

**OPTN/UNOS Patient Affairs Committee**  
**Report to the Board of Directors**  
**November 14-15, 2011**  
**Atlanta, GA**

**Summary**

**I. Action Items for Board Consideration**

- None

**II. Other Significant Items**

- The Committee responded to a request for policy changes generated by a Kidney Recipient. The consensus is that no policy changes are warranted at this time. (Item 1, Page 3)
- The Committee has been invited to work with the Minority Affairs Committee in drafting 'Educational Guidelines on Patient Referral to Kidney Transplantation. (Item 3, Page 4)
- The Committee continues to work with UNOS Communications and Astellas on completing *What Every Patient Needs to Know*. (Item 7, Page 5)

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**OPTN/UNOS Patient Affairs Committee**  
**Report to the Board of Directors**  
**November 14 & 15, 2011**  
**Atlanta, Georgia**

**Laura Ellsworth, Chair**  
**Kristie Lemmon, Vice Chair**

*This report reflects the work of the Patient Affairs Committee during its September 12, 2011 meeting in Chicago, Illinois, as well as a Committee conference call on July 7, 2011.*

1. Patient Request for Consideration of Modifications to Multiple OPTN Policies

The Committee received a formal written request forwarded from HRSA for consideration of changes in six policy areas from a kidney transplant candidate. The requests centered around four specific areas:

- Criteria for delisting;
- Wait Time Reinstatement;
- Candidate Evaluation; and
- Public Access to Regulatory and Peer Review Actions.

Many of the issues raised indirectly relate to kidney allocation and relate directly to waitlist management. As a result, the request was also forwarded to the Kidney Transplantation Committee.

The Committee formed a Subcommittee to consider the requests and make formal recommendations to the full Committee during its September Meeting. Subcommittee members included:

- Kidney Candidate
- Living Kidney Donor
- Kidney Recipient and Kidney Transplant Coordinator
- Administrator for Kidney Transplant Program
- UNOS Policy Analyst
- Liaison to the OPTN/UNOS Kidney Committee

The Subcommittee convened and received the following charge regarding the work:

- Look beyond the individual requester, as the Committee has no power to address individual patient issues
- Consider the request in light of the OPTN and UNOS vision and mission and the PAC Charge
- Consider the request in light of the accepted process for policy development within the OPTN

- Consider the universality of the request
- Consider each request in light of existing policy
- Consider each request from the patient perspective

After careful consideration, the Subcommittee determined that each request was valid when considered from the perspective of a single patient, but failed to meet the standard of universal patient experience. The Subcommittee further determined that existing policy provided adequate redress for each concern when considered against the standard of the usual and expected patient experience. The Subcommittee's final conclusion is that the requests spoke to a unique patient experience. No policy measures were recommended at this time.

The Subcommittee presented a summary of the overall discussion and individual recommendations for request to the Committee during the September 12, 2011. The Committee unanimously accepted the Subcommittee recommendations and agreed that a written copy of the discussion and the recommendations should be provided to the requestor and to the Kidney Transplantation Committee (**Exhibit A**).

## 2. Preparing for Response to PHS Guideline

The CDC specifically invited the Committee to opine regarding the proposed PHS Guideline for identification of high risk donors. In preparation for the anticipated release of the proposal, the Committee received a presentation on the work of the DTAC during the July Conference Call. The Liaison to DTAC also provided two articles, which further defined the charge and function of DTAC and the potential impact changes in high risk donor criteria could have on patients within the transplant community. The Committee has received the full proposal and will convene a conference call to discuss the proposal on October 13, 2011.

## 3. Proposal for Uniform Patient Notification Policy

The Committee has been charged with developing a proposal to re-organize the OPTN Bylaws such that patient notification requirements are more easily understood and more accessible to the transplant community. The Committee carefully assessed this issue. The Committee focused on gathering data and education about patient notification across the OPTN.

The Committee has begun preliminary work on a public comment proposal to address language, placement, and accessibility issues with Patient Notification. The Committee anticipates that a core component of this proposal will be a comprehensive statement regarding the intent for all patient notification. This statement would then provide a crosswalk of all patient notification requirements. The Committee expects to distribute this proposal for public comment during the spring 2012 public comment cycle.

## 4. Clarification of Policy Interpretation with Department of Evaluation and Quality

DEQ requested Committee input regarding whether candidates who were ruled out prior to completion of the entire battery of required tests would expect to receive written notification of their status. DEQ had received requests for clarification on this point from transplant programs. Some programs were interpreting the requirement from the Bylaws to mean candidates who were ruled out early in the evaluation process, in effect, had not completed an evaluation.

**Patient Notification.** *Transplant Hospitals are expected to notify patients in writing: (i) within ten business days (a) of the patient's being placed on the Waiting List including the date the patient was listed, ..... (b) of completion of the patient's evaluation as a candidate for transplantation, that the evaluation has been completed and that the patient will not be placed on the Waiting List at this time, which ever is applicable;*

Thus, the transplant program was not required to notify the candidate of the completion of their evaluation and/or that the candidate would not be placed on the waiting list. Since this scenario is not specifically addressed within the Bylaw DEQ sought clarification in order to ensure consistency of response.

After careful discussion, the Committee, by unanimous vote, determined that the evaluation was effectively completed at the point when a decision was made about the candidates' status. This interpretation was felt to be in line with current acceptable medical practice regarding evaluations for patient care. DEQ will include this interpretation in an update to the OPTN Evaluation Plan.

5. MPSC Inactive Waitlist Workgroup

The Committee has been invited to participate in the MPSC Inactive Waitlist Workgroup. This group previously developed standardized language for patient notification when a transplant program inactivates its waitlist. The Workgroup has now invited this Committee to provide input from a patient's perspective regarding which patients should be notified in the event that only a part of a program's waitlist is inactivated; e.g. the adult waitlist is inactivated, but the pediatric waitlist is still active. This group will convene its first meeting in October.

6. MAC Referral Guidelines Workgroup

The Minority Affairs Committee presented *Results of National Survey on Referral to Kidney Transplant* to the Committee during the September 2011 Meeting. The study focused on the timing and rate of referral of dialysis patients for transplant evaluation. One of the conclusions of the study was that educational efforts to encourage and improve timely referral for transplant evaluation are needed. MAC has now invited the Committee to participate in a workgroup to draft *Educational Guidelines for Patient Referral to Kidney Transplantation*. This group has not convened yet.

7. Re-write of *What Every Patient Needs to Know*

The Committee completed the re-write of *What Every Patient Needs to Know* in May 2011. Creative-Aid has completed the graphic design. The resource has been reviewed by Astellas. The Committee is waiting for feedback from Astellas. After a review of feedback from Astellas, the Committee will work with UNOS Communications to make suggested changes. The Committee anticipates that the project will then proceed to printing.

8. Living Donor Follow-up Interest

Presentations of public comment proposals from the Living Donor Committee during 2011 sparked interest in living donor follow-up. The Committee received an overview of the OPTN policy development process during the July 7, 2011 conference call. Recommendations from the LD/MPSC Workgroup were also reviewed during this call. Significant feedback from the discussion included:

- Transplant Administrators stressed the challenges that programs experience in attempts to meet the living donor follow-up requirements including lack of funding, and difficulty in locating patients
- Living donors and recipients of living donor transplants cited their feelings of disconnection from the transplant program
- Living donors and recipients of living donor transplant alike refuted the idea that living donors do not want to be contacted after transplant.
- Non-compliance with living donor follow-up was stressed as a major safety concern
- Questions were raised regarding efforts to procure Medicare coverage for Living Donor Follow-up

After considerable discussion, the Committee agreed that living donor follow-up is an area that PAC should become more involved with. The Committee determined to establish a Subcommittee to evaluate potential means for impacting living donor follow-up.

The Subcommittee met in August, 2011 and brought the following recommendations back to the Committee at the September 12, 2011, meeting:

- Develop an educational brochure on OPTN living donor follow-up Requirements for both living donor candidates and their recipients. This resource would be designed for use at several different junctures during the transplant process e.g. initial contact, consent for transplant, hospital discharge
- Pilot this brochure in small group of transplant centers and monitor effectiveness; and
- Work with community partners to develop living donor follow-up community awareness campaign

Efforts would be developed with support from the Living Donor Committee.

The Committee requested that the goals of the project be more clearly defined. The Committee also requested clarification of the responsibilities of both the Living Donor Committee and PAC with this project. It was also suggested that the Committee might more effectively focus its efforts by developing an informational tool like the patient information letter. The Committee agreed that this issue warrants further discussion.

## 9. Committee Education

The Committee received an overview of the DTAC in preparation for review of the USPHS Guidelines. The goal of this presentation was to introduce the Committee to disease transmission and the function of DTAC within the OPTN.

The Committee received an update on current activity within the legislature during the September 2011 meeting. A primary focus of this presentation was an update on progress with H.R. 2969, The Comprehensive Immunosuppressive Drug Coverage for Kidney Transplant Patients Act of 2011.

The Committee received a presentation from of the Minority Affairs Committee entitled *Results of National Survey on Liver Referral: The Transplant Program's Perspectives*. This presentation was followed by the results of the MAC sponsored study, *Ethnic and Gender Related Differences in the Risk of End Stage Renal Disease after Living Kidney Donation*. This study looks at the long term impact of living kidney donation across ethnic and gender lines. The study did not find significant differences in health issues over time. The study did conclude that there is a need for more follow-up. The study further identified the lack of funding for living donor follow-up as a barrier to safe and effective care.

Educational efforts within the Committee are intended to prepare the Committee for action in a specific area of interest.

#### 10. Increased At-Large Membership

At the direction of OPTN/UNOS President, John Lake, M.D., the Committee added three At-Large positions in an effort to increase minority representation within the Committee.

#### 11. Public Comment Proposal Responses

The Committee will begin reviewing Fall 2012 public comment proposals during the October 2012 conference call.

**PATIENT AFFAIRS COMMITTEE – Effective 7/1/2011**

<b>NAME</b>	<b>COMMITTEE POSITION</b>	<b>7/7/2011 Call</b>	<b>9/12/2011 Meeting</b>
Laura Ellsworth BA	Chair	x	x
Kristie Lemmon MBA	Vice Chair	x	x
Stephen Bruno	Regional Rep.		x
James Gleason	Regional Rep.	x	x
Kathleen Giery, APR, CPRC	Regional Rep.	x	x
Joseph Sharp EMT-P	Regional Rep.	x	x
Lee Ann Stamos RN, MS	Regional Rep.	x	x
John Fallgren RN	Regional Rep.	x	x
Deepak Mital MD	Regional Rep.	x	
Merle Zuel	Regional Rep.	x	x
Shari Kurzrok Schnall BA	Regional Rep.	x	x
Annette Humberson, MSW	Regional Rep.	x	x
Kim Phillips MSN, RN	Regional Rep.	x	
Kathe LeBeau BA	At Large	x	x
Sidney Locks M.Div	At Large		
Kim McMahon	At Large	x	x
Jennifer Browning CPTC	At Large	x	x
George Franklin	At Large	x	x
Carrie Simpkins CPAN, ACLS,	At Large	x	x
Alice Gray MD	At Large	x	x
Doni Bell BA, EMT	At Large		
Melvin Todd, JD	At Large		
Lan Phuong Vu-Yu	At Large		x
Marie Cook RN, CMP, MPH	At Large	x	x
Chinyere Amaefule	HRSA Ex-Officio	x	x
William(Bill) Lawrence	UNOS Staff	x	x
Anna Kucheryavaya	UNOS Staff	x	x
Stacey Burson	UNOS Staff		
Beverley Trinkle	UNOS Staff		
Freda Wilkins, MSW, M.Div	Liaison	x	x