

OPTN/UNOS Pediatric Transplantation Committee
Meeting Summary
November 19, 2014
Conference Call

Eileen Brewer, MD, Chair
William Mahle, MD, Vice Chair

Discussions of the full committee on November 17, 2014 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 Public Comment Proposals

1. Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs)

After a presentation of the proposal, the Pediatric Transplantation Committee verified that special consideration would be taken in the donor authorization process for families of potential pediatric donors. The Committee also confirmed that there have not yet been any VCA transplants in the United States and few internationally. Some programs in the US currently have IRB-approved protocols in place to perform pediatric VCA transplants. The Committee also discussed the potential benefit of abdominal wall VCAs to pediatric liver recipients in the future.

2. Proposal for Informed Consent for Kidney Paired Donation

After a presentation of the proposal, the Committee expressed support, especially to inform patients of the logistics of KPD programs. After brief discussion, Committee members were satisfied that any additional administrative burden would be offset by enhancements to patient and donor safety and consistency in consent rules for all KPD programs.

3. Improving the OPTN Policy Development Process

After a presentation of the proposal, the Committee expressed support without further discussion.

4. Proposal to Establish a QAPI Requirement for Transplant Hospitals and OPOs

After a presentation of the proposal, the Committee expressed concern that alignment between OPTN and CMS QAPI requirements cannot be maintained after implementation. After discussion, they suggested that the proposed QAPI Bylaw specifically reference CMS, to provide assurance that the OPTN Bylaw would always reflect CMS requirements.

5. Definition of a Transplant Hospital

Although generally supportive of the proposal, the Committee wanted to understand how it would impact a pediatric hospital that is affiliated with an adult hospital and shares an OPTN membership. In most instances under the proposed Bylaw, such a pediatric hospital would be required to have a separate program designation. However, the Committee learned that the MPSC historically has viewed applications in this way, so likely pediatric hospitals that are geographically separate from the affiliated adult hospital

already have a separate membership. It is not uncommon for these hospitals to share the same key personnel. The Committee asked for an estimate of how many pediatric hospitals currently in existence would have to apply for new membership. While that is difficult to estimate at this time, the implementation plan for this proposal includes a study that will answer that question. The Committee was assured that this will be a phased implementation that will be cautious of protecting access to transplantation.

Committee Projects

6. Pediatric Transplant Training and Experience Considerations in the Bylaws

The Chair summarized the Board's feedback of the update on the pediatric Bylaws proposal that she presented to the Board in November. Board members generally supported the need for pediatric requirements. Some members indicated that they would support more robust requirements (for example: larger transplant caseloads stratified by age, size, and clinically-relevant factors). One member was concerned that based on historical information from discussions in the past there will not be enough qualified pediatric primary physicians, specifically pediatric nephrologists, to meet the need for pediatric components of programs. However, the Chair assured the Board that times have changed and there are enough surgeons and physicians currently working who should meet the training and experience requirements.

The Committee then continued the discussion from October 15, regarding emergency transplants. The Chair explained that a subcommittee had met to discuss implementation of an emergency exception to pediatric component requirements. While subcommittee members had not yet endorsed such an exception, they had worked with UNOS staff to develop a plan for implementation.

If the Committee chooses to pursue an emergency exception, the Liaison explained that any program, regardless whether it has an approved pediatric component, will be permitted to list pediatric candidates. However, if a program does not have an approved pediatric component, pediatric candidates will be screened from the match run. In order for a pediatric candidate to appear on a match run, a designated person at the center would have to perform an override. The system would warn the person of the potential policy violation, lessening the chances that a program would unintentionally violate policy. If the organ is allocated to the patient and the program performs the transplant, the MPSC will retrospectively review the incident to ensure the emergency action was appropriate.

Committee members asked questions about details of an emergency exception. One asked if the Committee could require a two-person authorization for the override. The Liaison suggested that the Committee require that programs establish and follow their own protocols regarding emergency exceptions, and that two-person authorization could be a part of that protocol. Another member asked if the Committee should create organ-specific definitions of an "emergency." After brief discussion, the Committee agreed it would be better to leave that to individual medical judgment, which the MPSC would retrospectively review.

The Committee eventually agreed that emergency pediatric transplants would be very rare, especially since pediatric programs are increasingly adept at transporting critically-ill patients. Members requested that the Liaison draft language for an emergency exception for the Committee to review.

Finally, the Liaison clarified that the proposed Bylaw language did not provide a conditional pathway for the primary pediatric physician. The Committee requested that a conditional pathway be added. The Committee decided that a new pediatric component could be established through the conditional pathway, but that at least one key personnel member, either surgeon or physician, had to meet the full requirements.

Upcoming Meetings

- December 17, 2014
- January 21, 2015
- February 18, 2015