

OPTN/UNOS Patient Affairs Committee
Meeting Minutes
September 11, 2017
Chicago, IL

Kristie Lemmon, MBA, Chair
Darnell Waun, MSN, RN, Vice Chair

Introduction

The Patient Affairs Committee (Committee) met via Citrix GoToTraining and in person in Chicago, IL on 09/11/2017 to discuss the following agenda items:

1. Fall 2017 Public Comment
2. Improving Patient Understanding of the Waiting List
3. Other Significant Items

The following is a summary of the Committee's discussions.

1. Fall 2017 Public Comment Review

The Committee reviewed selected proposals out for public comment and provided feedback to the sponsoring committees.

Summary of discussion:

The Kidney Transplantation Committee presented the following proposals to the Committee for feedback.

a. Improving Allocation of En Bloc Kidneys

The OPTN/UNOS Patient Affairs Committee (PAC) supports the Kidney Committee's efforts to increase the number of transplants, improve outcomes and increase efficiency by proposing new policy for en bloc kidney allocation. The Kidney Committee specifically requested feedback from the PAC regarding keeping the new policy coupled with existing *Policy 5.9 Released Organs*, in which a transplant program is required to release an organ it cannot use in the originally designated recipient. Although there was some debate around cold ischemic time for an organ that had to physically leave the accepting center after being re-allocated, the Kidney Committee advised that en blocs are rarely split, and when they are, the cold ischemic time on the second organ was minimal. The PAC concurred that this seemed to be so remote an occurrence, based on data provided, that the current standard (*Policy 5.9 Released Organs*) was the most transparent, fair and patient-centered method to managing released kidneys. One PAC member (representing OPO's) noted that the proposed policy will be appreciated by the OPO community, as there is currently no policy for the allocation of en bloc kidneys. The following questions were asked and answered to PAC's satisfaction, and PAC moved to support the proposal:

- Q: Will pediatric candidates needing small single kidneys be disadvantaged by this proposed policy? Did the Kidney Committee look at utilization of small single kidneys in the pediatric population or request modeling to assess the impact of mandating allocation of kidneys from donors less than or equal to 18 kg as en bloc?

A: The Kidney Committee did review data on utilization of single versus en bloc kidneys in different age groups. A select number of pediatric programs (in select regions) are transplanting small single kidneys into pediatric patients routinely,

and for those programs, the outcomes are likely excellent. However, the outcomes associated with transplanting small single kidneys into candidates are sometimes inferior, and some programs may prefer the en bloc transplant for their candidates. The Kidney Committee does not feel that this proposal will disadvantage pediatric candidates, as the KDPI, as currently programmed into DonorNet®, doesn't consider how kidneys will be used (en bloc or single) or acknowledge the improved function of en bloc kidneys, screens potentially medically suitable candidates off the match run. Although en bloc kidneys are not typically transplanted into (small) pediatric candidates, they can be transplanted into adolescents. As the surgeon retains discretion whether or not to split an en bloc kidney unit and transplant two separate candidates, pediatric programs will still have access to small kidneys, providing they opt-in to receiving en bloc offers. The Kidney Committee will monitor the policy changes once implemented, and amend the policy if it appears a specific population is being disadvantaged.

One member of the PAC acknowledge that the KPDI fix may improve access, but thought that having data for how many single kidneys from donors 13-20 kg were offered pre-KAS versus post-KAS would be more convincing in terms of this proposal garnering her support. The Kidney Committee would discuss the possibility of requesting this data and analyzing before sending the final proposal to the Board of Directors for consideration. This PAC member was generally concerned that collectively, new (kidney) policies seem to be prioritizing special case adults to the detriment of children. The Kidney Committee advised that they will be looking at pediatric access and utilization on a more granular level in a different project with the Pediatrics Committee.

PAC encouraged the Kidney Committee to include outreach to pediatric kidney transplant programs as part of implementation efforts to inform them they should opt-in to en bloc allocation offers. That way, they then have the option, should their surgeons determine it is medically appropriate, to separate the en bloc unit and transplant two single kidneys into two separate candidates.

- Q: Why did the Kidney Committee opt for a mandatory en bloc allocation weight threshold of less than or equal to 18 kg rather than less than or equal 15 kg, which had the most consensus during the first round of public comment?

A: The Kidney Committee chose less than or equal to 18 kg as the weight threshold for mandatory en bloc kidney allocation as a compromise between centers currently transplanting en bloc kidneys from larger donors and centers that are comfortable transplanting kidneys singly from the smallest donors. The Kidney Committee did consider kidney size when determining allocation criteria, but ultimately went with donor weight, which is an approximate surrogate for kidney size. While programs can always split an en bloc unit if they feel it is appropriate, they will not be able to go from single to en bloc.

- Q: Will separate consent be required for this type of transplant?

A: En bloc kidney transplants are currently being performed, and because they confer excellent outcomes, a special consent for this transplant is unnecessary.

b. Improving Allocation of Dual Kidneys

The OPTN/UNOS Patient Affairs Committee (PAC) commends the Kidney Committee's efforts to increase the number of transplants and efficiency in allocating dual kidneys by updating the dual kidney allocation policy. One PAC member (representing OPO's) noted that the proposed policy was much clearer (for OPO's) than the current policy. The Kidney Committee specifically requested feedback from the PAC regarding keeping the

new policy coupled with existing *Policy 5.9 Released Organs*, in which a transplant program is required to release an organ it cannot use in the originally designated recipient. The Kidney Committee advised that dual kidneys are rarely split, and when they are, the cold ischemic time on the second organ was minimal, as they stayed within the same DSA, if not the same center. The PAC concurred that this seemed to be so remote an occurrence, based on data provided, that the current standard (*Policy 5.9 Released Organs*) was the most transparent, fair and patient-centered method to managing released kidneys. The following questions were asked and answered to PAC's satisfaction, and PAC moved to support the proposal:

- Q: How will patients be educated of these policy changes?
A: Transplant programs are responsible for educating their candidates about the new policy and the option to opt-in for this type of transplant.
- Q: Will separate consent be required for this type of transplant?
A: As there is already a special consent process for high KDPI kidneys (*Policy 5.3.C Informed Consent for Kidneys Based on KDPI Greater than 85%*), and a majority of dual kidneys convey a KDPI of greater than or equal to 85%, the Kidney Committee did not feel a special informed consent for dual kidney transplant was necessary.
- Q: Which candidates tend to receive dual kidney offers or transplants?
A: Candidates who receive dual kidney offers are the same patients that receive sequence D kidney offers (kidneys from older donors, or high KDPI kidneys based on medical conditions).

c. Allowing Deceased Donor-Initiated Kidney Paired (KPD) Chains

The OPTN/UNOS Patient Affairs Committee (PAC) commends the Kidney Committee's efforts to increase the number of transplants through innovations around living donation, in this case, with kidney-paired donation. The three models proposed in the paper seem to address possible concerns about the impact of incorporating deceased donors into a donation chain but there may be other models we are not considering. There was support for all three models. Although there was some angst with the "List Exchange" concept, in that requiring living donation prior to a candidate receiving a deceased donor kidney may discourage a living donor from participating, this model garnered the most support. While the PAC did not offer suggestions to protect vulnerable populations, they did ask whether the Kidney Committee has a sense how this initiative would impact socially disadvantaged groups. The Kidney Committee assured PAC that modeling would be conducted in collaboration with SRTR to assess the impact of the concept the Kidney Committee eventually chooses. One PAC member suggested that the last recipient in a chain could be a patient from a disadvantaged population, should the Kidney Committees identify any. The PAC agrees that increasing the number of transplants is a critical objective. This proposal appears to initiate a chain where one may not have existed so therefore it is important that this concept continue to be evaluated. The following questions were asked and answered to PAC's satisfaction, and PAC moved to support the initiative:

- Q: Logistically, is one model was more feasible than the others?
A: The Kidney Committee shared that they would be looking at logistics more granularly post-public comment when comparing the models.
- Q: Will candidates receiving a deceased donor organ in the chain be informed that the kidney they receive may not be of the same quality as a living donor kidney, as far as a longevity is concerned?

A: The Kidney Committee shared that the Committee would look at whether deceased donor kidneys should be limited to kidneys with a KDPI of less than or equal to 20%, which are fairly comparable to living donor kidneys. The Kidney Committee would also have to consider whether prioritized these kidneys for this purpose would disadvantage other populations, such as pediatrics.

d. Enhancing Liver Distribution – Liver and Intestinal Organ Committee

The OPTN/UNOS Patient Affairs Committee (PAC) commends the Liver Committee's efforts to increase equity in access to transplant through enhancing liver distribution. This proposal is aimed at reducing geographical inequity in access to transplant, broadening distribution to candidates with the greatest medical urgency, and thus reduce waitlist mortality. Therefore, PAC attempted to maintain a national perspective when evaluating the proposed policy.

A minority of PAC members cited the following reasons to oppose the proposal, although other Committee members noted these concerns are not unique to liver distribution:

- OPO performance
- Concern over the potential impact to MUA's and financial impact to rural populations

The PAC discussed OPO performance specifically. Members who opposed the proposal argued that OPO performance should be addressed before a major change in allocation, or that broader sharing should be contingent upon a low-performing OPO instituting a performance improvement plan. Members who supported the proposal argued that there were too many other variables impacting OPO performance (death rates, cause of death, demographics, access to medical care) to simply attribute an increase in donors would lead to an increase to access to livers. There are high-performing OPO's in regions of the country that have very healthy populations. Moreover, candidates in high-MELD areas have nothing to do with the OPO performance of their DSA, and have no recourse to affect it (among other cited concerns). It is not just.

In terms of impact to MUA's, the Liver Committee confirmed that at the time the proposal was composed, there was not enough information available for proper assessment. The proposal acknowledged this limitation and committed to continuing to investigate such. The Liver Committee has since received additional data from the SRTR and will share the results of this analyses via a webinar in October.

The PAC briefly discussed the proximity points and proposed scaling the MELD or PELD points to candidates within the proximity circle from the proposed 5 points to 3, as there is a significant difference in medical urgency in patients with higher MELDs.

The following questions were asked and answered to PAC's satisfaction:

- Q: Is the proposed calculated MELD of 29 akin to "Share 35"?
A: The Liver Committee confirmed correct understanding of the concept and that this proposal recommended sharing over a slightly larger geographic area.
- Q: If a patient already has a high MELD, would the score get capped if they fell within the proximity circle?
A: The Liver Committee acknowledged the question and shared this question had come up several times during this public comment cycle. The representative offered an example: if there were two candidates within the proximity circle, one with a MELD of 36 and the other a MELD of 38, under the proposed system, each would get 5 points added to their score. However, the max MELD a patient can have is 40. Unless something is changed, these patients would have a tied score, despite one patient initially having a slightly higher MELD. The Liver Committee will consider

lifting the cap so scores could be ranked (and in fact, this is what SRTR modeled). In the example cited, the patients would then have scores of 41 and 43, respectively.

- Q: The proposal does not indicate whether the Committee collaborated with a patient advocacy group, or if they plan to. The PAC suggested reaching out to the American Liver Foundation or TRIO International.

A: The Liver Committee clarified that patient advocacy groups were not specifically consulted during the development of the proposal, but may have had representatives participate in the consensus conferences. The Liver Committee noted that they expect several patient advocacy groups to post formal comments.

- Q: Patient education is another area that the proposal does not address. Was an education program put into place after Share 35 that could be replicated here?

A: The Liver Committee acknowledged that an educational product should be developed for patients, as they are directly impacted. UNOS staff shared that all major organ allocation changes have included patient education in some form.

- Q: There were several questions about implementation and monitoring. Would the solutions be phased in, or would they all be implemented at the same time? Will the National Liver Review Board (NLRB) and the guidance regarding HCC be implemented concurrently with this proposal, or would they be phased in? If the Liver Committee notices during monitoring that something might need to change (e.g. the calculated MELD), would the Liver Committee have to send that change back out for public comment?

A: The Liver Committee clarified that all proposed solutions contained therein would be implemented at the same time. The HCC guidance and NLRB will be implemented sequentially based on their Board approval date. Unless a patient-safety issue was identified, any change the Liver Committee might choose to make to the proposed changes post-implementation would have to go back out for public comment.

In conclusion, central to PAC's decision to support this proposed solution is the fact that the proposal seeks to level the playing field for *all* candidates, and is supported by the ethical construct of justice. There was some debate around regional concerns, but several members noted that if turf wars continue, no solution aiming to address a national issue will prevail. A majority of PAC members understand the OPTN/UNOS Liver Committee has limited purview, and that this proposal cannot solve complex, multifactorial issues such as access to healthcare generally. A majority of PAC felt this was a patient-focused proposal. The PAC voted (13-yes, 3-no, 1-abstention) to support this proposal, with the modification to scale back the number of proximity points from 5 to 3.

- e. Living Donation by Persons with Certain Fatal Diseases – Ethics Committee
The OPTN/UNOS Patient Affairs Committee (PAC) commends the Ethics Committee's efforts to increase the number of transplants through offering ethically-sound recommendations to remove administrative barriers (such as amending informed consent and compliance monitoring) so transplant hospitals are not disinclined to considering a terminally ill patient as a potential living donor. The PAC felt that additional education around operationalizing or implementing this guidance may be necessary, as it seems like a relevant end-of-life decision. One PAC member recommended considering cultural differences in end-of-life care, as some cultures may perceive this negatively if this was incorporated in standardized end-of-life care discussions and increase distrust around donation. The Ethics Committee clarified that

they recommended this guidance and related discussions be maintained separate from general end-of-life care discussions. Transplant personnel (or potentially even non-transplant hospital staff like social workers or critical care staff) should not be introducing the subject; rather the potential living donor broaches the topic and makes their intent known to the living donor transplant program. The PAC did not feel it was reasonable to categorize this as a “Living Donor Adverse Event” if in fact the donor dies as a result of their terminal illness and not from the surgery itself, and would encourage relevant OPTN committee to consider adjusting policy to exclude this scenario, or at a minimum, not penalize transplant programs. The following questions were asked and answered to PAC’s satisfaction, and PAC moved to support the guidance:

- Q: Would the legal community, or a hospital’s legal staff, need to be consulted with this type of donation? Did the Ethics Committee conduct any additional outreach beyond OPTN Committees for feedback?
A: The Ethics Committee shared that initially, they were seeking feedback from the transplant community, but the proposal had been forwarded to the ALS Association and the Muscular Dystrophy Association for comment.
- Q: Is there currently, or might additional verbiage need to be added to the consent form for the donor if the surgical risks are greater, based on their medical condition? If the potential living donor with a fatal disease provides consent when they are neurologically competent, but then a time of donation, they have lost neurologic capacity, are they still able to donate?
A: The Ethics Committee clarified that this verbiage does not currently exist on the living donor consent form, and that the Living Donor Committee would have to consider whether to amend the medical and psychosocial evaluation process and disclosure to include those kinds of risks.
The Ethics Committee clarified that no, if the terminally ill potential living donor does not have the neurologic capacity to articulate informed consent at time of actual donation, the Ethics Committee advises against that donation proceeding. Consent by proxy would be a form of imminent death donation, and is excluded in this particular context.
- Q: Would living donor candidates be informed that the donation is coming from a terminally ill patient? Are there more risks for these recipients and how is that addressed? The recipient’s grief process may be more complicated in this scenario, especially if the potential living donor with a fatal disease is a relative or close friend of the recipient. Would the Ethics Committee consider addressing this in the white paper?
A: The Ethics Committee confirmed they would bring both of these comments back to the full Committee for discussion and consider including a recommendation in the final guidance.
- Q: Are there any statistics that show how often these donations are occurring or being missed out on because of there not being a policy for it now?
A: The Ethics Committee confirmed that data and studies are extremely limited, as this scenario is relatively rare.
- Q: What can a potential living donor with a fatal disease donate?
A: The Ethics Committee viewed these potential living donors as any other potential living donor, so they would primarily be donating a kidney or partial liver. One PAC member suggested clarifying this, as the general public may assume everything can be donated.

2. Improving Patient Understanding of the Waiting List

The PAC revisited this project and new members were provided with background.

Summary of discussion:

Based on data and actual cases from the UNOS Patient Services department, in addition to published literature, it is evident that some transplant candidates do not understand the transplant listing process or what the “waiting list” is or how it works. PAC had previously brainstormed scenarios that can affect status and subsequently, further confuse patients:

- Removal
- Inactivation
- Multi-organ listing
- Multi-center listing
- Center-to-center transfers
- Waiting time/waiting time transfers
- Pending confirmation of evaluation/listing outcome

In the spring of 2017, the PAC voted to pursue an educational solution to this problem. Discussion was cut short due to time, but members agreed that the term “waiting list” in and of itself was confusing and that a multi-media delivery may be preferred by patients. Further, this effort, in whatever form, could strive to comply or align with current regulatory or requirements, which may encourage transplant program buy-in. CMS and other entities will be scrutinizing not only documentation of patient education, but comprehension. One member also suggested sharing the resource with dialysis centers. Several members encouraged the PAC to think creatively in terms of technology solutions that could bolster patient understanding of the waiting list (i.e. more interactive education methods) and transparency in the system. The PAC will continue this discussion during a future meeting.

3. Other Significant Items

- UNOS Research Orientation
- Scientific Registry of Transplant Recipients (SRTR) Orientation

The UNOS Research Department and SRTR provided overviews of how they each support Committee work. There were no questions or substantive discussion.

- Policy Oversight Committee Update
- What Every Parent Needs to Know

The PAC received updates from the Vice Chair on recent Policy Oversight Committee actions and strategic goal alignment, as well as an update from UNOs staff on “What Every Parent Needs to Know.” There were no questions or substantive discussion

Upcoming Meeting

- October, 2017

Attendance

- **Committee Members**
 - Kristie Lemmon, MBA
 - Darnell Waun, MSN, RN
 - Julia Coleman, MD
 - Leslie Wyers, M.ED
 - Denise Neal, RN
 - Mary Beth Callahan, LCSW
 - Luis Mayen
 - Debi Hammel
 - Stephanie Little, MSW, LCSW
 - Ann Grosscup, MS
 - Elizabeth Rubinstein
 - Mary Baliker
 - Garrett Erdle, MBA
 - Anil Kotru, MD
 - Sandi Amaral, MD
- **HRSA Representatives**
 - Joyce Hager, MPH
 - Melanie Deal
- **SRTR Staff**
 - Katie Audette, MS
- **OPTN/UNOS Staff**
 - Kim Uccellini, MS, MPH
 - Heather Neil
 - Liz Robbins Callahan, Esq.
- **Other Attendees**
 - Deanna Santana
 - Will Oler