OPTN/UNOS Kidney Transplantation Committee Meeting
Report to the Board of Directors
November 8-9, 2010
Saint Louis, Missouri

Summary

I. Action Items for Board Consideration

- The Board is asked to consider a proposal to include donor chains into the Kidney Paired Donation Pilot Program. (Item 1, Page 3)

II. Other Significant Items

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Kenneth Andreoni, MD, Chair
John Friedewald, MD, Vice Chair

I. Action Items for Board Consideration

1. Inclusion of Donor Chains in the Kidney Paired Donation Pilot Program

John Friedewald, MD, Chair of the Kidney Paired Donation (KPD) Work Group, presented the Group's progress on the KPD Pilot Program **(Exhibit A)**. A resource assessment and impact statement for this program is attached as **(Exhibit B)**. Dr. Friedewald explained that both the implementation of the Kidney Paired Donation Pilot Program (KPDPP or Pilot) and the policy development associated with the KPDPP have multiple phases. The Manual Solution is limited in scope and utilizes coordinating centers to keep logistics manageable. The Manual Solution is not integrated with UNet^{SM}. The Automated Solution will be open to any program approved to perform living donor kidney transplants and it will be integrated with UNet^{SM}. Both the Manual and Automated Solutions are a part of the Pilot Program. The purpose of the pilot is to test KPD on a national scale. The mechanism to be able to achieve a national system is integration with UNet^{SM}. Moving from a pilot to a non-pilot system is purely based on the policy development related to KPD.

Dr. Friedewald also explained how centers participate in the Pilot Program. Their participation is contractual. The contract includes guidelines that reflect the Living Donor resource documents for medical evaluation (including psycho-social evaluation) and informed consent. If guidelines are not followed, then the offending center will receive a referral to MPSC to drop the program from the Pilot. Since there are no OPTN policies requiring compliance with KPDPP guidelines, no other adverse actions are possible from MPSC.

At the request of HRSA, the OPTN is developing interim policies for the pilot program. These interim policies would allow for full MPSC action in the case of noncompliance. The Work Group is currently converting the contract requirements into interim policies. These interim policies would only apply to participants in the Pilot Program initially.

Final policies for participation in the ultimate OPTN KPD program will be developed following the Pilot. According to HRSA the final OPTN KPD policies may apply to all KPD programs, not just to participants in the one administered by the OPTN.

The phases of policy development for KPD are as follows:

- **Phase 1:** Operational guidelines and contracts (complete)

- **Phase 2: Interim policy (adaptation of Operational Guidelines to allow sanctions and adverse actions)**

- **Phase 3: Permanent policy (anticipated at the end of the Pilot, may apply to all KPD programs)**

There are currently, four coordinating centers participating in the Pilot Program: Alliance for Paired Donation, Johns Hopkins Hospital, New England Program for Kidney Exchange (NEPKE), and UCLA Medical Center/ California Pacific Medical Center. These coordinating centers represent 77 participating centers from all 11 regions. The coordinating centers are in the process of entering pair data and the first match run is expected on October 1, 2010.

Dr. Friedewald explained that the KPD Work Group Includes representation from many Committees and existing KPD systems. The following committees will serve as sponsors and are responsible for reviewing any proposals: Kidney Transplantation Committee, Living Donor Committee, and the Patient Affairs Committee. The proposed policy development process is following this basic pathway:

1) KPD Work Group Drafts Policy

2) Committee Review and Feedback

3) KPD Work Group Revisions and Recommendation to Kidney Committee

4) Kidney Committee Review and Vote

5) Public Comment

6) KPD Work Group Review and Revisions

7) Committee Review and Feedback

8) KPD Work Group Revisions and Recommendation to Kidney Committee

9) Kidney Committee Review and Vote

10) Board Consideration

The KPD Work Group last met on April 26, 2010. The roster includes 4 representatives from the Living Donor Committee and 4 living donors (a total of 6 people due to overlap in descriptions). The Work Group has three subcommittees including the Donor Chains Subcommittee which is charged with finalizing the proposal on whether to include non-directed donors and donor chains in the KPDPP; the Interim Policy Subcommittee which is charged with converting the KPDPP Operational Guidelines into interim policy for KPD; and the Financial Subcommittee which is charged with addressing financial and administrative barriers to KPD including reimbursement, payer relations, and contracts.

Dr. Friedewald asked the Committee to consider modifications to the Donor Chains Proposal that was circulated for public comment in 2009. He described the modifications that were made in response to feedback received during the public comment process. The proposal no longer utilizes the terms open and closed chains. The chain size will be limited to twenty incompatible pairs or less and chains can involve multiple hospitals. All donor surgeries must occur at the same time within a given segment but the centers involved in the chain can decide how many segments the chain will have and where the segments will break. In cases where surgeries are not simultaneous, the candidate must receive a transplant before his or her intended donor donates. A chain will end with a donation to a candidate on the deceased

donor waiting list. The final donor in the chain will donate to a candidate on the waiting list at the center in the same region who has entered the most non directed donors (NDDs) without an equal number of chains ending at the center (i.e., the number of NDDs entered – the number of chains ending with a candidate on that center's waiting list).

If there are two centers in a region with the same number, then the chain will end at the center that is closest in proximity to the donor's home center. If there are no centers in the region that have entered NDDs without an number of chains ending at the center, then the final donor will donate to a candidate on the deceased donor waiting list at his or her home center (the center that entered the living donor in the OPTN KPD Pilot Program). There are no required characteristics (e.g., blood type) for the living donor kidney that is sent to the deceased donor list. However, a deceased donor will not be used to start chains in the KPD Pilot Program at this time. If a transplant center or a pair is unwilling to participate in a non-simultaneous chain (i.e., one that may be broken into segments with quasi-bridge donors), they will only be matched in two-way or three-way matches.

Finally, the points system for chains is based on the 200 points value for a match between two incompatible pairs (100 points for each candidate from an incompatible pair who is transplanted) approved in the 2008 KPD proposal. 100 points will be assigned for points for each candidate from an incompatible pair who is transplanted as part of that chain. The waiting list candidate will be assigned no points.

The Committee discussed whether the changes would be acceptable modifications to the proposal. Some on the Committee remarked that these changes were necessary and appropriate for keeping the OPTN KPD program at the same level of innovation as existing KPD programs. The Committee ultimately decided to charge the KPD Work Group with finalizing the proposal and, barring any substantive changes, agreed to send the proposal to the Board of Directors for consideration with the following resolution:

> ****RESOLVED that the proposal to include chains in the Kidney Paired Donation Pilot Program described in (Exhibit A) is hereby approved pending programming and notice to members.**
>
> 23 in favor, 0 opposed, 0 abstaining

After the Committee meeting, the Living Donor Committee met and reviewed the proposal. While the Living Donor Committee plans to request additional work to improve follow-up and safety of living donors, it ultimately approved of the proposal with a vote of 23 in favor and 3 opposed.

II. Other Significant Items

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

Kenneth Andreoni, MD, Committee Chair, reviewed progress since the last meeting to develop a new, national kidney allocation system. During its February 2010 meeting, the Committee voted to send a proposal out for public comment. The proposal included the concepts of age matching for the majority of available kidneys, and survival matching for the remaining kidneys. The Committee presented its proposal to the Executive Committee during the spring of 2010. The Executive Committee recommended that instead of a public comment proposal, (since the Committee was not yet at the stage of a formal policy proposal), the Committee instead circulate a document describing the high-level concepts on which it intended to base a new kidney allocation system. A subcommittee drafted a concept document and is currently awaiting review of a communications plan for the document by representatives of HRSA. In the interim, the Committee has shared an advance copy of the concept document with the leadership of the American Society of Transplantation, The American Society of Transplant Surgeons, NATCO, and the Association of Organ Procurement Organizations.

While the Committee is awaiting release of the concept document, it is proceeding on several other fronts to develop the details for the system. Among its efforts, the Committee will consider how candidates should be ordered within the broad classifications, how variances will be handled in the new system, and how to transition existing candidates into a new system. To accomplish this work, the Committee established a number of subcommittees. Below is a list of the subcommittees with their respective charges. Each subcommittee is expected to fulfill its charge before the full Committee meets in December 2010.

- Rank Ordering Subcommittee: Evaluate current points and determine if any elements should be added/eliminated. Additionally, evaluate methodology for awarding points and propose revisions to better standardize priority across DSAs.

- Variance Review Subcommittee: Using the criteria stipulated in the OPTN Final Rule and OPTN policies, review each of the variances to kidney allocation. For each variance, determine whether to incorporate into the revised national system, to dissolve, or to continue as a local variance.

- Histocompatibility Subcommittee: Examine possible methods for improving access to moderately and highly sensitized candidates. Possible solutions should include changes to allocation (e.g., through a sliding scale for CPRA) and changes to distribution (e.g., increasing the local distribution unit for sensitized candidates).

- Kidney Donor Profile Index (KDPI) Implementation Subcommittee: Answer technical questions during the implementation of KDPI (all phases), develop supplemental materials for education of transplant professionals and general public.

- Pediatric Subcommittee: Determine if there is a KDPI threshold that similarly accomplishes the goal of expeditious transplantation for pediatric candidates as the current age threshold. Additionally, the subcommittee will examine possible solutions for improving access to transplant for sensitized pediatric candidates.

- Simultaneous Liver Kidney Subcommittee Charge: Determine minimum listing criteria for simultaneous-liver kidney (SLK) candidates.

Dr. Andreoni also reported that the Committee's proposal to incorporate KDPI into DonorNet® ahead of an allocation system overhaul was approved by the Board of Directors in June 2010. Work is underway on the first phase of this project to place a KDPI calculator on the OPTN website. Additionally, the Committee is working with Marc Melcher, MD, to develop an application that would allow KDPI to be calculated on iPhones and other hand held devices.

3. **Response to the Proposal for a New, National Pancreas Allocation System**
The Kidney Transplantation Committee reviewed its previously drafted response **(Exhibit C)** to the proposed pancreas allocation system. Some members of the Committee remained concerned that the BMI threshold of 30 would cause a substantial increase in the number of simultaneous pancreas kidney (SPK) transplants. Others on the Committee were less concerned about this potential outcome because SPK transplantation carries a substantial mortality and morbidity risk. In their view, it is unlikely that a surgeon would attempt to "game" the system by providing an SPK transplant to a candidate with type 2 diabetes only for the purpose of shortening the candidate's waiting time. Members of the Committee were not able to specify a BMI threshold that would permit access for candidates with type 2 diabetes that is phenotypically like type 1. Some on the Committee remarked that they were reluctant to support the proposed BMI of 30 only because OPTN policy changes are very arduous to implement and require quite a bit of time. The concern is that if the number of SPK transplants for candidates with type 2 diabetes balloons,the time required to remedy the situation through the policy development process will take years. The Committee expressed interest in a contingency plan that would allow for the BMI threshold to be modified in real time based on the number of SPK transplants for candidates with type 2 diabetes.

4. **Review of proposed clinical and administrative kidney scorecards**
Amy Putnam, of the UNOS Department of Evaluation and Quality, presented a request from the Membership and Professional Standards Committee (MPSC) regarding proposed scorecards for kidney transplant programs. Currently, kidney programs are reviewed subjectively by the MPSC for clinical and administrative policy compliance. At its July meeting, the MPSC asked for input from the Kidney Transplantation Committee before approving these scorecards **(Exhibit D).**

Ms. Putnam described the site survey process and how kidney transplant programs are currently assessed. While heart, lung, and liver transplant programs have been assessed with similar scorecards since 2005, kidney programs have been assessed subjectively. The Heart, Liver, Lung and OPO Compliance Scorecards are a numerical measure of compliance with OPTN Policies to improve consistency within the MPSC review process. The scorecards are comprised of two categories that represent compliance with clinical and administrative policies. Ms. Putnam shared the following proposed elements for the kidney program clinical score (Table 1).

Metrics	Weight
Non-transplanted listings	30
Transplanted listings	40
ABO typing prior to listing	15
Verification of Donor ABO Compatability prior to implantation	15
Total	100

Table 1: Proposed elements for kidney program clinical scorecard

Ms. Putnam explained how the scorecards would be used. Scorecards are only reported to the member and the MPSC. A numerical method is to compare programs compliance with clinical and administrative policies. Scores are protected under Confidential Medical Peer Review and are not published or released to any other entities.

The Kidney Transplantation Committee agreed that the current scorecards are an improvement over the current assessment approach and should be utilized going forward.

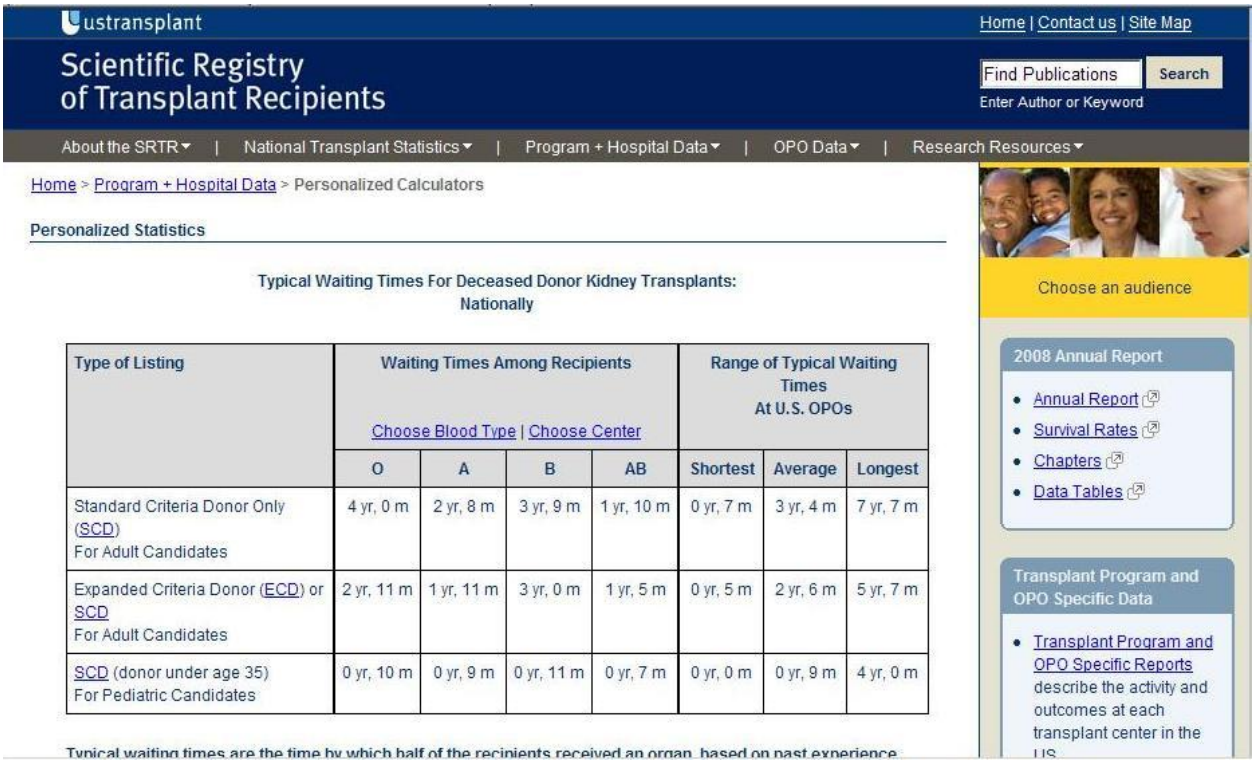
5. **Recommendations to CMS regarding transplant referrals from dialysis centers**
At the request of the Executive Committee, the Kidney Transplantation Committee reviewed a draft response to the Centers for Medicare and Medicaid Services (CMS) regarding metrics for a quality initiative program **(Exhibit E).** Under this program, reimbursement for dialysis centers would be partly based on how those centers achieve certain performance goals. Implementation of the program is slated for January 2012. As part of the program, the Executive Committee may suggest an additional standard for assessing appropriate referrals to kidney transplant.

The Committee discussed the possible benefits and risks of such a recommendation. It is understood that referral rates for kidney transplantation vary widely between dialysis centers. The Committee discussed unintended consequences of this recommendation including the possibility for overwhelming some transplant centers' resources with requests to evaluate many more dialysis patients than currently. One member of the Committee remarked that any metric should specify referral rates for patients who are medically suitable for transplant. Wasting resources to evaluate patients who are unlikely to benefit from transplant or who have contraindications to transplant would be an unfortunate consequence of a recommendation that rewards referral of all patients. Another Committee member remarked that the recommendation should also include an element of patient education so that medically suitable patients can make an informed decision about whether to pursue transplant.

Overall, the Committee determined that it supports the language in the draft letter and believes that utilizing referral to transplant for medically suitable dialysis patients is appropriate. As the details are worked out on the metrics, the Committee would urge CMS to consult with nephrology experts to develop effective standards.

6. **Review of Survival Calculator**

Keith McCullough, of the Scientific Registry of Transplant Recipients, presented his work to develop a survival calculator as requested by the Kidney Transplantation Committee during its prior meetings. In the calculator, an individual could select a transplant center and a blood type and view waiting times among recipients at area transplant centers. Additionally, the user could compare these waiting times against national data.



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Scientific Registry of Transplant Recipients

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Personalized Statistics

Typical Waiting Times For Deceased Donor Kidney Transplants: Nationally

Type of Listing	Waiting Times Among Recipients (Choose Blood Type | Choose Center)				Range of Typical Waiting Times At U.S. OPOs		
	O	A	B	AB	Shortest	Average	Longest
Standard Criteria Donor Only (SCD) For Adult Candidates	4 yr, 0 m	2 yr, 8 m	3 yr, 9 m	1 yr, 10 m	0 yr, 7 m	3 yr, 4 m	7 yr, 7 m
Expanded Criteria Donor (ECD) or SCD For Adult Candidates	2 yr, 11 m	1 yr, 11 m	3 yr, 0 m	1 yr, 5 m	0 yr, 5 m	2 yr, 6 m	5 yr, 7 m
SCD (donor under age 35) For Pediatric Candidates	0 yr, 10 m	0 yr, 9 m	0 yr, 11 m	0 yr, 7 m	0 yr, 0 m	0 yr, 9 m	4 yr, 0 m

Typical waiting times are the time by which half of the recipients received an organ, based on past experience

Choose an audience

2008 Annual Report

- Annual Report
- Survival Rates
- Chapters
- Data Tables

Transplant Program and OPO Specific Data

- Transplant Program and OPO Specific Reports describe the activity and outcomes at each transplant center in the US

In response, some on the Committee were concerned about the way that data are presented in this calculator. For one, showing waiting times among recipients can be fundamentally misleading. As one member explained, if a center has 100 candidates listed and transplants 10 candidates within one week but the rest never receive a transplant, then the center's waiting time would be displayed as one week. A few members were very concerned that the data presented in the calculator would lead to decision making based on incomplete or misleading information.

The Committee did not believe that the calculator fulfilled its earlier request to be able to compare survival data across various treatment modalities (e.g., dialysis, transplant from a deceased donor, and transplant from a living donor). Some on the Committee reiterated the importance of having a survival calculator for the purposes of counseling patients who are making treatment decisions. The KDPI Implementation Subcommittee will work with the SRTR to redefine this project before the next Committee meeting.

Attendance
OPTN/UNOS Kidney Transplantation Committee Meeting
August 30, 2010
Chicago, Illinois

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 Douzdjian, 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
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
Peter G. Stock, MD, PhD	Ex. Officio
Monica Lin, PhD *	Ex Officio
Keith McCullough, MD	SRTR Liaison
Alan Leichtman, MD	SRTR Liaison
Ciara J. Samana MSPH	Committee Liaison
Brian Shepard	UNOS Director of Policy
Wida Cherikh, PhD	UNOS Biostatistician
Darren Stewart, MS	UNOS Biostatistician
Maureen McBride, PhD	UNOS Director of Policy
Mary D. Ellison, PhD, MHSA	UNOS Assistant Executive Director

**participated by phone*