

**OPTN/UNOS Patient Affairs Committee
Report to the Board of Directors
November 16-17, 2009
Orlando, Florida**

Summary

I. Action Items For Board Consideration

- None

II. Other Significant Items

- Committee Members participating in the joint workgroup with the Membership and Professional Standards Committee discussed recent activities related to patient notification of periods of program waitlist inactivation and inactivation or relinquishment of program membership status (Item 1, Page 3).
- The liaison to the Kidney Transplantation Committee provided an update on the development of the national kidney paired donation system and the current status of the kidney allocation revision project (Item 2, Page 3).
- The Committee continued to examine inactive waitlist data (Item 5, Page 5).
- The Chair of the Minority Affairs Committee presented findings from a recent survey of dialysis patients to assess participants' perception of organ allocation policy and their ability to participate in the public comment process (Item 6, Page 6).

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Ray Gabel, Chair
Laura Ellsworth, Vice-Chair

The following report contains the deliberations of the Patient Affairs Committee (PAC) at its May 4, 2009 and September 2, 2009, teleconference meeting:

1. **Patient Notification Work Group** – Committee members of this work group with the Membership and Professional Standards Committee (MPSC) reported upon their recent activities related to patient notification of periods of program waitlist inactivation and inactivation or relinquishment of program membership status. Work group members discussed the sample letters created through a four-month period of Live Meetings. The Committee was informed that the initial decision to make such letters available online was changed as a result of liability concerns and potential unintended consequences. Concern was expressed that transplant centers may not tailor the letters to individual candidates, recipients, and living donors or adapt them to reflect specific program circumstances.

The Committee was informed that, alternatively, the OPTN Evaluation Plan will include an outline of the general content and provide format suggestions from the work group. It will also be noted within the Evaluation Plan that Members can contact the UNOS Membership Department for additional guidance in writing notification letters. The Committee will receive an update after the MPSC reviews additional data and begins evaluating the effects of the proposal.

Anna Kucheryavaya, UNOS Biostatistician, presented data requested by the Committee during the previous meeting in October, 2008. The Committee reviewed the total number and types of transplant programs with inactive waiting lists in 2008. The Committee specifically examined the number of programs (by program type) that were active during the whole period of time their waiting list was inactive. The Committee was also provided with data depicting the total number of days these programs had inactive waiting lists. Lastly, Ms. Kucheryavaya discussed relevant data regarding programs (by program type) that had periods of waitlist inactivity that overlapped with program inactivity, including the total number of days in which this occurred.

2. **Kidney Allocation System** -Ciara Gould, MSPH, liaison to the Kidney Transplantation Committee, provided an update about the Kidney Public Forum. The Committee reviewed the themes identified from the discussion, such as specific concerns surrounding the LYFT factor, the elimination of absolute priority for zero mismatched candidates, the inability to estimate wait time, and the impact on living donation (especially for younger candidates).

Ms. Gould described the general consensus about the need to improve the system and the preference for DPI over the SCD/ECD classification system, as well as dialysis time over waiting time. The Kidney Transplantation Committee will also consider incorporating GFR due to considerable expressed support for this measure of kidney function during the Forum. The

Committee was informed that there was general support for age-matching and specifically for preferentially allocating younger kidneys to younger candidates.

Upon inquiring about the path forward, the Committee learned that the Kidney Transplantation Committee will meet later in May, 2009 to continue reviewing the feedback and that a future proposal will include all three factors: the donor profile index, dialysis time, and some measure of benefit (but likely serving as a smaller weighted factor in the system). Ms. Gould also reported that the concept of age matching will be assessed further, including examining the suggestion from the ASTS to consider allocating kidneys from donors under 35 to candidates under 35. There was brief discussion surrounding the lack of a response from the HHS Office of Civil Rights.

3. **Kidney Paired Donation** – Ms. Gould also provided an update on progress towards development of the national kidney paired donation (KPD) system. The Committee was informed about the KPD pilot program, including the specifics of the following: two and three-way matching process, monthly match cycle system, and the priority point system. Members additionally learned about the requirements for participation in the pilot program and how recommendations from the Living Donor Committee were incorporated into the paired donation system.

Ms. Gould informed the Committee that the proposal to include donor chains in the KPD system will be sent out for public comment in June 2009. Upon inquiring about who will participate in the pilot program, the Committee learned that the Kidney Transplantation Committee is working on developing criteria for selecting approximately two to four centers. They are also considering allowing each participating center to coordinate the involvement of other local centers and to serve as the point of data collection and reporting. Since the pilot program will begin in September 2009, the Committee requested an update at the next meeting.

4. **Inactive Waitlist** – The Committee discussed the public perception of the inactive waitlist data and recalled how media attention to inactive waitlist data brought increased awareness of this issue to the public in 2008. It was agreed that since the considerable number of patients listed as status 7 are still in need of a transplant that it is still relevant and appropriate to present the total number of active and inactive patients as being representative of the national waiting list.

Ms. Kucheryavaya presented data to the Committee capturing the number of inactive candidates on the waiting list, by organ, age, and region (as of January 31, 2009). Members noted and questioned the regional variation. The Committee examined the number of days spent on the inactive list (during the most recent inactive period as of January 31, 2009) and the associated reasons for the change in status. The Committee also inquired about the large number of kidney candidates who are made inactive because their evaluations are incomplete. It was noted that this enables patients at only certain centers to begin accruing wait time prior to completion of their evaluations. The Committee also discussed how if the kidney allocation system is modified to include dialysis time that this inequitable listing practice could be addressed.

Ms. Kucheryavaya also presented 2008 data regarding the number of active and inactive candidates who were removed from the waiting list due to death. Brief discussion ensued regarding how death on the waiting list is defined. Members also questioned possible varying

practices across centers, such as removing patients from the list if they are too sick for transplant versus changing their status to inactive. The Committee questioned how differences in such practices could impact data reflecting deaths associated with each transplant center, and questioned the inherent financial incentive for removing patients from the waitlist versus listing them as status 7.

The Committee was updated by the UNOS Research liaison to the Transplant Coordinators Committee on the status of the survey to poll clinical transplant coordinators about their inactive waitlist practices. The Committee examined the content of the survey and learned that final results will be available for review during the Fall 2009 meeting.

5. **Update on the Dialysis Survey Project** – Dr. Pang-Yen Fan, Chair of the Minority Affairs Committee (MAC), discussed MAC’s recent survey of dialysis patients in Alabama and Massachusetts to assess participants’ perception of organ allocation policies, as well as their ability to participate in the public comment process. Dr. Fan outlined the survey methods and demographics of the 147 participants. In reviewing the results, it was noted the disparity between those subjects who expressed an interest in transplantation versus those who reported they had actually been evaluated. The Committee discussed how presented data illustrated that there is confusion on the part of some participants regarding whether they are truly listed.

The Committee questioned the data reflecting the large number of participants who described themselves as having a “good understanding of organ allocation policy” and suggested some type of assessment of this knowledge in future potential studies. It was noted the variation in responses regarding subjects’ perception of the fairness of allocation policies.

The Committee concluded it was evident from a review of the survey results that many participants do not have internet access and that correspondence by mail and phone were documented as being the preferred communication method. The Committee noted that very few dialysis patients responded that they had voted on any proposals, but the majority expressed a strong interest.

There was discussion regarding how some data suggested that participants from Alabama may have a greater distrust of medical providers. For example, Massachusetts subjects were considerably more likely to agree that doctors were more qualified to make policy decisions. Similarly, more Alabama participants believed that their opinions would not be taken seriously in the public comment process. Participants from Alabama were more likely than those from Massachusetts to rely upon patients as sources of transplant information, while Massachusetts subjects were more likely to rely upon doctors and nurses in comparison to Alabama subjects. Dr. Fan mentioned a possible impact upon data from Massachusetts subjects could be that residents of this state are required to have health insurance.

Optimism was expressed that the UNOS Patient Information Letter will increase awareness of the public comment process. A suggestion was made to examine hits on the website related to public comment before and after the effective date for implementation of this letter, if possible.

6. **Update on Disease Transmission** – Dr. Michael Ison, Chair of the Disease Transmission Advisory Committee (DTAC), briefly reviewed the history and composition of the DTAC, and informed the Committee about the process of reporting potential and confirmed donor-derived diseases (DDD) to the UNOS Patient Safety System. The Committee learned about the communication system that enables DTAC Members to quickly assess and respond to disease transmission reports. Dr. Ison also reported how routine DTAC meetings are held to assess and categorize reported transmissions, consider policy changes, and assemble reports to keep the transplant community and the Board informed.

The Committee examined data depicting the number and type of malignancies and infections reported from 2006 through 2008, noting the number of confirmed transmissions and deaths. Dr. Ison discussed the different types of testing and their associated challenges and limitations. He also reported concerns about discarding organs based upon false positive results. There was a discussion regarding the inherent challenge in collecting social and medical histories from donor families and the difficulties in determining if recipient malignancies and infections are in fact transmitted from donors.

The Committee inquired about data regarding the average number of donors who meet high risk criteria and transplant professional Members of the Committee shared their own general data. Dr. Ison briefly discussed OPTN policies pertaining to screening of donors and recipients and the Public Health Services donor screening and post-transplant management guidelines. Members discussed the variability in post-transplant testing and the inherent consequences from the lack of a standardized electronic medical records system.

Dr. Ison reported the upcoming conference to more extensively examine the consent process, and shared his concern about whether patients truly comprehend the risk involved when consent is being discussed at the time of listing. Members discussed the importance of also ensuring patients understand that they can change their decision about considering high risk donors as their health condition changes. Transplant professional Members of the Committee discussed their consent process, focusing especially on how they handle high risk donor offers.

7. **Post transplant self-care** – The Committee discussed how best to assist recipients with post transplant self-care efforts to extend the life of their graft and enhance their quality of life. Topics of the discussion included nutrition, medication compliance, exercise, and social support. Members additionally reviewed the article in their packets that focused on the impact of self care on transplant outcomes.

The Committee also discussed available resources, including one member's new camp service for pediatric tissue and organ recipients, and strategies for spreading the word about such services. Members described resources available at their affiliated transplant centers, including educational material and videos, support groups, and a "transplant school."

The Committee discussed communication strategies for self care education, such as including more extensive information within existing UNOS transplant educational material, developing new educational resources, and an information kit for use by facilitators of support groups. It was

agreed to continue to discuss this topic further in upcoming Committee conference calls and meetings.

8. **Legislative Update** - William G. Lawrence, J.D., UNOS Director of Patient Affairs, updated the Committee on numerous legislative initiatives. The Committee reviewed the steps involved in the appropriations process pertaining to kidney paired donation. Members also learned about the multi-organization effort to extend Medicare coverage of immunosuppressant medication for the life of the graft.

Mr. Lawrence discussed how some employers are denying coverage to living donors under the Family Medical Leave Act because they view living donation as non-essential or “elective” surgery. Members learned about a bill (to be reintroduced in the 111th Congress) that will attempt to cover living organ donation under this act. Members will be encouraged to make phone calls and send emails of support in the future regarding this initiative. The Committee discussed another bill that would authorize a tax refund for lost wages and other expenses directly related to living donation.

Lastly, Mr. Lawrence updated the Committee about the initiative to provide donor families with medals of honor. Although this bill passed last year, no funding has been made available. Other challenges are related to a lack of specific parameters for who should receive the medal. For example, should tissue donors, living donors and families of non-U.S. resident donors be included? Members also questioned if the medals will be provided only to current and future donor families. The Committee discussed how some OPOs already have their own medals and ceremonies in place to honor organ and tissue donors. Members learned that a less complex and expensive national certification of appreciation is being considered as an alternative, which would require an amendment of the current law.

9. **Consideration of Policy Changes Proposed by Other Committees**

February 6 – April 24, 2009 Public Comment Period:

1. Kidney Transplantation Committee and Liver and Intestinal Organ Transplantation Committee -Proposed listing requirements for simultaneous liver-kidney transplant candidates (Policy proposed: 3.5.10 - Simultaneous Liver-Kidney Transplantation)

The Committee supported this proposal with a vote of 10:0:2. It was questioned if other possible causes for the rise in SLK transplants since 2002 had been investigated, such as recent changes to diagnosis related group (DRG) classifications for hepatorenal syndrome. The Committee was informed that aside from the changes to the MELD calculation in 2002, the Kidney Committee had not found other possible causes for the increase.

2. Liver and Intestinal Organ Transplantation Committee - Proposal to create regional distribution of livers for Status 1 liver candidates (Policy affected: 3.6 - Allocation of Livers)

The Committee supported this proposal with a vote of 14:0:1. It was discussed that both local and regional boundaries are arbitrary and how region size can differ greatly. However, they agreed that the intent of this proposal is to prevent deaths on the waitlist and supported regional sharing to enable the sickest patients to receive transplants.

3. Liver and Intestinal Organ Transplantation Committee - Proposal to create regional distribution of livers for MELD/PELD candidates (Policy affected 3.6 - Allocation of Livers)

The Committee supported this proposal with a vote of 12:0:1. It was discussed how this policy could potentially decrease the need for patients to multiple list and how this could be beneficial to those patients who cannot do so due to limited financial means. There was discussion about the impact on centers with smaller numbers of candidates, as well as the impact on regions, such as region six, where travel time could be significant. It was agreed that the decision to accept an organ with longer cold ischemia time could still be made on a case by case basis.

4. Liver and Intestinal Organ Transplantation Committee - Proposal to standardize MELD/PELD exception criteria and scores (Policy affected: 3.6.4.5 - Liver Candidates with Exceptional Cases)

The Committee supported the proposal with a vote of 13:1:1 with no additional comment.

5. Thoracic Organ Transplantation Committee - Proposal to add the factors current bilirubin and change in bilirubin to the lung allocation score (LAS) (Policy affected: 3.7.6.1 (Candidates Age 12 and Older)

The Committee supported this proposal with a vote of 14:0:1. It was encouraged close monitoring of post-transplant outcomes for those patients with elevated bilirubin levels. This was viewed as being especially important since this policy is based upon data from such a small sample size and since members are supportive of maximizing the benefit of donated organs. Some Committee members also expressed support for monitoring future outcome data regarding Diagnosis Group C and D patients specifically.

6. Living Donor Committee - Proposal to modify the high risk donor policy to protect the confidential health information of potential living donors (Policy affected: 4.1.1 - Communication of Donor History)

The Committee supported the proposal with a vote of 11:0:1. There was brief discussion about national and state public health policies regarding the mandatory reporting of certain health conditions, as well as mandatory contact of partners.

7. Membership and Professional Standards Committee - Proposal to change the Bylaws to clarify the process for reporting changes in key personnel (Bylaw affected: Appendix B, Section II,E (Key Personnel); Appendix B, Attachment 1, Section III (Changes in Key Personnel)

The Committee expressed considerable concern about the application process, describing it as being too complex, redundant, and time-consuming. It was remarked that it is difficult to distinguish between those programs that don't have appropriate personnel versus those who can't manage the challenging application process. While the backlog in I.T. was acknowledged, Members agreed that the current process is contributing to such confusion and tedious work that making the application process electronic should be prioritized. There was discussion and some support expressed about requiring programs to inactivate or withdraw in comparison to relying on programs to do so voluntarily. There was also an inquiry regarding how short-term situations should be handled when programs aren't informed internally within 30 days of staff changes. The Committee supported the concept of the proposal, but due to the concerns above the proposal was largely opposed with a vote of 1:14:1.

8. Organ Procurement Organization (OPO) Committee - Proposal to clarify, reorganize, and update policies on OPO and transplant center packaging, labeling and shipping practices (Policy affected: 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials)

This proposal was supported with a vote of 14:1:1. Several Committee members supported the suggestion that after delivery to the transplant center for islet processing, the packaging and labeling responsibility should be relegated to the transplant center until islet production is done at the donor hospital. It was suggested that the packaging rules for transport of islets from the place of production to the place of implantation should be distinguished from the packaging rules for transport of other organs from donor hospital to transplant center. There were inquiries and brief discussion (with no actions taken) about the need for rigid containers for livers, lungs, and intestines and provisions for sanitizing mechanical preservation machines.

July 10-September 14, 2009 Public Comment Period:

On September 2, a Live Meeting was held to discuss the following seven proposals. Presentations were provided and questions fielded by liaisons from the sponsoring Committees.

1. Kidney Transplantation Committee - Proposal to Include Non-Directed Living Donors and Donor Chains in the Kidney Paired Donation Pilot Program (Affected Program: Kidney Paired Donation Pilot Program)

This proposal was supported with a vote of 15:0:0.

2. Living Donor Committee - Proposal to Improve the ABO Verification Process for Living Donors (Affected Policies: Policy 12.3.1 - ABO Identification; Policy 12.8.1. - Reporting Requirements)

This proposal was supported with a vote of 15:0:0 with no additional comment.

3. Living Donor Committee - Proposed Guidance for the Medical Evaluation of Living Liver Donors)

The Committee unanimously supported this proposal with a vote of 15:0:0.

4. Membership and Professional Standards Committee - Notification Requirements for OPOs, Transplant Hospitals, and Histocompatibility Labs When Faced with an Adverse Action Taken by Regulatory Agencies (Affected Bylaws: Appendix B (Sections I, II, III): Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership)

There was brief discussion about the number of violations associated with this original policy. The Committee recognized the challenges associated with a five day time frame for notification and supported the proposal with a vote of 14:1:0. The Committee also briefly discussed the separate entities and the critical nature of ensuring the MPSC is informed of patient safety related issues.

5. Membership and Professional Standards Committee - Proposal to Change the UNOS Bylaws to Reconcile Discrepancies in Patient Volume Requirements for Full and Conditional Program Approval When Qualifying Kidney, Liver and Pancreas Primary Transplant Physicians (Affected Bylaw: Appendix B, Attachment I)

The Committee supported this proposal with a vote of 15:0:0 with no additional comment.

6. Membership and Professional Standards Committee - Proposal to Add Language to the Bylaws Requiring Transplant Center and OPO Members to Follow State Law Regarding Anatomical Gifts (Affected Bylaws/Policy: Article I, Sec 1.10, Appendix B, Section I and II, and Policy 3.4: Organ Procurement, Distribution and Alternative Systems for Organ Distribution or Allocation)

Upon expressing concern surrounding the unanticipated observed need for this policy, The Committee unanimously supported this proposal (14:0:0) with the following amendment (which includes the addition of the term “operative”):

3.4.1 Avoidance of Conflicts of Interest. Neither the attending physician of the decedent at death nor the physician who determines the time of the decedent’s death may participate in the operative procedure for removing or transplanting an organ from the decedent. For purposes of this section, “organ” is defined as set forth in the OPTN Final Rule (42 C.F.R Part 121.2), and “decedent” is defined as a deceased individual whose body is or may become the source of a donated organ.

7. Organ Procurement Organization (OPO) Committee - Proposal to Change Requirements for Labeling and Packaging Organs Procured by Visiting Transplant Center Teams and for OPO Labeling of Tissue Typing Materials (Affected Policy: Policy 5.0 Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials (Organ Procurement Organization) (OPO) Committee)

The Committee expressed concern upon learning about the unanticipated variability in practice among OPOs. Members ultimately supported the transfer of responsibility of packaging and labeling to transplant centers when they recover their own organs for

transplant with a vote of 10:2:3. The Committee supported the use of two unique identifiers with a vote of 14:0:1.

August 17-September 30, 2009 Public Comment Period:

1. Ad Hoc Disease Transmission Advisory Committee - Proposal to Modify Requirements for Mandatory HTLV-1/2 Testing for All Potential Deceased Donors Affected/Proposed Policy: Policy 2.2.3.1 (For All Potential Donors)

The Committee supported this proposal with a vote of 12:0:1.

NAME	POSITION	May 4 In person	Sept 2 Teleconf
Ray Gabel	Chair	X	X
Laura Ellsworth	Vice Chair	X	
Keith Diaz J.D.	Regional Rep.	X	X
Michelle Christenson	Regional Rep.	X	X
Kenyon Murphy	Regional Rep.	X	N/A
Kathleen Giery	Regional Rep	N/A	X
G. Rodney Davis EMT	Regional Rep.	X	X
Grace Chang Esq.	Regional Rep.	X	X
Laura Ellsworth	Regional Rep.	X	
Alison Walsh	Regional Rep.	X	
Kim Burdakin	Regional Rep.	X	X
Laura Murdock	Regional Rep.	N/A	X
Karen Starr	Regional Rep.	X	X
Charles (Ted) Lawson	Regional Rep.	X	X
Michelle Crossley RN, BSN	Regional Rep.	X	N/A
Karen Starr MSN, MAC, RN, CS	Regional Rep.	X	X
Emma Griswold BS	At Large	X	N/A
Megan Lewis PhD	At Large		
Pete Mazula	At Large		N/A
Kim McMahon	At Large	N/A	X
Thomas Starr	At Large	X	X
Isabel Stenzel Byrnes	At Large	X	X
Heidi Yeh M.D.	At Large		

David Zaas M.D.	At Large	X	
Kathleen LeBeau	At Large	N/A	X
Mary Carpenter	BOD Liaison	X	N/A
Richard Laeng MPH	Ex Officio	X	X
Karen Mock LCSW	Committee Liaison	X	X