

OPTN/UNOS Policy Oversight Committee (POC)
Meeting Summary
January 16, 2015
3-4:30 pm EST, Conference Call

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

Discussions of the full committee on January 15, 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>.

Review of January 2015 Public Comment Proposals

This meeting was convened to review and vote on 10 committee public comment proposals and vote on a recommendation to the Executive Committee. The goal of the POC's review of public comment proposals is to validate whether the proposals meet OPTN/UNOS standards for policy development. To comply with the Final Rule, the following policy proposals are required to go out for public comment:

- Substantive changes to the OPTN Bylaws
- Substantive changes to OPTN Policies
- Proposals that change organ allocation, OPTN membership requirements, or data collection

POC leadership created a consent agenda and a discussion agenda based on the results of the survey and comments receive. These proposals were placed on the consent agenda:

- Re-Execution of the Match Run (DTAC)
- Improve Reporting of Aborted Procedures and Non-Transplanted Organs (Living Donor)
- Requirements Outlined in the HIV Organ Policy Equity (HOPE) Act (OPO)
- ABO Blood Type Determination, Reporting, and Verification Policy Modifications (Ops & Safety)
- Modify the Sterile Internal Vessels Label (Ops & Safety)
- Clarify Policy Language and Process for Individual Wait Time Transfer (PAC)
- Collect Ex Vivo Lung Perfusion (EVLP) Data for Transplant Recipients (Thoracic)
- Membership Requirements for Vascularized Composite Allograft Transplant Programs (VCA)

These proposals were placed on the discussion agenda:

The survey results and POC comments are below:

1. DTAC: Re-Execution of the Match Run

Total: 4.4 6 Yes; 0 No

- Current need for the re-execution of the match run seems to be decreasing each year. This may end up to have a pretty low impact on the overall distribution once it is programmed and in place.

2. LDC: Improve Reporting of Aborted Procedures and Non-Transplanted Organs
Total: 4.3 7 Yes; 0 No

- Not sure if this is a big issue or not by underreporting. Would help identify and protect the aborted living donor, especially if they even come to needing a kidney transplant.
- Important proposal in the context of the increase in swap transplants. May need to modify the language. A person who does not ultimately undergo donor nephrectomy is not "living donor"
- But, I would have liked to have known how often the problem has occurred in the past and I don't see any real assessment of cost to correct the perceived problem

3. Liver: Membership and Personnel Requirements for Intestine Transplant Programs
Total: 4.0 6 Yes; 1 No

- With the >40% decrease in the number of intestinal transplants in the past 7 years, this is problematic in of itself. Looking at 2013, only 16 centers performed at least 1 intestinal transplant and less than half (7) performed at least 5. To have a requirement of 7 transplants over 10 years hardly shows competency especially when outcomes are not even considered. This may have the outcome of decreasing access even further. Only reason for public comment is to hear other suggestions, if any not already noted, to address this issue.
- Why are the number of intestinal transplants falling and it is not clear to me how enacting this policy will change the number or quality of intestinal transplants performed. However, it makes perfect sense to develop criteria for intestinal transplant physician qualifications.
- Still need to address the impact on patients and the geographic availability of programs. What is a reasonable distance for a patient to travel to get to an approved program. Who will pay for the patients and their families to travel? Exactly how many programs will be left intact and exactly where are they located?

4. OPO: Requirements Outlined in the HIV Organ Policy Equity (HOPE) Act
Total: 4.2 7 Yes; 0 No

5. Ops & Safety: ABO Blood Type Determination, Reporting, and Verification Policy Modifications
Total: 4.4 9 Yes; 0 No

- I am still concerned about the cost and logistics of implementation. This can go out for public comment. Perhaps more guidance about how programs should implement the proposal and exactly how much it will cost would be helpful.

6. Ops & Safety: Modify the Sterile Internal Vessels Label
Total: 4.6 7 Yes; 0 No

- Contradiction in policy statements under expected impact sections? Can Hep B Core positive, Surface antigen negative vessels be stored for additional use? If so then label should specify type of Hep B. Living Donors or Living Donation will not be directly impacted. Promote living donor safety: Repackaging kits and training are important components
- The proposal is aligned with the strategic goals of promoting transplant patient safety and efficient management of the OPTN. The need for policy revision is grounded in evidence from an FMEA as well as reported patient safety situations related to extra

vessels. Intended and unintended consequences were considered. Minor comments: The policy does not appear to support the goal of promoting Living Donor safety (Goal 5 is related to the safety of the organ

- The issue identified in the document regarding "any" reactive serology result for HBV will need to be clarified though public comment. I would favor identifying which HBV test is reactive.
- To respond to the request for specific feedback re the Hep B documentation. I suggest that the label remain as Hep B and not have the drill down to Hep B Surface Antigen as it is my opinion that this will add clarity for transplant centers, OPOs and increase patient safety

7. PAC: Clarify Policy Language and Process for Individual Wait Time Transfer

Total: 4.6 7 Yes; 0 No

- Do acceptable modes of notification to the candidate need to be clarified for sake of auditing purposes?
- Collaboration with other relevant committees such as Transplant Administrators does not appear to be described.
- Although the policy in practice affects about 2% of patients, all patients have the potential to be affected by the policy if they so choose to transfer to another transplant program. How will patients be informed of the procedures for transferring waiting time to another transplant program?

8. Pediatric: Establish Pediatric Training and Experience Requirements in the Bylaws

Total: 4.4 8 Yes; 0 No

- What are the unintended consequences of this proposal? What happens to those programs that may not have these qualifications in place, or may not be able to meet them in the time required? Is this potentially limiting access to transplant for the pediatric population if a center cannot meet the requirements?
- The Committee has conducted a systematic effort, grounded in efforts of organ-specific subgroups and solicitation of stakeholder involvement/feedback, to address a controversial but important potential patient safety concern. While there is not strong evidence to support the existence of a patient safety concern or to ground the specific caseload requirements, the policy has been thoughtfully developed by consensus, including consideration of a potential unintended consequence of reduced access to transplant based on assessment of the geography of potentially affected centers. The proposal is ready for public consideration and comment.
- Time for this to go out for public comment! Will be interesting to see what the consensus will be in all the Regions.
- What does "primary" mean in regard to "primary pediatric surgeon" or "primary pediatric physician"? This term needs to be clarified or made explicit.
- One remaining question I have is, of the 61% of centers currently meeting the volume requirement, do the data show how many of the other 39% would meet the requirements on a conditional basis. My concern is related to access to transplant.
- The definition of 'primary' physician/surgeon should be clarified.

9. Thoracic: Collect Ex Vivo Lung Perfusion (EVLV) Data for Transplant Recipients

Total: 4.4 6 Yes; 0 No

- Educational component will be important, because people filling out the TRR may not be the people involved in EVLP procedure.

- We have information on kidneys that are pumped and should have the same level of reporting for any perfused organ, including lungs.

10. 10. VCA: Membership Requirements for Vascularized Composite Allograft Transplant Programs

Total: 4.3 7 Yes; 0 No

- The background states intended application to programs recovering from living VCA donors: “Therefore, any VCA recovery from a living donor must take place at a transplant hospital that is approved for VCA transplantation involving grafts from deceased donors.” However, background will be not included in policy language, and thus the policy language will be silent on this issue, leading to potential confusion. Can the policy language be directly modified to clarify?
- More background would be helpful. It is not clear to much of the public what type of medical providers might endeavor to undertake VCA transplants. The requirements are rather vague and refer primarily to "board certification". They provide little insights into the specific skills that might be relevant to VCA transplant.
- "Other VCA's" category may expand quickly, how often do we plan to revise/ update this policy?

During its review of the proposals, the committee offered these additional comments:

11. Re-Execution of the Match Run (DTAC):

A comment from one committee member: there’s statement that, it literally says something about gaming the system. And I, I don’t believe that that’s the kind of language that we should be putting out in public comment. So just a recommendation that that be cleaned up. It’s on Page 5 of the printed polls over Page 11 of the PDF.

The committee discussed these two public comment proposals simultaneously:

- Membership and Personnel Requirements for Intestine Transplant Programs (Liver)
- Establish Pediatric Training and Experience Requirements in the Bylaws (Pediatric)

The discussion on these two proposals centered primarily around whether the pediatric requirements would mean that too many programs would have to shut down, therefore increasing the travel burden on potential pediatric recipients and whether the numbers of required procedures for the intestinal proposal were realistic and made sense. In both cases, the committee expressed concern about the availability of transplant for these patient populations should these proposals pass, and worry that existing programs may need to shut down. The committee ended the discussion ultimately in agreement that they may be uncomfortable with any number, but that the proposals themselves, were ready to go out for public comment.

The POC Chair then held a vote to determine if the committee agreed that it would recommend to the Executive Committee that all 10 of the proposals were ready to go out for public comment. The committee voted unanimously in favor of that recommendation to the Executive Committee.

Discussion on the Public Comment Document

The committee had a discussion about the current public comment document’s format, readability, and content. The discussion was led by Gena Boyle, liaison to the Kidney Committee, who explain that UNOS staff is currently working on improving the public comment document and better tailor its contents and the information provided to readers. The discussion focused on the following questions:

- Was the material we provided sufficient for you to make your decision on this proposal?
- If not, what additional information would have made it easier for you to make your decision?
- Did we include too much information in this document?
- Do you think the material is organized in a user-friendly way?

Some major themes that arose during the discussion:

- More pictures (graphs) and tables than text when explaining complicated items.
- Provide summaries/overviews with the opportunity to read more detail if desired.
- The amount of information provided (for a general public member) is probably on the “heavy” side.
- More bullet points with the opportunity to drill down to details if you want them.

Upcoming Meetings:

- March 10, 2015, 8:30 am CST, Chicago, In-person Committee Meeting
- April 14, 2014, 3:00 pm EST, Full Committee Conference Call