

**OPTN/UNOS Patient Affairs Committee
Meeting Minutes
March 13, 2017
Chicago, IL**

**Kristie Lemmon, MBA, Chair
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Introduction

The Patient Affairs Committee (PAC) met in Chicago, IL on 03/13/2017 to discuss the following agenda items:

1. What Every Parent Needs to Know
2. Waitlist Education Project
3. Other Significant Items

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

1. What Every Parent Needs to Know

A workgroup continues to work on a companion brochure to *What Every Patient Needs to Know* tailored for parents or caregivers of pediatric transplant candidates and recipients. The PAC reviewed a draft and provided feedback to workgroup representatives on the Committee. The goal is to have a finished product to distribute during the June OPTN Board of Directors meeting in Richmond, VA

Summary of discussion:

The Committee commended the workgroup on progress-to-date and provided the following feedback:

Content:

- *Explaining deceased donation to your child:* The brochure includes this topic but does not expound upon it. The Committee recommended including examples and collaborating with the donor family member on the Committee. The donor family member on the Committee advised against writing a letter to the donor family at one year-many donor families are simply not ready. The Committee recommended changing the language to "when the recipient is ready" and waiting at least a year which is in line with many transplant center and OPO requirements.
- *Medication:*
 - A Committee member was concerned that this section advised monitoring medicine supply and refilling or re-ordering a few days before it runs out. This member felt the recommendation should be more conservative and direct caregivers to refill or reorder a few weeks before supply runs out. There may be differences in shelf-life of liquid versus pill medications, which was why the original advice was included. The workgroup will distinguish that the form a medicine comes in may impact when it needs to be refilled or reordered.
 - *Tools for Caregivers:* Several Committee members suggested including examples of tools caregivers could use (for medication tracking and in other instances). For medication, the Committee suggested replacing the specific recommendation with a method to help caregivers track medication supply, such as using a calendar or a cheat sheet.

- *Travel and medication:* A Committee member suggested adding the recommendation to bring original bottles/packaging when traveling so the medication is not confiscated or dumped. Another member suggested having the pharmacy or transplant center provide a print out of the patient's medication list, which should include the most pertinent information. The Committee agreed that it should be noted to never pack medication in checked luggage. The section on traveling was missing from this version of the draft.
- *Vaccinations:* A Committee member suggested including the shingles vaccination in this section.
- *Transplant team roles:* The Committee recommended including a disclaimer that transplant centers staff and responsibilities may vary. In addition, adding that the transplant psychologist can help with coping and elaborate on the transplant pharmacist's role.
- *Transplant evaluation:* Some of the content was thought to be too organ-specific, and the Committee recommended generalizing this topic because there are different tests involved with different organs and transplant centers will evaluate candidates using different tests and practices.
- *Side effects and medical complications:* The Committee suggested including more detail on medication side effects and general common complications, such as feeding tubes, diarrhea, how prednisone affects adolescents.
- *Living donation:* The brochure's content currently focuses on deceased donation, but there are many cases of living donation to pediatric candidates. The Committee recommended including.
- *Second opinion:* The Committee suggested including advice on getting a second opinion, and in what cases that might be appropriate.
- *Genetic counseling:* A Committee member suggested adding genetic counseling to the brochure. It would be relevant to include in the discussion of hereditary diseases and fertility, but also a consideration for parents who are contemplating having another child.
- *SRTR website:* It was suggested to add the SRTR's website to the brochure, but it will likely appear on the TransplantLiving website in case the contractor or site changes.
- *Neurocognitive disabilities:* There was mention of including language around what to do if your child has a disability and needs a transplant.

Structure:

- *Reading level:* The PAC advised that the reading level be assessed and content adapted to ensure the information is presented at a sixth-grade reading level. There are various readability applications and experts that will assess reading level.
- *Topics relevant to adults:* The Committee suggested cross-referencing *What Every Patient Needs to Know* for topics that are relevant to everyone, not just pediatrics. Topics that may change often (e.g. policies relevant to pediatrics) will be covered in detail on TransplantLiving.org, and the brochure will only direct caregivers to the site.

Next steps:

The workgroup will incorporate the Committee's feedback. Several external stakeholders will review the piece, as well as OPTN Committees.

2. Waitlist Education Project

The Committee has heard several presentations regarding the waiting list in an attempt to better understand it themselves to evaluate whether to pursue a project to help patients better understand the waiting list.

Summary of discussion:

The Committee was in favor of pursuing a project pertaining to the waiting list that would benefit patients. The Committee reviewed the problems:

- The overall process, from being referred, evaluated, listing and waiting, is confusing to patients
- Transplant centers are not required by policy to notify patients when they have been made inactive
- There is inconsistency among centers in how (i.e. method by which) they notify patients of their status, and whether they notify inactive patients at all
- The longer the patient is exposed to certain conditions while waiting for an organ, the poorer the outcome for the patient
- Communication breakdowns erode trust with the medical establishment generally, which impacts trust in the OPTN

The Committee agreed that there was a need for patient education to understand the waitlist generally. There was some discord about what type of solution would be the most effective in helping patients better understand the waitlist. The Committee discussed the pros and cons of policy, IT, guidance (for transplant centers) and education solutions. Members acknowledged that there may be barriers to patients getting access to a brochure or online education modules, if the transplant center is a gatekeeper of information. A way to mitigate this is to make the resources available directly to patients, however, many patients do not know who UNOS is. A policy solution would standardize requirements across centers and would be monitored by UNOS, but may not address patient understanding and would create additional administrative burden for transplant centers.

However, some members felt the lack of policy requiring transplant centers to inform patients when they have been made inactive was the most significant problem and that a policy solution was the best option. As of December 30, 2016, there were 42,658 patients with an inactive status. There are a variety of reasons why a patient might be listed as inactive. Some centers currently have policy and process in place to notify patients that have been made inactive, but others do not. Members hypothesized that enough time had passed since a policy solution addressing this issue was proposed by the Transplant Coordinator Committee (TCC) that the community might be more open to a policy solution. If transplant centers do not inform patients that they have been made inactive, they do not know that they need to take some action to get reactivated so they receive organ offers. A policy solution addressing only this issue would not address some of the other problems the Committee identified about general confusion regarding the waiting list or what an inactive status means. Committee members felt that even if this issue was rolled into a general education product for patients, a policy solution needed to be evaluated for this issue specifically.

The Committee felt this would be a Goal 2 (Equity in access) or Goal 3 project (Improving outcomes).

The Committee voted to move forward with education on the waitlist for patients (13 yes; 0 no; 0 abstentions)

Next steps:

The Committee requested the analyses prepared for the TCC's proposal "Proposal to Notify Patients of Extended Inactive Status." They were interested in having someone from the TCC who was involved in the project come and speak with the Committee at a future date.

3. Other Significant Items

Policy Oversight Committee Update

The Vice Chair provided an update on strategic alignment of the OPTN project portfolio and recently approved projects.

Spring 2017 Public Comment Proposal Review

a. National Liver Review Board – Liver Committee

The OPTN/UNOS Patient Affairs Committee (PAC) supports the Liver Committee's effort to reduce geographic variation in exception practices and improve equity in access to transplant for all liver candidates through a national liver review board. PAC supports the specialty boards and appreciates the development of guidance to assist practitioners in evaluating exception requests. PAC members asked the following questions, which were answered during the meeting to the Committee's satisfaction:

Q: Would a review board member recuse themselves on cases from their own center?

A: Yes. Operationally, a review board member from the center submitting the request will not be able to review that case. Programming will prevent this from occurring.

Q: What concerns have the Committee received regarding this proposal this round of public comment?

A: The only opposition the Liver Committee has heard thus far has been around the median MELD at transplant (MMAT) calculation. For adults, the calculation is based on the MMAT in the DSA. One region suggested the calculation be based on MMAT in the region. The Liver Committee opted for DSA over region for several reasons:

The allocation of livers is by DSA.

In many regions, there is considerable variation in median MELD among the DSA's. Candidates in a DSA with a higher median MELD compared to the region's median MELD would be disadvantaged compared to non-exception candidates in their DSA if the region's MMAT was used to calculate their exception score.

The MMAT will be recalculated every six months, so the MMAT could potentially change a lot-increase or decrease-for a candidate. The Liver Committee did this on purpose, so the score is more dynamic and reflects a more "real-time" picture of medical urgency.

The only other feedback the Liver Committee has received is that this change will require significant education of liver transplant center staff.

The PAC voted unanimously to support this proposal (13-Approve, 0-Oppose, 0-Abstain).

b. Improving En Bloc Kidney Allocation – Kidney Committee

The OPTN/UNOS Patient Affairs Committee (PAC) supports the Kidney Committee's efforts to increase the donor pool by creating policy to mandate allocation of kidneys from small pediatric donors.

PAC members asked the following questions, which were answered during the meeting to the Committee's satisfaction:

Q: If the weight threshold was increased to 20 or 25 kg, would pediatric centers continue to miss these offers? Some pediatric centers prefer small single kidneys for young pediatric patients based on their anatomy.

A: No, regardless of what the weight threshold for mandatory en bloc allocation is, because the KDPI will be masked and these offers allocated according to Sequence A (Policy 8.5.G), pediatric centers should start receiving these offers, provided that they opt-in to receive en bloc offers. If the center just wants a single kidney from the donor, that is a possibility. If the donor is <15 kg, the surgeon may opt to split the en bloc kidneys and keep one, releasing the other according to Policy 5.9. Or, if the donor is above 15 kg, or whatever the Kidney Committee determines the ultimate weight threshold will be, those kidneys will be allocated as they are now, according to deceased donor KDPI.

Q: What type of candidate generally is appropriate for this type of kidney offer?

A: Practice will vary by center, but typically, these kidneys might be appropriate for a small adult or older/larger adolescent. Sometimes they are transplanted into pediatric patients, but that practice is still rare. These kidneys may not be perfect for every type of candidate.

Q: What is the life expectancy of these organs, and do they grow with the recipient?

A: The graft survival of these kidneys are excellent, comparable to an ideal deceased or living donor kidney. Patients do very well with these kidneys. They may hypertrophy a bit, and grow a little bit bigger.

Q: Would a patient who agreed to accept en bloc kidneys be notified if an en bloc offer was accepted for them, but then was split based on the surgeon's medical judgment?

A: The policy does not mandate a center inform candidates who have opted in to receive en bloc offers that it is possible that an en bloc kidney offer may be split, and that the candidate might only receive one kidney. A center should inform the candidate that this is a possibility. Single kidneys from small pediatric donors have good outcomes.

Q: Shouldn't the second kidney from a split en bloc stay local or regionally versus attempting to reallocate nationally? It may take quite a bit of time to reallocate the second kidney and may lead to discards.

A: An OPO will reallocate a second kidney from a split en bloc according to deceased donor KDPI, as single kidneys are currently allocated. This is in accordance with current Policy 5.9 Released Organs. The number of split en blocs is a fraction of the total number of en bloc kidney transplants, which in and of itself is a modest number (about 200 a year). In addition, these kidneys tend to be a bit hardier and can withstand longer cold ischemic time. Finally, representatives from high-volume en bloc transplant centers, including centers comfortable splitting en blocs-were part of the workgroup that developed this proposal and were comfortable with the language and concepts being proposed.

Q: What is the difference between en bloc kidneys and any other kidneys in their ability to withstand longer cold ischemic times?

A: En bloc kidneys are from younger donors, and practically, generally would have lower KDPI scores than kidneys from older donors.

Q: What KDPI scores do en bloc kidneys currently reflect?

A: A majority of en bloc kidneys have a score between 50-85%, but these scores do not reflect the true graft survival of these kidneys. The current KDPI calculation in DonorNet assumes all kidneys are single kidneys and does not account for two. In addition, the KDPI was validated for adults, but is applied to all donors-including pediatrics. The workgroup

explored several options around fixing the KDPI issue, but in light of the small number of en bloc transplants currently being done, they opted to remove the KDPI from factoring into allocation, as opposed to re-estimating KDRI/KDPI or creating a pediatric-specific KDRI.

The two clinicians on the PAC supported the <15 kg weight threshold for mandatory en bloc kidney allocation. The PAC voted unanimously to support this proposal (13-Approve, 0-Oppose, 0-Abstain).

Board of Directors Recruitment

UNOS staff presented operational changes and open positions on the 2018-2019 Board of Directors roster. Staff advised how to nominate themselves or someone else for a Board position.

UNOS Patient Services 2016 Report to PAC

UNOS Patient Services provided a summary of 2016 calls, including cases that were escalated to UNOs Member Quality or organ-specific Committees for follow-up.

Scientific Registry for Transplant Recipients (SRTR) Presentation of New Website

The Committee launched a monthly policy learning series to ensure members are comfortable with OPTN policies and related topics and are able to contribute informed feedback. This month, the topic was the Scientific Registry of Transplant Recipients (SRTR). The SRTR launched a brand new website in December 2016. The redesign's primary goal was to improve the user experience and increase the ease of access to information. The Committee invited the SRTR to provide an overview of what they do and engage members (as representatives of the patient community) to assess whether they could not only navigate the site, but understand the information presented.

After providing an overview of SRTR's roles and responsibilities, the SRTR facilitated an interactive discussion to garner feedback on the new website and how information is generally presented and explained, using the beta site that retained the 5-tier rating system. The Committee provided feedback and the patient representatives unanimously voted that they preferred the 5-tier website (6-yes, 0-no, 0-abstentions).

Upcoming Meeting

- April, 2017