

**OPTN/UNOS Policy Oversight Committee
Meeting Summary
March 10, 2015
Chicago, IL**

**Yolanda Becker, MD, Chair
Sue Dunn, RN, BSN, MBA, Vice Chair**

Discussions of the full committee on March 10, 2015 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov>.

Committee Projects

1. Definition of Transplant

The committee liaison started the discussion with the definition of transplant and transplant date proposal. She reported that the proposal had mostly positive feedback and recommended making no changes to the language that went out for public comment. However, one committee member suggested that a simple re-formatting of the current language to reflect the beginning and end better. We define the beginning and the end and these are two different events and that could be better reflected. After discussion, the committee decided to reformat the original language to reflect this. The research liaison offered to do this at the lunch break and bring it back to the committee for a vote after. After lunch the committee reviewed the reformatted language and voted to approve it 14-0-0 (one committee member had already left).

2. Multi-organ Policies Clean-up

The liaison moved onto the multi-organ policies clean-up and also presented the major themes and comments about the proposal, including the comments from ASTS. In particular, a discussion about the changes to Policy 2.15.F Multiple Start Time for Organ Procurement that the ASTS believed was too extreme to say that all must agree on the start time for procurement. The committee discussed this but felt strongly that the intent of this policy had not changed, but that the language is indeed stronger and makes this a true requirement and this is what is needed to give the OPO the power to make this decision. Thus, the committee decided to leave the language as is.

A committee member brought up the larger multi-organ policy issues that remain in the policies and a discussion about what still needs to be addressed and how these issues will be addressed ensued. The committee liaison reminded them that this was an item on the agenda that was coming up very shortly, and the committee agreed to hold the discussion until then and that this language served its purpose for the clean-up, as much as possible, of the existing multi-organ language.

The committee finally voted on the proposed language and voted unanimously (15-0) to send the proposal to the Board for consideration at the June board meeting.

3. Multi-organ Policies Clean-up

The committee then moved on to the policy rewrite quick fixes proposal. The liaison outlined the comments received, focusing on the major objections expressed that changes to proposed 9.3.G (Candidates with Hepatocellular Carcinoma (HCC)) which changes “should” to “musts”. The recommendation to remove that from the proposal was made to the committee, and they agreed that this should be removed with the message to the Liver Committee to please move this to a guidance document since a “should” is not a true policy requirement and there should not be in policy. The liver committee vice chair agreed that this was never meant to be a policy requirement and the committee would work to remove this from policy in the near future and made into a guidance document.

In addition, some comments (ASHI plus others) wanted to ensure that we include the changes to Policy 2.11.A (Required Information for Deceased Kidney Donors) for donor HLA requirements passed at the Nov 2014 Board meeting. The liaison noted that while passed in November, these changes were not yet Board-approved or programmed when this proposal went to PC. The proposal will be updated with the new approved language before going to the Board that reflects the new donor HLA requirements.

The liaison showed the edited language that removed section 9.3.G removed from the proposal and explained that by removing this section, the language would remain “as is” in the policy.

The committee ended the discussion by voting on the proposed language and voted unanimously (15-0) to send the parking lot quick fixes proposal to the Board for consideration at the June board meeting.

4. Committee Terms Project

The POC research liaison presented the results of the survey sent to OPTN/UNOS committee members about term length. Chair Yolanda Becker and Vice Chair Sue Dunn led the discussion on the POC’s project that proposes to increase committee terms to three years.

The committee reviewed the results of the survey and discussed the fact that there was surprising consensus about increasing terms to 3 years. The research liaison provided the following bullet points as background:

- Current committee terms are two years for each position held – member, vice-chair, and chair (except TCC, TAC, and Ethics)
- Committee members sometimes express wish to remain on a committee longer since it takes time to get “up to speed”
- Committee chairs and liaisons sometimes note that two years is not long enough to finish large projects, and historical knowledge needs to be retained

The results included 123 responses broken down as follows:

| Current Committee Role | Response Percent |
|--------------------------------|-------------------------|
| At large/Public | 43.0% |
| Regional Representative | 49.6% |

| Current Committee Role | Response Percent |
|-------------------------------|-------------------------|
| Vice Chair | 2.5% |
| Chair | 5.0% |

The presentation showed the number of committee members and the committee represented, as well as the percentage in favor of an increase from 2 to 3 years. He noted that 85% of the responders said that they favor an increase in term length from 2 to 3 years. In addition, 91 percent of the responders said that they would be willing to serve a 3-year term. The research liaison also noted that 53% of the responders said that leadership terms should be different, since the commitment would be longer for them.

The chair commented that it seems that people want to serve on committees longer, but recognize that the chair and vice chair role is a huge commitment at 9-10 years total.

The liaison also pointed out that there is currently an informal option to renew committee members for an additional year as an at large committee member. Committee leadership can make this request to the RAs and leadership if there is a member they feel they need to retain to complete a project or provide historical knowledge. UNOS staff have also pointed out that anyone can serve on a committee work group, so that is another option for someone that the committee wants to retain. In 2013 this happened 16 times, in 2-14 20 times, and in 2015, 5 times. For those committee members who already serve three year terms (TAC, TCC, and Ethics) those committee members feel that a 3-year term is "just right" in more than 80 percent of the cases.

The committee ended the discussion by deciding to ask for each of the committees to discuss and take a formal vote before considering the next steps for this project. This will also help the committee to see any variation by committee and also register a vote and a commitment from the committee.

Other Significant Items

5. Multi-organ Allocation Projects

The Kidney Committee liaison presented the work of the SLK (Simultaneous Liver Kidney) work group and plans for addressing the remaining components of the multi-organ policy issues. The goal of this discussion was to create a POC work group with representatives from the other relevant committees to begin work on these issues.

The problems with current policies regarding multi-organ allocation were identified as follows:

- For many combinations, not based on objective medical criteria or medical need; only consideration geographic proximity of donor/candidate
- Only address local allocation, no consistency in regional or national allocation
- Do not address order when multiple candidates eligible for allocation (either multi-organ or single organ candidate)

Some additional complexities include:

- Ethics/Values decisions—Which candidate can afford to wait longer?
- What allocation order is fair?

Complex programming—UNetSM is currently programmed to allocate organs based off of one main organ system match run

The presentation went on to summarize the current policies that deal with multi-organ combinations, kidney-pancreas allocation, and SLK allocation.

And finally, it was pointed out that Where the policy 'conflicts' or two policies require different allocation schemes, the OPO has the discretion to choose which match run to use. But, once the OPO chooses a match run they must follow that match run.

Two projects are currently in progress that address this issue:

1. Simultaneous Liver Kidney (SLK) project (Kidney Transplantation Committee)
2. Heart/Lung Allocation project (Thoracic Transplantation Committee)

SLK- proposal this summer that has medical criteria for a SLK as well as a safety net for kidney after liver only transplant. Then would see how this could be expanded to apply to kidney/heart and lung/kidney allocation.

Heart-Lung allocation project – Projected for fall public comment. Will weigh medical severity of candidates.

Staff recommends:

- Expanding SLK working group composition and scope; POC will become primary project lead with all other committees collaborating
- Developing policy addressing order of allocation for all combinations and when single organ allocation must come ahead of multi-organ allocation
- Starting with prior Ethics Committee guidance around Principles of Allocation and multi-organ candidates
- Allowing organ specific committees to finalize recommendations with regard to medical criteria and medical need projects into one comprehensive proposal

It was noted that the SLK workgroup will be adding thoracic representation to the SLK workgroup and have identified two people to do that from the thoracic committee. The committee will reach out to the pediatric committee to find some pediatric volunteers for the workgroup.

Recap:

- Need to broaden the representation: pediatrics (more than one that represents the different organs), peds kidney, peds multi-visceral, peds thoracic, histo, TAC, and coordinator representative.
- Need to get the data to see how often we really occurs that we have multiple candidates that are eligible since that will be important information to know going forward.
- Timeline may need to be reconsidered; may be too aggressive.
- But clearly this is important so we need to get moving

6. Plan for Ongoing Review of Policies and Bylaws

The POC liaison presented a plan for the ongoing review of OPTN Policies and Bylaws, with the aim to implement a cyclical process to review these important documents on an ongoing basis to ensure clarity, accuracy, and consistency, including a process for collecting public input. This will be an ongoing project under the POC. The presentation is included as Exhibit D of these meeting minutes.

After the presentation, committee members had the following comments:

- The factors we'll take into account and the scope of the review should also include the overall burden on the transplant center and the burden on data submission. We need to look at these not in a vacuum but also in relation to the entire body of policies. All these policies taken piecemeal make sense but we need to consider the overall burden on members. This is an important view from the member perspective.
- Another committee member echoed that. Need to look at the entire body of policies and the requirements to members.
- Committee liaisons on the phone noted that there is currently in effort in the policy department to take a look "impact" and coming up with an impact statement as part of all policy proposals. This effort is happening with TAC and OPO to see how these things will affect the members, this includes, equipment, costs, personnel, etc. This would be a document that goes to the board along with the resource assessment we provide to the Board.
- Also need to look at the evaluation plan to make sure the policy and the interpretation (evaluation plan) are in alignment.
- Also look for alignment with CMS; that should be part of the scope of the review. Enforceability and compliance management...
- Need quality metrics... are the quality metrics pertinent to the overall safety and goals of the organizations? Are they relevant?

7. Committee Project Review

POC members reviewed and completed surveys on a total of 48 committee projects: 2 new projects and 46 ongoing projects. The purpose of this review is to make recommendations to the Executive Committee and provide a recommended Committee Project Work Plan to the Executive Committee in June 2015.

The POC did not review projects with a BOD approved and pending implementation, pending board approval, or public comment status.

The policy director provided a presentation about the new proposed OPTN strategic plan and how this will affect the POC's review of these projects.

After discussion and review led by the committee Chair, the POC did not approve the following projects to continue (Liaisons should change these projects' statuses to On HOLD):

1. Timing requirements for deceased donor testing (DTAC)
2. Pancreas/Kidney/Pancreas Post Implementation Clarifications (Pancreas) Comments: Put on hold until they have time to review this and properly assess the new PAS
3. Pancreas as Part of a Multi-visceral (Pancreas) Comment; Committee itself decided to put the project on hold and POC agreed.
4. Pediatric to adult care transition project (Pediatric) Comments: Put on hold to reassess and come back to it if necessary.

5. Develop system for review and sharing of safety events reported through multiple portals at UNOS (Ops & Safety) Comments: This is a staff-driven project and should not be a committee project.

Some other important comments to note (Liver, MPSC, Ethics):

1. Change the National Liver Review Board (Liver) project goal to Increase Access.
2. Facilitated liver placement (Liver): TCC is also discussing a lot of these same issues so seek collaboration with TCC. Also perhaps the OPO committee or at least be sure to have OPO representation.
3. Definition of Transplant Hospital (MPSC): Important project. Please get it back out for public comment so this can get completed.
4. Other MPSC projects: The POC “tagged” the 8 other MPSC projects with the primary goal to “Promote transplant patient safety” and asked that the primary goal be re-evaluated since perhaps they could meet the “Increase Access to Transplants” goal.
5. Consider if living donor recovery hospitals should be responsible for providing care for post-operative complications (Ethics): POC suggest renaming this project to “Consider **WHO** should be responsible for...” The POC also said the Ethics Committee needs to pay attention to what comes out of the ACOT meeting since it is likely going to discuss this issue.

8. KAS Implementation

The committee looked at the new KAS and kidney allocation and how that’s going. The concern was raised that you get a lot of points for 99-100% CPRA candidates.

Comments:

- OPOS have looked at the data and how they are affected. It’s interesting that the individual OPOS is very different from what we’re getting from UNOS, the overall data.
- Very encouraging that the age matching is working; donor recipient age is more closely aligned.
- Of the 99-100 what was the KDPI of those kidneys? Are we sending good kidneys to the 99-100 at the detriments to others?
- Good kidneys are being sent out and could be that the higher KDPI are not being accepted? Is that data we can get?
- Have to remember we’re only 2 months into this and we only have 2 months of data. We still have a long time to go. If you look at the pediatrics in Jan 2014 pediatric transplant rate was 2.4% as of Jan 2015 it is 3.6% so we’re watching that trend. We’ve had a real bump in African Americans receiving transplants, whether that will be sustained or it’s from waiting time being added to time of dialysis remains to be seen. The 99-100 percenters went from 2.45 to 17%. We still need to figure out where the less than 35 KDPI kidneys are going.
- Was the 17-18% we’re seeing for the 99-100 percenters consistent with the SRTTR models we had predicting what we would have? Response: Too soon to tell at only 2 months in.
- One data point we might ask for: impact on low EPTS versus highly sensitized what is the waiting time under KAS. Drop off of 20 to 15 for over age 65. They may be being loss to the 99-100 percenters due to broader sharing. They’re a huge group on the waiting list.

- More boarder sharing KDPI >85% how will that affect decision making at the individual transplant centers? We have some that would never take an ECD kidney and how is this affecting this?
- Have to keep in mind how this is all affecting the vulnerable populations.
- Question from kidney committee vice chair: Anything we need to drill down more one, data-wise? That we could add to some of our requests? Answer: Often there is not a lot of variation on the backup offers that come from outside the OPO? How often are the backup offers being done or a backup match run locally? Is there a separate run when the kidney is coming in from the outside... a backup run locally. It would be good to see if any of these organs that are being discarded was any attempt made to try to allocate this locally?
- Taking a look at table 3 on the web and looking at the non-local percent of accepted kidneys discards, the historical rate 8-10 % and the early data is 7.6% now thru Jan 31 (looking at about 400 kidneys that were shipped out). Twenty five percent were not transplanted to the original but 17% of those were transplanted to another candidate... don't have the data to know if they went back to the original transplant or whatever.
- The OPO may say they want it back, and it's been a long time waiting for the HLA results but they'll still say they want it back and if it's back to the West Coast and the OPO will still insist they want it back with all the cold time. But some say that of course they don't want it back and you run the local match run.
- There are growing pains and a big educational effort is needed.
- Remember what you say you'll do and what you actually do is often dinner. So you may say you'll take a 40 hour old kidney but will you really?
- Going back to the 99-100 percenters and can we find out why the kidney wasn't used? After it was shipped? Can we find out what's the impact of the crossmatch? Were there opportunities to send serum? If we're not shipping from NY to CA are there reasonable opportunities that make sense from a cost perspective to ship blood to get typing done more quickly?
- Need to really focus on discards and if we're not reducing discards then we're not improving and the best way to see that is to look at backup offers.

Upcoming Meetings

- April 14, 2015
- May 12, 2015
- Jul 14, 2015
- August 10, 2015