

**OPTN/UNOS Minority Affairs Committee
Report to the Board of Directors
June 1-2, 2015
Atlanta, Georgia**

**Meelie DebRoy, MD, Chair
Jerry McCauley, MD, MPH, Vice Chair**

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This report reflects the work of the OPTN/UNOS Minority Affairs Committee during the period of October 2014 – March 2015.

Action Items

1. Guidance on Informed Consent for Living Donors Representing Vulnerable High Risk Populations

Public Comment: N/A

Board Consideration: June 2015

For a number of years, the Committee has been concerned about the safety of living donation for patients representing vulnerable populations, particularly with respect to those individuals who donated their kidneys and may have ended up developing End Stage Renal Disease (ESRD) post-donation. These living donors often represent underserved and/or vulnerable populations, or may be susceptible to coercion and other pressures to donate despite the risk.

Despite the known underlying risk factors for specific donors, there is no consistency across transplant programs as to how potential vulnerable living donors are counseled about their unique risks. A workgroup comprised of representatives from the Minority Affairs, Ethics, Living Donor, Kidney and Transplant Administrators Committees was formed to develop guidance defining potential risk factors for prospective vulnerable or high risk living donors. The resource would also provide guidance to professionals on how to standardize discussions they initiate with potential living donors with specific risk factors to help ensure that the practice of living donation remains accessible and safe as a transplant option. Ongoing workgroup discourse further clarified what groups were most vulnerable or at greatest risk for developing ESRD post living donation. OPTN/UNOS staff conducted a literature review and identified several risk factors that who may lead to an increased risk for ESRD post-donation.

Ultimately, the workgroup wanted to avoid developing a resource that was overly prescriptive or duplicative of existing Centers for Medicare & Medicaid Services' Conditions of Participation or OPTN/UNOS policies. The resource provides insight into factors associated with increased risk and offers recommendations that would not burden centers. In addition, there was a concerted effort to overcome potential unintended consequences of these recommendations, such as the risk of discouraging members of these groups from donating at all.

The final product contains thoughtful revisions the workgroup made after considering the full Committees' feedback. At their spring in-person full committee meeting in Chicago on March 23rd, the Committee voted to recommend that the Board of Directors consider the guidance document.

RESOLVED, that the guidance document entitled “Guidance on Informed Consent for Living Donors Representing Vulnerable High Risk Populations,” as set forth in Exhibit A and Exhibit B, is hereby approved, effective June 2, 2015.

Committee Projects

2. The Patient’s Guide to Referral to Kidney Transplantation

Public Comment: N/A

Board Consideration: N/A

Minorities may experience delays in referral, wait listing, and eventual transplantation as compared to Whites. Late referral has negative medical consequences for patients and limits future opportunities for successful transplantation. There is no established system to ensure that medically appropriate candidates are referred to transplantation. Late referral:

- Impacts the number of transplants, as patients who may have initially been suitable candidates wait too long on dialysis, subsequently losing the ability to be considered for a transplant
- Impacts preemptive transplantation
- Contributes to excess patient mortality

After developing a guidance document for referring providers([Educational Guidance on Patient Referral to Kidney Transplantation](#)), the Committee determined that much of the information would also be appropriate for patients. Therefore, members of the Committee formed a workgroup with members of the Patient Affairs Committee and developed a patient-focused companion resource to the original guidance document.

The UNOS communications team consulted with the workgroups that developed the resource and will shepherd it through the HRSA and internal review, design, and dissemination process.

Committee Projects Pending Implementation

None

Implemented Committee Projects

None

Review of Public Comment Proposals

Committee leadership reviewed the slate of proposals released for public comment January 27, 2015 and selected five for the full Committee to review at their spring meeting March 23rd, 2015. The Committee received presentations on the following proposals from a representative of each respective Committee or the Committee liaison. Committee comments and sentiment are summarized below.

3. Improve reporting of aborted procedures and non-transplanted organs (Living Donor Committee)

The Committee received the presentation and remained neutral with no comment.

4. Clarify Individual Wait Time Transfer Policy and Process (Patient Affairs Committee)

The Committee supported the clarification of current policy. However, although this proposal does not address “gap time” (the interval between registrations when a patient is ineligible for transfer), the Committee expressed concern over patients delisted from one transplant program who have yet to be relisted at another transplant center. This “gap time” could potentially have a negative impact on access to transplant for patients, especially patients from vulnerable populations. While there are many circumstances why a patient may be delisted from a transplant center’s waiting list and the population affected is fewer than 3,000 patients each year, the Committee would like to collaborate moving forward with the Patient Affairs Committee and the Transplant Administrators Committee in determining whether this is a problem. In particular, the Committee would like to be included when data is available to examine this issue.

5. Address Requirements Outlined in the HIV Organ Policy Equity Act (OPO Committee)

The Committee supported this proposal as it supports the OPTN’s Strategic Plan goals to increase the number of transplants and increase access to transplants, particularly in regards to a vulnerable population. The Committee is supportive of including living donors in the research study although they acknowledged that it is currently unknown how many HIV+ people would be eligible to be living donors and felt that special attention be paid to informed consent, whether as part of the IRB protocol, the transplant evaluation process or both. The Committee is interested in the data to be collected as well as additional metrics set by NIH.

6. Membership Requirements for VCA Transplant Programs (VCA Transplantation Committee)

The Committee received the presentation and remained neutral with no comment.

7. Establish Pediatric Training and Experience Bylaws Requirements (Pediatric Transplantation Committee)

The Committee does not support this proposal. Members expressed concern in regards to two specific aspects of the proposal: 1) access and 2) definition of a pediatric patient. In regards to the former concern, the Committee discussed disparities in access—not just the physical geography of where pediatric centers are located, but socioeconomic factors that affect families. In regards to the proposal’s definition of a pediatric patient, while legally the age of < 18 is true, in terms of transplantation, other criteria might be more critical, e.g. weight, size. Members agreed that that smallest and youngest patients would indeed benefit from being cared for by experienced pediatric specialists, however there were concerns raised about the mandate to transfer older children to pediatric centers, when admitted to adult centers (for e.g. 17- yr old patient in acute liver failure). Given that 98% of programs already appear to be within the parameters of the proposed requirements, it would behoove the MPSC to communicate with the 2% of programs that do not meet these requirements, if indeed outcomes of pediatric patients transplanted at those centers are worse than expected. Members of the Committee also questioned that of the 2% of centers that do not meet standards, are their outcomes significantly different than the other 98%?

8. Increasing Committee Terms to Three Terms (Policy Oversight Committee)

The Committee unanimously voted to extend service terms to 3 years for MAC members.

Other Committee Work

9. KAS Desensitization Workgroup

The Histocompatibility Committee has invited MAC to participate in the Kidney Allocation System (KAS) Desensitization Workgroup. For more information see the **Histocompatibility Committee's Report to the Board** and the minutes from the March 30, 2015 Histocompatibility Committee meeting.

10. SLK Subcommittee

The Kidney Transplantation Committee has invited MAC to participate in the Simultaneous Liver Kidney Subcommittee. For more information see the **Kidney Transplantation Committee's Report to the Board** and the Minutes from the April 13, 2015 Kidney Transplantation Committee meeting.

Meeting Summaries

The committee held meetings on the following dates:

- March 23, 2015
- November 19, 2014

Meetings summaries for this Committee are available on the OPTN website at:
<http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=19>