

**OPTN/UNOS Policy Oversight Committee
Meeting Summary
April 14, 2015
Conference Call**

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

Discussions of the full committee conference call on April 14, 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. Policy Rewrite Parking Lot Quick Fixes

The committee Chair presented an issue that an OPO Committee member identified as an inadvertent substantive change from the policy rewrite that needs to be fixed.

Summary of discussion

There appears to have been a substantive change as part of the policy re-write that could impact OPOs, specifically the requirement to use a rigid container to package either the kidney or pancreas.

In the old policy it did not have to be sterile, but if it is sterile, it could be one of the 3 sterile layers.

In the new policy, it has to be sterile.

This is relevant because in the old policy it gave the OPO room to still package a kidney if the Nalgene's sterility became compromised (you could still package in 3 sterile bags then place in the unsterile rigid container). This actually used to be part of the questions they had in the CPTC certification test.

The liaison reported to the committee that staff and policy leadership discussed this and determined that the best and most expeditious way to handle this would be to add it to the quick fixes proposal. Staff worked with leadership from the OPO committee to develop proposed language for the fix. The proposed language restores the original policy requirement pre-rewrite for the internal packaging requirements of organs and vessels.

16.4.A Internal Packaging

A triple sterile barrier must protect organs and vessels. A sterile rigid container must be used when packaging kidneys, pancreas, and vessels that are packaged separately from the organ. If the rigid container is sterile, it can serve as one layer of the required triple sterile barrier. The use of A a rigid container is optional may be used as one layer of the triple sterile barrier for all other organs. and must be used as one layer when packaging kidneys, pancreas, and vessels that are packaged separately from the organ. If

After minimal discussion, the committee voted unanimously to approve the change and add it to the proposal (12-0-0).

Next steps

- This change will be added to the proposal for the Board vote in June.

2. Proposal to Increase Committee Terms to Three Years

The committee reviewed the votes and comments from the other OPTN/UNOS committees about the proposal to increase committee terms to three years.

Summary of discussion

The discussion centered around the long time commitment that would be required of both Chairs and Vice Chairs and the general consensus was that the proposal should increase committee member terms to three years while leaving leadership terms at two years. There was also some discussion about whether or not the MPSC should have three year terms given that they have a huge volume of work and they did not unanimously vote for three year terms as most of the other committees did. There is also the added wrinkle for MPSC councilors moving to the Board at the end of their terms, which would also be a very long time commitment to the OPTN/UNOS. The committee agreed that the MPSC likely needed to be treated differently than the others and should likely remain at 2 years. It was finally decided to move forward to get something out for public comment hopefully by August public comment.

After further discussion, the committee decided to form a work group to start working on the proposal, with the goal to work on bylaws language to move the proposal forward. The following individuals will serve on the working group: Mark Aeder, Sue Dunn, Yolanda Becker, Robert Bray, Jennifer Prinz, Simon Horslen, Ryo Hirose, James Pittman.

Other Significant Items

3. Updated Strategic Plan – POC Review and Public Comment

The committee reviewed the proposed 2015 OPTN Strategic Plan that is currently out for public comment.

Summary of discussion

The committee had these comments, which will be submitted to the public comment site:

- Distinguishing improving outcomes and safety- is it clear what the distinction is between outcomes and safety? I think safety might be considered a subset of outcomes, but in most quality programs, they are completely separate. Good outcomes for living donors that do not have to do with safety, i.e. psychological benefits of donation.
- Is the correct definition of outcomes that it refers to more positive events? I think we're talking a little bit semantics... patient safety includes adverse events and outcomes we talk about (and we don't look at that for living donors in a very robust way), but I think they are different things.
- Question about whether patient safety is too low? Ten percent is low.
- Question about weighting of increase transplant at 40%. The OPTN has already given to a lot of other organizations the task of increasing donation. Is 40% what we really mean when these other organizations are already doing that. So what does this mean to the OPTN? We don't want to have redundant efforts that have not really increased transplants in the past. UNOS and OPTN need to be much more focused on their strategies to do this.

- Five percent at efficient when efficiency could actually increase transplants. That 5% gives me pause because if you're more efficient you have resources for the other things.
- Pieces of the pie oppose each other sometimes. We need to recognize that, as long as we recognize that, I think we're OK.

Next Steps: The committee liaison will enter these comments into the public comment site.

Upcoming Meeting(s)

- May 12, 2015 Conference Call 3:00 PM EST
- July 14, 2015, Conference Call 3:00 PM EST