

OPTN/UNOS TRANSPLANT ADMINISTRATORS COMMITTEE
Report to the Board of Directors
November 16-17, 2009
Orlando, FL

Summary

I. Action Items for Board Consideration:

- None

II. Other Significant Items:

- The Committee will work to develop DonorNet® educational tools for the transplant community. (Item 1, Page 4)
- The Committee partnered with the Transplant Coordinators Committee to administer and evaluate the results from a survey, which will be used to develop inactive waitlist management best practices. (Item 1, Page 4)
- The Committee has partnered with AOPO to develop key recommendations/guidelines for contractual relations between transplant centers and OPOs. (Item 1, Page 4)
- The Committee reviewed a MPSC memo requesting the assistance of various constituency committees to assist with the development of clear responsibilities and guidelines for individuals serving as a data coordinator and for feedback regarding whether or not this position should be defined with the bylaws. (Item 3, Page 5)
- The 2010 Transplant Management Forum will be held in Orlando, FL on April 21-23. (Item 4, Page 5)

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Gene E. Ridolfi, BA, RN, Chair

The Committee meets monthly by conference call except in April, when the Transplant Management Forum occurs, and July and October when the Committee meets in person.

1. Committee Goals- The Committee continues to devote considerable time to working on four goals that were approved by OPTN/UNOS President James Wynn, MD and one continued goal from 2007-2008. Those goals are:
 - To provide input regarding all proposals with potential to impact transplant program operations, and particularly with regard to: a) Member and patient communications regarding a new kidney allocation system and the OPTN kidney paired donation program and b) Proposed revisions to living donor data submission policies and forms. The Committee received a request from the Kidney Transplantation Committee to have transplant centers/hospitals host kidney transplant patients on site to participate in a Live Meeting to learn about the Kidney Allocation System (KAS) RFI. The Committee's response to the Kidney Transplantation Committee was that while interested in promoting opportunities to engage and educate transplant patients and their families there is concern that hosting a specific event on a focused proposal could be viewed as biased support towards a defined patient population. Alternatively, the Committee suggested that Transplant Administrators could be encouraged to communicate opportunities for public comment to patients and families.

The Committee Kidney Paired Donation (KPD) workgroup representative provided the history and reviewed the requirements for participation in the KPD pilot program. There will continue to be a Transplant Administrator Committee (TAC) KPD workgroup representative, and there will also be a TAC representative on the KPD Finance Subcommittee. These two representatives will report any updates on KPD to the committee during the monthly conference calls and in- person meetings.

The Committee provided feedback to the Living Donor Committee (LDC) regarding various proposals prior to being released for public comment. Those proposals were the proposal to improve the safety of living donation through an improved ABO verification process (Entry and Verification of Living Donors Policy [Policy 12.0]) and the 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) (Living Donor Committee). The LDC also requested feedback from the Committee regarding creating a separate category for living donor policy, which the Committee supported. The Committee also supported the LDC by posting various items on the Transplant Administrators' Listserv. The LDC requested that the Transplant Management Forum (TMF) have Living Donor breakout sessions. Living Donor sessions were added to the draft TMF agenda. The TAC crossover member continues to provide the committee updates on current LDC activities/issues and will continue to do so throughout the year.

The Committee requested to be involved in the policy development process at the beginning instead of waiting to be asked for their recommendations at the end during public comment, which the Committee feels is too late. A TAC representative will participate in the Policy Oversight Committee (POC) conference calls and meetings. The representative will report to the full Committee any developing policies/proposals so the Committee can provide early input. UNOS Committee liaisons have been requested to involve the TAC in relevant workgroups.

The Committee also discussed the 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) (Membership and Professional Standards Committee). The Committee recommends that the process be automated and that it is too repetitive. A conference call was arranged by MPSC liaisons with several Committee members to discuss the revisions to the proposal and to obtain further input. The Committee representatives will discuss during its October in-person meeting the possibility of presenting the revised proposal at the 2010 TMF. The MPSC liaisons also requested the TAC's assistance with developing a transplant administrator help book for UNOS compliance.

- To develop educational strategies for members regarding more effective use of DonorNet®. The DonorNet® workgroup plans to develop some educational tools for the community. The workgroup will partner with AOPO and the Transplant Coordinators Committee (TCC) to examine the use of non-standardized abbreviations and the documentation of donor information in DonorNet®. Possible educational tools include webinars, presentation at the 2010 TMF, and a DonorNet® Do's and Don'ts document.
- To partner with appropriate committees and develop strategies for improved Wait List Management within transplant centers. The TCC created and administered a survey on February 10, 2009, which will be used to study real-world practices, timing, and communication related to listing and managing candidates at inactive status on the waitlist. It is the intent of the TCC to study the results and use them to help develop inactive waitlist management best practices. The Committee has three members who are currently working with the TCC on reviewing the results of the waitlist survey. The Committee representatives reported that the workgroup continues to await the results of the survey and will have conference calls to discuss the results and how to move forward with presenting them to the community. One suggestion is to present the results at the TMF.
- Long Term Goal: To work with staff to develop potential strategies for improving the quality of data submission. The Committee will provide ideas to improve program specific reports.
- Continued Goal: To partner with AOPO to define and disseminate Best Practices for flight standards and insurance. The OPO/Transplant Center Transportation Safety workgroup was charged with creating and administering a survey for OPO's and Primary Program Administrators that evaluates best practices for transportation and insurance with respect to organ recoveries, following the tragedy in Michigan. The workgroup had several conference calls with AOPO and per AOPO's suggestion partnered with Dr. Michael Englesbe, Assistant Professor of Surgery, Division of Transplantation at the University of Michigan Health System, to develop the survey. UNOS provided the transplant administrators contact

information to the University of Michigan researchers to facilitate the survey process. The University of Michigan collected the results and presented them at a national meeting in March 2009. Mr. Jim Cutler, OPO At Large TAC member, presented some of the important findings of the survey on April 24 at the 2009 TMF in Seattle, WA. The University of Michigan is in the process of writing a white paper based on these results. The workgroup has also been working on the development of recommendations/guidelines for contractual relations between transplant centers and OPOs. They are working with AOPO representatives on this initiative.

2. OMB Data Collection Forms Review. The Committee formed a workgroup that reviewed the Transplant Candidate Registration Form (TRR), Transplant Recipient Registration Form (TRR), Transplant Recipient Follow-up Form (TRF), Deceased Donor Registration Form (DDR), Living Donor Registration Form (LDR), and the Living Donor Follow-up Forms (LDF) via several conference calls for the OMB data collection forms review. In summary, the workgroup recommended that for data entry efficiency, all fields identified by the Data Reduction effort of 2007 and 2008 for removal should be physically removed from the forms instead of just made optional. Since these optional fields are not entered consistently, they are of little or no value and only serve to make unnecessary work. The workgroup also recommended that the Malignancy form be removed in its entirety from the forms submission requirements. Transplant programs are ill-equipped to formally report malignancy data elements asked on the form. The appropriate source documentation for this form resides with the oncology staff, not with the transplant staff. Therefore, the workgroup recommended that, if these data are to be collected, a relationship between the American College of Surgeons and the National Tumor Registry could advantage that effort. All the pertinent information for the Malignancy form is collected by the latter and information from that Registry would be more accurate and robust than what transplant centers are able to provide. Also, transplant information systems vendors (e.g., HKS/Ottr) should be involved in early stages of the OMB forms change process so that they are apprised of upcoming changes enabling them to be better prepared to make concomitant changes to their software. The workgroup also noted that source documentation for data abstraction should be explicitly stated in the instructions and that specific definitions are given for all required fields. The workgroup also stated that it would be helpful if the clinical relevance of the fields be described in the instructions to give the data abstractor a frame of reference. These recommendations will be submitted to the Ad Hoc Data Management Group (AHDMG) for review and then to the Policy Oversight Committee (POC) for public comment.
3. Program Review Workgroup. This workgroup will focus on any OPTN requests the Committee receives. The Committee reviewed a Membership and Professional Standards Committee (MPSC) memo requesting the assistance of various constituency committees to assist with the development of clear responsibilities and guidelines for individuals serving as a data coordinator and for feedback regarding if this position should be defined within the Bylaws. Current Bylaws provide similar information for clinical transplant coordinators, transplant pharmacists, and financial counselors; however, there are no descriptions for primary data coordinators. The MPSC is requesting the TAC workgroup to discuss the need to put their suggestions into the Bylaws as well as the responsibilities, etc. The workgroup leader has discussed this further with an MPSC liaison and will develop their response at the October 2009 in-person Committee meeting.
4. 2009 Transplant Management Forum. The 2009 Transplant Management Forum was held April 22-24 in Seattle, Washington. A total of 340 participants attended the meeting. The Committee accepted a total of 62 abstracts. There were 36 exhibitors, 16 sponsors and 6 abstract award sponsors supporting the meeting. The agenda included nine plenary sessions and five breakout

session tracks. Evaluations of the meeting were very positive. The 2010 Transplant Management Forum will be held in Orlando, FL on April 21-23, 2010. A draft agenda has been developed and speakers and sponsors/exhibitors are currently being pursued.

5. Staffing Survey. The Committee continues to evaluate how the staffing survey might be helpful and useful for the MPSC as it evaluates new program applications or considers the performance of centers having outcome problems. The 2008 Staffing Survey was released on the Transplant Administrators section of the UNOS Secure Enterprise Web Site (<https://portal.unos.org>) several months ago. Comparison statistics for transplant program staffing benchmarks with the 2008 data are scheduled to be available to any member who has already submitted a survey by late May or early June. As in prior years, only programs that complete surveys for their organ specific programs will have access to the summary and comparison data. The goal for the 2008 Staffing Survey is to have seventy-five percent of all transplant programs complete the surveys in each organ specific grouping. In previous years, there was an increase in submissions in May and June, most likely due to exposure at the Forum. At the time of this writing, the responses from programs range from twenty percent for pancreas to forty-three percent for kidney. This represents an increase of twenty percent to thirty percent response from the same period last year. A reminder notice is planned for the next issue of the UNOS Update to solicit more survey submissions.
6. Request for Information Payer Workgroup. The Committee continues to explore how the Request for Information (RFI) Payer workgroup could assist UNOS in understanding the perspective and concerns of the payer while balancing the needs of transplant centers for adequate reimbursement. The workgroup began working on 2010 updates at the July 2009 in-person Committee meeting. Annual updates along with text revisions have been submitted to the UNOS Information Technology (IT) Department for review. Also, the workgroup discussed developing a FAQ document and field definitions. The 2010 RFI is scheduled for release in mid- January. In July, the chair for the workgroup met with Blue Distinction Centers for Transplants (BDCT) representatives in Chicago where they presented their request for RFI data in an electronic format. BDCT has requested to work with the Committee to set up an electronic transfer of data to prevent the need for manual entry for all concerned. The programming for their electronic version is slated to begin by fall 2010 and be completed by January 2011. The workgroup agreed that further exploration of the request of BDCT should occur and identified the following individuals to participate: Greg Levine (SRTR), Janie Morrison (TAC), Blaine Hess or John Lombardi (UNOS IT), Robert Walsh (HRSA). A meeting of the previously named persons with BDCT will occur after the in-person Committee meeting on October 16th in Chicago. The next Bi-annual UNOS Payor meeting is July 2010, which solicits feedback from payors for RFI updates and improvements and provides payors with educational information.
7. Public Comment Proposal Distributed on July 10, 2009. The Committee discussed and made recommendations for the following proposals released for public comment:

1. OPTN notification requirements for OPOs, Transplant Hospitals, and Histocompatibility Labs when faced with an adverse action taken by other regulatory agencies. (Policy affected: Modification to Bylaws, Appendix B (Sections I, II, III): Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership) (Membership and Professional Standards Committee)

Committee Response—This proposal had full Committee support. The Committee had a concern about hospital compliance and recommends that any adverse actions taken by other

regulatory agencies be submitted to a compliance officer at the hospital and he/she relay the information to the transplant administrator.

(Support 10, oppose 0, abstain 0)

2. Proposal to change the Bylaws to reconcile volume requirement discrepancies concerning full and conditional program approvals under training and experience pathways for kidney, liver and pancreas primary transplant physicians. (Bylaw affected: Appendix B, Attachment I) (Membership and Professional Standards Committee)

Committee Response-The Committee reviewed this proposal and had no further recommendations.

(Support 9, oppose 0, abstain 1)

3. Proposal to add language to the Bylaws requiring transplant center and OPO members to follow state law regarding anatomical gifts. (Bylaws/Policy affected: 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)(Membership and Professional Standards Committee)

Committee Response-The Committee unanimously supported this proposal with the following amendments:

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 procedure for the surgical ~~removal~~ ~~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.

The Committee strongly recommends being clear and concise with the policy language and not leave it open for interpretation.

(Support with amendment 11, oppose 0, abstain 0)

4. Proposal to Modify Requirements for Mandatory HTLV-1/2 Testing for All Potential Donors (Ad Hoc Disease Transmission Advisory Committee)

Committee Response-The Committee unanimously approved the discontinuation of prospective testing.

(Support 11, oppose 0, abstain 0)

The Committee unanimously opposed the proposal for retrospective testing due to cost, logistics, and legal liability and sees no clear value.

(Support 0, oppose 11, abstain 0)

5. Proposal to include non-directed living donors and donor chains in the Kidney Paired Donation Pilot Program (Program Affected: Kidney Paired Donation Pilot Program) (Kidney Transplantation Committee)

Committee Response—The Committee unanimously supported this proposal and had no further recommendations.

(Support 11, oppose 0, abstain 0)

6. Proposal to Improve the Safety of Living Donation through an Improved ABO Verification Process (Policy affected: ABO Identification (Policy 12.3.1); Reporting Requirements (12.8.1.1 and 12.8.1.2) (Living Donor Committee)

Committee Response—The Committee unanimously supported this proposal and had no further recommendations.

(Support 11, oppose 0, abstain 0)

7. Proposed Guidance for the Medical Evaluation of Living Liver Donors (Living Donor Committee)

Committee Response—The Committee unanimously supported this proposal and had no further recommendations.

(Support 11, oppose 0, abstain 0)

8. Proposal to transfer responsibilities of labeling and packaging to the transplant centers when they recover their own organs (Policy Affected: 5.0 – Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials (Organ Procurement Organization) [OPO] Committee)

Committee Response—The Committee reviewed this proposal and voted on the proposal's two sections separately.

Section 1-The goal of this proposal is to promote patient safety by clearly assigning responsibility of labeling and packaging to the transplant center when its recovery team elects to procure organs and transport the organ(s) directly to their transplant center for transplant.

The Committee would like the OPO Committee to consider that if there are no ramifications then there will be no change in practice. There needs to be consistency in practice among the OPOs and there is the need to address the surgeons' behaviors in not following policy.

The Committee unanimously opposed this proposal and feels that labeling is not a transplant center's responsibility.

(Support 0, oppose 11, abstain 0)

Section 2-This proposed modification requires OPOs to label tissue typing materials with two unique identifiers (e.g., donor initials; donor hospital ID; donor date of birth) in order to optimize a safe testing environment.

The Committee unanimously supported this section of the proposal.

(Support 11, oppose 0, abstain 0)

OPTN/UNOS Transplant Administrators Committee
July 23-24, 2009
Chicago, IL

Committee Members in Attendance

Gene E. Ridolfi BA, RN
Timothy Stevens RN, BSN, CCTC
Sharon Mathews NS, RN, CPTC
Kim Barnett RN, BSN, CCTC
Gary Sigle RN, MBA, BSN
Pam Gillette MPH, RN
Pamela Hester RN, BSN, CCTC
Nancy Long RN, CCTC
Nancy Metzler
Janie Morrison FACHE
Kimberly Nicoll RN, BSN
Jacqueline Colleran
Robert Walsh

Greg Levine
Cassandra Smith-Fields RN, MBA, MSN

Committee Members Unable to Attend

Mesmin Germain, MBA, MPH

Sylvia Odom RN, MSN, NHS, CCTC
David Hester
James Cutler CPTC

Staff in Attendance

Angel Carroll MSW
Cherri Carwile
Jude Maghirang MS

Staff in Attendance via Conference Call

Kerrie Cobb

Chair
Vice Chair
Region 1 Representative
Region 2 Representative
Region 4 Representative
Region 5 Representative
Region 6 Representative
Region 8 Representative
Region 9 Representative
Region 10 Representative
Region 11 Representative
At Large
Division of Transplantation,
Ex Officio, non-voting
SRTR Liaison
Ex-officio

Division of Transplantation,
Ex Officio, non-voting
Region 3 Representative
Region 7 Representative
At Large

Liaison
Assistant Liaison
UNOS Staff

UNOS Staff