

OPTN/UNOS Minority Affairs Committee
Report to the Board of Directors
June 28-29, 2011
Richmond, VA

Summary

I. Action Items for Board Consideration

- None

II. Other Significant Items

- The Committee presents the results of its *Survey on Referral to Liver Transplantation* for Board information. The survey attempts to document transplant center practices in tracking and monitoring referrals to liver transplantation as well as explore barriers to referral and wait listing for different ethnic groups. (Item 1, Page 3)
- The Committee presents its initiative to develop guidelines for appropriate patient referral to transplantation for Board information. (Item 4, Page 6)

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Report of the OPTN Minority Affairs Committee to the Board of Directors

June 28-29, 2011

Richmond, VA

Henry Randall, MD, Chairman

Silas P. Norman, MD, Vice Chairman

This report includes items addressed by the Minority Affairs Committee (MAC) during its conference call meeting held on November 16, 2010, full meeting held on March 8, 2011 and subcommittee conference calls.

1. 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 particularly for African American patients. The Committee has been interested in trying to gain a better understanding of the reasons for the variability in the MELD/PELD scores and exception points and in bringing some uniformity to the system. The questions the Committee has attempted to address are:

- What is driving the variability for these patients?
- Is the problem limited access to the waiting list or are patients being referred late in the process?

The Committee developed an online *Survey on Referral to Liver Transplantation* to explore barriers to liver referral and wait listing for different ethnic groups. The survey was modeled after the *MAC Survey on Referral to Kidney Transplantation* and attempted to examine data regarding the timing and rate of ESLD patient referral for transplant evaluation. During its meeting on March 8, 2011, the Committee viewed preliminary survey results. (**EXHIBIT A**). Dr. Wida Cherikh, presented the information to the Committee.

The survey results demonstrated the following:

- 100% of respondents monitor referrals and more than half (61%) monitor the number of eligible patients referred
- Almost half (42%) are unsure of the percentage of medically eligible patients who 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 that specific medical complications 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.

During discussion, a committee member noted that one quarter of the reasons listed for delayed referral were 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. For example, patients without access to a gastroenterologist will not have access to transplantation. 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 the option 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 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. The Committee will consider plans to pursue publication of the data.

2. Update on Kidney Allocation Concepts

During its meeting on March 8, 2011 the Committee was updated on the recent release of the Kidney Concept Document by Ciara Samana, MS, liaison to the Kidney Committee. It was reported that the best case scenario for release of a public comment proposal on the kidney allocation concepts would be a public comment cycle timed to correspond with review by the Board of Directors in June 2012. Following Board approval, implementation would be expected to occur within 1.5 to two years.

The Committee briefly discussed the negative press coverage surrounding the release of the concept document. A Committee member noted that education of patients about the concepts in the document needs to occur now to allow as much time as possible for the public to understand and become familiar with the concepts being proposed for the allocation of deceased donor kidneys. Similarly, another member remarked that the recent new stories highlight the need for patient specific educational materials to be developed. Further, to address the misperceptions in the media, the Committee suggested a proactive response to the negative press coverage to include public/patient education in the mainstream media (television, radio appearances, etc.) where the average public receives the majority of its information, rather than a response to specific published news stories.

The Committee also inquired about the response from the professional associations. It was reported that feedback on the proposed new kidney allocation concepts had been solicited from the professional associations during the summer. The groups have indicated their support of the concepts in theory but have expressed an interest in being engaged in more specific feedback once the details surrounding implementation of the system emerge.

The Committee reiterated its support for the concepts included in the document with a request for future modeling for unintended consequences to minority patients following implementation.

3. Survey on Referral to Kidney Transplantation

Over the past several years, the Committee has sought to examine the factors leading to lower referral rates and delayed placement on the kidney waitlist for minority patients. The subcommittee reviewed data which showed large geographic differences in access to the kidney transplant waiting list and once listed, to a kidney transplant. The Committee also previously reviewed data from the CMS Medical Evidence 2728 Form (Certification of End Stage Renal Disease) which was revised in recent years to add a question asking whether or not patients have been informed about their transplant options. A very high percentage of African-Americans are reported as having been informed about

renal transplantation by the time they begin dialysis. Thus, there is an unexplained discordance between the high rates with which African-Americans are reportedly informed of transplant options and the low rates of referral for transplant evaluation (See Figures 1 and 2).

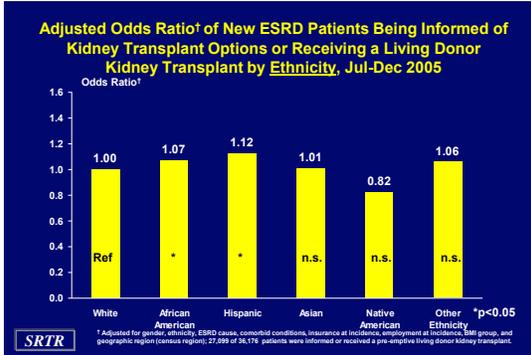


Figure 1

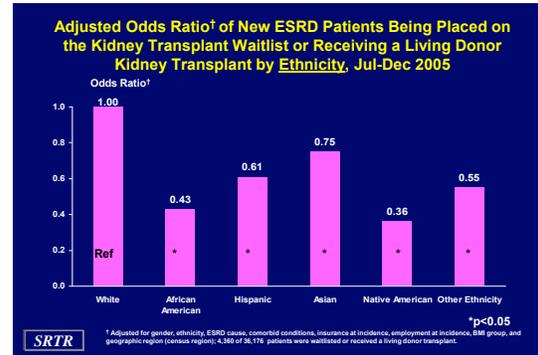


Figure 2

B. COMPLETE FOR ALL ESRD PATIENTS IN DIALYSIS TREATMENT

20. Name of Dialysis Facility	21. Medicare Provider Number (for item 20)
22. Primary Dialysis Setting <input type="checkbox"/> Home <input type="checkbox"/> Dialysis Facility/Center <input type="checkbox"/> SNF/Long Term Care Facility	23. Primary Type of Dialysis <input type="checkbox"/> Hemodialysis (Sessions per week____/hours per session____) <input type="checkbox"/> CAPD <input type="checkbox"/> CCPD <input type="checkbox"/> Other
24. Date Regular Chronic Dialysis Began MM DD YYYY	25. Date Patient Started Chronic Dialysis at Current Facility MM DD YYYY
26. Has patient been informed of kidney transplant options? <input type="checkbox"/> Yes <input type="checkbox"/> No	27. If patient NOT informed of transplant options, please check all that apply: <input type="checkbox"/> Medically unfit <input type="checkbox"/> Patient declines information <input type="checkbox"/> Unsuitable due to age <input type="checkbox"/> Patient has not been assessed <input type="checkbox"/> Psychologically unfit <input type="checkbox"/> Other

FORM CMS-2728-U3 (06/04) EF(03/2005)

Figure 3

Committee members have noted that although CMS mandates that all patients be assessed for referral for transplant evaluation and informed about transplant options, there are no requirements or standards for how providers should do this (See Figure 3).

As a result the subcommittee initiated an online *Survey on Referral to Kidney Transplantation* to collect information on referral practices in transplant centers. The information was presented to the committee and to the Board of Directors in 2010.

During its meeting on November 2010, the committee was informed that results had also been presented at the September Association for Multicultural Affairs in Transplantation (AMAT) formerly the Association for Multicultural Health and Transplant Professionals (ASMHTP) meeting and to the most recent meeting of the Patient Affairs Committee (PAC). In summary, the survey results showed the following:

- 92% of respondents monitor patient referrals.
- 44% of respondents monitor the percentage of eligible patients referred.
- Most utilize methods such as transplant center staff visits to dialysis units, transplant surgeon or physician review of medical records, or primary nephrologist determination of eligibility.

- 59% take some form of action if eligible patients are not referred, such as a letter to the dialysis unit, patient or primary nephrologist.
- On average, only 15% of the patients are referred before the initiation of dialysis.
- The most common reasons for delayed referral are medical co-morbidities, patient not being informed of transplant options, and financial constraints.
- 90% of responders use some methods to enhance referrals, such as letters/brochures/presentations to dialysis units and referring physicians.
- This survey demonstrates that even though kidney transplantation is the optimal treatment for ESRD, there is no system that monitors timely referral of all potential recipients.
- Transplant centers generally do not have the resources to determine if eligible patients are referred for evaluation or even informed of transplant options.
- Educational efforts to encourage and improve timely referral are needed.

The Committee was informed that the PAC committee inquired whether the MAC planned to solicit more responses or other follow-up activity. The PAC is interested in being included in the initiatives mentioned above and would like to be involved early in the process.

4. MAC Subcommittee on Education and Awareness of Transplant Options

Data reviewed by the committee over a number of years has shown that minority patients experience significant delays in referral, wait listing and transplantation as compared to their white counterparts. Data reviewed by the Committee has also suggested that providers (such as dialysis staff) are not educated sufficiently about transplantation to adequately inform patients about this treatment option and that many referring physicians are not up to date regarding the more liberal acceptance criteria for patients with ESRD and their suitability for transplantation. Consequently, many patients who are appropriate for transplantation are never referred for transplant or are referred late in their disease progression.

During the November 2011 meeting, the MAC resumed its discussions from July regarding development of an educational initiative to improve referral to kidney transplantation for all candidates and institute standards for referral and transplant education for providers to be used for monitoring purposes. The Committee discussed the need for a subcommittee that would combine the work of the Dialysis Survey and Kidney Referral Survey Subcommittees with an expanded focus in the area of transplant education and referral practices.

The Committee discussed a plan to assemble a broad based subcommittee to develop recommendations and specific products (white paper, consensus statement, training module, etc.) to address the issue. The subcommittee would include members of specific named OPTN committees, transplant related professional organizations, individuals and other groups who would commit to serve on such a subcommittee and work to develop and implement a course of action within a one year to 24 month time frame. An initial internal MAC member subcommittee call would be scheduled first to help focus the work of the subcommittee before involving additional members. Several additional MAC members volunteered to participate on the subcommittee. Members were asked to forward the names of possible other prospective subcommittee candidates to the Chairman and committee liaison.

The Committee was also informed that in August the government issued a Federal Register notice requesting public feedback on a proposed Dialysis Facility Quality Initiative Program that would be tied to reimbursement through CMS. The Committee has advocated similar action that would include tracking and monitoring existing dialysis facility measures, as well as measures for other providers, in

the areas of transplant education and referral to transplantation. The Committee was also informed that the PAC has also supported regulatory activity as appropriate to encourage provider compliance in the above areas.

The Committee discussed the subcommittee work occurring as part of a two pronged activity – an education work group and a legislative or regulatory work group. The subcommittee is only able to begin work on the educational initiatives discussed by the committee. The educational initiatives proposed will involve additional OPTN committees as well as professional associations and interested individuals. Committee involvement in legislative issues must wait for appropriate permission and recommendation from the OPTN leadership and HRSA.

Committee recommended activities:

Education Work Group

The MAC will collaborate with other OPTN/UNOS committees, professional associations, and other organizations and individuals to:

- Develop recommendations/guidelines for transplant education and referral for shared distribution among members.
- Educate referring providers/dispel myths about the type of patient who can be referred as a suitable transplant candidate (through publications, consensus statement, educational interventions, etc.)
- Develop a white paper or journal article summarizing the results of the kidney and liver referral surveys in conjunction with the above activities.

Legislative Work Group

The MAC hopes to make a recommendation to HRSA that is shared with CMS encouraging standards for dialysis patient education with consideration of incentives to achieve early referral. The standards should also:

- Communicate that referral is the default/expected action from dialysis providers (in the absence of specific exclusions).
- Include specific language/expectations outlining what "informed of transplant options" should entail for dialysis providers to show compliance with CMS.
- Be built upon the existing CKD 4 reimbursement structure.
- The MAC also advocates strengthening existing CMS referral measures, including standardization and consistency in application of the measures and appropriate monitoring processes.

The meeting discussion concluded with a defined subcommittee of MAC members and other groups and individuals to be named.

The *MAC Subcommittee on Education and Awareness of Transplant Options* met via LiveMeeting conference call on February 4, 2011 for the purpose of establishing the goals and basic framework for the proposed committee activity to educate providers on appropriate patient referral to kidney transplantation.

The overall goal of the project was discussed. The purpose of the educational initiative would be to provide an opportunity for every medically appropriate patient to be referred for evaluation due to the

significant lifestyle and survival benefit experienced from transplantation. Various options for delivering the education were proposed, including the development of an educational module presented at a professional association meeting, a consensus statement, a white paper or journal article, a written guidance document developed in collaboration with professional transplant partner organizations, and a professional webinar. Following brief discussion, it was determined that a combination of several of the suggested activities would be ideal. The intent should be to raise awareness among referring providers about current trends in the field of transplantation, particularly with regard to patient appropriateness for transplant. The subcommittee determined that this information should be delivered to referring physicians as targeted education in the form of written guidelines on referral to transplantation. Subcommittee members suggested that the use of the term guidelines would be better accepted by the medical community and would be less likely to be construed as recommendations for medical/clinical practice. The guidelines should be marketed as an educational tool to increase their acceptance and use. If successful, the guidelines would help providers become more knowledgeable about patient referral, establish some standardization in the type of patients who are referred and how they are referred, and create some accountability for patient referral that does not currently exist.

The subcommittee proposed the following plan for the project:

- Development of written guidelines for appropriate patient referral that would be widely disseminated to the transplant community.
- The written guidelines would be paired with a strategy for implementing the guidelines that could be undertaken by a dialysis unit or physician practice group to track patient referrals in the unit over time to determine if the intervention has increased referrals.

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.

These understandings would be shared with the community of referring physicians/ESRD providers through written guidance promoted through the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKDOQI) on their website and through other channels. It is intended that the guidelines would eventually pave the way for the development of national standards for referral with specific expectations for providers. The Committee determined that any activities addressing quality monitoring practices for referring providers would be best implemented following the development of the guidelines.

The subcommittee discussed a plan and timeline for completing current projects as well as the guidelines project. The first phase of the project is expected to be completed within 12 months. The second phase is projected to be completed within 27 months: As a follow-on activity to the call, it was suggested that subcommittee members submit their center's current inclusion and exclusion criteria for review. The information would then be evaluated and examined for common criteria and compiled into a draft guidelines document.

During the full committee meeting on March 8, 2011, Dr. Fan reported on a preliminary review of transplant center criteria submitted by subcommittee members. He noted that the criteria transplant

centers are using for inclusion are fairly open with most patients accepted as a referral. Most 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 vague language. Therefore; the approach he used in developing the draft guidelines was the identification of specific categories in which there appears 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* – (There is a need for clinicians need to stay up to date with new developments the field of transplantation. As the field evolves and more knowledge is gained, the guidelines will be revised.)
- *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* (The mere existence of a co-morbidity should not be used as an exclusionary factor when considering transplantation, but should be considered as one factor at play when 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* (Timely issue which needs to be fleshed out further for more discussion)
- *Barriers to Transplantation* (Identification of specific barriers facing patients and how they might be removed)

The meeting discussion concluded with a plan for the subcommittee to be reconvened to review and refine the draft guidelines during the expanded subcommittee meeting that would include members of additional OPTN Committees (Kidney Committee, Patient Affairs, Living Donor, and Transplant Administrators) as well as professional transplant partner organizations (NKF, AST, ASTS, NKODQI, etc.) A member noted that the Southeastern Kidney Council (SEKC), consisting of the states of GA, SC and NC, is working on a similar initiative and it was suggested that the Committee consider collaborating with this group as well. The Committee was also asked to give some thought to the barriers to transplantation that should be included in the guidelines.

The *MAC Subcommittee on Education and Awareness of Transplant Options* reconvened on May 6, 2011 for the purpose of reviewing the draft document establishing guidelines for referral to kidney

transplantation. The subcommittee was provided with background information on referral to kidney transplantation, including articles on preemptive transplantation, kidney transplant referral measures developed by the ESRD networks and a study on Dialysis Facility Specific Kidney Transplant Referral Measures completed in 2005, along with other supporting materials (meeting summary, etc.)

The subcommittee used the recommendations and feedback from the technical expert panel of the Dialysis Referral Measures study as well as discussion from the last subcommittee meeting as a yardstick against which to review the draft document. Questions to run on were developed and posed in the agenda based on review of materials.

During the subcommittee meeting, the following broad framework for the guidelines document was recommended:

The following information should appear in the introduction:

- Present the benefits of transplantation vs. dialysis citing data (survival benefit for transplantation among all levels of recipients and across all ethnic groups and ages.)
- Highlight the different rates of progression to ESRD in racial ethnic groups and age categories, (as well as other demographic areas) the rate of transplant differences, as well as the fiscal benefit of transplantation, etc.)
- Present the goal of the guidelines as promoting referral to transplantation for ALL patients with few exceptions (Ex. no active untreated malignancies, reasonable functional status, etc.) Final medical suitability will be determined by the individual transplant center.
- Present as an additional goal the encouragement of referral prior to start of dialysis (preemptive transplantation)
- The guidelines will focus on patients with Stage 4 and Stage 5 chronic kidney disease (CKD).
- The guidelines will recommend a GFR range to determine referral. All patients with a GFR of 30 should be approached to begin the conversation about transplantation to allow enough time for self-education and to locate a living donor for preemptive transplantation. The specific GFR used for recommending referral would be within a range (25 to 35) based on individual patient characteristics that would help identify the patients' anticipated progression to ESRD. The subcommittee recommended using a GFR less than 25 for slower progressors (the example of the little old lady with hypertension with relatively stable kidney function) and GFR less than 30 for faster progressors (the younger person with diabetes who is quickly losing his kidney function).
- The guidelines would include a recommendation for a national internet resource for locating transplant center program specific inclusion/exclusion criteria for referring physician use. (UNOS, NKF website, etc.)
- The guidelines would include a recommendation for the (voluntary) institution of a designated position (or an individual in a functional role) that would be responsible for follow through of the referral process. The functional role would be broad enough to fit any number of job categories (dialysis nurse, social worker, etc.)
- The guidelines would include a FAQ section at end of document.
- The guidelines would list specific barriers to transplantation for provider education.
- The project should be strongly associated with a catch phrase for marketing purposes (Ex. 30 First)

The subcommittee determined that the next step would be to incorporate the subcommittee recommendations into the draft guidelines and then convene the larger subcommittee meeting to include external groups and organizations.

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

During the meeting on March 8, 2011, the Committee was updated on a joint subcommittee call on January 17, 2011 to discuss proposed revisions to Policy 6.0 (Transplantation of Non-Resident Aliens), being initiated by the Ad Hoc International Relations Committee (AHIRC). The AHIRC is soliciting feedback from other committees (including the Living Donor, Patient Affairs, and Ethics committees) with regard to issues identified in the policy which need to be addressed.

Dr. Meelie Debroy, MAC member and representative on the joint subcommittee presented a brief background on the issue and summarized the main purpose of the review to committee members. Upon receiving approval by the OPTN/UNOS Executive Committee on November 8, 2010, the AHIRC has undertaken efforts to revise Policy 6.0.

The objectives of this effort are to:

1. Evaluate the currency of each policy in 6.0;
2. Ensure that each policy that remains in 6.0 is measurable; and,
3. Revise Policy 6.0 as needed.

The AHIRC has solicited the assistance of other OPTN/UNOS committees in this effort and requested several other committees to evaluate the content of Policy 6.0 and provide responses to the following questions:

- What policies in 6.0 seem no longer current?
- Which policies in 6.0 cannot be measured as written?
- What concepts in Policy 6.0 should the AHIRC consider revising?
- What concepts in Policy 6.0 should the AHIRC consider eliminating?

A small group representing the AHIRC, MAC, and PAC met via teleconference call to discuss the concepts in Policy 6.0 (Transplantation of Non-Resident Aliens). The AHIRC initiated this meeting to learn MAC's and PAC's concerns about one or more policies in 6.0, and to incorporate these concerns in its effort to this section.

A history of the audit threshold for the transplantation of non-resident aliens due to deceased donation was provided to the group. Initially, the threshold was the transplantation of more than 10% non-resident aliens, though over time this number has decreased to 5% or more. It was suggested that the decrease in the percentage was because transplant programs in the U.S. are not transplanting non-resident aliens at a rate that exceeded 10%. Further, since the audit threshold has decreased to 5% or more, the national rate of non-resident alien transplantation remains at around 1%.

The chairman of the AHIRC provided an overview of the concepts in Policy 6.0:

- Transplantation of non-resident aliens and the audit performed by the AHIRC;
- Definitions of non-resident aliens;
- Exportation and importation of deceased donor organs;
- Valuable consideration and that it must not be provided for recoveries and transplants of organs – deceased or living; and,

- Some of the policies as written cannot be monitored.

The group discussed the following concepts:

- The policy that triggers the monitoring of non-resident alien transplants when a program exceeds the rate of 5% annually should be strengthened.
- The concepts of importation and exportation need to be separated from the concept of non-resident alien transplantation.
- Non-resident alien recipient and donor populations should be considered separately.
- It is far less expensive to transplant a non-resident alien patient experiencing renal failure than to maintain that patient on dialysis.
- Explore ways to verify the citizenship data entered in UNetSM as this might help understand the number of undocumented residents. Some were concerned, however, that this would result in transplant centers becoming immigration gatekeepers
- Explore living donation from foreign nationals in Policy 6.0.

It was reported that the committees are continuing to evaluate Policy 6.0 in their respective meetings, and have been requested to forward their suggestions to the AHIRC to consider during its face-to-face meeting on April 10-11, 2011.

During its discussion of the issue, the Committee noted that the primary concern with regard to the issue of patient immigration status should be the determination the patient's insurability and the existence of a support system following the transplant. Many of the other issues being addressed in the current policy are not based upon medical criteria and perhaps should not be included in the policy, especially when they cannot be measured. A committee member also noted that since organs are accepted from undocumented individuals there should not be increased scrutiny of undocumented transplant candidates; otherwise this may deter individuals from donating in the future.

6. Discussion of Public Comment Proposals Distributed October 1, 2010

1. *Proposal to Require Collection of Human Leukocyte Antigen (HLA) Type for Thoracic Organs (Thoracic Organ Transplantation Committee)* During discussion of the proposal, the Committee expressed interest in the number of minority patients who are sensitized. It was noted that the proposal would likely benefit minority patients who are more likely to have higher PRA. The Committee also proposed to work with the Thoracic Committee to determine how often minority patients are offered VAD assistance. The Committee voted unanimously to approve the proposal.
2. *Proposal to Clarify Adult Heart Status IA Language to Enable Consistent Interpretation of Policy and Reflect Current Programming in UNetSM (Thoracic Organ Transplantation Committee)* The Committee did not identify an inherent minority impact and did not address the proposal with a formal vote.

3. Proposal to Clarify which Transplant Program has Responsibility for Elements of the Living Donation Process and to Reassign Reporting Responsibility for Living Donation from the Recipient Transplant Program to the Transplant Program Performing the Living Donor Nephrectomy or Hepatectomy (Living Donor Committee and Membership and Professional Standards Committee) The Committee did not identify a minority impact with the proposal but determined that it supported the concept of clarifying language to assign responsibility for aspects of the living donation process. The Committee declined to render a formal vote.
4. Proposal to Establish Qualifications for a Director of Liver Transplant Anesthesia in the OPTN Bylaws (Membership and Professional Standards Committee) The Committee discussed the proposal at length and noted several concerns. Members expressed overall concern that the policy was introducing an unenforceable mandate at the institutional level. Concern was also expressed about the proposal being introduced without accompanying qualifications or guidelines for the position. It was also remarked that even if a center hired someone in the position, that person could not be available at all times. Several members noted that the proposal had the potential to disadvantage smaller and start up liver programs.

Finally, members determined that the proposal presented no obvious benefit at the patient care level. As such the Committee voted unanimously to disapprove the proposal as written, unless information is included in the proposal to better define the responsibilities and qualifications for the position that have been developed by the appropriate oversight bodies (ASA, AST and ASTS, ILTS, etc.)

5. Proposal to Modify the Requirements for Transplant Hospitals that Perform Living Donor Kidney Recoveries (Membership and Professional Standards Committee) The Committee did identify an inherent minority impact and as such declined to discuss the proposal.
 6. Proposal to Prohibit Storage of Hepatitis C Antibody Positive and Hepatitis B Surface Antigen Positive Extra Vessels (Operations and Safety Committee) The Committee attempted to identify a minority impact from the proposal. The Committee inquired whether the proposal would impact blood groups dominated by minorities. The Committee also discussed a concern that the proposal could have a disproportionate negative impact in populations where Hepatitis disease is endemic. The Committee also discussed whether or not a proposal prohibiting storage of these vessels is the appropriate response for dealing with a problem resulting from human error. Members remarked that the vessels are important for surgical purposes and need to be available at a moment's notice. Synthetic vessels, while an option are not ideal, especially when vessels from human tissue are far superior. The Committee determined that a better solution to address the problem would be the availability of a simple checklist to make sure that the wrong vessel is not transplanted into the wrong patient. As such, the Committee voted unanimously to disapprove the proposal as written.
7. Discussion of 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.

8. Discussion of 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 make 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 represented 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 would be built into the system with committee evaluation of any negative impacts from the proposal following its implementation.

The Committee also reiterated its concerns 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 advocated for full disclosure to patients that they would be 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 as written.

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 OPO's. 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 as it 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.

The Committee declined review and comment on the additional 7 proposals.

9. Legislative Update: Discussion of Transplant-Related Issues

During the November meeting, the Committee discussed recent legislation eliminating certain organ transplants from benefits available to Arizona residents under Medicaid. The legislation eliminates coverage the following transplants: lung, pancreas only, pancreas after kidney, heart for non-ischemic cardiomyopathy and liver transplantation for diagnosis of Hepatitis C. The benefit changes became effective on October 1, 2010. The Committee was informed that AST, ASTS, and UNOS have issued a letter to the governor requesting a meeting to discuss the cuts.

The Committee discussed the implications the legislation would have for transplant candidates in Arizona, particularly minorities, as well as any future legislative implications the actions may pose. The Committee was informed that the PAC recently issued a resolution expressing concern about the impact the cuts will have on children and minorities, among others. The Committee expressed a similar desire to provide feedback on the legislation with a focused subcommittee, to the extent that legislative activity is permitted within the confines of the OPTN contract.

During its March 8, 2011 meeting, the Committee was updated on new developments regarding the Arizona Medicaid cuts and also discussed two other transplant related issues appearing in recent news media with the potential to impact minority transplantation. These two issues included the Mississippi Scott Sisters case, and the death row prisoner who offered to donate his organ to a relative in exchange 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. The budget cuts have severely limited access to heart transplantation for patients with 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. ACCESS is the Arizona local Medicare/Medicaid funding source and the new restrictions have severely limited access for certain groups, particularly Hispanic and African American groups as a large percentage of these patients participate in the ACCESS public assistance program. A committee member expressed concern that transplantation is being denied for these patient groups on the basis of historical data as opposed to current data in an attempt to achieve cost savings for the state. It was commented that it will be important to provide accurate, relevant, and timely data using effective and knowledgeable messengers in order to counter the short sighted solution that has been implemented. The Committee

was informed that AST, ASTS and UNOS are working to try to appeal to the Governor and legislature of Arizona. Committee members 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 for both sisters). 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 decision seemed to potentially violate valuable consideration. Also, the ethics surrounding appropriate patient consent were expressed as a concern with the question being raised about whether or not incarcerated individuals are in a position to say no to a 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.

Overall, 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 the subject of 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. 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; but 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.

10. Ongoing Evaluation of CPRA

Calculated PRA (CPRA) is a measure of candidate's sensitization level that is based on unacceptable HLA antigens listed for candidates. The goal of CPRA is to provide a more accurate and consistent measure of patient sensitization and to improve the efficiency of organ allocation by reducing the number of predictably positive crossmatches. Because CPRA is obtained by determining the actual frequency of potential deceased donors who have one of more unacceptable antigens for a given transplant candidate, CPRA may benefit ethnic minority candidates who are sensitized to HLA antigens that are relatively common in the deceased donor population.

Phase I of the calculated PRA (CPRA) policy was implemented on 12/5/07 requiring centers to enter at least one unacceptable antigen in order for their highly sensitized patients (PRA \geq 80%) to receive the additional 4 points to receive deceased donor kidney transplant. The MAC has monitored results of CPRA policy as part of ongoing kidney allocation policy development to ensure that potential implications of the program for minority populations are addressed. The Committee has been reviewing the results of on-going Histocompatibility Committee analysis to monitor the policy by comparing CPRA and PRA by ethnicity.

During its meeting on March 8, 2011, the Committee reviewed results from the Histocompatibility Committee showing CPRA results over a 12 month period (**EXHIBIT B**). Dr. Wida Cherikh, presented the information to the committee.

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 presentation during the next meeting on July 12th. The Committee also suggested an update from the Histocompatibility Committee with regard to progress on the proposed sliding scale for CPRA proposal.

11. Kidney Paired Donation Pilot Program (KPDPP)

The Committee was provided with a brief summary of recent matches made under the Kidney Paired Donation Pilot Program by Ciara Samana, MS.

Kidney paired donation involves the coordinated matching of living donors with medically compatible recipients in cases where the original intended recipient is not compatible with his or her potential donor. The OPTN is coordinating a national pilot program to facilitate kidney paired donation transplants.

It was reported that there have been two transplants under the program and there are 88 candidates in the pool. However, because the system operates based on an examination of every possible match (or set of matches) from the list of potential donor/candidate pairs, the larger and more diverse the pool of candidates, the more matches are possible. Recent data has showed that the program could benefit by broadening the donor pool. As a result, the KPD working groups is requesting input from the MAC on ways to increase minority involvement and participation in the program.

The Committee discussed several possible ways to accomplish this. It was noted that in addition to the disadvantage that minority patients face with blood and tissue matching, they also face the increased challenge of locating a potential living donor. It was suggested that the KPD community consider encouraging transplant centers to determine ways to increase non-directed donation, particularly in the African American community as this is the largest minority group of patients on the kidney waiting list. It was also suggested that centers reexamine their list of living donors who have been previously declined as living donors. In some areas, many donors are declined due to medical reasons rather than blood type incompatibility or positive crossmatch. Over time, the acceptable living donor criteria have changed and some donors who were not appropriate donors ten years ago could be considered appropriate medical living donors (more liberal BMI numbers, etc.) It was also noted that the medical situation for some of these donors may have improved, making it even more likely for them to be considered for donation. A member also remarked that some patients do not understand the issues surrounding medical blood type compatibility and may not know that they can be compatible with a person of another blood type. Improved education could help those patients identify suitable living donors.

The Committee discussed the need for educational initiatives targeted to minorities to introduce KPD as an option for receiving a transplant. Some transplant centers routinely discuss KPD as part of the overall transplant education process. It was remarked that this discussion should be a part of the living donor guidelines. It was further noted that some OPO's include KPD in its discussions with potential minority donors. However, for many potential minority living donors there remains a

negative perception and spirit of distrust with regard to donating to a pool and not to an individual candidate. Additional education will be needed to combat this perception.

12. DaVita Collaboration Update

The Committee was updated regarding ongoing efforts within UNOS to collaborate with DaVita Inc., to provide their dialysis patients with supplemental transplant-related educational information. During the March meeting, the Committee was updated on MAC input with regard to an advertisement promoting transplantation that will appear in the NAACP *Crisis* magazine. The Committee expressed interest in further updates once the advertisement is published.

13. Dialysis Survey Journal Article Update

In November, the Committee was briefly updated on the new proposed timeline for the *Dialysis Facility Public Comment Opinion Survey* manuscript. The Committee continues its work on the article.

14. Highlights of Board Actions

During the November and March meetings, the Committee was updated on items presented for Board action during the November 8-9 OPTN Board of Directors meeting. Items of interest and relevance to the committee were highlighted for members. These included BOD sentiments on policy proposals being distributed for public comment and those preparing to be distributed. The Committee was also updated on the work of the Executive Committee in determining the appropriate role for the Policy Oversight Committee (POC) in the policy development process as well as OPTN Strategic Planning activities being undertaken to establish organizational key goals and indicators to prioritize committee work.

**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
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		

**ATTENDANCE FOR THE NOVEMBER, 2010
OPTN/UNOS MINORITY AFFAIRS COMMITTEE Conference Call 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	No
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	No
Bruce A. King, MSW	Region 7 Representative	Yes
Ioana Dumitru, MD	Region 8 Representative	Yes
Lani V. Jones, PhD, MSW	Region 9 Representative	No
Remonia A. Chapman	Region 10 Representative	Yes
David G. Jacobs, MD	Region 11 Representative	Yes
L. Ebony Boulware, MD	At-Large	No
Oscar H. Grandas, MD	At-Large	No
Camille Hill –Blue, PA-C	At-Large	No
Eddie Island, MD	At-Large	Yes
Meelie A. DebRoy, MD	At-Large	Yes
M. Christina Smith, MD	At-Large	Yes
Maria R. Lepe, MD	At Large	Yes
Karen A. Sullivan, Ph.D	At-Large	Yes

Pang-Yen Fan, MD	At-Large	Yes
Bobby A. Howard	Visiting Board Member	Yes
Mesmin Germain, MBA, MPH (phone)	Ex-Officio, HRSA	No
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 (phone)	Business Analyst	Yes
SRTR Staff		
Monica Colvin-Adams, MD	Principal SRTR Researcher	Yes
Guests		
None		