

**Interim Report of the OPTN/UNOS Minority Affairs Committee Meeting
Chicago O'Hare Hilton
July 20, 2010**

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

Summary of the Meeting of the Board of Directors, June 2010

The Minority Affairs Committee (MAC) was provided with a summary of Board actions resulting from the June 21-22, 2010 meeting of the Board of Directors in Richmond, VA. Items of interest and relevance to the committee were highlighted for members.

Minority Affairs Committee Report

The committee was referred to the final report prepared for the June 21-22, 2010 meeting of the OPTN/UNOS Board of Directors summarizing the November 20, 2009 and March 23, 2010 MAC meetings.

Explore Transplant Presentation

The committee viewed a presentation by Amy Waterman, Ph.D summarizing her research on educating dialysis patients about transplantation. Dr. Waterman's research shows that a very high proportion of minority patients remain poorly informed about transplantation as the preferred treatment option for ESRD. Her research also reveals that the individuals designated to explain this option to patients are often not well educated on the subject of transplantation. Further, minorities have a very negative perception about transplantation as well as a great deal of fear about the subject and are more unlikely to consider the option without specific targeted education.

Dr. Waterman also presented an overview of her education program "Explore Transplant" which was developed to present the subject of transplantation to dialysis patients as an exploratory rather than action-oriented concept. The goal of the program was to assess whether improved transplant education in dialysis centers can increase patients':

- Informed transplant decision-making
- Discussion about transplant with other family members (potential living donors)
- Pursuit of transplant

The program encourages patients to explore transplantation as an option by providing factual information about the advantages of transplantation over dialysis and encouraging a discussion between the patient, family members and friends about the benefits transplantation might have for the patient, thus providing the tools for informed decision making for patients as individuals. Results of the program demonstrate improvements in patient knowledge about transplantation, as well as an increase in patient action to pursue transplantation.

During discussion, the committee acknowledged the probability that Dr. Waterman's research demonstrates that the CMS 2728 data previously viewed by the committee grossly overestimates the percentage of patients who are truly "informed" about kidney transplantation. This concern spurred the committee to consider adopting an expanded approach to addressing the problem which would utilize OPTN professional medical and transplant partner organizations as well as the Centers for Medicaid and Medicare Services (CMS).

MAC Committee Service Overview

The committee viewed a brief presentation summarizing the roles and responsibilities associated with membership on the Minority Affairs Committee.

Overview of OPTN Data Requests

The committee viewed a brief presentation summarizing the OPTN committee data request process, outlining the responsibilities of members for data submission, and explaining the events that trigger data collection (either through forms or through other mechanisms).

SRTR Overview

The committee viewed a brief presentation summarizing the role of the SRTR in providing inferential data and simulation modeling to the Minority Affairs Committee.

OPTN/UNOS Strategic Planning

The committee was updated on efforts within the OPTN to prioritize committee activities and help define the strategic direction for the committees and the Board in the coming years. The OPTN is also developing a process to use the Executive Committee of the Board to assist in prioritizing committee activities rather than the full Board.

MAC Public Education and Outreach Initiatives

Update on MAC Dialysis Facility Public Comment Opinion/Outreach Survey

The committee was briefly updated on the purpose and results of the *MAC Dialysis Facility Public Comment Opinion Survey* for the benefit of the new members. The committee was also informed that a manuscript summarizing the results of the survey is being prepared for submission. The results have also been accepted for a mini oral presentation at the upcoming American Society of Multicultural Health and Transplant Professionals (ASMHTP) meeting.

Survey on Referral to Kidney Transplantation

The committee was briefly updated on the purpose and results of the *MAC Survey on Referral to Kidney Transplantation* for the benefit of the new members. In light of Dr. Waterman's presentation, the committee discussed the need to combine the work of the dialysis survey and kidney referral survey subcommittees in developing specific initiatives to better educate and inform dialysis patients about transplantation and ensure that suitable dialysis patients are referred for transplant evaluation.

The results of the kidney referral survey will be presented at the upcoming ASMHTP meeting and later developed into a journal article.

Update on North Carolina Pilot Program Decreasing time for Referral to Wait Listing

The committee was updated on the pilot project initiated by the North Carolina Baptist Hospital which successfully reduced the time between the referral and wait listing stage of the transplant evaluation process. The total pre-transplant cycle has been reduced 46% (from 286 to 150 days).

MAC Outcomes Article

The committee was referred to the manuscript on minority transplant outcomes which recently appeared in the annual American Journal of Transplantation (AJT) State of Transplantation series. The article was authored by former and current MAC committee members and chairs.

MAC Review Article

The committee was updated on plans to pursue publication of an article addressing access to transplantation from the historical perspective of the MAC. The article will discuss the concepts of equity and utility and the inherent tradeoffs that must be made in developing kidney allocation policy aimed at increasing minority access to transplantation. The article will use the policy proposal removing HLA B points from the national system of kidney allocation to illustrate these principles.

The committee was informed that preliminary historical information has been compiled. The committee will actively begin the process of writing the article upon completion of the dialysis survey manuscript.

Ongoing Review of CPRA

The MAC was updated on data resulting from monitoring of the second phase of the CPRA policy implemented in UNetSM on October 1, 2009. Under this policy, highly sensitized candidates are assigned 4 extra points based on Calculated PRA (CPRA) value of 80% or greater. Prior to October 1, 2009 these points were assigned based on candidate's PRA value of 80% or greater.

The results of the data show the following:

- On 03/31/2009, 11 (4%) out of 257 programs did not list unacceptable antigens for any of their kidney candidates. Most of these programs (8/11) had less than 10 kidney candidates listed at that time.
- On 03/31/2010, 10 (4%) out of 255 programs did not report any unacceptable antigens. Only three of these programs had more than 10 kidney candidates listed at that time.
- There was an increase in the number of unacceptable antigens reported on the waiting list and a substantial decrease in the number of kidney refusals due to positive crossmatch.
- The number of low sensitized registrations (PRA/CPRA of 20% or less) decreased and the number of very highly sensitized (PRA/CPRA 97%+) registrations increased.
- The overall transplant rate seemed to have decreased for registrations with 1-20% sensitization level, remained the same for patients with 21-79% sensitization level, and increased for patients with 80%+ sensitization level.

Update on Development of a New Kidney Allocation System

The committee was updated on the progress of development of a new kidney allocation based on recent discussions by the Kidney Committee. The primary goals for the system are to:

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

In the proposed system, the majority of kidneys (80%) will be allocated based on a wide range of age matching where the organ is offered first to the entire group of candidates who are within 15 years older and younger than the donor's age. The remaining 20% of kidney grafts with the longest estimated potential function will be allocated first to the group of candidates with the 20% longest estimated post-transplant survival.

The results of the computer simulation models used to develop the proposed concepts, show the following:

- There are no changes observed to the proportion of transplants by
 - Race/ethnicity
 - ABO Blood Types
 - HLA mismatch
- There are changes observed to the proportion of transplants by
 - Primary Diagnosis
 - Recipient age (compared to last few yrs)

The committee was also updated on plans to distribute a second concept proposal document which will present the concepts to be used in the proposed kidney allocation system for public review and feedback. The communication plan will include webinars for patients, professionals, and the media. The Kidney Committee will consider feedback to the concepts before crafting a policy proposal

Kidney Paired Donation Pilot Project (KPD-PP) Update

The committee was updated on the status of the Kidney Paired Donation Pilot Project (KPDPP). The purpose of the pilot project is to test KPD on a national scale. The system will utilize UNetSM as the mechanism for integrating the national system. Advancement of the KPDPP system from a pilot project to a non-pilot system will be based upon policy development related to KPD.

There are currently three phases of Implementation:

- Phase 1 -Operational guidelines and contracts (This phase has been completed.)
- Phase 2-Interim policy (Adaptation of operational guidelines to allow sanctions and adverse actions.)

- Phase 3-Permanent policy (Will occur at the end of the pilot project. Depending on the results of the pilot it may eventually apply to all KPD programs.)

The interim policy development process includes the following groups:

- KPD Work Group (Consists of a drafting group which includes representation from many committees and existing KPD systems).
- Committee Sponsor Review:
 - Kidney Committee
 - Living Donor Committee
 - Patient Affairs Committee

The KPD Work Group Subcommittees include:

- Donor Chains Subcommittee- finalizing the proposal on whether to include non-directed donors and donor chains in the KPDPP.
- Interim Policy Subcommittee- converting the KPDPP Operational Guidelines into interim policy for KPD.
- Financial Subcommittee- addressing financial and administrative barriers to KPD including reimbursement, payer relations, and contracts.

The committee was also informed that an additional MAC member recently joined the KPD work group as a member.

Issues Regarding Geographic Variation

Access to Liver Transplantation

On-going Evaluation of Region 8 “Share 29” Liver Policy: Analysis of characteristics of Candidates and Recipients, Waiting List Death Rates, Number of Transplants and Post Transplant survival, Stratified by MELD/PELD Scores by Ethnicity, Before and After Share 29 Implementation.

Various data reviewed by the committee over time has shown higher MELD/PELD scores for minorities at wait listing and a lower overall wait listing rate for minorities. Further, the results show a fairly consistent wait listing rate for all groups, except a significant reduction is shown for the African American group. 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:

- 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 committee requested data on the following:

- Wait list death rates by candidate ethnicity
- Distribution of deceased donor transplants by MELD/PELD (M/P) score and recipient ethnicity
- Basic demographics and characteristics of transplant recipients
- Kaplan-Meier survival by recipient ethnicity before and after Share 29 implementation.

The data reviewed during the meeting show that:

- There did not seem to be any reduction in death rates per 100 patient years after Share 29 implementation, overall and for MELD/PELD 29+.
- Median MELD/PELD at transplant was comparable before and after Share 29 across ethnic groups
- There were higher number and percentage of transplants done in M/P 29+ after Share 29
- Across ethnic groups, graft and patient survival rates within 1 year of transplant were similar for transplants done before and after Share 29.

Draft Liver Referral Survey

The Committee has been developing an online *Survey on Referral to Liver Transplantation* to explore barriers to liver referral and wait listing for different ethnic groups. The survey is in the final stages of development and was modeled after the *MAC Survey on Referral to Kidney Transplantation*.

The Committee was informed an analysis of the raw data from the kidney survey revealed a need to revised the wording of several questions. The revised questionnaire will be distributed to the subcommittee before final distribution.

Liver Forum

The Committee was updated regarding the public forum on liver distribution held on April 12, 2010 in Atlanta, GA. The purpose of the forum was to gain a greater understanding among all stakeholder groups about hopes and concerns associated with liver allocation and distribution, and to open up discussions about policies regarding liver allocation/distribution concepts that do and do not resonate with the community. It is also hoped that the discussions will reveal desired directions for further work on the subject.

During the forum, the following sentiments were revealed:

- MELD score not “broken”
- Changes to distribution should be made in small incremental steps.
- The community is split on many issues.
- There are strong feelings about geographic inequities caused by using the DSA and regions for distribution.
- There were many comments about OPO effectiveness and single-center OPOs
- There was support for some tiered sharing, Share 15 National, and the “risk equivalent threshold” (RET) concepts.
- There was not much support for concentric circles
- There was strong support for increased utilization, decreased discards, and/or expedited placement of livers.
- The Committee must collaborate with OPO Committee and community.
- The Committee needs clear goals and objectives.

Two outgrowths of the forum was development of a Liver Allocation & Distribution Subcommittee to evaluate proposals/concepts discussed at the forum and formation of a Subcommittee on Liver Utilization. The subcommittee will examine the following:

Processes for expedited placement of livers

Increased utilization of organs and organ discards.

Evaluation of CPRA

Phase I of the calculated PRA (CPRA) policy was implemented on 12/5/07. During this phase, centers are required to enter at least one unacceptable antigen in order for their highly sensitized patients (PRA >80%) to receive the additional 4 points to receive deceased donor kidney transplant. As of 10/1/09 CPRA instead of PRA is used for allocation in the match run. Since this time, the MAC has viewed results of on-going Histocompatibility Committee analyses to monitor the policy by comparing CPRA and PRA by the old method. During the meeting, the committee viewed updated results of the on-going Histocompatibility Committee analysis by ethnicity. The data show that:

- Over one third of the active registrations have CPRA values present.
- Concordance between match PRA and CPRA for registrations with PRA 80+% is 90% or higher across all races.
- Concordance between match PRA and CPRA for black registrations is comparable with concordance for other ethnicities.
- The distribution of Match PRA and CPRA for White and Black registrations are similar to the distribution for the overall active registration with PRA> 0 and CPRA>0.
- Fifty percent of the registrations have CPRA equal to or within 10% of Match PRA.
- Distribution of differences between CPRA and Match PRA are similar for all ethnicities.

Request from Tennessee Transplant Society (TTS) to Study Statewide Alternative Allocation System (AAS)

The committee considered a request from the Tennessee Transplant Society to conduct computer simulation modeling comparing the current national system with the TTS AAS local unit which gives priority to patients with good CREG and BDR matching as well as high PRA patients, to determine if the AAS is creating a disparity in waiting times for sensitized candidates within the local area.

After brief discussion it was determined that data from the TTS variance is being provided to another transplant center within the OPO. Committee staff will investigate whether or not this information can be provided to the TTS as well.

Living Donation Issues

The committee was updated on the status of the manuscript *Prior Living Kidney Donors Who Subsequently Developed End Stage Renal Failure*. The manuscript is in the final stage of completion and is hoped to be submitted for publication in the Fall.

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
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	No
Bruce A. King, MSW	Region 7 Representative	Yes
Ioana Dumitru, MD	Region 8 Representative	Yes
Lani V. Jones, PhD, MSW	Region 9 Representative	Yes
Remonia A. Chapman	Region 10 Representative	No
David G. Jacobs, MD	Region 11 Representative	Yes (on phone)
L. Ebony Boulware, MD	At-Large	Yes

Oscar H. Grandas, MD	At-Large	Yes
Camille Hill –Blue, PA-C	At-Large	Yes
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	No
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)

Arbor Research Staff		
Valarie Ashby, MS	SRTR Analytic Staff	Yes
Natalie Lueth, MS	SRTR Analytic Staff	Yes
Alan B. Leichtman, MD	SRTR Principal Biostatistician	Yes
Guests		
None		