

**OPTN/UNOS Membership and Professional Standards Committee (MPSC)
Meeting Summary
August 31, 2015
Chicago, Illinois**

**Jeffrey Orlowski, Acting Chair
David Cronin, M.D., Acting Vice Chair**

Discussions of the OPTN/UNOS Membership and Professional Standards Committee (MPSC) committee on August 31, 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. Transplant Hospital Definition

The Committee Vice Chair presented an update on recent Transplant Hospital Definition Work Group teleconferences and additional considerations that were prompted by these discussions. Since the Committee's last update at its July meeting, the work group has primarily focused on:

- The possibility of establishing transplant "sites" that are affiliated with a transplant hospital.
- Characteristics that define a site and differentiate single-site and multi-site transplant hospitals.
- Preliminary discussions regarding the association between CMS and the OPTN's definitions of a transplant hospital.

The Work Group suggested that each transplant "site" must have independent key personnel, functional and inactivity reviews, and coverage plans. Additionally, each transplant hospital member must at least have HLA and blood bank services, mental health and social services, clinical and financial coordinators, and a transplant pharmacist available (not necessarily dedicated to) for each of its transplant sites. Subsequent work group discussions started to define a "transplant site" as characterized by a dedicated OR, post-op care unit, and transplant ICU/floor, but each "site" cannot have more than one program within the same contiguous campus.

UNOS staff and the Committee Vice Chair further reviewed and discussed these potential elements of a transplant hospital definition. That discussion prompted additional options for the Committee to consider:

- Move away from the concept of "sites" as it seemingly creates another layer of complexity without comparable value or benefit for members.
- Establishing that a transplant hospital includes all facilities within a contiguous campus, all facilities within the radius of a to-be-determined distance, and other scenarios outside of these criteria as reviewed and approved at the discretion of the MPSC.

- Establishing that a transplant hospital may include multiple ORs, ICUs, post-OP care units, etc. as long as these facilities include the appropriate infrastructure for transplant patient care and are documented with the OPTN.

To conclude the Transplant Hospital Definition Work Group update presentation, the Committee reviewed maps of some cities with transplant hospitals to consider how these potential transplant hospital definition elements may be applied.

Committee members questioned if it was necessary to mandate that individuals could only serve as key personnel at one program, providing the example of a small-volume pediatric program in close proximity to adult programs. Acknowledging that the Bylaws do not currently prevent individuals from serving as key personnel at multiple programs, other Committee members expressed caution with proceeding in this manner as it somewhat undermines the purpose of key personnel. If key personnel are spread among multiple transplant facilities, it is difficult to effectively provide the necessary support to lead the transplant program. Committee members replied that they are aware of individual key personnel leading multiple successful programs, but that it is a challenging endeavor that would unlikely be successful in all situations. The Work Group agreed to continue discussing whether the Bylaws should prevent individuals from serving as key personnel at more than one hospital.

UNOS Staff asked the committee if it had any particular comment on the distance that could define a transplant hospital if the facilities are not on a contiguous campus. While any distance will be arbitrary, the intention of this consideration is to accommodate facilities not located in one connected area (e.g., transplant hospitals in urban environments) and considering the possibility of hospital expansion. The Committee's initially responded that the boundary should not be extremely expansive, and only allow situations that the Committee would always consider appropriate. Essential to this approach is also allowing members to explain their scenario and make a case to the MPSC if it falls outside these criteria. Regarding the distance itself, and noting that the ease at which one can traverse a mile is different depending on the city, a Committee member suggested the driving time between locations as another alternative measure. Others replied that driving time is also relative, depending on the time of day, who is driving, and other unpredictable events. Committee members responded that an expected response time is often required by hospitals upon hiring clinicians, and although relative, it would not be that unique of a consideration. Another Committee member proposed a two-mile radius, noting most can walk a mile in about fifteen minutes, which would allow approximately 30 minutes to traverse between sites in just about all scenarios.

Another Committee member commented that part of the Committee's challenges stems from trying to define a transplant hospital with geographic considerations, when it is really transplant infrastructure and administration that characterizes these things. Might the Committee want to focus more on these characteristics? The Work Group considered transplant hospital administration as a defining characteristic, and was concerned that organizational charts, titles, and responsibilities varied too much across the board to define a transplant hospital by these positions. Along those lines, the Vice Chair stated to the Committee that the goal is to draft a definition that will appropriately accommodate the overwhelming majority of members. It does not seem realistic to develop a clear definition that works well for the OPTN and every transplant hospital. Recognizing this provides additional support for the need to allow members an option to explain their preferred arrangement if it falls outside the final criteria that defines a transplant hospital.

The Working Group will continue discussing these matters and will provide another update for the Committee at its October 2015 meeting.

2. Review of Public Comment Proposals and Preliminary Proposals

The Committee leadership reviewed the list of proposals distributed for public comment and believed that seven of the proposals were relevant to this Committee and should be considered during before the end of the public comment period. Three of the proposals were presented by a representative of the sponsoring committee and discussed during this meeting.

- Revise OPTN/UNOS Data Release Policies. The Committee had no significant concerns about this proposal
- Proposal to Increase Committee Terms to Three Years. The Committee had no significant concerns about this proposal
- Establish and Clarify Policy Requirements for Therapeutic Organ Donation

The MPSC appreciates the efforts to clarify which policies apply to domino donors, but it would like to see more details regarding what could be programmed for these donors.

The MPSC raised concerns about the therapeutic donors addressed in this proposal who are not domino donors. They did not support extending the policy exceptions to this group, and believed that these non-domino therapeutic donors still need all the protections established by living donor policies. Specifically, they expressed the following concerns:

Consent

Consent from the donor is still necessary, just as for any other living donor. The proposal highlights two examples of a therapeutic donor with a renal cell carcinoma and a ureteral trauma. If kidneys from these donors could be safely transplanted to another individual, why would they not be auto-transplanted? If the donor does not want the kidney to be auto-transplanted, then the donor should be treated as a living kidney donor just like all other living kidney donors. In those cases, it would be appropriate to include additional informed consent regarding that possibility. If kidney removal is just one of many possible treatment options available to a non-domino therapeutic donor, the therapeutic donor should be required to meet with an independent living donor advocate and undergo the same informed consent process that is provided to a living donor regarding the risk associated with donation.

Follow-up

Follow-up is still necessary. Removing the follow-up requirement creates conflicts within the Policies 18.5.A and 18.5.B that detail follow-up form submission requirements. Additionally, the proposed policy and current programming will not be aligned since follow-up forms for these donors will be created and appear as expected for the transplant hospital.

Programs are also required to report all living donor deaths within two years of donation under Policy 18.5.C, and the MPSC is required to review all of these reports. Because this policy proposal does not require members to follow therapeutic donors after donation, the MPSC is concerned that not all therapeutic donor deaths will be reported. It is important to have death of these donors reported to the OPTN to ensure sufficient oversight.

Evaluation There is still a risk of disease transmission with these donors, but the proposal does not specify who is responsible for these evaluations, even though it is specified for other living donors.

If the Living Donor Committee does go forward with these exemptions for all therapeutic donors, the MPSC has the following additional concerns:

1. This proposal creates a possible loophole by which members could approve an individual as a therapeutic donor that does not meet living donor criteria. For example, active malignancy is an exclusion criterion specified in current OPTN living donor policy. According to the proposal, potential therapeutic donors may have conditions such as renal cell carcinoma. What if a hospital, during its evaluation of a potential living donor, determines that the donor has renal cell carcinoma? What would prevent the program from classifying the individual as a therapeutic donor, rather than a living donor, and allow the patient to donate their kidney without completing all living donor evaluation requirements and without any follow up after donation? There is not a sufficient system in place, nor does the proposal address how, to evaluate whether programs are accurately classifying potential donors as therapeutic or living donors. If the above scenario was referred to the MPSC, the MPSC may need to determine whether the program appropriately classified the donor as therapeutic. Should there at least be a requirement that the hospital document the clinical justification for the organ removal?
2. It is unclear which polices would apply if a kidney from a therapeutic donor was part of KPD.

Other Significant Items

3. Member Related Actions

Due Process Proceedings and Informal Discussions

The Committee conducted an interview with an OPO and an informal discussion with a transplant hospital. These proceedings were convened as provided for in Appendix L (Reviews, Actions, and Due Process) of the Bylaws.

Upcoming Meetings

- September 9, 2015, Conference Call
- October 27-29, 2015, Chicago
- December 8, 2015, Call
- March 15-17, 2016, Chicago
- July 12-14, 2016, Chicago
- October 25-27, 2016, Chicago