLA-DP testing at the time of registration in the Kidney Paired Donation Pilot Program will be made optional for a period of six months.**

19 in favor, 1 opposed, 1 abstention

5. Waiting Time Modification Subcommittee Update

In March, Patricia McDonough, Chair of the Waiting Time Modifications Subcommittee, shared a recently received request for a 52 year old man who received a kidney from a deceased donor. Six months following transplant, the recipient developed a renal clear cell carcinoma and subsequently underwent a nephrectomy. The nephrectomy fell outside of the 90 day window for waiting time reinstatement as defined in policy. Ms. McDonough asked the Committee to consider whether a policy change was warranted to accommodate any similar future instances. Ms. McDonough shared three possible pathways for policy modification: 1) the current policy could stand with exceptions considered on a case-by-case basis, 2) the policy could be modified to allow for reinstatement if the case meets certain standards (e.g., no evidence of metastasis, limit of 2 years since transplantation, agreement by all local centers), or 3) the current policy could remain unchanged. The Committee discussed whether modifying the policy to allow for waiting time reinstatement would lead to negative effects such as riskier acceptance behavior. In the presented case, the donor's CT scan showed lesions in the kidneys which were thought to be scarring at the time of transplant.

The Committee determined that it would not undertake a policy change at this time for several reasons. Transplanted kidneys are removed for a number of reasons including early thrombosis, kidney stones, or transmission of cancer. The Committee did not find that a policy modification could be necessarily inclusive enough to accommodate everyone who may experience an adverse outcome without allowing an unsustainable number of waiting time reinstatements. The Committee did not necessarily agree that a cancer transmission versus a technical complication or some other transmitted condition was more serious or necessitated its own policy exception.

The Committee advised the local OPO to consider whether this case was medically urgent for a second transplant and to pursue local agreement. It did not agree that a waiting time reinstatement or modification was warranted for this case. The Committee will consider modifications to the waiting time reinstatement policy when it releases a proposal for a new kidney allocation system.

6. Discussion of a Possible New Living Donor Category

The Committee discussed a situation presented by a member where a patient had a therapeutic nephrectomy and the removed kidney was later transplanted into a transplant candidate. Under current OPTN policy, this patient would be classified as a living donor, and possibly subject to all of the related evaluation and follow-up policies. The Committee considered whether a new category should be created for individuals who need to have a kidney removed due to a disease process (e.g., renal artery stenosis) and who would prefer that the removed kidney benefit another person. The Committee identified several issues related to patient safety (e.g., would using these kidneys for transplantation result in any increased risk to the potential donor), billing, and outcomes assessment. Some members remarked that these potential donors may not be as healthy as traditional living donors and so what would be reported as a donor complication as opposed to a complication related to the donor's disease process. One member remarked that this situation was similar to domino transplants for heart and liver.

The Committee agreed to ask the Executive Committee and the Policy Oversight Committee to add this issue to its workplan for further consideration.

7. Policy Language Review: Listing Criteria for Kidney Candidates

The Committee reviewed a memo from the Department of Evaluation and Quality regarding policy language (**Exhibit G**). There appears to be some confusion in the community regarding listing for kidney candidates. Currently, there are no listing criteria for kidney candidates. The only criteria set forth in policy pertain to the accrual of waiting time. The Committee reviewed the language and determined that it was clear. The Committee advised UNOS Staff to circulate educational material (e.g., through the Communications newsletter) alerting members to the correct interpretation of the policy.

8. Review of Recommendations to Change Cardiac Death Language

Franki Chabelewski, liaison to the OPO Committee, reviewed that Committee's work to revise language in the DCD Model Elements document. Ms. Chabelewski emphasized that the OPO Committee was requesting the Kidney Transplantation Committee's feedback prior to circulating a proposal for public comment.

The OPO Committee undertook a rewrite of the DCD Model Elements because of changes in practice and terminology. This will be moved into policy rather than the bylaws. The Committee reviewed a document with the substantive changes highlighted (**Exhibit H**). Among the changes, Donation after Cardiac Death would be changed to Donation after Circulatory Death to correspond with the terminology in the Uniform Anatomical Gift Act. Additionally, the age barrier to DCD donation would be removed because the committee believes that this is a matter for physician judgment.

A member of the Committee asked if the title change would allow for heart donation following circulatory death. Ms. Chabelewski responded that the OPO discussed this matter and believes that aligning the language with the language of the UAGA would allow for heart donation from these donors. The current terminology, "donation after cardiac death" suggests that the heart has died and is no longer suitable for transplantation, neither of which is necessarily correct.

Some members asked questions about changes to the types of transplant professionals who would be allowed to be present during the procurement. Section E of the document suggests that no member of the transplant surgical team can be present. Ms. Chabelewski agreed to ask the OPO Committee to clarify the

language to specify that only those transplant professionals involved in the actual recovery should not be present at the time of pronouncement. Another member remarked that additional clarification may be necessary regarding medications. For example, sometimes low doses of heparin are necessary prior to declaration of death to prevent clotting.

9. Update from the Scientific Registry of Transplant Recipients (SRTR)

In March, Jon Snyder, PhD, from the SRTR, updated the Committee on efforts to presented delivered a presentation on the kidney pancreas simulated allocation model (KPSAM) (**Exhibit I**). Dorry Segev, MD, presented some preliminary thoughts for improvements and revisions to the program specific reports.

10. Review of Public Comment Proposals

a. Proposed Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization

Jacqueline O’Keefe, Assistant Director of UNOS Membership, and Erick Edwards, Assistant Director of UNOS Research, presented a proposal jointly sponsored by the Organ Procurement Organization (OPO) Committee and the Membership and Professional Standards Committee (MPSC). The Committees proposed the use of a statistical model to analyze OPO performance. This model utilizes a comparison of observed (actual) to expected organs transplanted per donor (yield) based upon donor specific characteristics in each Donation Service Area. The model will be used in aggregate (for all organs) in addition to organ specific performance measures, and predicts how many organs would have been recovered and transplanted if the OPO performed at the level of the national average for donors with similar characteristics. The MPSC will use the model to monitor OPO performance, similar to existing practices for monitoring transplant program performance. Through this approach, the MPSC will identify opportunities for improvement at OPOs whose observed organ yield falls below expected levels by more than a threshold. The bylaw proposal provides information regarding the model and intended use by the MPSC as well as the threshold that will result in MPSC inquiry.

Following the presentation, the Kidney Transplantation Committee discussed the proposal. One member asked if the model included factors to account for transplant program effects. Since OPOs cannot place organs without transplant programs that are willing to accept those organs, the member offered that performance should somehow be adjusted to reflect these circumstances. Another member remarked that the directives for transplant programs and OPOs are quite different. OPOs are instructed to procure “every organ every time” while transplant programs are encouraged to be risk averse due to the program specific reports. Ms. O’Keefe explained that the MPSC had discussed incorporating such a factor to account for transplant program effect, but ultimately determined that some OPOs procure high numbers of organs even without a local program to utilize those organs. Finally, the Committee asked if the MPSC had considered whether public disclosure of this information could lead to unintended consequences such as those observed following the development of program specific reports. Ms. O’Keefe stated that the Committee had carefully considered potential unintended consequences and weighed those against the potential for performance improvement prior to issuing the proposal.

While the Committee understood that the proposal was jointly sponsored by the OPO Committee, it requested that UNOS staff share any formal response from the Association of Organ Procurement Organizations (AOPO). The Committee delayed its decision on the proposal until after the meeting when this information could be shared. AOPO’s formal comment (**Exhibit J**) was circulated to the Committee on March 23, 2011. Following review of this comment, the Committee electronically voted to support the proposal with a vote of 7 in favor, 0 opposed, and 0 abstaining.

b. Proposal to Improve the Reporting of Living Donor Status

Christie Thomas, MD, member of the Living Donor Committee, presented a proposal to require submission of data for living donors beyond “lost to follow-up”. The OPTN currently relies on Living Donor Follow-up (LDF) forms to collect data on the short-term health status of living donors. The transplant community must collectively improve patient information on the LDF form to allow for meaningful analyses to objectively study the short-term effects of living donation. Data on living donors who donated in 2006 through 2008 demonstrate that many programs do not report the status of their living donors at required reporting intervals. Under this proposal, transplant programs would be required to accurately report if the living donor is alive or dead at the required post operative reporting periods (6, 12 and 24 months). Follow-up information on donors is especially important in the current climate where the public and the media seek data on the safety of living donation. Without accurate and comprehensive living donor follow-up data, it will not be possible to answer questions and address concerns.

The Committee discussed whether there are existing sources for data on living donor survival that could be used to achieve the stated objective. One member remarked that the Social Security Death Masterfile may be a reasonable source. However, a living donor in attendance at the meeting remarked that the SSDMF would not capture deaths of living donors who elect not to provide their social security numbers. A member asked if compliance could be improved by changing the time points at which the data are required to be submitted. While the Living Donor Committee discussed changing the time points, this was not viewed as the major reason for nonsubmission of data. Following discussion, the Committee voted to support the proposal with a vote of 17 in favor, 1 opposed, and 1 abstaining.

c. Living Donor Committee: Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs, Vessels and Tissue Typing Materials

Dr. Thomas then presented a proposal from the Living Donor Committee to improve the packaging, labeling, and shipping of living donor organs, vessels and tissue typing materials. Dr. Thomas explained that the majority of living donor organs recovered for transplant are not shipped or transported outside the recovery center, and therefore would not be affected by this proposal. However, the packaging and shipping of living donor organs is increasing, especially as "kidney paired" donation increases throughout the country. Changes to the policies for the packaging and shipping of deceased donor organs, vessels, and tissue typing materials were approved by the OPTN/UNOS Board in November 2010, and took effect in January 2011. The implementation of these new policies has created a situation where the rules for packaging, labeling and shipping deceased donor organs are more stringent than policies for the packaging, labeling and shipping of living donor organs. In response, this proposal would update living donor policy to more closely align with recent changes to the policy requirements for the packaging, labeling and shipment of deceased donor organs, vessels and tissue typing materials. The proposal also clarifies procedures when the living donor organ is not packaged, shipped or transported. The Committee anticipates both transplant centers and Organ Procurement Organizations (OPOs) would benefit from the standardization of packaging and shipping requirements for all organs. The Committee further expects that applying the existing requirements for the packaging and shipping of deceased donor organs to living donor organs, vessels and tissue typing materials will increase the safety of living donor organs that are packaged and transported outside the recovery facility. The proposal would not preclude transplant centers from entering into an agreement with an OPO to coordinate the packaging and shipping of living donor organs, vessels and tissue typing materials. The Committee voted to support the proposal with a vote of 19 in favor, 1 opposed, and 1 abstaining.

d. *Living Donor Committee and Membership and Professional Standards Committee - Proposal to Clarify Transplant Program Responsibility for Reporting Living Donor Follow-up*

During the December, 2010 meeting, Lee Bolton, liaison to the Living Donor Committee, presented a public comment proposal. The purpose of the proposal was to clarify which transplant program has responsibility for elements of the living donation process and to reassign reporting responsibility for living donation from the recipient transplant program to the transplant program performing the living donor nephrectomy or hepatectomy. Following the presentation, a member asked whether donors who travel across the country to donate would be required to return to the nephrectomy center for follow-up. Mr. Bolton clarified that the follow-up could be done at the donor's local hospital and information sent to the recovery hospital for submission to UNOS. The recovery center is only required to submit the follow-up information but it is up to their discretion how to obtain the information. Some members expressed concern that this proposal would ultimately eliminate the ability of centers to formally transfer follow-up responsibility. A member of the committee asked whether the Living Donor Committee and the MPSC had considered whether to require centers to have an agreement to transfer follow-up responsibility. Mr. Bolton stated that this was a consideration which may be put forward as a proposal in the future but is not included in this proposal. Currently, it is a manual process for UNOS to transfer the responsibility for submitting forms between centers. In general, the Committee agreed that this proposal would reduce confusion surrounding the submission of follow-up information and voted to support the proposal with a vote of 13 in favor, 1 opposed, and 0 abstentions.

e. *Review of a Proposal to Prohibit Storage of Hepatitis C Antibody Positive and Hepatitis B Surface Antigen Positive Extra Vessels*

Kimberly Taylor, liaison to the Operations and Safety Committee, presented a public comment proposal to prohibit storage of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels. The proposed modifications are meant to reduce actual risk of disease transmission from stored extra vessels into secondary recipient(s) by prohibiting storage of hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels. Additionally, the proposal aligns policy / practice for extra vessel(s) by requiring verification of ABO, all serology results, container contents, date of expiration and UNOS Donor ID with intended vessel recipient prior to implantation, and documentation of this verification in the recipient's medical record. Finally, the proposal removes the requirement for the implanting transplant center to provide detailed explanation to OPTN when hepatitis positive extra vessels are transplanted into a secondary recipient.

The Committee discussed the proposal. Many members shared the viewpoint that a robust labeling and tracking system is not mutually exclusive from disposal of these vessels. Transmission of HCV through vessel transplantation is a low frequency event. Some were concerned with discarding vessels after the initial surgery and potentially leaving a recipient without access to additional vessels should the need arise. However, other members stated that this risk was not worth retaining the vessels if the regulatory burden was going to increase substantially.

The Committee voted to support the proposal with a vote of fourteen in favor, one opposed, and one abstaining.

f. *Proposal to modify requirements for open versus laproscopic nephrectomy*

The Membership and Professional Standards Committee, along with the Living Donor Committee put forward a proposal to modify the requirements for the type of nephrectomy performed by surgeons involved in living kidney donation. The goal of this proposal is to provide an additional means for open donor nephrectomy qualification now that laparoscopic nephrectomy is more commonplace than it was

when this bylaw was originally adopted. The proposal recognizes surgeons who are qualified to perform laparoscopic living donor nephrectomies as qualified to perform open donor nephrectomies as well. The revisions also eliminate the requirement for kidney transplant programs to be specifically designated to perform open donor nephrectomies since the majority of donor surgeries are performed laparoscopically. A member remarked that there was less than a 3% rate of conversion from laparoscopic to open. Additionally, when a surgeon undertakes a laparoscopic procedure, the hospital requires that the surgeon be able to handle any complications of that procedure (e.g., conversion to open nephrectomy). The Committee did not find any objectionable issues with the proposed policy changes.

**Attendance at the Meeting of the
OPTN/UNOS Kidney Transplantation Committee
December 13, 2010
Conference Call
Ken Andreoni, MD, Chair
John Friedewald, MD, Vice Chair**

Kenneth A. Andreoni, MD	Chair
John J. Friedewald, MD	Vice Chair
Richard N. Formica Jr., MD	Regional Rep. Reg. 1
Shamkant P. Mulgaonkar, MD	Regional Rep. Reg. 2
Ari J. Cohen, MD	Regional Rep. Reg. 3
Bernard V. Fischbach, MD	Regional Rep. Reg. 4
William I. Bry, MD	Regional Rep. Reg. 5
Viken Douzajian, MD	Regional Rep. Reg. 6
Mikel Prieto, MD	Regional Rep. Reg. 7
Alexander Wiseman, MD	Regional Rep. Reg. 8
Lloyd E. Ratner, MD	Regional Rep. Reg. 9
Mark I. Aeder, MD	Regional Rep. Reg. 10
Douglas S. Keith, MD	Regional Rep. Reg. 11
Eileen D. Brewer, MD	At Large
Harold J. Fassnacht, JD	At Large
Oscar H. Grandas, MD	At Large
Erica L. Hartmann, MD	At Large
Dixon B. Kaufman, MD, PhD	At Large
Karen Kennedy, RN, CPTC	At Large
Patricia M. McDonough, RN, CPTC, CCTC	At Large
Stephen C. Rayhill, MD	At Large
Nancy L. Reinsmoen, PhD, D(ABHI)	At Large
Sharon E. Swofford, MA, RN, CNN, CCTC	At Large
David E. Burgio, MPA, LFACHE	Visiting Board Member
John C. Hodges, MA	Visiting Board Member
Marla Jill McMaster, MA, CAPT-USNR(Ret)	Visiting Board Member
James S. Bowman, III, MD*	Ex. Officio
Monica Lin, Ph.D*	Ex Officio
Ba Lin, MS, MPH*	Ex Officio
Christopher J. McLaughlin*	Ex Officio
Adrine Chung*	SRTR Liaison
Jon Snyder	SRTR Liaison
Dorry Segev, MD	SRTR Liaison
Ciara J. Samana, MSPH	Committee Liaison
Wida S. Cherikh, PhD	Biostatistician
Maureen A. McBride, PhD	Director of Research
Darren E. Stewart, MS	Biostatistician
Mary D. Ellison, MHSA, PhD	UNOS Staff
Brian Shepard	UNOS Staff

**Attendance at the Meeting of the
OPTN/UNOS Kidney Transplantation Committee
March 21, 2011
Chicago, IL
Ken Andreoni, MD, Chair
John Friedewald, MD, Vice Chair**

Kenneth A. Andreoni, MD	Chair
John J. Friedewald, MD	Vice Chair
Richard N. Formica, Jr., MD	Regional Rep. Reg. 1
Shamkant P. Mulgaonkar, MD	Regional Rep. Reg. 2
Ari J. Cohen, MD	Regional Rep. Reg. 3
Bernard V. Fischbach, MD	Regional Rep. Reg. 4
William I. Bry, MD	Regional Rep. Reg. 5
Viken Douzajian, MD	Regional Rep. Reg. 6
Mikel Prieto, MD	Regional Rep. Reg. 7
Alexander Wiseman, MD	Regional Rep. Reg. 8
Lloyd E. Ratner, MD	Regional Rep. Reg. 9
Mark I. Aeder, MD	Regional Rep. Reg. 10
Douglas S. Keith, MD	Regional Rep. Reg. 11
Eileen D. Brewer, MD	At Large
Harold J. Fassnacht, JD	At Large
Oscar H. Grandas, MD	At Large
Erica L. Hartmann, MD	At Large
Dixon B. Kaufman, MD, PhD	At Large
Karen Kennedy, RN, CPTC	At Large
Patricia M. McDonough, RN, CPTC, CCTC	At Large
Stephen C. Rayhill, MD	At Large
Nancy L. Reinsmoen, PhD, D(ABHI)	At Large
Sharon E. Swofford, MA, RN, CNN, CCTC	At Large
David E. Burgio, MPA, LFACHE	Visiting Board Member
John C. Hodges, MA	Visiting Board Member
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James S. Bowman III, MD*	Ex. Officio
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Christopher J. McLaughlin*	Ex Officio
Adrine Chung*	SRTR Liaison
Jon Snyder	SRTR Liaison
Dorry Segev, MD	SRTR Liaison
Ciara J. Samana, MSPH	Committee Liaison
Wida S. Cherikh, PhD*	Biostatistician
Maureen A. McBride, Ph.D*	Director of Research
Darren E. Stewart, MS	Biostatistician

**Denotes participation by phone*

**Attendance at the Meeting of the
OPTN/UNOS Kidney Transplantation Committee
May 13, 2011
Teleconference
Ken Andreoni, MD, Chair
John Friedewald, MD, Vice Chair**

Richard N. Formica, Jr., MD	Regional Rep. Reg. 1
Shamkant P. Mulgaonkar, MD	Regional Rep. Reg. 2
Ari J. Cohen, MD	Regional Rep. Reg. 3
William I. Bry, MD	Regional Rep. Reg. 5
Mikel Prieto, MD	Regional Rep. Reg. 7
Alexander Wiseman, MD	Regional Rep. Reg. 8
Mark I. Aeder, MD	Regional Rep. Reg. 10
Harold J. Fassnacht, JD	At Large
Oscar H. Grandas, MD	At Large
Stephen C. Rayhill, MD	At Large
Sharon E. Swofford, MA, RN, CNN, CCTC	At Large
John C. Hodges, MA	Visiting Board Member
James S. Bowman, III, MD	Ex. Officio
Monica Lin, PhD	Ex Officio
Ba Lin, MS, MPH	Ex Officio
Christopher J. McLaughlin	Ex Officio
Jon Snyder	SRTR Liaison
Ciara J. Samana, MSPH	Committee Liaison
Wida S. Cherikh, PhD	Biostatistician
Kerrie Cobb	Support Staff
Darren E. Stewart, MS	Biostatistician