

**Interim Report of the OPTN/UNOS Minority Affairs Committee Meeting  
Teleconference Call  
November 20, 2009**

**Henry Randall, MD, Chairman  
Silas P. Norman, MD, Vice Chairman**

Summary of the Meeting of the Board of Directors, November 16-17, 2009

The Committee was provided with the highlights of Board actions resulting from its meeting on November 16-17, 2009 in Orlando FL.

Update on Development of a New Kidney Allocation System - Oscar Grandas, MD, Kidney Committee liaison to the MAC Committee, provided the Committee with an update on development of a new kidney allocation system based on recent discussions by the Kidney Committee (**Exhibit A**). The Board of Directors directed the Kidney Committee to focus on allocating kidneys with the longest survival potential to candidates who can realize that potential. The feedback to the Kidney Committee was to avoid extreme mismatches, improve matching of donors and recipients and investigate other outcome metrics besides LYFT. As a result, the Kidney Committee is investigating prioritizing kidneys with the 20% best projected survival to candidates with the best projected survival within 15 years of the donor's age. They are also considering using post-transplant survival in a limited fashion in an allocation system instead of LYFT. The new system would:

- Allocate kidneys from the top 20% of DPI donors to candidates with the top 20% post transplant survival.
- Allocate kidneys from donors less than the age of 35 to candidates less than the age of 35.
- Allocate kidneys to candidates who are within 10 years of the donor's age.
- Allocate kidneys to candidates who are within 15 years of the donor's age; and
- Restrict kidneys from the top 20% of donors from going to the shortest lived 20% of candidates.
- Priority for pediatric candidates and prior living donors maintained
- Sliding scale priority for sensitized candidates
- Eliminate absolute priority for 0-ABDR mm to unsensitized candidates
- Eliminate kidney payback system
- Blood group A2 kidneys to B candidates with low anti-A titers
- SPK candidates given absolute priority over other kidney candidates since most have very high LYFT scores

The Committee was informed that the Kidney Committee is also collaborating with the Pancreas Committee, the Pediatric Committee and the Histocompatibility Committee in the development of the proposal. The Kidney Committee is currently reviewing assumptions used for simulation modeling and will test a system later this year. It was noted that policy development will continue into 2010.

During discussion, the Committee expressed some concern with regard to restricting the allocation of kidneys from donors to recipients within a certain age range due to the potential to disadvantage minority candidates, particularly African Americans, who tend to be waitlisted at a much younger age as compared to Caucasians. Members also noted that under the proposed system there will be two different allocation systems for adult and pediatric kidney allocation. In addition, there was a concern

expressed that some of the benefits for minority candidates may be lost in the proposed system as compared to the previous system incorporating LYFT. The Committee also discussed the proposed inclusion of cardiovascular risk (CVR) measures in the new system. Members commented that the current measures of CVR risk are not stable or accurate enough to accurately predict patient outcomes and as such are able to be manipulated. These concerns will be communicated back to the Kidney Committee.

Kidney Paired Donation (KPD) Update - Dr. Grandas also provided the Committee with an update on the status of the KPD pilot program. The Committee was informed that the project is on hold while the KPD Work Group, UNOS Leadership, and HRSA review the requirements of the program. They are specifically going to focus on what safeguards we have in place for living donors and whether the consequences for misconduct within KPD need to be codified in the bylaws.

#### MAC Public Education and Outreach Initiatives

*Update on MAC Dialysis Facility Public Comment Opinion/Outreach Survey* – The MAC has completed its survey of dialysis patients to collect baseline information on public perception of organ allocation policy and the public’s ability to provide input into the development of these policies. The purpose of the survey was to determine the overall level of understanding of organ allocation policy and awareness of public comment as well as identify barriers to the public comment process for all participants in transplantation, especially minority populations. The final survey results were presented by Dr. Randall at the OPTN/UNOS Board meeting in November.

Highlights of the study include the following:

- Nearly all patients were aware of transplantation (99%).
- 74% discussed transplant as an option with their physician.
- A low percentage of respondents (across all demographic categories) were aware of public comment (25%) but very few have participated in the process (2%).
- 76% were interested in expressing their opinion (but 23% did not know how to obtain a copy of the policies and 12% did not know how to express their opinions).
- Of those NOT interested in expressing their opinion (77% believed doctors were more qualified to make policy decisions and 23% did not believe their opinion would be taken seriously).

The results suggest the need for revisions and refinement of the public comment process and better education of patients with ESRD about organ allocation policy development. It was determined that the challenges with regard to patient education and outreach are multi-factorial and should involve a wide breadth of interventions across multiple communities (patient level, provider level, center level, and UNOS level interventions.) The committee is in the process of preparing a manuscript summarizing the results and discussing multi-level approaches to address the issue.

Kidney Referral Questionnaire: Preliminary Results – The Minority Affairs Committee has been interested in learning more about access to transplantation and best practices with respect to referring dialysis patients to the kidney waiting list for transplant. In August, the Committee launched an online survey to kidney transplant centers to determine practices that were used to ensure dialysis patients eligible for transplant were referred to the kidney waiting list. Charlotte Carroll, MS, provided the Committee with preliminary results from the survey (**Exhibit B**). The data show that:

- 50% of responders were surgical directors, and 32% were medical directors.

- Center sizes are distributed evenly across all size categories.
- The majority of responders are from Regions 4, 5, and 11.
- 92% of respondents monitor patient referrals.
- < 50% monitor the percentage of eligible patients referred.
- The most frequently used methods for determining eligibility for transplant are transplant physician review and nephrologists' review.
- 41% take no action if eligible patients are not referred, followed by other actions and letter to the nephrologist.
- The majority of patients are referred in < 6 months of dialysis or 1 – 2 years of dialysis (~ 23% each).
- Medical co-morbidities, other reasons, and patient unaware of transplant opportunity are the majority of reasons for delayed referral.
- 65% of respondents receive >150 referrals a year.
- On average over 50% responders felt that 75% -100% of referrals come in for evaluation.
- On average 50% of the kidney wait list for a center is Caucasian, 29% are African American, and 20% are Hispanic.
- Ethnic distribution of referrals is similar to ethnic distribution of patients on the wait list.
- Transplant centers use letters, brochures, and presentations to physicians and dialysis staff to enhance referrals.

MAC Review Article - To support the Committee objective to build upon the body of evidence to improve minority access to transplantation, the Committee has been charged by the OPTN president and leadership to continue its goal of preparing a paper for publication documenting the committees work in the area of OPTN policy on minority access to transplantation. The article will address issues of equity and utility in kidney allocation policy with regard to improving access to kidney transplantation presented from the historical perspective of the Minority Affairs Committee. A subcommittee of the full Committee has also submitted a manuscript focused on minority transplant outcomes which will be published in the American Journal of Transplantation as part of the Annual State of Transplantation.

#### Ongoing Review of CPRA

Phase I of the calculated PRA (CPRA) policy was implemented on December 5,2007. During this phase, centers are required to enter at least one unacceptable antigen in order for their highly sensitized patients (PRA >80%) to receive the additional 4 points to receive deceased donor kidney transplant. As of October 1, 2009, CPRA instead of PRA is used for allocation in the match run. Since this time, the MAC has viewed results of on-going Histocompatibility Committee analyses to monitor the policy by comparing CPRA and PRA by the old method. Charlotte Carroll, MS presented the Committee with updated results by ethnicity. **(Exhibit C)** The data show that:

- Over one third of the active registrations have CPRA values present.
- Concordance between match PRA and CPRA for registrations with PRA 80+% is 90% or higher across all races.
- Concordance between match PRA and CPRA for black registrations is comparable with concordance for other ethnicities.
- The distribution of Match PRA and CPRA for White and Black registrations are similar to the distribution for the overall active registration with PRA> 0 and CPRA>0.
- Fifty percent of the registrations have CPRA equal to or within 10% of Match PRA.
- Distribution of differences between CPRA and Match PRA are similar for all ethnicities.

## Access to Liver Transplantation

*Descriptive Data Analysis of Liver MELD/PELD Scores by Region, Age and Ethnicity* - The Committee was shown results of the waiting list and transplant MELD/PELD (M/P) by region at the July 14, 2009 meeting. The Committee requested the addition of wait list and transplant metrics to include age group and exception status. Charlotte Carroll, MS provided the Committee with liver waiting list death rates, the number of additions, and the number of transplants in different regions by MELD/ PELD (M/P) score and ethnicity (**Exhibit D**). The data show that:

- Adult registrations for Blacks have a higher median MELD score than Whites or Hispanics within region.
- Median MELD scores for Hispanics within region were very similar to white MELD scores.
- Distribution of MELD scores at transplant vary across regions, but not so much by race.
- Region 3 had the highest percentage of status 1 transplants when compared to the other regions.
- Transplants in MELD < 15 were mostly White.
- For the most part median MELD scores for white and black transplants were similar.
- Median MELD scores for Hispanics were similar to whites.
- Adult death rates decrease slightly by race, with White being the highest death rate and Other being the lowest death rate.
  - Adult transplant rates were similar across ethnicities.
  - Transplant rates vary by status across the regions.
  - Transplant rates for Whites are similar to Blacks within regions.

*Region 8 “Share 29” Liver Policy: Results from the Second Year* - The Share 29” liver policy was implemented in Region 8 on May 9, 2007. Under this allocation sequence, livers from adult donors would be shared regionally for adult and pediatric candidates with MELD/ PELD of 29 or greater. The MAC was presented with the preliminary results of the 1<sup>st</sup> year of this regional sharing at its meeting in March 2009. As in prior years, the data continues to indicate potential differences in access to the liver waiting list by ethnicity and by ethnicity within regions. The Committee requested to see updated information on 1) wait list death rates by candidate ethnicity, 2.) distribution of deceased donor transplants by MELD/PELD (M/P) score and recipient ethnicity, and 3.) Kaplan-Meier survival by recipient ethnicity after implementation of the “Share 29” policy in Region 8 (excluding registrations/ patients with exception points) (**Exhibit E**). Charlotte Carroll, MS presented the data to the Committee.

The data show that:

- Death rates remained relatively similar or seemed to go down for all ethnicities all status/score categories combined.
- Death rates for Status 1A/1B seemed to have decreased for whites, blacks, and other ethnic category.
- Death rates increased for all ethnicities in the M/P 15-28 group, with the exception of other ethnic category.
- Death rates in M/P 29+ seemed to have decreased for the Black and Hispanic populations, but increased in the white population.
- Median MELD/ PELD scores at transplant for all ethnicities were comparable before and after the implementation of the “Share 29” policy in Region 8.

- One year graft survival rates were not any worse across all ethnic groups after “Share 29” policy implementation.

*Draft Liver Referral Survey* – The Committee is developing a *Survey on Referral to the Liver Waitlist* to explore barriers to liver referral and wait listing for different ethnic groups. The initial online survey questionnaire will target transplant centers, and then another more specific questionnaire will target hepatologists and gastroenterologists through the use of newsletters and websites from the professional organizations and other relevant communication vehicles. During the meeting the Committee conducted a review of the draft questionnaire and determined that additional refinements to questionnaire were needed before the survey was distributed.

*Liver Forum and RFI* - The Committee was updated with regard to the Board approved resolution calling for a public forum on liver distribution to be held on the spring of 2010. Two subcommittees have been created to direct this work: a Public Forum Subcommittee and a Broader Distribution Subcommittee. The Committee was also informed that the Liver Committee plans to issue a Request for Information which will help frame the questions and concepts that will be considered at the forum.

#### Discussion of Public Comment Proposals Distributed on October 15, 2009 and November 13, 2009

Proposal to Improve the Variance Appeal Process - The Committee reviewed and discussed a policy proposal that would clarify how an OPTN member may appeal a variance decision and the role of the relevant committee and POC in the appeal process. The Committee determined that there was no minority impact resulting from the proposal.

After very brief discussion, Committee members participating on the call unanimously approved the proposal.

Proposal to Add a Valuable Consideration Disclosure to the Bylaws – The Committee reviewed and discussed a bylaw proposal requiring that transplant centers document that potential living organ donors be informed that the sale or purchase of human organs is a federal crime and that centers maintain this documentation as part of the patient’s medical record.

A member of the Committee expressed concern about the language included as part of the policy proposal. It was commented that the language was intimidating with regard to a center’s potential legal liability and seemed to place the burden on the center as far as proving that there was no advance knowledge of illegal activity between a donor and recipient. It was responded that the intent of the proposal was not be prescriptive, but incorporate a documentation requirement for this issue as part of the normal informed consent process. The member acknowledged that though there is no requirement in the proposal specifying how a transplant center should document the discussion, developing the procedure that should be followed to comply with the policy would still need to be approved by the legal counsel at the transplant center, which would not be a simple process.

A suggestion was made that UNOS develop a standard form for donor recipient pairs to sign indicating that they understand the law as it applies to human organ trafficking. It was noted that this would encourage uniformity and consistency in documentation, would address the issue from both sides, and make it easier for UNOS to audit compliance with the policy. Further, if UNOS were responsible for developing the documentation, it would more likely include the appropriate language to withstand scrutiny.

After additional discussion, the Committee determined that it supported the proposal in concept but recommended that uniformity be applied to the process with a standard form developed by UNOS to be signed by both the donor and recipient.

As such, Committee members participating on the call voted to disapprove the proposal as written.

Vote: 9 For, 4 Against, 0 Abstentions

#### OMB Forms Changes

The Committee was updated on the upcoming submission of changes to OPTN data collection forms through the process mandated by the federal government. The Committee was informed that it would have an opportunity to view the proposed changes when the information is submitted for public comment in the Spring of 2010.

#### OPTN Policy Rewrite Project

The Committee was informed of a plan in progress to translate all of the OPTN policies into plain language. UNOS has created a detailed plan to approach and implement the project. While the policies are being translated, other policy development activities will continue concurrently. The Committee was informed that there would be routine updates regarding the process for the Board and Executive leadership. There would also be targeted stakeholder communication to the transplant community, the Committees and Regions, as well as a dedicated page on the OPTN website to solicit feedback on the rewritten policies. The Committee was also informed that due to the administrative nature of the project, it will not be necessary for the rewritten policies to be subject to public comment.

Proposed New Pancreas Allocation Concepts - Due to time considerations, the Chairman deferred the presentation to the next Committee meeting at which time the concept proposal is expected to be available.

2009-2010 Committee Goals - The Committee was referred to its Committee goals for the 2009-2010 year as an informational item.