

**INTERIM REPORT OF THE  
OPTN/UNOS PEDIATRIC TRANSPLANTATION COMMITTEE**

**MARCH 6, 2008  
TELECONFERENCE/LIVE MEETING**

The OPTN/UNOS Pediatric Transplantation Committee met by teleconference on March 6, 2008, and considered the following items:

Update Regarding Kidney Allocation System (KAS) and How It Will Affect Pediatric Candidates

Dr. Peter Stock, Chair of the OPTN/UNOS Kidney Transplantation Committee, presented slides (**Exhibit A**) detailing the simulated changes to the kidney allocation system and how these changes are expected to affect pediatric candidates. After providing a brief progress update on the current status of this proposal, Dr. Stock outlined major proposal's components for adults including:

- Ranking candidates based upon objective medical criteria using Life Years From Transplant (LYFT)
- Replacing standard criteria donor (SCD) and expanded criteria donor (ECD) kidney designations with donor profile index (DPI)
- Changing from time since listing to time on dialysis (DT)
- These components (LYFT, DPI and DT) along with a candidate's sensitization level are combined into a kidney allocation score

In this new simulated allocation system, priority for pediatric candidates and prior living donors are maintained. While absolute priority for zero antigen mismatch offers will be eliminated for adults, a sliding scale priority for sensitized adults has been modeled. The kidney payback system is expected to be eliminated in this new allocation system.

Pediatric allocation is expected to continue utilizing waiting time (defined as time since listing) and points. Children will no longer compete with adults for zero antigen mismatch offers. The central difference between current and simulated allocation policy is that children will only receive offers for donors 35 years old and younger.

Dr. Stock posed several questions for the Pediatric Committee to consider:

- **Is there a need for pediatric access to donors < 35 years of age?**

Since the September 2005 implementation of Share 35, giving pediatric candidates priority on organ offers from donors < 35 years of age, only 2% of pediatric transplants (n=30) have been from donors older than 35. The Kidney Committee requested feedback from this Committee as to whether access to donors < 35 is necessary in the proposed system and/or whether access to these organs should be considered for highly sensitized pediatric candidates.

- **Should sensitization points be awarded to pediatric candidates on a sliding scale in the same manner that has been modeled for adults?**

Current policy awards four points to candidates with PRA > 80%. Candidates with a PRA < 80% do not receive any priority points. The simulated allocation policy would generate a sliding scale for priority so that even moderately sensitized candidates get improved access to organ offers.

➤ **Should pediatric priority be based upon DPI instead of donor age?**

DPI is a continuous measure which provides more clinical information than the current ECD and SCD categories about a donor's kidney. More information about an organ is expected to improve clinical decision making at the time of offer. Elements included in the DPI calculation are:

- Age
- Gender
- Race
- Height
- Weight
- Creatinine
- History of smoking
- Donor after cardiac death
- Hepatitis C virus
- History of hypertension
- History of diabetes
- Cause of death (i.e., anoxia, stroke, CNS tumor, other)

Would DPI be more indicative of donor quality than age for pediatric candidates? What analyses would be useful for assessing this?

Dr. Stock noted that age may not be the best measure to guarantee a quality kidney for pediatric transplant.

➤ **What is the effect of multi-organ allocation (especially the simultaneous kidney-pancreas (SPK) priority) on pediatric transplantation?**

Current policy allocates combined kidney-liver and combined kidney-heart according to the liver or heart match run. SPK allocation varies by donor service area. The Kidney Committee is currently working with the Liver and Intestinal Organ Transplantation Committee to establish criteria for liver-kidney allocation. The proposed allocation of SPK will have the kidney following the pancreas.

It was suggested that the Committee may want to discuss requesting at least one kidney from each > 35 year old donor be allocated to a child to prevent both kidneys from being utilized for multi-organ allocation in adults.

An OPO representative noted that current policy does not require sharing the second organ with a lifesaving organ, though it is suggested. Members noted that the choice between kidney and SPK allocation is not specifically directed in current policy, and OPOs have latitude in determining how they want to offer but isolated kidney, pancreas, or SPK. Kidneys are expected to follow the pancreas in the KAS simulation. SPK allocation is expected to follow pancreas

allocation policy. Dr. Stock noted that local SPK offers will be made before pediatric offers are extended in the simulated system.

The Kidney Committee is already working with the Liver and Intestinal Organ Transplantation Committee to establish criteria for combined liver-kidney allocation.

Dr. Stock reminded Committee members that pediatric candidates cannot be in the same allocation categories as adults because adults are expected to be allocated organs based on their kidney allocation score. Pediatric candidates will not utilize a kidney allocation score. (This is similar to current lung allocation for children  $\leq 11$  years of age as compared to adolescents and adults with lung allocation scores.)

Since the September 2005 implementation of Share B5, giving pediatric candidates priority on organ offers from donors  $\leq 35$  years of age, only 2% of pediatric transplants ( $n=30$ ) have been from donors older than 35. The Kidney Committee requested feedback from this Committee as to whether access to donors  $\geq 35$  is necessary in the proposed system and/or whether access to these organs should be considered for highly sensitized pediatric candidates.

A Kidney Working Group member questioned why zero antigen mismatch offers would no longer be made to adults as proposed in KAS. Dr. Stock explained that zero antigen mismatch offers for adults are not given absolute priority in the simulation because they are given biological priority within the LYFT calculation. Candidates with a PRA of 80% or greater will appear as local candidates on any donor match run nationally that is a zero antigen mismatch. With accurately defined donors, the frequency of kidneys available to these highly sensitized adult candidates is expected to increase without the impact of the current payback system.

In reviewing a number of simulated effects of implementing KAS, Dr. Stock noted that distribution of recipients by age indicated the 0-17 age group remained constant while the 18-34 age group rose from 18% under the current system, to 22% under the proposed system. The donor/recipient age correlation is expected to increase from 10.2% using the current system to 12.3% using the proposed system.

After Dr. Stock's presentation, the Committee decided to defer discussion of the list of questions outlined by him until the next Kidney Working Group call. Dr. Ruth McDonald noted the importance of keeping the one point priority for pediatric candidates  $\leq 11$  years of age as part of the new system. The Pediatric Committee is unaware of any plans to remove this point, but wants to ensure that this point remains. She also suggested allowing candidates listed at  $\leq 18$  years of age to maintain their absolute priority for zero antigen mismatch if they remain on the waiting list beyond their 18<sup>th</sup> birthday. These issues will also be discussed during this call, to be held before the April 24 full Committee meeting.

To prepare for these discussions, the Committee requested the following data for consideration when the Kidney Working Group reconvenes:

- Donor and recipient characteristics of the 28 candidates listed before age 18 that received kidneys from donors  $\geq 35$  since implementation of the Share B5 policy.
- DPI for all pediatric and adult deceased donor kidney alone transplants from 1-1-05 through 12-31-07 by the following characteristics:
  - PRA percent:  $\leq 10$ , 10-79,  $\geq 80$

- Primary transplant versus re-transplant
  - HLA-ABDR mismatch
  - Donor age 17, 18-34, >35
- Distribution of DDI in all deceased donor kidney alone transplants by donor age (<35 versus >35) in the last two years
  - Proportion of deceased donor transplants that are pediatrics and the corresponding DDI

The Working Group will consider this data as it formulates responses to the questions Dr. Stock outlined and then share their feedback with the Kidney Committee after final discussion at the April 24 full Pediatric Committee meeting in Chicago.

Review of Policies and Bylaws Currently Issued for Public Comment on February 8, 2008

The Committee reviewed the ten proposals out for public comment, and provided the following feedback during its March 6 teleconference:

1. Proposal to Limit Mandatory Sharing of Zero Antigen Mismatch Kidneys to Children and Sensitized Adult Candidates (*Modifications to Policy 5.3 (Mandatory Sharing of Zero Antigen Mismatch Kidneys)*) (Kidney Transplantation Committee)

After brief discussion, the Committee voted to support this proposal, noting that this change should be expected to benefit children waiting for a kidney. (Committee Vote: 16-0-0)

2. Proposal to Allow an Additional Method for Waiting Time Reinstatement for Pancreas Recipients (*Modifications to Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients)*) (Pancreas Transplantation Committee)

After discussion, the Committee determined there was no specific pediatric issue requiring further comment.

3. Proposal to Change the OPTN/UNOS Bylaws to Require Written Notification (or Disclosure) to Living Donors from the Recipient Transplant Programs (*Proposed Modifications to Appendix B, Section II, (F) "Patient Notification" of the OPTN Bylaws and Appendix B, Attachment, XIII, D (13) of the UNOS Bylaws*) (Living Donor Committee)

The Committee noted that while on the surface this appears to benefit patient safety, there appears to be little direction regarding how the collection of living donor data is to be managed. Adult living donors for pediatric recipients and paired exchanges were raised as examples where follow-up can be challenging. The proposal does not outline any requirements for follow-up in centers, most likely because it is unclear who pays for this extended care. Members noted that follow-up care for living donors is generally left to clinical judgment. Follow-up care is not paid for beyond a limited number of post-operative tests. As a result, members suggested that it will be difficult for centers to collect this data, leaving many as potentially non-compliant with policy.

The timing of sending contact information for living donors to report concerns or grievances to the OPTN was also questioned. Living donors are usually not feeling well and not focused on such information immediately after surgery. Members felt strongly that this information should be discussed and dispersed prior to donation.

Due to these substantial concerns, the Committee was uncomfortable with supporting this proposal. Members suggested that as written, it may not achieve the Living Donor Committee's desired goals and ultimately may create paperwork without changing outcomes. As a result, the Committee voted unanimously to oppose the proposal as written (Committee vote: 16-0-0).

4. Proposal to Change the OPTN/UNOS Bylaws: Restoration of Membership Privileges Following an Adverse Action (Proposed Changes to Appendix A, Section B.01A Paragraphs (1) and (3) and Section B.05A, Addition of Section B.07A) (Membership and Professional Standards Committee)

After discussion, the Committee agreed that the additions outlined in the proposal were reasonable. The Committee voted unanimously to support this proposal (Committee vote: 16-0-0).

5. Proposal to Change to Elector System for Histocompatibility Lab Members and Medical/Scientific Members: OPTN and UNOS Bylaws Article I, Sections 1.9 and 1.12; Article II, Section 2.2 and 2.4; Article VI, Section 6.1 (Membership and Professional Standards Committee)

After discussion, the Committee determined there was no specific pediatric issue requiring further comment.

6. Proposal to Change Organ Time Limits to Organ Offer Limits for Zero Antigen Mismatched Kidneys; Pancreata and Kidney/Pancreas Combinations (Modifications to Policy B.5.3.5 (Organ Offer Limit), Policy B.8.1.7.1 (Time Limit), and Policy 7.6.1.2 (Validation of Offers of Organs Placed through the Organ Center)) (Operations Committee)

After discussion, the Committee determined there was no specific pediatric issue requiring further comment.

7. Proposal to Require Transplant Centers to Inform Potential Recipients about Known High Risk Donor Behavior (Proposed Revisions to Policy 4.0 (Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Recipient Diseases or Medical Conditions, including Malignancies, of Donor Origin)) (Executive Committee)

After discussion, the Committee determined there was no specific pediatric issue requiring further comment.

8. Proposal to Change How 0-10 Year-Old Donor Livers and Combined Liver-Intestines are Allocated (Modifying Policies B.6 (Allocation of Livers) and B.11.4.2 (Combined Liver-Intestinal Organs from Donors 0-10 Years of Age)) (Pediatric and Liver and Intestinal Organ Transplantation Committees)

The Committee sponsored this proposal and will consider it in light of comments received at its April 24, 2008, meeting.

9. Proposal to Change Allocation of Pediatric Lungs and Allow Creation of a Stratified Allocation System for 0-11 Year-Old Candidates (Modifying Policies B.7.6.2 (Candidates Age 0-11), B.7.11 (Sequence of Adult Donor Lung Allocation) and B.7.11.1 (Sequence of Pediatric Donor Lung Allocation)) (Pediatric and Thoracic Organ Transplantation Committee)

The Committee sponsored this proposal and will consider it in light of comments received at its April 24, 2008, meeting.

10. Proposal to Allocate Pediatric Donor Hearts More Broadly (Modifying Policies B.7.5 (Allocation of Adolescent Donor Hearts to Pediatric Heart Candidates) and B.7.10.1 (Sequence of Adolescent Donor Heart Allocation)) (Pediatric and Thoracic Organ Transplantation Committee)

The Committee sponsored this proposal and will consider it in light of comments received at its April 24, 2008, meeting.

#### Review of Regional Meeting Slide Set to Present Pediatric Committee Proposals

In preparation for the upcoming regional meetings, Dr. Sweet reviewed a slide deck (**Exhibit B**) detailing the Committee's three proposals currently out for public comment with the Committee's regional representatives, regional administrators, and other interested committee members. Regional representatives will be responsible for sharing this information with their colleagues during these meetings and responding to questions that may arise.