

**Interim Report of the OPTN/UNOS Minority Affairs Committee Meeting
Live Meeting Teleconference Call
November 16, 2010**

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

1. Highlights of Board Actions

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.

2. Minority Affairs Committee Report

The committee was referred to the final report prepared for the November 8-9 meeting of the OPTN/UNOS Board of Directors. The report summarized the March 23rd and July 20th, 2010 committee meetings.

3. MAC Public Education and Outreach Initiatives

Dialysis Survey Journal Article Update

The committee was briefly updated on the new proposed timeline for the *Dialysis Facility Public Opinion Survey* manuscript. A mini oral presentation of the survey results was presented at the September meeting of the American Society for Multicultural Affairs in Transplantation (AMAT) formerly ASMHTP. The manuscript is hoped to be completed by February 2011.

Survey on Referral to Kidney Transplantation

The committee was presented with the results of the *Survey on Referral to Kidney Transplantation* presented at the September meeting of the Association for Multicultural Affairs in Transplantation (AMAT – formerly ASMHTP). The committee was informed that the results were also presented to the Patient Affairs Committee (PAC) during their recent meeting.

In summary, the survey results showed the following:

- 92% of respondents monitor patient referrals.
- Less than half (44%) monitor the percentage of eligible patients referred.
- Most utilized methods such as transplant center staff visits to dialysis units, transplant surgeon or physician review of medical records, or primary nephrologist determination of eligibility.
- Over half (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 were referred before the initiation of dialysis.
- The most common reasons for delayed referral were medical co-morbidities, patient not being informed of transplant options, and financial constraints.

- The majority (90%) of programs use some methods to enhance referrals, such as letters/ brochures/presentations to dialysis units and referring physicians.

In conclusion:

- The survey results demonstrate the lack of oversight of the transplant referral process.
- 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 PAC committee inquired whether the MAC planned to solicit more responses or other follow-up activity. The PAC is interested in being a part of initiatives such as those mentioned above (especially a legislative approach) but wants to be involved early in the process.

4. Legislative Update: Transplant Organizations Take Stand Against Arizona Medicaid Cuts Impacting Transplant Coverage

The committee discussed recent legislation which eliminated certain organ transplants from benefits available to Arizona residents under Medicaid. The legislation eliminates coverage for lung, pancreas only, pancreas after kidney, heart for non-ischemic cardiomyopathy and liver for diagnosis of Hepatitis C. The benefit changes became effective on October 1, 2010. The 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 similar concern about the impact the cuts will have on children and minorities, among others. The committee expressed a 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.

5. MAC Subcommittee on Awareness of Transplant Options

The MAC resumed its discussions from the July meeting regarding improving referral to transplantation for all candidates, and instituting monitoring and standards for referral to transplant and transplant education for providers. The committee discussed the need for a subcommittee that would combine the work of the Dialysis Survey and the Kidney Referral Subcommittees but with an expanded focus in the area of transplant education improving referral to transplantation.

The committee discussed the plan to assemble a broad based subcommittee to develop a path forward to propose recommendations, specific products (white paper, consensus statement, training module, etc.) to address the issue. The subcommittee should include members of specific named OPTN committees, transplant related professional organizations, individuals and related organizations and groups who would commit to serve on such a subcommittee and commit to work to develop and implement a course of action with related timeline (within one year to 24 months time frame). An initial internal MAC member subcommittee call would be

scheduled first to help focus the work of the subcommittee and the resulting products and activities before involving additional members. Several additional MAC members requested to participate on the existing subcommittee. Committee discussion also focused on identifying subcommittee members outside of the MAC committee who could serve. Members were asked to forward names of possible members to the Chairman and committee liaison.

The committee was also informed that 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 also supported regulatory activity as necessary for provider compliance in the above areas. The meeting discussion concluded with a defined subcommittee of MAC members and other groups and individuals to be named.

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 (NKF, KDOQUI, etc.) 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.

Path Forward

An internal MAC subcommittee call will be scheduled to help focus the work of the subcommittee and define the work products and activities.

Once these work products and activities are clearly defined, the MAC will convene an expanded subcommittee to address implementation of the projects. The MAC is also seeking to identify possible subcommittee members outside of the MAC committee who would be interested in serving in this capacity. Desired OPTN committee participation would include at a minimum, the Kidney Committee, Patient Affairs Committee and Transplant Administrators Committee, and members of professional associations and other groups and/or individuals.

6. Kidney Allocation Update

The committee was provided with an update on the proposed new Kidney Allocation System concepts as well as implementation of the Kidney Paired Donation Pilot Project.

7. Survey on Referral to Liver Transplantation

The committee was updated on the status of the *Survey on Referral to Liver Transplantation*. Data reviewed by the committee over time have shown higher MELD/PELD scores for minorities at wait listing and a lower overall wait listing rate for minorities. There is also a fairly consistent wait listing rate for all groups, except a significant reduction is shown for the African American group. The committee developed an online *Survey on Referral to Liver Transplantation* to explore barriers to liver referral and wait listing for different ethnic groups and modeled the questionnaire after the *Survey on Referral to Kidney Transplantation*. The survey attempts to gain a better understanding of the reasons for the variability in the MELD/PELD scores and exception points and help propose initiatives to bring more uniformity to the system. The questions the committee is attempting to address are:

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

The initial online survey questionnaire targets transplant centers. Another more specific questionnaire will target hepatologists and gastroenterologists through newsletters and websites of professional organizations and other communication vehicles.

The committee was informed that the online survey was distributed on November 3, 2010. Following the final response deadline, an expanded subcommittee will be convened to discuss the second phase of the survey and/or other activities.

8. Ongoing Review of CPRA

The review of CPRA data was postponed to the November 2011 meeting to allow the committee to view a full years worth of CPRA data that will be presented at the next Histocompatibility meeting.

9. 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 team up 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 1A 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 local 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 to 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.

**ATTENDANCE FOR THE JULY 20, 2010
OPTN/UNOS MINORITY AFFAIRS COMMITTEE MEETING**

Committee Members	Position	In Attendance
Henry B. Randall, MD	Chair	Yes
Silas P. Norman, MD	Vice-Chair	Yes
Sayed 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. DeRoy, 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	No
Mesmin Germain, MBA, MPH	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	Business Analyst	Yes
SRTR Staff		
Monica Colvin-Adams, MD	Principal SRTR Researcher	Yes
Guests		
None		

Kidney Transplantation Committee Update

Ken Andreoni, MD, Chair

Board of Directors Meeting
November 9, 2010

OPTN



Progress

- Concepts circulated to societies
- Ongoing review of variances
- Development of rank-ordering methodologies
- Development of KDPI calculators

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Deceased Donor Kidney Allocation System

- Primary concepts
 - Age matching (+/- 15 years)
 - Survival matching (top 20% of donors/candidates)
 - Kidney Donor Profile Index

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Developing Consensus

- Circulated concepts to major organizations in July
- Received supportive feedback from each regarding concepts
 - awaiting additional details



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Working to Develop Details

- Rank ordering
- Variances
- Histocompatibility
- Pediatric

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Rank-ordering

- Charge: evaluate methodology for awarding points and propose revisions to better standardize priority across DSAs.
- 1 point = 1 year, all else based on fractional points specific to DSA
- First step to addressing geography issue

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Variations

- Charge: Using the criteria stipulated in the OPTN Final Rule and OPTN policies, review each of the variations to kidney allocation. For each variance, determine whether to incorporate into the revised national system, to dissolve, or to continue as a local variance.

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Histocompatibility

- Examine possible methods for improving access to moderately and highly sensitized candidates.
- Joint subcommittee with Histocompatibility

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Pediatric

- Charge: Determine if there is a KDPI threshold that similarly accomplishes the goal of expeditious transplantation for pediatric candidates as the current age threshold. Also examine possible solutions for improving access to transplant for sensitized pediatric candidates.
- Joint subcommittee with Pediatrics

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Other ongoing issues

- Current outcome evaluation policies (CSR) decrease access to high risk candidates
 - Historically aggressive programs have become more stringent on their listing practices due to SRTR outcome reports
 - This mathematical calculation of outcomes relative to other programs and not a defined level of clinical proficiency is different than assessment of most other specialty programs (VADs, lung reduction surgery, etc.)

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Path Forward

- Concept Document to be released as soon as cleared by HRSA
- Next Committee meeting: December 13
- Committee will work to finalize details for a proposal

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Kidney Paired Donation Pilot Program Update

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First Match Run

- October 28, 2010
- 43 candidates, 45 donors
- 15 transplant centers, 6 regions represented

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First Match Run

- 7 matches (16% of the candidates) from 6 different centers and 4 different regions
- 3 highly sensitized candidates
- 2 two-way matches and 1 three-way match

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Candidate Characteristics

	All Candidates	Matched Candidates
Total	43	7
Blood Type O	53.5% (23)	28.6% (2)
CPRA ≥ 80%	44.2% (19)	42.9% (3)
Ethnicity- Black	11.6% (5)	14.3% (1)
Ethnicity- Hispanic	9.3% (4)	0% (0)
Age over 50	32.6% (14)	28.6% (2)
DD Waiting Time > 1 year	48.9% (21)	42.9% (3)
Previous Kidney Transplant	51.1% (22)	57.2% (4)
Willing to accept a shipped kidney from any center	90.7% (39)	100% (7)

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Donor Characteristics

	All Donors	Matched Donors
Total	45	7
Blood Type O	31.1% (14)	28.6% (2)
Age over 50	33.3% (15)	28.6% (2)
BMI over 30	20% (9)	28.6% (2)
Willing to ship a kidney	97.8% (44)	85.7% (6)
Willing to travel to any center	28.9% (13)	28.6% (2)

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Upcoming Match Runs

- Tentatively scheduled for:
 - December 8, 2010
 - January 12, 2011

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Ongoing Work

- Working with the Living Donor Committee to address issues around transportation, psychosocial outcomes, and informed consent
- Continuing discussion on the potential use of bridge donors
- Addressing questions that arise from what we are learning through the Pilot
- Converting the Operational Guidelines to interim policy

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