

**OPTN/UNOS Ethics Committee  
Meeting Minutes  
August 16, 2018  
Conference Call**

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**Introduction**

The Ethics Committee met via teleconference 08/16/2018 to discuss the following agenda items:

1. Public Comment Review: Pediatric Transition and Transfer Guidance
2. Geography Frameworks Proposal and Update
3. Committee Work Groups Update

The following is a summary of the Committee's discussions.

**1. Public Comment Review: Pediatric Transition and Transfer Guidance**

Data summary:

Many resources describe effective transition and transfer practices that can help lay groundwork for positive transplant outcomes. Suboptimal transition and transfer can increase the risk of the recipients not adhering to follow-up, impacting graft and long-term survival, and cause more patients lost to follow-up (highest in pediatric liver and kidney recipients). Data integrity is important for transplant outcomes. Providers use OPTN data to drive policy decisions and when communicating to patients and families about realistic goals of transplant.

When looking at kidney transplants performed 2000 to 2010, highest rate of lost to follow-up was for recipients transplanted at ages 12 to 17, and then for ages 6 to 11. Similarly, there are high lost to follow-up rates for 6- to 11-year-old liver recipients, followed by 12- to 17-year-olds after liver transplant.

Goals of guidance are to support improvements in transplant outcomes, improve transition and transfer practices, and to reduce instances of lost to follow-up for non-adherence. Pediatric transplant programs were surveyed in early 2018 and the responses were linked to transplant programs that had average or better-than-average lost to follow-up rates. Publication resources were also looked at. Even though highest rates of lost to follow-up were seen in kidney and liver transplants, the Subcommittee and Pediatric Committee felt the practice outline could be applied to any pediatric transplant program.

Examples of recommendations:

A. Pediatric transplant team

- Emphasis on preparing recipients and family members/guardians for transfer
- Transfer to adult provider within the same institution if possible
- Encourage independence and self responsibility
- Recipients need to become strong advocates
- Provide complete medical history information to recipient and adult provider.

B. Accepting adult providers

- Should have an understanding of childhood/adolescent psychosocial development
- Be aware of congenital conditions that lead to organ failure
- Recipients may need time to fully adjust to adult clinic
- Need for ongoing communication with transplant hospitals

Benefits of the resource document include improving transplant outcomes, improving transition/transfer practices, and enhancing data submission to OPTN. If the transplant program implements the practices, transition practices should be recipient-driven and not age-driven. Maintaining relationships with the accepting providers will allow for a smooth transfer process ("the catch" on the other side). Additional time may be needed by staff to obtain the health information they need for the transfer. Transplant programs will best decide what and how to best implement recommendations of the guidance.

Feedback is requested from transplant communities and adult providers that receive the patients on what makes an effective transfer.

Summary of discussion:

Feedback through public comment so far has been very positive. One idea was of a mentorship between the pediatric and adult hospital to develop the relationship and familiarize them with the transplant program. Another idea was to involve the transplant pharmacist in the transfer. There was also interest in future policy development on transfer requirements.

One Committee member felt the pediatric presentation was not very relevant to the Ethics Committee. One point of relevance might be the decision-making authority during transfer moving from parent to patient responsibility, particularly if they have contrary views about the transfer. It was pointed out that one area of guidance is encouragement of recipient's independent and self-responsibility, which is viewed differently in different cultures. Many cultures depend on families for decision-making and they should caution against isolated recipients from their families. Any issues of guardianship being addressed well before transfers should help protect against that. An example was given at one center that when listing a pediatric patient for transplant, a family or support system must first be demonstrated. This might be an ethical consideration.

The issue of insurance-related barriers was brought up. The data set is poor on frequency that children age out of parents' insurance or Medicaid and could be analyzed further as to how that affects adherence and a smooth transition. Another Committee member also felt in addition to that, it is important for the Committee to decide what materials should go with the child during transition.

Another pediatric transplant program does incorporate education in the transplant evaluation for preteens and teens about independence and if they can handle their own medications, etc.; however, the education does not include any formal documents or resources. The question would be whether to make this a requirement or not. The concern might be overwhelming the family of a child who is very ill and focusing on the transplant, perhaps having some of the transfer details discussed at a later time.

It is important to enforce the idea of adherence due to receiving a scarce organ, as well as protecting their health. This type of reinforcement is also done with adults. The feeling is that if they understand the importance, they would be adherent and not lost to follow-up.

**2. Geography Frameworks Proposal and Update**

Data summary:

In June 2018 the Board of Directors approved five principles of geographic distribution and three geographic frameworks that align with those principles. The principles include deceased donor organs are national resource and should be distributed as broadly as possible, reduce inherent differences in supply and demand, reduce travel time that affects cold time, increase organ utilization and prevent wastage, and increase efficiency and transplant system resources.

The three frameworks that align with those principles are fixed distance from donor hospital, mathematical optimization, and continuous distribution are out for public comment now.

- Fixed distance from donor hospital creates fixed geographic areas with distance between donor hospital and transplant candidate's hospital. This allows for wider distribution, particularly for medically urgent patients. Disadvantages are it still uses fixed boundaries and differences in population density may affect similar matching patients.
- Mathematically optimized boundaries are based on data and formula with one or more specific goals such as having consistent ratio of donors to potential recipients within each distribution area. It provides consistent results that can be scaled and monitored and takes into account overlapping neighborhoods. Disadvantages would be fixed boundaries again which might not be uniform.
- Continuous distribution uses a statistical formula that combines important clinical factors such as medical urgency, likelihood of graft survival, as well as proximity to donor hospital to give the candidate a distribution score. The score would prioritize candidates and determine where they would appear on the match run, allowing organ offers to be matched more efficiently to the candidates with highest medical priority. Disadvantage is the new and difficult to understand concept that will produce unpredictable matches.

Feedback is requested on the frameworks because the Board will adopt one at their December 2018 meeting. The Liver Committee due to litigation issues have submitted new liver modeling requests for fall 2017 public comment. The other committees are working on replacing DSA and region for January 2019 public comment and June 2019 Board approval. The Geography Committee will provide oversight and feedback to the Committees.

#### Summary of discussion:

The Committee should familiarize themselves with the principles and frameworks in preparation for review organ-specific committee proposals.

One concern was that equity and access to transplant was not noted as impact of the goal, but rather efficient management of OPTN. It was clarified that the actual organ-specific policies adopted following these frameworks will have equity listed as primary goal, whereas frameworks are to achieve efficiency in distribution and operation as a whole.

Additional concerns include the impact on patients already on the list before distribution change, if there is any data projecting success of any of the three frameworks, as well as how income disparity/insurance might play a role. All proposals will definitely consider transition of patients and grandfathering into the new system. Internal modeling and data from SRTR will hopefully guide the committees' decisions. Then with the broader distribution, socioeconomic factors should be taken into consideration.

One Committee member described an OPO that is being threatened of being non-accredited in New York which will result in either an expensive fight against it or a reassigning of the OPO with geographical redistribution. The Board has not authorized the Geography Committee to intervene at this time, but it is on the OPTN's radar.

### **3. Committee Work Groups Update**

#### Summary of discussion:

Updates will be deferred until next meeting due to time constraints. An email will be sent out to Work Group members with possible items to be discussed at the next meeting.

#### **Upcoming Meetings**

- September 20, 2018, 11 a.m. EST
- October 29, 2018, in-person meeting in Chicago