

**Interim Report of the OPTN/UNOS Minority Affairs Committee Meeting
March 23, 2010
O'Hare Hilton and Conference Center
Chicago, IL**

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

Update on Development of a New Kidney Allocation System

The Committee reviewed the most recent computer modeling simulations for a new kidney allocation scheme and discussed the path forward and timeline of distribution of the concepts proposed by the Kidney Transplantation Committee (**EXHIBIT A**). Keith McCullough, MS of the SRTR, presented the data to the Committee. The Committee was also presented with an overview of the path forward chosen by the Kidney Committee by Silas Norman, MD, Vice-Chairman of the MAC Committee.

The goals of the new kidney allocation system are to:

- Better match graft longevity and recipient longevity within biological reason and acceptable levels of accessibility
 - Foster graft survival
 - Minimize loss of potential functioning
 - Improve system efficiency and organ utilization
- Make comprehensive data better available to patients and transplant programs.
- Address differences in accessibility for populations described in the National Organ Transplant Act.

The framework of the system would be to:

- Utilize a kidney donor profile index (KDPI) to better characterize donor kidneys and to provide additional clinical information for patients and providers to consider during the transplant evaluation process and organ offer process.
- Allocate the majority of organs (80%) by age matching so that candidates within 15 years (older and younger) than the donor are prioritized.
- Allocate some kidneys (20%) by a kidney donor profile index (KPDPI) and estimated recipient post-transplant survival.

The timeline for public distribution of the proposed system would be as follows:

- A kidney allocation concept document is planned to be released in the Spring 2010.
- A proposal document incorporating feedback from the document would be finalized during the Summer/Fall 2010.
- A public comment proposal including the details of the policy and policy language would be released in the Fall of 2010
- The policy proposal would be revised based on public comment feedback during the Winter/Spring 2011

- A final proposal would be sent to the Board for consideration in June 2011

The Committee discussed the elements of the new allocation system as compared to the system previously considered. The Committee noted that the benefit to minority candidates would be similar to the previously proposed system. Committee members also observed that the same groups (older age candidates and older age diabetics) would receive less benefit under the system currently proposed as they would have under the previously proposed system. Further, it was commented that the new model using the 20% threshold could be perceived to be a less scientific, less accurate, and less defensible way of reaching the net benefit goal.

Kidney Paired Donation (KPD) Update

The Committee was provided with a brief update on the status of the KPD pilot program.

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.

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 suggested 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 has prepared a draft manuscript summarizing the results which is hoped to be published in the Summer of 2010. The Subcommittee will be reconvened to discuss additional ways in which the information might be distributed to dialysis patients to increase education and knowledge about transplantation and opportunities to comment on policies, including:

- Expanding patient outreach efforts

- Collaboration with other groups (dialysis companies, ESRD Networks, NKF, NATCO, ASMHTP, ASN, HRSA, CMS, etc.) as appropriate.
- Further refinement of the OPTN public comment process.

Collaboration with DaVita on Patient Education Efforts - The Committee was updated on ongoing discussions within UNOS to collaborate with DaVita to provide their dialysis patients with supplemental transplant related educational information. One of several proposed initiatives will be the publication of a feature entitled “Mythbusters” which will appear in the quarterly *DaVita Lifelines* newsletter. The article will present and refute myths about transplantation and donation commonly heard among dialysis patients. Because the MAC Committee has been very interested in finding ways to reach out to this patient population for some time, the Committee was encouraged to submit the ideas for these myths which would then be developed into articles authored by staff in the UNOS Communication Department.

Kidney Referral Questionnaire: Path Forward

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 transplantation. In August 2009, the Committee launched an online survey to kidney transplant centers to determine practices that were being used to ensure dialysis patients eligible for transplant were referred to the kidney waiting list. In November 2009, the Committee viewed preliminary results which showed that many centers are actively monitoring and attempting to stimulate referrals; though many centers do not currently have a process in place to do this.

- 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.

In March 2010, the Committee briefly revisited highlights of the survey results and discussed ways in which the information could be used, including:

- Analyzing survey results and data for trends (geographic differences, waiting list activity, ethnic composition, prevalence of disease, impact of the economy on minority donation rates etc.)
- Supplementing data with anecdotal information collected from individual regions/transplant centers.
- Disseminating results to support best practices for monitoring and stimulating referrals to the liver waiting list.

It was determined that the MAC Subcommittee on Referral to Kidney Transplantation would be reconvened to consider these and additional activities.

Geographic Variation in Access to Liver Transplantation

The Committee has been actively reviewing data on access to liver transplantation by OPTN region and recipient ethnicity. In July 2009, the Committee was shown results of the waiting list and transplant MELD/PELD (M/P) by region. In November 2009, the Committee viewed 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. The data showed that adult registrations for Blacks have a higher median MELD score than Whites or Hispanics within regions. Further, distribution of MELD scores at transplant vary across regions, but do not vary as much by race.

Diagnosis of Status 1 Liver Registrations/Transplants in Different Regions by Ethnicity and Age Group (Pediatric vs. Adult) - To obtain a better understanding of the differences of MELD/ PELD score and ethnicity across regions, the MAC requested to view results by age group (pediatric vs. adult) and separately for candidates/transplants with and without exceptions. As follow-up, the MAC requested to see diagnoses of registrations/ transplants by status.

At its meeting on March 2010, the Committee viewed data which showed that frequent diagnoses at listing do not seem to vary across regions for both the pediatric and adult cohorts. However, differences in diagnoses in the adult population across ethnicities are noticeable with Hispanic patients showing a higher percentage of registrations with Non-Cholestatic Cirrhosis and Black and Other patient populations showing higher percentages of registrations with a diagnosis of Acute Hepatic Necrosis (**EXHIBIT B**). Members suggested that there appears to be misreporting within diagnosis categories as many adult patients with acute hepatic necrosis and cirrhosis are incorrectly being included in the Status 1 category. For the July meeting, the Committee has requested to view an updated analysis with re-categorization of individual diagnoses included in the diagnosis categories.

Region 8 "Share 29" Liver Policy: Results from the Second Year - The MAC was presented with the preliminary results of the 1st year of the Share 29 policy 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. In November 2009, the Committee viewed updated information on wait list death rates by ethnicity, distribution of deceased donor transplants by MELD/PELD (M/P) score by ethnicity, and graft survival by recipient ethnicity following implementation of the "Share 29" policy in Region 8 (excluding registrations/ patients with exception points).

The data showed that death rates remained relatively stable or decreased for all ethnicities in all status/score categories combined following the Share 29" policy in Region 8. However, death rates increased for all ethnicities in the M/P 15-28 group, with the exception of the "Other" ethnic category.

Additionally, one year graft survival rates were no worse across all ethnic groups after “Share 29” policy implementation.

Liver Referral Survey

The Committee has been developing an online *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. Another more specific questionnaire will target hepatologists and gastroenterologists through newsletters and websites of professional organizations and other communication vehicles. The Subcommittee will be reconvened to finalize the questionnaire and determine the launch date and appropriate response period.

Discussion of Public Comment Proposals Distributed on March 5, 2010 and March 19, 2010

Proposed Modifications to Data Elements on Tiedi Forms – In March 2010, a MAC Data Forms Subcommittee reviewed the details of the OMB forms revision changes and presented its comments and recommendations to the group during the full Committee meeting. Committee feedback consisted of the following overall themes:

- Many data items are being proposed for addition, but their utility is questionable.
- There is a need to better define and clarify some of the proposed additions.
- Certain fields may not be appropriate to be collected by the OPTN, especially if being used primarily for research purposes.
- Travel for additional tests may be difficult for minorities who live in remote regions, and this may delay the wait listing of these patients.
- The additional testing required will increase costs to patients and may negatively impact minorities.
- The proposed data additions will significantly increase staffing resources and will be an additional burden to members.

Summary of Discussion of Liver Proposals – The Committee discussed the four liver proposals as a unit and provided the following feedback to the Liver Transplantation Committee.

The Minority Affairs Committee supports the concept of split liver transplantation but has significant concerns regarding adequate protection of the index patient. The Committee recommends that split liver transplantation should be performed only if the index patient is size unsuitable for a whole organ transplant. The Committee also supports the concept that the institution performing the split should retain the second portion of the liver for transplantation of a candidate on its own waiting list.

Further, if the proposal is approved, the Committee wishes to examine data before and after implementation of the ALU showing the impact on minorities from the patient safety perspective.

Proposal to Develop an Efficient, Uniform Pancreas Allocation System - The Committee viewed a presentation of the pancreas proposal by David Axeltod, MD, vice-Chair of the Pancreas Pancreas Transplantation Committee. After reviewing the data presented in the proposal, the Committee determined that there would be no net change in the distribution of pancreata among ethnic groups. The Committee did not identify a minority impact or other reason why the proposal should not proceed; however it declined a formal vote.

Proposal to Modify OPO and Transplant Center Requirements for Screening, Communicating and Reporting All Potential or Confirmed Donor-Related Disease and Malignancy Transmission Events - After brief presentation of the proposal, the Committee determined that there was no minority impact and declined a formal vote. However, the Committee noted that it supports appropriate reporting of information on all infectious diseases.

Proposal to Update HLA Equivalency Tables – The proposal was presented to the Committee by Karen Sullivan, Ph.D, of the Histocompatibility Committee. Following the presentation, the Committee discussed the possibility that minorities could be disadvantaged in OPO's unable to split antigens, though data was unavailable to prove this has occurred. The broader the antigen is defined the lower the likelihood of receiving organ offers. Therefore, the Committee believes that the proposal may have a beneficial impact on organ offers in areas with a high minority population, as minorities are more heterogeneous with regard to HLA.

Proposal to Require that Deceased donor HLA typing Be performed by DNA Methods and Identify Additional Antigens for Kidney, Kidney-Pancreas, and Pancreas Islet Offers - The proposal was presented to the Committee by Karen Sullivan, Ph.D, of the Histocompatibility Committee. After brief discussion, the Committee determined that it supports the Histocompatibility Committee in its efforts to standardize HLA typing and clean up reporting of split antigen HLA typing. The Committee is also very interested in examining the data following implementation to review for minority impacts.

Proposal for the Placement of Non-Directed Living Donor Kidneys - The Committee discussed the potential of the proposal to increase inappropriate bypassing of patients on the list versus the societal responsibility to the altruistic donor to make best use of the organ. The Committee also expressed concern about whether minorities would be more likely to be listed at Centers that do not have the infrastructure or resources to attract altruistic donors.

After brief discussion the MAC determine that it supported the policy proposal as written.

Proposal to Require Reporting of Non-Utilized and Redirected Living Donor Organs - After brief discussion, the Committee did not identify a minority impact with the proposal and voted to support the proposal as written.

OPTN Board and Committee Strategic Planning Activity

The Committee was updated on the OPTN/UNOS Board and Committee strategic planning activity held on March 1, 2010. The activity included the President and vice-President of the OPTN, Committee Chairs, Committee staff, and the SRTR. The purpose of the activity was to attempt to prioritize Committee activities within to help define the strategic direction for the Committees and the Board in the coming years. The Committee was informed that internal efforts were currently underway in preparation for meetings with the President and Executive Committee. The Committee requested to be updated as new developments arise.

MAC Submitted Priorities:

- (1) Issue findings from the MAC *Dialysis Facility Public Comment Opinion Survey* and publish as appropriate. Propose future actions on the part of the OPTN based on survey results.

- Educational efforts
- Patient outreach efforts
- Collaboration with other groups (Dialysis companies, ESRD Networks, NKF, NATCO, ASMHTP, ASN, HRSA, CMS, etc.) as appropriate.

(2) Review and analyze findings from the MAC Kidney and Liver Referral Surveys

- Disseminate survey findings as appropriate and supplement with available analytic and anecdotal data to identify and share best practices in improving referral and wait listing rates.
- Analyze survey results and data for trends (geographic differences, waiting list activity, ethnic composition, prevalence of disease, impact of the economy on minority donation rates etc.)
- Supplement with anecdotal information collected from individual regions/transplant centers.
- Disseminate results to support best practices for monitoring and stimulating referrals to the liver waiting list.

3) Provide input on minority population perspectives to other Committees as they develop policies aimed at reducing geographic/regional variation in access to transplantation.

Continue to examine issues related to geographic variation in liver allocation to determine potential reasons for differences in access to the liver waiting list by ethnicity and by ethnicity within regions.

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 Committee's work in the area of OPTN policy on minority access to transplantation. The article, *Addressing Issues of Equity and Utility to Enhance Access to Transplant: A Historical Perspective of the Minority Affairs Committee*, will examine OPTN policy development to improve access to transplantation for minorities over the last decade as seen from the eyes of the Minority Affairs Committee.

MAC Outcomes Article

A manuscript focused on minority transplant outcomes will be published in the American Journal of Transplantation (AJT) as part of the Annual State of Transplantation. The article includes original research provided by the SRTR using OPTN data and is authored by current and past committee chairs, members and SRTR staff. The article is expected to appear in the late Summer or early Fall issue of the AJT.