

**Interim Report of the Minority Affairs Committee Meeting**  
**LiveMeeting Teleconference Call**  
**November 27, 2012**  
**10-1 EST**

**Silas P. Norman, MD, Chairman**  
**Meelie Debroy, MD, Vice-Chairman**

1. Minority Affairs Committee Report to the OPTN Board of Directors, November 12-13 2012

The Minority Affairs Committee was updated on the following Board actions relevant to its work:

*Kidney Paired Donation*

- The Board approved formal policies for the KPD Pilot Program as a new Policy 13 (Kidney Paired Donation) and existing related OPTN Bylaws Appendix E.
- The Board also approved the inclusion of bridge donors in the KPD Pilot Program and related changes to Policy 13 (Kidney Paired Donation).

*Lung Allocation*

- The Board approved changes to Policies 3.7.6 (Lung Allocation) and 3.7.9.2 (Waiting Time Accrual for Lung Candidates Age 12 and Older Following Implementation of Lung Allocation Scores Described in Policy 3.7.6). The revisions include: 1) modifications to the covariates in the waiting list urgency and post-transplant survival models, coefficients of the covariates, and baseline waiting list and post-transplant survival rates used in the LAS calculation; and 2) revisions to the LAS system to prioritize candidates using data derived from a candidate population transplanted due to their LAS, instead of their waiting time.

*Liver Allocation*

- The Board considered but declined to approve changes to Policy 3.6.4.4 (F) (Extensions of HCC Exception Applications) that would have allowed transplant programs to voluntarily place candidates with stable or well-treated Hepatocellular carcinoma (HCC) in inactive status without losing accumulated exception points.

*Living Donation*

- The Board approved modifications to Policies 3.5.11.6 (Donation Status) and 12.9.3 (Priority on the Waiting List) to clarify the allocation priority assigned to prior living organ donors who later require a kidney transplant.
- The Board approved new Policy 12.8.3.1 (Living Kidney Donor Reporting Requirements); and modifications to Policies 7.2 (General Submission of Forms), 12.8.3 (Reporting Requirements), and 12.10 (Required Protocols for Kidney Recovery Hospitals) to establish minimum requirements for living kidney donor follow-up.

- The Board approved changes to Policies 12.2 (Informed Consent of Living Kidney Donors), 12.4 (Independent Donor Advocates), 12.7.10.1 (Vessel Recovery and Transplant), and 12.10 (Required Protocols for Kidney Recovery Hospitals) to establish policies for the informed consent of living kidney donors.
- The Board approved new Policies 12.3.3 (Psychosocial Evaluation of the Living Kidney Donor) and 12.3.4 (Medical Evaluation of the Kidney Living Donor); and modifications to Policy 12.10 (Required Protocols for Kidney Recovery Hospitals) to establish policies for the medical evaluation of living kidney donors.
- The Board approved changes to Policies 4.5 (Post-Transplant Reporting of Potential Transmission of Disease or Medical Conditions, Including Malignancies) and 12.2 (Informed Consent of Living Donors) to require reporting of unexpected potential and proven disease transmission involving living organ donors.
- The Board approved “Guidance for Reporting Potential Deceased and Living Donor-Derived Disease Transmission Events.” The Board approved “Guidance for Identifying Risk Factors for Mycobacterium tuberculosis (MTB) During the Evaluation of Potential Living Kidney Donors.”

#### *Other Board Actions*

- Based on concerns over potential conflicts with the OPTN Final Rule, the Policy Oversight Committee withdrew its proposed rewrite and consolidation of Policies 9 and 10 into a single Policy 9 (Release of Data), pending further review.
- The Board approved a resolution recognizing that the existing geographic disparity in allocation of organs for transplant is unacceptably high, and directing the organ-specific committees to define the measurement of fairness and any constraints for each organ system by June 30, 2013.

## 2. Committee Project Update

### *Educational Guidance on Patient Referral to Kidney Transplantation*

The Committee was provided with a historical overview and current status update on the project from Silas Norman, MD, Chairman and Deanna Parker, MPA, Liaison to the Committee. Data reviewed by the Committee since its existence has shown that minority patients experience significant delays in referral, wait listing and eventual transplantation as compared to their white counterparts. Furthermore, many patients who are appropriate for transplantation are never referred for transplant or are referred late in their disease progression. To better focus its work, the Committee combined several subcommittees to create a *Subcommittee on Education and Awareness of Transplant Options*. The purpose of the subcommittee was to develop an educational initiative aimed at improving patient referral to transplantation by helping to raise awareness among physicians, practitioners and their national societies about appropriate and timely patient referral to kidney transplantation. The overall goal of the initiative is to provide an opportunity for every medically eligible patient to be referred for transplant evaluation. The Committee is nearing completion of its educational guidelines on timely referral to kidney transplantation.

Key elements of the guidelines include:

- The default pathway for CKD and ESRD patients should be transplant referral
- Preemptive transplant is the goal and can only be achieved with “early” referral
- Education about transplant has to begin long before ESRD (Stage 3-4 CKD) to be most effective

The Committee was then provided with specific guidance and direction from OPTN leadership. The Committee was informed that the document has been reclassified as a “guidance document” rather than “guidelines” for consistency with other related OPTN/UNOS documents. The guidance document has been approved by the joint subcommittee and full Committee and has undergone internal review. A final review cycle will include review by constituent organizations outside of the traditional transplant community. The Committee is also seeking additional support in the form of a cosign arrangement or endorsement from a transplant related organization (ANNA, AMA, ACP, STSW, NKF, APN, ASN, KDOQUI, etc.) to assist the Committee in publicizing and disseminating the document. A number of volunteers were solicited to make personal contacts with key individuals in the above and related organizations to obtain additional reviews and formal support for the resource.

One suggestion for publicizing the document to audiences who would benefit included providing promotional materials and/or a PowerPoint presentation at national and local medical association meetings. A number of organizations were named and discussed. It was suggested that there may be more substantial impact from targeting local rather than national organizations. A member of the Committee also volunteered to publish the information in the document when finalized. The manuscript is planned to be developed outside of OPTN Committee activities with staff assistance. However, because the guidance document was created using OPTN contract funds, it will need to be posted on the OPTN web site in addition to suggested posting on the NKODOQI site. The Committee also agreed to aim for Board consideration and approval for the June Board meeting.

#### *Dialysis Facility Survey Manuscript*

The Committee was provided with a historical overview and current status update on the project from Silas Norman, MD, Chairman and Deanna Parker, MPA, Liaison to the Committee. In 2005, the Committee conducted a survey of ESRD patients in dialysis facilities to discern patient understanding about allocation policy and public comment; and learn patient preferences for receiving information. Overall, survey results show that both African Americans and Caucasians are not well informed about the OPTN public comment process, but that there is a desire among *all* dialysis patients to provide input into the development of allocation policy. However, survey results suggest that limitations in access to technology may be hampering dialysis patient participation in discussions about policy changes.

The Committee was informed that work revising the manuscript has been completed with a more streamlined format, new tables and discussion, and additional references. A final review by one of the primary authors is currently being undertaken, with Executive Committee review, and then HRSA review to follow. The Committee is planning a possible submission to the American Journal of Transplantation (AJT) in January.

### *Kidney and Liver Referral Survey Manuscript*

The Committee was provided with a historical overview and current status update on the project from Silas Norman, MD, Chairman and Deanna Parker, MPA, Liaison to the Committee. The Committee conducted a survey of kidney and liver transplant centers to analyze processes for monitoring and stimulating referrals to transplant evaluation. Survey results demonstrated a lack of oversight of the transplant referral process and a need for greater educational efforts to encourage and improve timely referral to transplantation. The Committee was informed that a draft manuscript summarizing the results of both surveys has been developed and is currently under review by the Research department. This review will consist of edits made to the manuscript as well as separating the paper into two articles, one focused on referral to kidney transplantation, and the other focused on referral to liver transplantation.

Following review by the OPTN Research Department, the manuscript will undergo additional review by OPTN leadership and then author assignments will be made. A subcommittee will then be convened for additional review and editing of the manuscript. Prior to journal submission, the paper will also undergo final HRSA review.

### *Survey on Referral to Heart Transplantation*

The Committee was provided with a historical overview and current status update on the project from Silas Norman, MD, Chairman and Deanna Parker, MPA, Liaison to the Committee. The MAC has proposed to conduct a survey on referral to Thoracic (heart) transplantation. The challenge facing the Committee has been identifying a captured population of patients with heart failure (denominator) in order to assess if potential candidates are not being referred. A small informal work group of the MAC consisting of Thoracic physicians and surgeons, met to discuss options for locating/building a data source of patients with heart failure to estimate the likely population of eligible heart transplant candidates.

The options proposed during the workgroup meeting were:

- The InterMacs Ventricular Assist Device (VAD) registry
- Source data from the study by Clyde Yancy, *Quality of Care of and Outcomes for African Americans Hospitalized With Heart Failure Findings From the OPTIMIZE-HF (Organized Program to Initiate Lifesaving Treatment in Hospitalized Patients With Heart Failure) Registry*.

During the Committee meeting, OPTN data was provided on the number and percent of adult heart alone transplants reported with a VAD at time of transplant. Between 1/1/2008 and 8/31/2012, 30% of adult heart transplants were reported with LVAD at transplant (40% for Status 1A and 23% for Status 1B) which showed that only about 30% of patients in the registry are going on to transplantation. Therefore, a large percentage of patients with end stage heart failure are not being captured on the VAD registry. Consequently, the Committee determined that the registry did not include sufficient patients to serve as a denominator for the purposes of the survey. As an alternative, the Committee began discussing a potential survey of the Heart Failure Society of America (HFSA) membership on its criteria for referral. It was noted that this would be out of scope for OPTN, and that

staff would need to discuss the recommendation with internal OPTN leadership prior to beginning any work.

#### *MAC Donor Conversion Education Project*

The Committee was provided with a historical overview and current status update on the project from Silas Norman, MD, Chairman and Deanna Parker, MPA, Liaison to the Committee. The Committee has been reviewing data on minority conversions by geography and ethnicity. The data show significant variation in donor conversions by ethnicity and DSA and other factors. The Committee is unable to determine the reasons for the variation using OPTN data. Patient level data would be needed.

The Committee is interested in indentifying all of the factors contributing to variations in donor conversions; particularly, any factors or barriers which may impact an eligible donor from progressing to an actual donor. However, problems identified by the Committee as affecting conversion rates are numerous and solutions may vary depending on many factors. A follow up goal would be to identify the best practices that OPOS in different donor service areas (DSA's) have developed to address these specific issues and then promote them with a possible consensus conference.

During the meeting, the Committee reviewed and provided additional information to supplement the development of a comprehensive listing of all factors which might prevent an eligible donor from being converted into an actual donor. The Committee decided to focus on deceased donor factors because these are used in the eligible death calculation. The factors were classified according to several major categories:

- Legal Factors
- OPO Factors
- Hospital Factors
- Donor Factors
- Public Attitudes
- Family Issues
- Religious/Cultural Factors
- Economic Factors

During discussion, the Committee acknowledged differences between OPOs in the possible successful resolution/handling of these issues. It was suggested that there is a need to focus on how these issues are resolved by different DSA's and the reasons for the variation focusing on the factors previously identified. The Committee hopes to measure and compare these in terms of their success and impact on improving conversions and then possibly partner with the NLC or other group in a consensus conference where OPOs would present solutions. It was determined that the list developed by the Committee should be forwarded to other organizations (Ex. OPOs using the communities of practice listserv, AOPO, the NLC/Donor Alliance, Donate Life, MOTTEP) for further refinement and classification of all of the categories.

#### *MAC Comprehensive Review Article*

The Committee was provided with a historical overview and current status update on the project from Silas Norman, MD, Chairman and Deanna Parker, MPA, Liaison to the

Committee. The MAC is planning to author a manuscript documenting Committee work developing and collaborating on UNOS policy proposals aimed at improving access to transplantation for minorities. Previous recommendations for focusing the paper have included the following:

1. A historical reflection (*then, now, and future*) and directions examination of OPTN policy changes; or;
2. Case study of the allocation policy process with a special focus on the evolution of a policy idea into OPTN policy.

Dr. Win Williams and Dr. Jerry McCauley, members on the MAC Committee, will serve as primary authors of the paper, with staff support provided by the OPTN in compiling historical background information and data analyses, in addition to helping to coordinate reviews, edits and submission of the final paper. As with the referral guidance manuscript, work conducted on the manuscript will be completed outside of the OPTN committee activities; with the Committee acknowledged in the paper. Following a review of the background information, the authors will determine a focus and path forward for the manuscript.

3. Review and Discussion of Public Comment Proposals Distributed September 21, 2012

The Committee reviewed the following proposals distributed for public comment:

**1. Proposal to Substantially Revise The National Kidney Allocation System (Kidney Transplantation Committee)**

The proposal seeks to substantially revise the national kidney allocation system to enhance post-transplant survival benefit, increase utilization of donated kidneys and increase transplant access for biologically disadvantaged candidates. The proposal incorporates new features such as an expanded definition of waiting time, a sliding scale for assigning points to sensitized patients, expanded access for blood type B candidates who can accept kidneys from subtypes of blood type A donors, broader sharing for extremely highly sensitized candidates, longevity matching of some kidneys, and regional sharing for kidneys with the highest risk of discard. The proposed changes are estimated to result in an additional 8,380 life years achieved annually from the current pool of deceased donor kidneys while improving access for sensitized candidates and minority candidates.

In August, the Committee reviewed the simulation results that served as the basis for the concepts outlined in the proposal. At that time, the Committee expressed some concern with regard to the diminished benefit to minority candidates shown in the chosen simulation run as compared to previous runs, as well as voicing a concern that the priority awarded for the highly sensitized may have a detrimental impact on transplants to pediatric candidates.

During the meeting, Pang-Yen Fan, MD, Minority Affairs Committee liaison to the Kidney Committee, presented the proposal to the Committee. Following the proposal presentation, the Committee inquired about the proposed timeline for implementation of the policy as well as planned educational efforts to communicate the changes to both providers and patients. Committee members emphasized the importance of developing educational materials and other aids to help in simplifying discussions with regard to the elements of the new policy, particularly at the patient level. One Committee member

inquired about the potential impact upon waiting times, particularly in large urban transplant centers with long waiting lists. It was responded that that there should be no negative impact to these centers resulting from the new policy. The regional distribution provided for in the policy was proposed to assist these transplant centers by allowing more efficient and expedient allocation of kidneys.

In its summary discussions, the MAC Committee acknowledged and commended the Kidney Committee for its nine year commitment to developing and vetting the concepts outlined in the proposal. The Committee continues to support the proposal in its stated goal of improving access to transplantation for minority candidates. The Committee particularly supports the inclusion of dialysis waiting time and the A2/A2B into B National Variance protocol in the policy, as these are elements that the Committee was integral in developing.

As a follow up to its concerns voiced at the previous meeting, the Committee specified that upon implementation of the policy, it should continue to be monitored for its impacts on special populations as described in the Final Rule (i.e., pediatric and minority candidates and the highly sensitized).

Committee vote: 15, 0, 0.

**2. Proposal to Require Reporting of Every Islet Infusion to the OPTN Contactor within 24 Hours of the Infusion (Pancreas Transplantation Committee)**

The goal of this proposal is to require the accurate and timely reporting of every islet infusion to the OPTN Contractor and to update language in policies and bylaws to reflect current practice for reporting islet infusions and outcomes information. Currently, islet Transplant Programs are not required to report every islet infusion to the OPTN Contractor. Therefore, it is possible that the OPTN Contractor may be unaware which islet recipients have received infusions, which could have implications for patient safety or disease transmission. This proposal:

1. Requires islet programs to report each islet infusion to the OPTN Contractor within 24 hours of the infusion, while still allowing islet candidates to retain their waiting time through three consecutive islet infusions.
2. Removes outdated requirements in the bylaws for submitting islet logs.
3. Adds language in the bylaws to reflect current programming for when an additional registration fee is generated after an islet candidate is removed from the waiting list for transplant and immediately re-registered for another infusion.

Bob Carrico, Ph.D, UNOS Biostatistician, Research Liaison to Pancreas Committee, presented the proposal to the Committee. After brief discussion, the Committee determined that there were no inherent minority impact as a result of the proposal and declined a formal vote.

**3. Proposal to Remove the OPTN Bylaw for the Combined Heart-Lung Transplant Program Designation (Thoracic Organ Transplantation and Membership and Professional Standards Committees (MPSC))**

The proposed change removes an OPTN bylaw for designating a single combined heart-lung transplant program. There are no such bylaws for designating other single combined organ transplant programs.

A combined heart-lung transplant program must concurrently have both an approved heart transplant program and an approved lung transplant program. The requirement needlessly burdens the transplant hospital to obtain approval for an additional organ transplant program designation to transplant organs for which the transplant hospital has already been approved. Aside from submitting often duplicative key personnel information, there are no additional requirements a transplant program must meet in order to qualify for the designation. The combined heart-lung transplant program designation also creates unnecessary programming work for the OPTN Contractor.

Following brief discussion, the committee did not determine an inherent minority impact resulting from the proposal and declined a formal vote.

#### **4. Proposal to Change the Composition of the OPTN Finance Committee (Executive Committee)**

To improve the efficient management of the OPTN, this proposal recommends changing the composition of the OPTN Finance Committee so that it consists of members of the OPTN Board of Directors. Currently, the OPTN Finance Committee is a permanent standing committee with regional and at-large appointments, and it reports to the OPTN Board of Directors. For most organizations, financial governance begins with a finance committee that resides at the board level.

Following brief discussion, the committee did not determine an inherent minority impact resulting from the proposal and declined a formal vote.

#### **5. Proposal to Change the OPTN/UNOS Bylaws to Better Define Notification Requirements for Periods of Functional Inactivity (Membership and Professional Standards Committee (MPSC))**

The purpose of this proposal is to better define the notification requirements for periods of functional inactivity. Currently, the Bylaws do not clearly outline the actions a Member must take when it becomes functionally inactive. This Bylaw proposal clarifies the current notification requirements for functional inactivity by including specific requirements for notification of functional inactivity, including waiting list inactivation in UNet<sup>sm</sup>. These modifications also specify what a member must do in terms of notifying patients when a program voluntarily ceases performing a specific type of transplant.

Following brief discussion, the committee did not determine an inherent minority impact resulting from the proposal and declined a formal vote.

**6. Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions (Organ Procurement Organization (OPO) Committee)**

The proposed changes clarify the data collection definitions for determining whether a death can be classified as “imminent” or “eligible.” OPOs must classify a death as one of the following: Imminent Neurologic Death (“imminent”), Eligible Death (“eligible”), or neither “eligible” nor “imminent” (“neither”). The OPOs then report the “imminent” and “eligible” deaths to the OPTN. Because OPOs interpret reporting definitions differently and because brain death laws vary from state to state, OPOs are inconsistent in the way they report death data.

The changes proposed by the Committee eliminate multi-system organ failure (MSOF) as an exclusionary criterion for classifying a death as “eligible” and add a list of organ-specific exclusionary criteria to give OPOs more guidance. The Committee also changed the definition of “imminent” to restrict it to those deaths that would most likely be classified as “eligible” had brain death been legally declared. This change could allow the combination of “eligible” and “imminent” deaths to mitigate the effect of the variation in brain death laws.

Following brief discussion, the committee did not determine an inherent minority impact resulting from the proposal and declined a formal vote.

**ATTENDANCE FOR THE NOVEMBER 27, 2012**

**OPTN/UNOS MINORITY AFFAIRS COMMITTEE**

**LIVEMEETING® TELECONFERENCE CALL**

<b>Committee Members</b>	<b>Position</b>	<b>In Attendance</b>
Silas P. Norman, MD	Chair	Yes
Meelie A. Debroy, MD	Vice-Chair	Yes
Amy Tien, MD	Region 1 Representative	No
Sylvia E. Rosas, MD	Region 2 Representative	Yes
Yma Waugh, MBA	Region 3 Representative	No
Terrie L. Boyd, RN, MSN, CCM	Region 4 Representative	Yes
Dorothy Rocha, MSW, LCSW	Region 5 Representative	Yes
Nidyanandh Vavidel, MD	Region 6 Representative	Yes
Patty S. Rees, RN, BSN, CCTC	Region 7 Representative	Yes
Antonio Sanchez, MD	Region 8 Representative	Yes
Karen A. Gans, RN	Region 9 Representative	No
Asif A. Sharfuddin, MD	Region 10 Representative	Yes
Kelly C. McCants, MD	Region 11 Representative	Yes
Remonia A. Chapman, MD	At-Large	Yes
Pang-Yen Fan, MD	At-Large	Yes
Mohamed A. Hassan, MD	At-Large	Yes
Julie Houp	At-Large	No
Bruce A. King, MSW	At-Large	Yes
Rosaline Rhoden, MPH	At-Large	Yes
M. Christina Smith, MD	At Large	No
Winfred W. Williams, MD	At-Large	No
Jerry McCauley, MD	At-Large	Yes
Mesmin Germain, MBA, MPH	Ex-Officio, HRSA	
<b>UNOS Staff</b>		
Deanna L. Parker, MPA	Committee Liaison/Policy Analyst	Yes
Wida Cherikh, PhD	Sr. Research Biostatistician	Yes
<b>Guests/Visitors</b>		
Angela Allen, Ed. D	UNOS	Yes
Bob J. Carrico, Ph.D	UNOS	Yes
<b>MMRF Staff</b>		
Monica Colvin-Adams, MD	SRTR	Yes
Ajay Israni, MD	SRTR	(Phone)