

**Interim Report of the Minority Affairs Committee Meeting
March 8, 2011
Chicago, IL**

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

1. MAC Public Education and Outreach Initiatives

MAC Subcommittee on Education and Awareness of Transplant Options

Data reviewed by the committee has shown that minority patients experience significant delays in referral, wait listing and eventual transplantation as compared to their white counterparts. Many patients who are appropriate for transplantation are never referred for transplant or are referred late in their disease progression. Further, many referring physicians are not up to date regarding the more liberal acceptance criteria for patients with ESRD and their suitability for transplantation. Subsequently, the MAC Committee formed a *Subcommittee on Education and Awareness of Transplant Options* to develop educational guidelines for appropriate patient referral for dissemination to the transplant community and publication on the (NKDOQUI) website. The educational guidelines would be paired with an implementation strategy that could be undertaken by dialysis providers or physician practice groups to track patient referrals over time to determine if the intervention has increased referral. The guidelines would:

- Better define who is an appropriate transplant candidate by including suggested absolute and relative contraindications to transplant.
- Establish the optimal timeframe for patient referral with examples (emphasizing that referral is a continuous process with annual reassessment)
- Emphasize the benefits of transplantation preemptively and in general from a fiscal and societal perspective.

It is intended that the guidelines would eventually pave the way for the development of national standards for referral with specific expectations for providers. Any activities addressing quality monitoring practices for referring providers would be implemented following the development of the educational guidelines.

Dr. Fan reported on a preliminary review of transplant center criteria submitted by subcommittee members. The criteria transplant centers are using for inclusion are fairly open with most patients being accepted as a referral. Patients are being considered on a case by case basis making it difficult to establish structured guidelines. Further, the exclusionary criteria being used seem to focus on secondary criteria using more vague language. Therefore; the approach used in developing the draft guidelines was the identification of specific categories in which there appear to be pervasive misperceptions regarding appropriateness for transplant. These categories would be examined individually and then addressed using factual information.

Suggested categories include the following:

- Medical Evaluation for Candidacy (Should be performed on a serial basis and not at one point in time)
- Maintaining Currency in the Field – (The need for clinicians need to stay up to date with new developments the field as the guidelines will change over time.)
- Medical Appropriateness for Transplantation (Using GFR requirements may be too strict and limiting in terms of patient education and the opportunity for preemptive transplantation, particularly for minority patients do not have the same access.)

- Patient Interest in Transplantation (Patients interested in transplant should be referred and appropriate patient education should be provided to all patients to ensure that they understand and are aware of all of their options for renal replacement therapy.)
- Age (Chronological age should not to be used as an exclusionary factor but should be considered as one factor in examining the unique biology of the individual patient to determine medical appropriateness for transplant.)
- Co-Morbid Factors (Co-morbidities should not to be used as exclusionary factors on their own but should be considered as factors in examining the unique biology of the individual patient to determine medical appropriateness for transplant.)
- Financial Status
- Infection
- Malignancy
- Substance Abuse
- Non-Compliance
- Cognitive Impairment
- Obesity
- Immigration Status
- Barriers to Transplantation (Identification of specific barriers facing patients and how they might be removed)

The subcommittee will be reconvened to review and refine the draft guidelines and then an expanded subcommittee meeting will be convened to include members of additional OPTN Committees (Kidney, Patient Affairs and Transplant Administrators) as well as professional transplant partner organizations (NKF, AST, ASTS, etc.). It was noted that the Southeastern Kidney Council SEKC is working on a similar initiative and it was suggested that the committee consider collaborating with this group as well.

DaVita Collaboration Update

The committee was updated on MAC input with regard to an advertisement promoting transplantation that will appear in the NAACP *Crisis* magazine.

2. Discussion of Transplant-Related News Stories

The committee discussed three stories which appeared in recent news media which have the potential to impact minority transplantation. These include the Arizona Medicaid cuts impacting transplant coverage, the Mississippi Scott sisters case, and the death row prisoner who offered to donate his organ to a relative in return for an early release.

A committee member reported that Arizona transplant centers have begun to remove heart patients from their waiting lists based on certain criteria or are having to deny access to transplantation based on finances. This has severely limited access for heart patients in Arizona to ischemic cardiac disease. It was remarked that access is being limited for those patients who would potentially experience the best outcomes and extended years of life. The decision particularly impacts Hispanic patients in Arizona as a large percentage participates in the public assistance program that has had its transplant benefits cut. The committee expressed concern that transplantation is being denied for certain patient groups on the basis of historical data in an attempt to achieve cost savings for the state. It will be important to provide more accurate, relevant, and timely data using effective and knowledgeable people in order to counter a short sighted solution. It was reported that AST, ASTS and UNOS are working to try to appeal to the Governor and legislature of Arizona. It was remarked that the argument to the Arizona legislature should be rational and unemotional with a focus on irrefutable, factual data surrounding the costs savings as well as the medical benefits of transplantation.

Committee members were also updated on the recent case surrounding two sisters in Mississippi who were imprisoned for 14 years but were recently granted an early release by the Governor on the condition that one sister donate a kidney to the other. The decision was supported by the NAACP. The committee was informed that both sisters had been evaluated and the medical team determined that the transplant could not occur until certain conditions were met (smoking cessation and weight loss). A member of the committee noted that this case is more problematic on the surface as clear issues of race and poverty seem to have played into the decision that was made. The committee discussed the fact that the act seemed to fly in the face of valuable consideration. Also of concern were the ethics surrounding consent with the question of whether or not incarcerated individuals are in a position to say no to the donation. Committee members also expressed concern with regard to elected officials making transplant decisions. The committee also briefly discussed the issue of another incarcerated individual who has been bargaining in favor of an early release if he donated one of his kidneys to a relative.

Committee sentiment on all three issues focused on the need for better education of elected officials, the general public and agencies such as the NAACP etc., on transplantation. The committee also noted particular concern regarding the slippery slope being approached on the issues of consent and valuable consideration as they relate to incarcerated individuals, particularly minorities. Although the committee recognized that it was not in a position to act on any of the issues discussed as there has been no OPTN member involvement as of yet; the committee expressed its intent to appear on the record as acknowledging these issues and the impact they may have on minority transplantation now and in the future.

3. Request to Review Policy 6.0 –Transplantation of Non-Resident Aliens

The committee was updated on a joint subcommittee call to discuss proposed revisions to Policy 6.0: Transplantation of Non-Resident Aliens, being initiated by the Ad Hoc International Relations Committee (AHIR). The AHIR is soliciting feedback from other committees (including Living donor, Patient Affairs, and Ethics) with regard to issues identified in the policy which need to be addressed.

During its discussion, the committee noted that the primary concern with regard to the issue of patient immigration status should be the determination of a patient's insurability and support system following the transplant. Many of the other issues addresses in the policy are not based upon medical criteria. A committee member also noted that since organs are accepted from undocumented individuals there should not be increased scrutiny of these patients; otherwise this may deter individuals from donating in the future.

4. Survey on Referral to Liver Transplantation

Various data reviewed by the committee have shown higher MELD/PELD scores for minorities at wait listing and a lower overall wait listing rate for this group, with a significant lower rate shown for the African American group. With the survey, the committee is attempting to examine data regarding the timing and rate of ESLD patient referral for transplant evaluation. Preliminary survey results viewed by the committee show the following:

- 100% of respondents monitor referrals and more than half (61%) monitor the number of eligible patients referred
- Although almost half (42%) are unsure of the % percentage of medically eligible patients are referred.
- Transplant physicians and surgeons review of medical records is the most common method for determining medical eligibility for referral.
- More than 90% indicate that they receive referrals from gastroenterologists, hepatologists and primary care physicians
- 80% take action when a medically eligible patient is not referred
- More than 90% of respondents reported specific medical complications as indications used to determine if a patient is medically eligible for referral.
- 77% of respondents specified a MELD/PELD score of <15 as an early referral cut off point.
- Three most common reasons for delayed referral (substance abuse, medical co-morbidities, financial/insurance constraints).
- On average, 70% of patients referred complete an evaluation in less than 3 months.
- There appears to be no ethnic differences between patients on the waiting list and patients referred.
- Over 80% of respondents indicate they use some methods to enhance referrals (letters, brochures, presentations to referring physicians at events, seminars, etc.
- Distance does not appear to have an effect on patient completing their evaluation.

A committee member noted that one quarter of the reasons listed for delayed referral are patient driven. Patients are either not aware of their transplant options or are refusing transplant, etc. These results continue to support the need for improved education at the patient and provider level. The committee also discussed ethnic differences in access to health care as a continued area of challenge. Patients who do not have access to a gastroenterologist will not have access to a transplant. Further, the likelihood of self-referral in certain patient populations is very low. The committee also discussed the disadvantage poorly-informed end stage liver disease (ESLD) patients face compared to kidney patients. If a kidney patient initially refuses a transplant due to lack of knowledge or understanding about the procedure the patient can still spend some time on dialysis, become educated about that option, and then pursue it in the future. For a liver patient, once the patient is sick enough to need a transplant the patient usually does not have the luxury of taking time to decide to pursue the option at some future point. Data has shown that by the time many liver patients are referred they are often medically too sick for a transplant.

5. Ongoing Evaluation of CPRA

The committee reviewed results from the Histocompatibility Committee showing CPRA results over a 12 month period. After the policy implementation on October 1, 2009:

- There was an increase in the reporting of unacceptable antigens on the waiting list and a substantial decrease in the number of kidney refusals due to positive crossmatch.
- The percentage of low sensitized registrations (1-20% PRA/ CPRA) decreased; while the percentage of non-sensitized (0/Not reported PRA/CPRA) and very broadly sensitized (PRA/CPRA > 95%) registrations went up.
- Transplant rates for broadly sensitized candidates significantly increased.

After brief discussion, the committee requested to be able to review transplant rates per patient years during pre- and post-CPRA policy by sensitization level and ethnicity for the July 12th meeting.

6. Policy Proposal Distributed January 21, 2011

1. Proposed Model for Assessing the Effectiveness of Individual OPO's in Key Measures of Organ Recovery and Utilization.

The committee did not identify an inherent minority impact from the proposal but offered general feedback to the Membership and Professional Standards Committee (MPSC).

A suggestion was made that prior to active flagging, the MPSC should develop an interim mechanism for identifying and accounting for specific extenuating circumstances (i.e. location in non-contiguous DSA's, conservatism of transplant centers within the DSA's, etc.) which might impact OPO performance, similar to how the SRTR evaluates programs in order to determine the observed and expected yield. This could potentially save time and resources for the MPSC.

The committee determined that it supported the concepts outlined in the proposed model for assessing the effectiveness of OPO's.

7. Policy Proposals to be Distributed March 11, 2011

The committee reviewed and provided feedback on the following policy proposals:

1. Proposal for Improved Imaging Criteria for HCC Exceptions (Liver and Intestinal Organ Transplantation Committee)

The committee did not identify an inherent minority impact from the proposal or any other issues and declined comment.

2. Proposal to Reduce Waiting List Deaths for Adult Liver-Intestine Candidates (Liver and Intestinal Organ Transplantation Committee)

The committee did not identify an inherent minority impact from the proposal but offered the following feedback to the Liver and Intestinal Organ Transplantation Committee.

Following presentation of the proposal and brief discussion, a committee member suggested that patients with portomesenteric venous thrombosis be included in the proposal due to specific characteristics of the disease which makes these patients a high risk waitlist mortality group. Another member expressed concern with regard to the 15-28

MELD range used for the proposal. The member commented that there was a vast difference between patients at these scores. Although many of these patients are listed locally with priority points, many patients are listed with a true MELD score of 25 or above. It was responded that because this group represents a fairly small set of patients, the Liver Committee believed that the proposed change would not dramatically impact other patients waiting for a liver alone. The member also inquired about how the HCC policy which had been recently applied to pediatric patients, impacted that population. It was responded that death rates for these patients were reduced dramatically.

3. Proposed Committee-Sponsored Alternative Allocation System (CAS) for Split Liver Allocation (Liver and Intestinal Organ Transplantation Committee)

Following the presentation, the committee reiterated concerns it had previously expressed following distribution of the split liver proposals on March 19, 2010, primarily in the area of patient safety and consent.

The committee voiced significant concern with regard to the safety of the procedure. Although data has shown that split liver transplant outcomes are equivalent to whole organ transplant outcomes, it was remarked that this is largely due to the fact that the data is coming from transplant centers experienced in performing split liver transplantation. Although the proposal presumes that only transplant centers experienced in performing splits will apply for the CAS, the proposal incentivizes other centers to begin undertaking the procedure by allowing the left segment of the liver to be used in the transplant center which performed the split. As centers would now directly benefit from the procedure by being able to keep the segment for their own patients, these centers could be placed in jeopardy if there are bad outcomes as a result. A member of the committee also commented that language contained in the proposal itself appears to be contradictory. For example, the proposal acknowledges that the partial organ may carry increased morbidity and mortality risks for the recipient but also asserts that receipt of these partial organs is acceptable. It was responded that safeguards will be built into the system with committee evaluation of any negative impacts from the proposal following its implementation.

The committee also reiterated its concern regarding adequate protection of the index patient with full disclosure of the potential complications of split liver transplantation. The committee remains concerned about the possibility of patients being coerced to take a split organ, without understanding the potential additional risks they may be assuming. The committee also expressed concern that minority patients may be more at risk for not understanding the full implications of accepting a partial organ. As the committee believes that the procedure is not risk free, it should be disclosed to patients that they are assuming a personal risk for a societal benefit. Patients should understand exactly what they are accepting when they agree to take a split liver. A member of the committee suggested that a protective measure for both the patient and the transplant center could be developed in the form of a uniform consent document or informational packet. The member compared this procedure with the additional consent required for the acceptance of ECD/DCD kidneys. It was responded that during its deliberations of the previous proposals, the Liver Committee determined that since split liver transplantation is already occurring, additional consent would not be requested as it is not required as part of the existing split liver policy. Accordingly, in order to incorporate an additional consent provision, the entire split liver policy would have to be changed. The committee believes that there continues to be inherent safety and ethical issues present with the proposed CAS, particularly if participation in the procedure increases as a result of its implementation.

Following the discussion, the committee voted unanimously to disapprove the policy proposal.

4. Proposal to Encourage Organ Procurement Organizations (OPO) to Provide Computed Tomography (CT) Scan if Requested by Transplant Programs (Thoracic Organ Transplantation Committee)

The committee did not identify an inherent minority impact from the proposal but offered general feedback to the Thoracic Organ Transplantation Committee.

Following presentation of the proposal and brief discussion, a member of the committee supported stronger language for the proposal rather than simply encouraging OPO's to use a CT scan. A member of the committee also suggested that the availability of a CT scan and an on-call radiologist available to interpret the results a timely manner, could be used as a performance metric for the function of OPOs. Another member remarked that from the transplant coordinator perspective it is sometimes difficult to provide the results of these tests in a timely manner, though they would be easier to provide than some other requested tests. It was commented that they could be uploaded as a simple adobe file. Several other committee members acknowledged the importance of these test results as they also impact abdominal organs, when suspicious nodules are present.

The committee indicated its general support of the proposal, but declined a formal vote.

5. Proposal to Require Updates of Certain Clinical Factors Every 14 Days for Lung Transplant Candidates Whose Lung Allocation Scores (LAS) Are at Least Fifty (Thoracic Organ Transplantation Committee)

The committee did not identify a minority impact from the proposal or any other general issues and declined comment.

6. Proposal to Allow Outpatient Adult Heart Transplant Candidates Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time (Thoracic Organ Transplantation Committee)

The committee did not identify an inherent minority impact from the proposal but offered targeted feedback to the Thoracic Organ Transplantation Committee.

Following presentation of the proposal and brief discussion, a member of the committee voiced strong concern with regard to the comparison of a TAH patient to a patient with a Left Ventricle Assist Device (LVAD). The member remarked that she was currently managing the fifth patient to be discharged with a TAH driver. Because these patients have no ventricles, there is no rescue option available to them as there is with a patient on an LVAD. If an LVAD stops working or malfunctions, CPR, chest compressions, etc. are able to be performed to rescue the heart while an attempt is made to stabilize the mechanical support. For a TAH patient, there are no such options. The member strongly supported the ability of these patients to be allowed to remain at Status IA without the need to distinguish them from Status IA patients currently in the hospital. Another member of the committee noted that as there does not appear to be agreement on the adequacy or inadequacy of the policy proposal by the Thoracic experts in the field, it would be premature to weigh in on the issue before the experts have come to consensus.

As such, the committee declined a formal vote on the proposal.

8. Update on Kidney Allocation Concepts

The committee was updated on the recent release of the Kidney Concept Document. The committee reiterated its support for the concepts included in the document with the request for future modeling for unintended consequences to minority patients following implementation. The committee briefly discussed the negative press coverage surrounding the release of the concept document. To address misperceptions in the media, the committee suggested a proactive response to include public/patient education in the mainstream media (television, radio appearances, etc.) where the average public receives the majority of its information.

9. Kidney Paired Donation Pilot Project

The committee was also briefly updated on the recent matches through the Kidney Paired Donation Pilot Program. The committee provided feedback regarding ways to increase minority participation in the KPD Pilot Program including actively encouraging transplant centers in regions with a large population of minority patients to participate in the pilot study, as well as minority donor education efforts focused on Kidney Paired Donation.

ATTENDANCE FOR THE MARCH 8, 2011

OPTN/UNOS MINORITY AFFAIRS COMMITTEE MEETING

Committee Members	Position	In Attendance
Henry B. Randall, MD	Chair	Yes
Silas P. Norman, MD	Vice-Chair	Yes
Sayeed K. Malek, MD	Region 1 Representative	Yes
Stacey H. Brann, MD	Region 2 Representative	Yes
Rosaline Rhoden, MPH	Region 3 Representative	Yes
Sherilynn A. Gordon Burroughs, MD	Region 4 Representative	Yes
Ricardo Elizondo, RN, CPTC	Region 5 Representative	No
Stephen A. Kula, Ph.D, NHA	Region 6 Representative	Yes
Bruce A. King, MSW	Region 7 Representative	Yes
Ioana Dumitru, MD	Region 8 Representative	No
Lani V. Jones, PhD, MSW	Region 9 Representative	Yes
Remonia A. Chapman	Region 10 Representative	Yes
David G. Jacobs, MD	Region 11 Representative	No
L. Ebony Boulware, MD	At-Large	No
Oscar H. Grandas, MD	At-Large	No
Camille Hill –Blue, PA-C	At-Large	Yes
Eddie Island, MD	At-Large	No
Meelie A. DebRoy, MD	At-Large	Yes
M. Christina Smith, MD	At-Large	Yes
Maria R. Lepe, MD	At Large	No
Karen A. Sullivan, Ph.D	At-Large	No
Pang-Yen Fan, MD	At-Large	Yes

Committee Members	Position	In Attendance
Henry B. Randall, MD	Chair	Yes
Silas P. Norman, MD	Vice-Chair	Yes
Sayeed K. Malek, MD	Region 1 Representative	Yes
Bobby A. Howard	Visiting Board Member	Yes
Mesmin Germain, MBA, MPH	Ex-Officio, HRSA	Yes
Richard Laeng, MPH	Ex-Officio, HRSA	No
UNOS Staff		
Deanna L. Parker, MPA	Committee Liaison/Policy Analyst	Yes
Wida Cherikh, PhD	Sr. Research Biostatistician	Yes
Stacy J. Burson, MS	Business Analyst	Yes(Phone)
MMRF Staff		
Ajay Israni, MD	SRTR	Yes
Guests		
None		