

OPTN/UNOS PATIENT AFFAIRS COMMITTEE
Report to the Board of Directors
June 28-29, 2011
Richmond, Virginia

Summary

I. Action Items for Board Consideration

- None

II. Other Significant Items

- The Committee completed a rewrite of the OPTN Contractor Patient Information Letter. The updated Letter became active in March 2011. (Item 1, Page 3)
- Committee members authored a series of three articles on patient notification and benefits received from the OPTN Contractor Patient Information Letter. The articles appeared in consecutive issues of UNOS Update beginning in November/December 2011. (Item 1, Page 3)
- The Committee sponsored a webinar with The Department of Evaluation and Quality (DEQ) on March 9, 2011. The Webinar was entitled *—An Introduction to Patient Notification: A Webinar for Transplant Professionals—*. (Item 3, Page 3)
- The Committee developed a resource document entitled the *Waitlist Notification Quick Reference Guide* with support from the UNOS Bylaw Writer and Policy Analysts in the Department of Evaluation and Quality. The *Waitlist Notification Quick Reference Guide* will be housed on the OPTN website. (Item 4, Page 4)
- The Committee is continuing its work on a re-write of *What Every Patient Needs to Know*. The goal is to present a patient-focused perspective on preparing for transplant. (Item 5, Page 4)

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OPTN/UNOS Patient Affairs Committee
Report to the Board of Directors
June 28 & 29, 2011
Richmond Virginia

Ray Gabel, Chair
Laura Ellsworth, Vice Chair

This report reflects the work of the Patient Affairs Committee during its November 15, 2011, and March 28, 2011, meetings in Chicago, Illinois, as well as Committee conference calls on January 13, 2011, February 8, 2011, and May 5, 2011.

1. Proposal to Modify the OPTN Contractor Patient Information Letter to More Simplified Language.

The Committee developed a plain language version of the OPTN Contractor Patient Information Letter (**EXHIBIT A**). The Committee also added health care icons in an effort to make the Patient Information Letter more user-friendly. The updated version of the Patient Information Letter was to be implemented in all transplant programs no later than March 20, 2011. The updated Patient Information Letter is now available on the OPTN website in Spanish as well as English.

The Committee developed a four-pronged education plan to be presented in conjunction with the introduction of the updated Patient Information Letter.

- Regional Administrators sent notices of the transition to the updated Patient Information Letter to all Transplant Administrators
- An announcement was included in the January 20, 2011 UNOS Membership Notice
- Committee Members authored three *Update* articles highlighting the personal impact of patient notification from the perspective of a recipient, a candidate and two living donors. These articles were published consecutively beginning with the November/December, 2011 issue of *the UNOS Update*. Each article highlighted:
 - the timeframes for implementation of the updated OPTN Contractor Patient Information Letter
 - the location of the updated Patient Information Letter on the OPTN website
 - the Bylaw requirement mandating use of the Patient Information Letter
- The Committee partnered with the UNOS Department of Education and Quality (DEQ) to present a webinar on Patient Notification on March 9, 2011.

2. Plain Language Rewrite and Proper Positioning of the Patient Notification Bylaw Appendix B.II.F

The Committee developed an Early Evaluation Tool to explore the potential for addressing errors in Patient Notification by completing a plain language rewrite of the Patient Notification Bylaw and moving the Bylaw into Policy. After further investigation, it was determined that both goals would be accomplished through the Bylaws Rewrite Project.

3. Patient Notification Webinar

The Committee held extensive discussions with both TAC and TCC, via email; LiveMeeting and email listserv's regarding patient notification practices. From this, PAC determined that one of the most significant hindrances to patient notification compliance is confusion regarding the Patient Notification

requirements and a lack of consistency between the OPTN/UNOS Patient Notification Requirements and the CMS requirements of notification. The Committee further found these areas to be aggravated by confusion between the Transplant Program Patient Notification letter and the OPTN Contractor Patient Information Letter.

The Committee partnered with the Site Surveyors from DEQ to develop a webinar that would provide the following:

- An Overview of the OPTN/UNOS Patient Notification Requirement
- Outline distinctions between the Transplant Program Patient Notification Letter and the OPTN/UNOS Patient Information Letter
- Present best practices for patient notification
- Highlight the personal impact of patient notification

The Webinar was presented on March 9, 2011. Presenters for the Webinar were Committee Members and DEQ Staff. There were more 241 registrants and 160 phone lines, most with multiple participants on the call. Presentations from the webinar are available for participants online.

4. Patient Notification Quick Reference Guide

The Committee worked with the UNOS Bylaws Writer and DEQ Policy Analysts to develop a one page high level overview of the OPTN/UNOS Patient Notification Bylaws. This overview is meant to be a resource that could be kept at the desk and which would outline the basics of Patient Notification. The document was also designed to be updated annually. There is an effective date plainly posted in the first paragraph of the document. The Quick Reference Guide also hyperlinks the user to the Evaluation Plan and Bylaws B.II.F (Patient Notification). **(EXHIBIT B)**

The Quick Reference Guide was approved by HRSA and will be housed on the Professional Resources page of the OPTN website.

5. Rewrite of *“What Every Patient Needs to Know”*

The Committee has completed a draft of the updated *What Every Patient Needs to Know*. Astellas has committed to continue corporate sponsorship of *What Every Patient Needs to Know* for an additional year. The Committee is moving forward to continue production of the resource.

6. Patient Information Sharing Task Force

Two members of the Committee serve on the Patient Information Sharing Task Force. This Task Force has the responsibility of assessing the current status of information sharing between OPO's and Transplant Programs and between recipients and living donors, and as appropriate, developing guidance in this area. Members of the Patient Information Sharing Task Force facilitated a focused discussion with PAC on their first-person experiences with information sharing. Emphasis was placed on the types of information which the Committee felt would be most relevant for deceased donor families, living donors, and recipients to receive. A summary of this discussion was reported during the full Task Force Meeting on April 28, 2011 in Chicago.

Key points in this discussion included the following:

- Some recipients find it difficult to write to their donor families

- The Committee feels that the Donor-Recipient system is hampered by staff turnover and lack of clear guidelines
- Staff need training on how to communicate with both donor and recipient families
- Recipients should be able to waive their HIPAA rights
- There is a need to develop educational materials on donor family communication

Committee Members also participated in discussion groups on Information Sharing for Deceased Donor Families and Information Sharing for Living Donors respectively at the April Task Force meeting.

7. Review of OPTN/UNOS Policy 6.0 (Transplant of Non-resident Aliens)

Committee Members are currently participating in a workgroup to examine the continued relevance and impact of OPTN/UNOS Policy 6.0 (Transplant of Non-resident Aliens). The Committee participated in a focused discussion regarding Policy 6.0 (Transplant of Non-resident Aliens) and highlighted the following points:

- The citizenship of deceased donors is fairly equal to the citizenship status of non-resident recipients. Contrary to popular opinion, non-residents are not disadvantaging US citizens by being transplanted here. Data was shown to support this statement
- Illegal immigration is a significant political issue. This impacts the discussion significantly.
- Transplant of persons who arrive in the US under a medical visa is a humanitarian act, and thus should be encouraged.
- Allowing persons from other countries to seek transplant in the US can be a double-edged sword: encouraging patients to seek healthcare in an ethical and safe system, but also discouraging persons of means from developing safe and ethical transplant systems within their own countries.
- Establishing clear definitions for non-resident and illegal aliens is imperative.
- All transplants should be monitored
- Direct contributions to centers by candidates who come to the US for transplant should be monitored, if not limited.

8. Public Comment Proposal Summary

The Committee sought to support non-clinical members in review of public comment proposals by developing a summary document to accompany proposal. The Public Comment Proposal Summary provides an overview of the proposal. The document then defines the problem the proposal seeks to address and finally outlines the potential impact of the proposal upon patients. The Public Comment Proposal Summary is meant to be used as a guide as persons review the full public comment proposal. Public Comment Proposal Summaries are prepared by Committee members who have expertise in the area of the proposal.

9. Post-Transplant Handbook

The Committee has tabled work on the Post-Transplant Handbook.

10. Organ Allocation

The Committee responded to a query from the Kidney Transplantation Committee on common misconceptions regarding kidney allocation held by the general public. PAC highlighted the following areas:

- Wealth, fame or social status allow for faster access to transplant
- General confusion regarding criteria for listing
- Perceptions that persons on the waiting list have an actual number in a linear process
- Belief that there is a national standard for kidney allocation

A Committee Member developed a comprehensive plain language summary of the Kidney Concept Proposal. The Committee received this overview at the March 28, meeting. The Liaison to the Kidney Committee offered clarification. The Committee agreed that the Kidney Concept Document does not comprehensively address all issues in Kidney Allocation. The Committee determined that the Kidney Concept Document is an excellent start at overhauling kidney allocation in the United States.

The Committee received an overview of Heart Allocation in response. The Liaison provided a written summary of thoracic allocation. The presentation provided an overview of both waitlist and transplant trends across all thoracic organs. The Committee raised questions about:

- Reasons for the larger numbers of inactive candidates in thoracic transplant
- Reasons for the significant shift in diagnoses from pre-LAS to post-LAS

11. Committee Education

During the November 15, 2010, meeting, the Committee received the UNOS Primer presentation *How Transplant Policy is Made*. The presentation was adapted slightly to more appropriately fit the learning needs of PAC. This proposal provided the Committee with an overview of how work done by the Committee fits into the overall policy development process. An understanding of the policy development process enhances a committee members ability to objectively consider the validity of a particular proposal.

The Committee received a summary of *The Results of the National Survey on Referral to Kidney Transplant: The Transplant Program's Perspectives*, conducted by the Minority Affairs Committee. The presentation provided an excellent overview of the timing and frequency of referral for transplant in the renal population. A primary concern for all patients, and therefore the Committee, is timely and equitable access to transplant. The Committee raised questions regarding financial incentives that dialysis units may have for keeping patients on dialysis versus referring for transplant evaluation.

The Committee raised questions regarding the role of UNOS in living donation during the March 28, 2011 Chicago Meeting. The Committee received a brief retrospective of monitoring of living donor transplants by UNOS. The Committee expressed a particular interest in education and monitoring of living donors.

12. Public Comment Proposal Responses

- Proposal to Clarify Adult Heart Status 1-A Language

The Committee discussed this proposal on November 15, 2010, and voted to support the proposal without qualification. [Yes – 18, No – 0, Abstain – 1]

- Proposal to Clarify Which Transplant Program Has Responsibility for Elements of the Living Donor Process

The Committee discussed this proposal during the November 15, 2010, meeting, and voted in support of the proposal as written. [Yes – 19, No – 0, Abstain – 0]

- Proposal to Establish Qualifications for a Director of Liver Transplant Anesthesia in the OPTN Bylaws

The Committee discussed this proposal at the November 15, 2010, meeting and voted to support this proposal without qualification. [Yes – 18, No – 0, Abstain – 1]

- Proposal to Modify the Requirements for Transplant Hospitals that Perform Living Donor Kidney Recoveries

The Committee discussed this proposal at the November 15, 2010, meeting. The Committee voted in support of this proposal without qualification. [19-Support, 0-Opposed, 0-Abstain]

- Proposal to Prohibit Storage of Hepatitis C Antibody Positive and Surface Antigen Positive Vessels

The Committee heard this proposal during the November 15, 2010, meeting. The Committee voted in support of this proposal without qualification. [Yes – 19, No – 0, Abstain – 0]

- Proposal to Require Collection of Human Leukocyte (HLA) Type for Thoracic Organs

The Committee considered this proposal during the November 15, 2010, meeting. The Committee voted to support the proposal with the following recommendation:

While this is a positive start, HLA testing should be run prospectively on all thoracic organ offers. Requiring transplant centers to request HLA testing may actually delay organ placement. This is especially significant considering the small numbers of thoracic organs that are offered without an accompanying kidney offer. [Yes – 19, No- 0, Abstain – 1]

- Proposed Model for Assessing the Effectiveness of Individual OPO's in Key Measures of Organ Recovery and Utilization

The Committee reviewed this proposal during its' February 8, 2011, meeting. After discussion the Committee voted to support the proposal as presented: [Yes 16 , No 0, Abstain - 0]

- Proposal to Encourage Organ Procurement Agencies to Provide Computer Tomography (CT) Scans

The Committee reviewed this proposal during the March 28, 2011, meeting. The Committee is concerned that the additional costs of CT scans will be transferred to transplant centers, and then indirectly to patients, without sufficient evidence that additional CT scans will significantly impact patient outcomes. [Yes – 16, No – 0, Abstain – 0]

- Proposal to List All Non-metastatic Hepatoblastoma Pediatric Liver Candidates as Status 1B

The Committee reviewed this proposal during the March 28, 2011, meeting and voted in support of the proposal. [Yes – 1, No – 10, A – 3]

- Proposal to Eliminate the Requirement that Pediatric Liver Candidates Must Be in the Hospital

The Committee reviewed this proposal during the March 28, 2011, meeting and voted in support of the proposal. [Yes – 15, No – 0, A – 0]

- Proposal for Improved Imaging Criteria for HCC Exceptions

The Committee reviewed this proposal during the March 28, 2011, meeting. The Committee wanted to see evidence that current radiology results are not sufficient. The Committee also requested additional clarification on what constituted a transplant center radiologist. The Committee felt that this proposal could result in more appropriate allocation of livers, but may also have some negative cost ramifications with insurance companies due to increased radiologic testing. These costs would then, potentially be passed on to patients. The Committee voted to support this proposal. [Yes – 15, No – 1, Abstain – 0]

- Proposal to Reduce Waiting List Deaths for Adult Liver-Intestine Candidates

The Committee reviewed this proposal during the March 28, 2011, meeting. The same donors are chosen for both liver-intestine candidates and small women. The Committee felt that this proposal gives preference to liver-intestine candidates, but may disadvantage both liver-alone candidates and smaller women at the local level. The Committee further felt that there should be modeling of the impact on waitlist deaths for all candidate groups as a part of this proposal. The Committee voted not to support this proposal. [Yes – 1, No – 9, Abstain – 6]

- Proposed Committee Sponsored Alternate Allocation System CAS for Split Liver Allocation

The Committee received the proposal during the March 28, 2011, meeting. The Committee requested a strong informed consent process for candidates who are offered split livers. The consensus from the Committee is that split livers bring more livers into the donor pool. This allows the opportunity for more candidates to receive more transplants. The Committee would have liked to have seen estimates of the potential number of additional transplants that could be performed by this policy. The Committee voted to support this proposal. [Yes – 14, No – 2, Abstain – 0]

- Proposal to Require Updates of Certain Clinical Factors Every 14 Days for Transplant Candidates

The Committee reviewed the presentation during the March 28, 2011, meeting. The Committee stresses that status updates can be made more frequently if medically indicated. The concern was that some centers might interpret the 14 day requirement as the practice standard, and not a guideline. Lung Recipients on the Committee pointed out that the clinical status of Lung candidates can be very tenuous, changing very frequently. This makes the timing of status updates critically important. The Committee also questioned whether there could be a scenario where lung candidates might lose priority for organs because of a decline in health status, which would be captured in the frequent reviews. The Committee voted to support this proposal with the caveat that the single lung recipient on the committee felt the 14 day time frame was arbitrary and could be problematic for the above stated reasons.

[Yes – 15, No – 1, Abstain– 0]

- Proposal to Allow Outpatient Adult Heart Implanted with Total Artificial Hearts (TAH) Thirty Days of Status 1A Time

The Committee felt that this proposal would give candidates who are discharged home with a TAH and additional 30 days at Status 1A an unfair advantage. Anecdotally, the Committee related that Status 1A patients are most often transplanted. This same patient, in Status 1B at home, would potentially languish on the waiting list, while technically meeting the same acuity as the TAH candidate who remains hospitalized. This creates an inequity in the system, which the Committee felt should be addressed. The Committee further felt that UNOS policy should never interfere with discharge home when clinically indicated and feasible. The Committee further affirmed the psychological and emotional benefits to being managed at home whenever possible. The Committee voted to support this proposal. [Yes – 16, No – 1, Abstain – 0]

- Proposal to Improve the Reporting of Living Donor Status

The Committee supports the intent of this proposal, which is improved reporting of living donor status in order to objectively document the impact of living donation, both short and long term. However, the Committee believes that this proposal does not meet its stated goal, specifically by neglecting to collect data in the areas of renal function and quality of life/psychosocial effects. The Committee acknowledges the delicate balance involved in meeting the needs of all parties when implementing any policy requirements.

Living donors and recipients of living donor organs on the Committee state “Living donors are patients with all the protections inherent in that status.” Living donor and recipient candidates everywhere desire outcome data to guide them in making healthcare decisions. The Committee strongly believes that living donors are willing to actively participate in their health maintenance post-transplant if properly educated.

True informed consent is impossible without even rudimentary data on medical functional and psychosocial outcomes. The Living Donor Follow-up Form has more than 40 possible data elements, including the potential to capture creatinine, blood pressure, weight changes, functional status and adverse health events. One possible unintended consequence of this proposal could be that the proposed minimum standard for reporting - ‘alive’ or ‘dead’ after two years - becomes the clinical standard for practice in many centers. The end result therefore is that there is less follow up data—the exact opposite of what the proposal intends.

The transplant community relies on the OPTN/ UNOS to set the standard for policy development, data collection and monitoring in transplantation. The Committee is very mindful of the potential

negative media coverage should this proposal be made public in its current form, and that it would might suggest a lack of concern for living donors.

The Committee recognizes and commends the efforts of the Living Donor Committee in taking a first step with this proposal and strongly encourages strengthening the requirements with additional data collection standards at the earliest opportunity. [Yes – 15, No – 2, Abstain – 0]

- Proposal to Improve the Packaging, Labeling and Shipping of Living Donor Organs

The Committee reviewed this proposal during the May 5, 2011, conference call. The Committee voted in support of this proposal. [Yes – 11, No – 0, Abstain – 0]

- Proposal to Require Confirmatory Subtyping of Non A1 and Non A1B Donors

The Committee reviewed the proposal. Many centers are already providing confirmatory results as part of their allocation process. It is believed that this contributes to the small numbers of reported rejection events annually due to donor ABO subtyping incompatibility. [Yes – 16, No – 0, Abstain – 0]

- Proposal to Update and Clarify Language in the DCD Model Elements.

The Committee reviewed this proposal during the May 5, 2011, conference call. The Committee voted in support of this proposal. [Yes -, No – 0, Abstain – 0]

- Proposal to Standardize Labels Requirements for Vessel Transport and Vessel Storage

The Committee reviewed this proposal during the May, 5, 2011, conference call. The Committee voted in support of this proposal. [Yes - , No – 0, Abstain – 0]

PATIENT AFFAIRS COMMITTEE – Effective 7/1/2010

NAME	COMMITTEE POSITION	11/15/2010 Meeting	1/15/2011 Call	2/8/2011 Call	3/28/2011 Meeting	5/5/2011 Call
Ray Gabel	Chair	X	X	X	X	X
Laura Ellsworth	Vice Chair	X	X	X	X	X
Keith Diaz JD	Regional Rep.	X				
James Gleason	Regional Rep.	X	X	X	X	X
Kathleen Giery, APR, CPRC	Regional Rep.	X	X		X	
Joseph Sharp	Regional Rep.	X	X	X	X	
Lee Ann Stamos	Regional Rep.	X	X		X	
Kristie Lemmon, MBA	Regional Rep.	X	X	X	X	X
Alison Walsh	Regional Rep.	X			X	
Merle Zuel	Regional Rep.	X		X	X	X
Shari Kurzrok Schnall	Regional Rep.	X	X		X	
Laura Murdock-Stillion, MHA	Regional Rep.	X	X	X	X	X
Karen Starr, MSN, APRN, BC, LADC	Regional Rep.	X			X	
Kathe LeBeau	At Large	X	X	X	X	X
Sidney Locks	At Large	X	X	X		
Kim McMahan	At Large	X	X		X	X
Thomas Starr	At Large	X	X	X	X	
Isabel Stenzel Byrnes, MSW, MPH	At Large	X	X	X	X	X
Heidi Yeh, MD	At Large	X	X		X	
David Zaas MD, MBA	At Large	X				
Doni Bell	At Large *Added after 7/13	X	X			
Donna Banks	UNOS Board	X		X	X	
Tom Falsey	UNOS Board	X		X	X	X
Richard Laeng, MPH	HRSA Ex-Officio	X	X			
Holly Berilla MSW	HRSA Ex-Officia	X	X	X	X	X
William(Bill) Lawrence	UNOS Staff	X		X	X	
Anna Kucheryavaya	UNOS Staff	X	X	X	X	X
Stacey Burson	UNOS Staff			X		
Beverley Trinkle	UNOS Staff		X			
Freda Wilkins MSW, M.Div	Liaison	X	X	X	X	X