

OPTN/UNOS Patient Affairs Committee

SUMMARY

Action Items for Board Consideration

- None

Other Significant Items

- Dr. Peter Stock, Chair of the OPTN/UNOS Kidney Transplantation Committee, provided an update about the continued development of a kidney allocation system that incorporates the concepts of Life Years From Transplant (LYFT), years on dialysis (DY), and the Donor Profile Index (DPI). The Committee provided varied feedback consisting of specific concerns, support, and recommendations. (Item 2, Page 4)
- The Committee reviewed the letter (developed in response to a referral from the OPTN/UNOS Membership and Professional Standards Committee) to be included in centers' initial candidate listing letters to inform them of the following: role of the OPTN/UNOS, information available through UNOS patient services staff, and accessible transplant data and policies. Members unanimously approved the content with pending modifications to the data section to be submitted by HRSA. (Item 3, Page 6)

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**Report of the
OPTN/UNOS Patient Affairs Committee
to the Board of Directors**

**February 21, 2008
Orlando**

**David Burgio, MPA, LFACHE, Chair
Ray Gabel, BA, Vice-Chair**

The following report contains the deliberations of the Patient Affairs Committee at its October 15, 2007 meeting and subsequent conference call on January 3, 2008:

1. **Patient Access to Center Performance Information** - Members briefly reviewed Committee activities and discussions that led to the final OPTN/UNOS Bylaws, Appendix A, Section 2.06A Modification proposal presented at the June 2007 Board Meeting. The Committee discussed the deliberations among Board Members and noted their support of the Committee's initial proposal (prior to making modifications based upon feedback obtained from the public comment process). The Board supported broader written notification throughout the duration of the adverse action to include patients in the evaluation process, candidates, and recipients. The Committee supported the Board's recommendation that such written notification be provided in the patient's spoken language.

The Committee reviewed the final wording that was subsequently approved by the Executive Committee on August 3, 2007. Members supported the new bylaws language; however, they discussed the concern relayed at a recent regional meeting about the use of the term "given" in the notification description within each adverse action. For the sake of clarity and consistency, Members preferred to utilize the term "sent in writing."

(3) Probation

c. **Additional Notice Requirements if the Member Placed on Probation is a Transplant Center.** Notice of this adverse action must be given by the Member to all Patients directly associated with the cited transplant program. For purposes of this requirement, "Patients" shall include the following individuals:

- Patients undergoing the cited transplant program's evaluation process;
- Candidates on the waitlist of the cited transplant program;
- Candidates added to the cited transplant program's waiting list; and
- Recipients being followed by the cited transplant program.

If the Member placed on Probation by the OPTN is a Transplant Center, then the Member Transplant Center must notify its patients that the Member received this adverse action. This notice to Patients must be ~~given~~ sent in writing within 30 days of the Member receiving formal notification from the OPTN that it has been placed on Probation. The notice must be sent by the Member Transplant Center to each Patient as defined above during the time the Member is on Probation.

The notice to Patients must be provided in writing, in each Patient's spoken language, and as specified by the Executive Committee or Board of Directors.

The Member shall comply with any additional notification requirements specified by the MPSC-PCSC, MPSC, Executive Committee, or Board of Directors.

The Committee supported the above modification with a vote of 14:0:0.

Members reviewed the content of the policy notice, as well as the list of the types of transplant professionals who received this notification. The Committee also examined the total number of each type of adverse action that had been imposed from July 2006 to May 2007.

The Committee discussed the likelihood of patients contacting their centers and UNOS upon notification of adverse actions in order to obtain additional information which may not be available to them. Members expressed concern for those patients who may want to transfer to another center as a result of the notification, but who may have difficulty due to insurance coverage or proximity of other centers. Members remarked upon the fact that the actions that lead to such citations can vary greatly in regards to the impact upon patient safety. The Committee supported the broader center-specific patient notification of the more severe adverse actions and inquired about posting a notice about such citations on the OPTN and UNOS websites.

During a subsequent conference call on January 3, 2007, concern was expressed regarding whether it was necessary to utilize time and resources to propose a modification to OPTN/UNOS Bylaws, Appendix A, Section 2.06A for such a minor change since the overall objective of the original proposal had been met. **Members supported the decision to halt efforts to pursue the above modification by a vote of 13:0:0.**

2. Report from the Kidney Allocation Review Subcommittee (KARS) - Dr. Peter Stock, Chair of the OPTN/UNOS Kidney Transplantation Committee, discussed the process in which the Committee comprehensively reviewed the kidney allocation system and developed current recommendations. Members briefly compared the existing kidney allocation system to the other organ allocation systems, some of which were recently modified. Upon Dr. Stock describing the need to implement a system that is consistent with the Committee's charge, he reviewed these relevant overarching requirements and goals: OPTN Final Rule, NOTA, principles of equitable organ allocation, and HHS program goals.

Dr. Stock discussed the concept of Life Years from Transplant (LYFT), including the specific variables used to calculate LYFT scores. The Committee examined why certain data elements were included or excluded in the model. Dr. Stock also reviewed how both years on dialysis (DY) and the Donor Profile Index (DPI) factor into the new system.

The Committee examined the advantages, disadvantages, and predicted outcomes of implementing alternative systems that the OPTN/UNOS Kidney Transplantation Committee considered, including matching donors and candidates based on categories of LYFT, DY, and DPI, as well as simply matching based on age exclusively. The Committee compared these systems by examining predicted outcome data regarding race, specific diagnoses, and age. Members inquired about the median age of deceased donors in comparison to candidates upon discussing the age matching system. Members were informed that, although a final proposal has yet to be drafted, there is unanimous agreement among the Kidney Committee to pursue a continuous system that utilizes the concepts of LYFT, DY, and DPI as a platform on which to build. OPTN/UNOS Kidney Transplantation Committee Members were described as supporting this approach because it balances the concepts of justice and utility.

The Committee inquired about the response from the public, transplant professionals, and special interest groups. Members reviewed a summary of the responses from the American Society of Transplantation (AST), the OPTN/UNOS Ethics Committee, Public Forum participants, and the National Kidney Foundation.

Dr. Stock informed Members of the changes in the OPTN/UNOS Kidney Transplantation Committee composition and the path forward, including their goal to have a potential proposal by February of 2007. Members learned that geographical disparities are not being addressed at this time, but that they would be examined more closely within future phases. Dr. Stock mentioned that the Committee will focus upon

improving access to transplantation among minorities and sensitized candidates in future simulation modeling. The OPTN/UNOS Kidney Transplantation Committee will also more extensively examine the potential impact on living donation rates, predictability of waiting times, and how to expedite placement of kidneys with a high DPI.

Concern was expressed regarding those recipients whose LYFT scores would be lower should they need another transplant. Members discussed the even more pronounced negative impact upon those recipients who are older than 50 years of age. Some Members described the allocation system as being discriminatory against the aging and the dialysis population. There was discussion about older individuals on dialysis being at a distinct disadvantage. Though the concept of LYFT was supported, concern was expressed by some that it shouldn't be at the expense of older individuals, especially since many are maintaining their health longer.

Some Committee Members also expressed their concern about racial discrimination since some of the medical conditions that factor into the LYFT score are more prevalent among certain ethnicities. Others remarked that members of some cultural groups may be less likely to have equal access to medical services and that older candidates/recipients of certain ethnicities would be at a real disadvantage.

Some Members commended the system's focus on keeping transplanted organs functioning as long as possible in order to help recipients live longer, healthier lives. Some support was expressed for prioritizing LYFT to maximize the benefit of the organ. Although compliance among younger patients and the disadvantage to older patients were mentioned as potential concerns, some Members still supported the system. There was also agreement among Members about the plan to continue to prioritize the needs of pediatric patients. Some Members agreed that since no kidney allocation system will be viewed as fair by everyone, some sort of compromise is necessary.

Members were asked by Dr. Stock to provide their ongoing feedback. They were encouraged to visit the OPTN website to obtain additional historical information on the development of the kidney allocation system and to stay informed of its current status.

In December, the Committee was sent a survey (Exhibit A) in order to formally collect their opinions and suggestions regarding the kidney allocation system. During a conference call on January 3, 2008, Members discussed the results of the 12 returned surveys. Ciara Gould, UNOS Liaison to the OPTN/UNOS Kidney Transplantation Committee fielded questions and provided data upon request. Below is a summary of the discussion.

Concerns about the new system included:

- **Discrimination:** Many Members viewed the new system to be discriminatory against older individuals, remarking that many are in good health and living longer. Some Members questioned if the following assumptions were being made: younger recipients are largely "better" recipients; and older patients will not get as many years from a transplant as younger patients. Many feared that older diabetics would be at a considerable disadvantage. Specific concern was expressed for transplant recipients who may face re-transplantation because they are already at a disadvantage due to matching difficulties.
- **Fairness of system and resulting impact on organ donation:** Some Members thought that justice should not be sacrificed in the name of utility and that donation rates could be impacted if the public perceived the system to be unfair. A few Members, however, commented that since individual perspectives on the system and the concept of "fairness" differ greatly and are relative to each person's unique situation, donation rates could actually experience an increase as a result of support for the new system.

- Education challenges: Concern was expressed by the Committee about the inherent difficulty in providing education to candidates, recipients, professionals, and the public about the complex new system. There was support among Members to fully inform patients, especially older individuals, during the evaluation process about the likelihood of receiving a transplant.
- Minimal benefit: Many Members commented that the current allocation system works and that adoption of the new system isn't substantiated since the anticipated increase in average life years gained per transplant is minimal.

The Committee suggested that the OPTN/UNOS Kidney Transplantation Committee network with the following organizations to gain patient participation in the public comment process: National Kidney Foundation, Transplant Recipients International Organization, Donate Life America Affiliates, dialysis units, and transplant centers (specifically corresponding with coordinators and social workers). Some Members also suggested contacting the media and Transplant Game attendees.

Suggested methods of communication included posting information on the websites of the above organizations, providing professionals with talking points and answers to frequently asked questions, developing brochures for transplant and dialysis centers, and providing comprehensive press releases. The Committee stressed the importance of developing a specific budget for such outreach efforts and allowing enough time for a thorough review all responses received through the public comment process.

Members provided the following recommendations, should the system be adopted: monitor changes in living donation and deceased donation rates carefully; have key contacts in each transplant center with an in-depth understanding of the system, consider an incentive opportunity and support the recovery of organs from older donors to assist older patients who are disadvantaged in the system.

Members had additional suggestions regarding the education of relevant groups about the new system, should it be adopted. Recommendations included using effective and evidence-based health communications. Members remarked that a variety of communication techniques should be employed, such as newsletters, emails, presentations, seminars, mailings, TV talk show "blitzes," and information in packets at the Transplant Games.

Ms. Gould provided a brief update to the Committee about modifications the OPTN/UNOS Kidney Transplantation Committee is currently considering regarding the weight of the LYFT score in the kidney allocation system. She will provide additional information to the Committee's liaison, who will send it to all Members to review.

3. Referral from MPSC: Content of Patient Acceptance Letters – The Committee reviewed the referral from the Membership and Professional Standards Committee (MPSC) about including correspondence from the OPTN/UNOS in transplant centers' initial patient listing letters. Members examined the drafted letter based upon recommended content from the MPSC, as well as from PAC Members (from the last meeting). There was a request from Chris McLaughlin, OPTN Project Officer and the Chief of the Operations and Analysis Branch within the HRSA Division of Transplantation, to expand upon the information presented about the SRTR website, as well as the types of accessible data. There was a suggestion to repeat the hotline number in the letter to display this patient resource prominently.

There was discussion about the importance of providing easy access to data to assist patients in making informed decisions. Upon Members expressing concern that the SRTR site is not patient-friendly, Members were informed by an SRTR Representative that there are plans to include a page for patients on

the website that will provide them with easier access to relevant data. The Committee was also informed that the SRTR and OPTN websites are transitioning into government-based websites.

There was discussion about the center-specific data already provided to patients during the evaluation process; however Members agreed that access to additional data would be helpful, especially keeping in mind those patients considering multiple listing or transfers. The Committee discussed how the UNOS patient services staff members help patients to obtain data through the patient services hotline. This service can be especially helpful to those patients with no internet access.

The Committee unanimously approved the letter with the slight modification described above, as well as the pending edits to be submitted by Chris McLaughlin, HRSA OPTN Project Officer, by a vote of 14:0:0.

4. **Living Donor Committee Update** - Lee Bolton, liaison to the OPTN/UNOS Living Donor Committee, reviewed the goals and current composition of the Committee, explaining how the increase in the number of living donors has changed the focus of the Committee. Mr. Bolton provided an update on the following activities of the OPTN/UNOS Living Donor Committee:

- extend living donor follow up to two years and make corresponding changes in the registration forms
- clarify the reporting criteria for adverse events in living donors
- work with the MPSC to implement the new Board-approved bylaws for centers that perform living kidney and living liver donor transplants
- develop a resource document that provides living donor consent best practices

The Committee was informed about the development of the proposed resource document for the medical evaluation of living kidney donors and the mixed reactions received through the public comment process. The Committee reviewed the components of the medical evaluation and discussed the current variations in practice among centers. Members discussed how this resource can serve as an evaluation framework centers can choose to adopt and how it differs from proposed OPTN/UNOS policies. The Committee also considered how it can be a valuable tool for individuals considering living donation. Mr. Bolton informed the Committee about the OPTN/UNOS Living Donor Committee's plan to pursue this initiative further.

Members learned that living donors can contact the UNOS patient services hotline to discuss problems they are experiencing with transplant centers. The Committee reviewed the living donation brochure and provided their feedback. Members discussed the Committee goal of continuing to work with the OPTN/UNOS Living Donor Committee on the brochure and other important initiatives.

5. **Paired donation** - Ciara Gould, liaison to the OPTN/UNOS Kidney Transplantation Committee, provided a brief update regarding the development of a national kidney paired donation system. Members reviewed the legislative advocacy work that was conducted in order to clarify that kidney paired donation did not constitute valuable consideration. Members learned that the OPTN/UNOS Kidney Transplantation Committee corresponded with the transplant community to inform them of the initiative to create an OPTN/UNOS national kidney paired donation system and to request they submit proposals for its development. The Committee is working with those who responded, as well as UNOS staff from multiple departments, to determine the best approach to this critical initiative. Members were encouraged to weigh in on the proposal when it is released.

6. **Review of Committee Goals** – Members reviewed the Committee's goals: 1. continue to provide PAC representation and feedback through work with the OPTN/UNOS Kidney Transplantation Committee on the development of the kidney allocation system; 2. increase candidate/recipient awareness of the role and

services of the OPTN/UNOS, the public comment process, policies, the ability to seek services at other centers, and access and transparency surrounding center-specific data; 3. continue to provide PAC representation and feedback through work with the OPTN/UNOS Kidney Transplantation Committee on the issue of paired kidney donation; and 4. provide resources and assistance to the OPTN/UNOS Living Donor Committee, as well as the Professional Services and Communications Departments, in developing living donation educational material. Members were also informed of the goals of the other OPTN/UNOS Committees.

The Committee reviewed the short and long-term HHS Program Goals and discussed how they serve to guide the focus of the OPTN/UNOS Committees. Members discussed how the Committee goals are aligned with the six challenges of the strategic plan. There was additional brief discussion about the history, structure, and function of the Final Rule and the OPTN contract.

7. Report on the Transplant Coordinators Joint Subcommittee - Committee Member Laura Ellsworth, who participated in the Transplant Coordinators Joint Subcommittee, provided a final update to the Committee regarding the development of a release form/brochure for releasing recipient information to donor families. The Committee was informed that the document had been approved as a recommended resource for communication between transplant centers and organ procurement organizations. Members reviewed the material, as well as the communications plan.

Members expressed support for the brochure as there are no standardized processes or resources for communication between centers and OPOs regarding this issue. A discussion ensued about the variation in information provided to donor families about recipients. Members commended the resource for making the donation “real” and enabling recipients to immediately give back and express their gratitude to donor families.

8. Survival Rate Data and Center Review Process – As a result of the request during the April 2007 meeting for additional information and clarification regarding survival rate calculations and center performance evaluation, representatives from the SRTR and the UNOS Membership and Policy Department provided presentations to the Committee.

David Dickinson, MA, Arbor Research Collaborative for Health, provided an overview of the role and services of the Scientific Registry of Transplant Recipients. He explained how data are used to support OPTN/UNOS Committees in developing policies and assist patients in making informed decisions. Members learned about the variety of data that are collected, as well as who most frequently requests and utilizes such data. Mr. Dickinson reviewed the types of program-specific reports to which patients have access through the website. Members were informed about how survival rates are calculated and given examples of factors used for risk adjustment in outcome data. Mr. Dickinson briefly reviewed how centers are evaluated based upon their survival rates since the UNOS representative addressed this issue more extensively.

Jacqueline O’Keefe, MBA, UNOS Membership and Policy, described the charge and composition of the Membership and Professional Standards Committee. She focused her presentation on explaining how the OPTN/UNOS MPSC Data Subcommittee reviews transplant program performance. Ms. O’Keefe outlined the outcome review process, noting differences in small and large volume programs. Members also learned about the functional inactivity program review process. Ms. O’Keefe spoke with the Committee about the responsibilities that are distributed among Members of this Subcommittee and the variety of sanctions that can be imposed.

9. Division of Transplantation (DoT) - Richard Laeng, MPH, Program Analyst, Division of Transplantation, updated the Committee about progress towards the goals of the Breakthrough

Collaborative. The Committee reviewed deceased donation rates from 2002 through June 2007, noting that SCD gains have not been as considerable in 2007 in comparison to previous years. Mr. Laeng reviewed data illustrating the HHS Program Goal for non cardiac death donors is being maintained. Members reviewed the relatively consistent climb in DCD donation rates, but noted that the HHS Program Goal is not currently being met. The Committee learned that through June of 2007, ECD donation rates have largely been maintained from 2006 and the number of organs transplanted from deceased donors has declined, falling below the HHS Program Goal.

Members additionally examined the consistent increase in deceased donation rates among the African American and Hispanic populations. Lastly, Mr. Laeng reviewed slides illustrating the decreasing trend in living donation rates during the past four years, especially within the first half of 2007.

10. **Data Report from UNOS Research Department** – Anna Kucheryavaya, Research Policy Analyst of UNOS, presented the Committee with national conversion rate data that were requested during the spring meeting. Members reviewed how conversion rates are calculated. Ms. Kucheryavaya also briefly discussed the criteria for eligible death. Members discussed the wide range of conversion rates by DSA and the impact of the Breakthrough Collaborative. The Committee also inquired about the potential impact of states developing donor registries.

11. **Patient and Professional Education** – The Committee reviewed the Patient Services report from the UNOS Professional Services Department to examine the type and frequency of requests for information received through the UNOS patient services hotline. Members remarked upon the increased number of calls regarding living donation, but the overall decrease in the number of individuals serving as living donors in the past few years. The Committee noted the importance of continuing to work on the living donation brochure in order to provide potential living donors, as well as candidates, with a hard copy of educational material. Members also noted the large volume of callers requesting information on transplant policies, the role of UNOS, and how to become listed. This reinforced the importance of continuing to partner with the MPSC regarding the potential inclusion of an OPTN/UNOS letter in initial patient listing letters. The Committee reviewed how the patient services staff can help those callers who are choosing among centers by assisting them to access relevant data reports and patient informational packets.

12. Consideration of Policy Changes Proposed by Other Committees

September 28-December 21, 2007 Public Comment Period:

1. **Proposed Modification to the OPTN Bylaws, Appendix B, *Transplant Hospitals*; Section B. *Survival Rates*; and Section C “*Inactive Membership Status*”; and Attachment I, Section II, “*Inactive Program Status*”; and to the UNOS Bylaws, Attachment I, Section II “*Inactive Program Status*” and Attachment II, Section XIII, C, (10) “*Survival Rates.*” (Membership and Professional Standards Committee)**

The Committee supported the proposed Bylaws modification in assisting the MPSC in the performance review process and clarifying requirements of Members. No concerns were expressed.

The proposal was approved with a vote of 11:0:1.

November 12-December 21, 2007 Public Comment Period:

2. **OPTN/UNOS Proposed Resource Document for the Medical Evaluation of Living Kidney Donors (Living Donor Committee)**

Members supported the OPTN/UNOS Living Donor Committee's efforts to encourage consistency across programs that are conducting living kidney donor medical evaluations. The Committee viewed the resource document as an important tool in educating and protecting living donors and assisting in the process of obtaining informed consent.

The proposal was approved unanimously with a vote of 11:0:0.

13. **Future policy proposal discussion and voting:**

Members re-examined the Committee challenges surrounding public comment cycles that occur between face-to-face meetings. The Committee agreed that it would be helpful to have the sponsoring Committee liaison or Chair available via conference call for more complex proposals. Some Members supported the use of the committee management system, but participation in this type of communication in the past has varied. The majority of Members favored email as a preferred means of correspondence. Members were encouraged to reply to the entire Committee with their questions, thoughts, concerns, and votes in order to generate discussion.

14. **Spring Meeting date:** April 21, 2008, in Richmond, Virginia.

PATIENT AFFAIRS COMMITTEE

	MONTH	OCTOBER	JANUARY
	DAY	15	3
	FORMAT (select)	In Person	Conference Call
NAME	POSITION		
David Burgio MPA, LFACHE	Chair	X	X
Ray Gabel	Vice Chair	X	X
Bonnie Boulanger ESQ	Regional Rep.	X	X
Michelle Christenson	Regional Rep.	X	
Kenyon Murphy	Regional Rep.	X	X
Laura Ellsworth	Regional Rep.	X	X
Michele Snyders MSW	Regional Rep.		X
Michelle Crossley RN, BSN	Regional Rep.		X
David Burgio MPA, LFACHE	Regional Rep.	X	X
Bruce Brooks	At Large	X	
Emma Griswold BS	At Large	X	
Robert S Higgins MD, MSHA	At Large	X	X
Anne Lally MD	At Large		
Lynn Martin MPH	At Large	X	X
Pete Mazula	At Large	X	X
William Lawrence	UNOS Staff		X
Mary Carpenter	BOD - Liaison	X	X
Richard Laeng MPH	Ex Officio	X	X
Jim Galloway Ph.D.	SRTR Liaison	X	
Friedrich Port MD	SRTR Liaison	X	
Karen Mock MSW, LCSW	Committee Liaison	X	X
Anna Kucheryavaya	Research Liaison	X	X
Stacey Burson	I.T. Liaison	X	X
Diane Steffick	SRTR Liaison		X