OPTN/UNOS Pediatric Transplantation Committee
Meeting Summary
August 26, 2014
Chicago, Illinois

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

Discussions of the full committee on August 26, 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.

Committee Projects

1. General Principles for Pediatric Allocation

The Ethics Committee Chair presented the progress of the Joint Subcommittee of the Pediatric Transplantation and Ethics Committees in producing a white paper for the OPTN/UNOS Board of Directors' consideration in November. The white paper describes ethical principles that justify priority for pediatric patients in an equitable national allocation system. He explained that the National Organ Transplant Act (NOTA) and the Final Rule charge the OPTN with developing equitable allocation policy that makes the best use of deceased donor organs, while also providing for the unique health needs of children awaiting organ transplant. In addition to this regulation, the Joint Subcommittee has identified two principles of justice that support priority for pediatric candidates: the Prudential Lifespan Account (or the prudent allocation of healthcare resources over the lifespan) and the Maximum Principle (or giving priority to the most disadvantaged groups). After describing these principles in more detail, including clinical examples and other evidence the Joint Subcommittee has gathered, the Ethics Committee Chair asked for feedback on the following:

- When does prioritizing pediatric candidates enhance the utility of the allocation system?
- Are you supportive of the inclusion of evolutionary psychology or a generativity argument in the white paper?

After an engaging discussion, Committee members agreed that prioritizing pediatric candidates enhances the overall utility of the allocation system if the utility function being examined is patient life years gained. They also felt strongly that the paper should acknowledge a common psychological tendency, also described as a drive, to protect the young. The Ethics Committee Chair thanked members for their feedback and said he would share their recommendations with the Joint Subcommittee as they work to produce a final draft. The Committee will vote on the final draft in September.

2. Pediatric Transplant Training and Experience Considerations in the Bylaws

Pediatric transplantation is a specialty within the field of transplantation; however, in the current Bylaws, pediatric experience is not required for surgeons or physicians to serve as key personnel at programs that perform transplants in pediatric patients. The

Committee has proposed training and experience requirements it believes reconciles professional societies' requests for more restrictive requirements with the community's concern for preserving pediatric access to transplant.

On June 17, 2014, Committee leadership met with the ASTS Executive Committee, at their request, to discuss their feedback on this proposal. The ASTS Executive Committee requested time to convene a Task Force to provide more specific recommendations. Pediatric Transplantation Committee leadership agreed to postpone putting this proposal out for Fall 2014 Public Comment so they could consider the ASTS' recommendations at the full Committee meeting on August 26, 2014.

During the August 26, 2014 meeting, after the Committee Chair presented a comprehensive overview of the project, its history, and the current proposed requirements, the current ASTS President presented the ASTS Task Force's recommendations by phone. To summarize the recommendations, the Task Force felt that the OPTN had not clearly defined the problem the proposal seeks to address. However, if the OPTN can produce evidence of a patient safety issue, then the proposed requirements are not robust enough. They mentioned that this proposal may benefit from Joint Societies Work Group (JSWG) review. The Pediatric Transplantation Committee Chair led a discussion afterwards in which she acknowledged the Committee's shared frustration with the ASTS in not being able to secure community support for more robust training and experience requirements. However, the Committee believes that these minimal requirements address the most egregious issue of surgeons and physicians without transplant experience serving as key personnel in programs that perform pediatric transplants. The Committee affirmed their interest in submitting this proposal for January 2015 Public Comment and committed to continuing to work with ASTS to secure their support.

Committee Projects Pending Implementation

3. **Proposal to Change Pediatric Heart Allocation Policy**

   The Committee Vice Chair, who is also a member of the Thoracic Organ Transplantation Committee, presented recent changes to pediatric heart allocation policy passed by the Board of Directors this past June. The changes seek to reduce waitlist mortality by redefining Status 1A criteria, expanding qualifying criteria for ABO-incompatible heart offers, and increasing the allocation priority of candidates eligible for an ABO-incompatible heart transplant. Additionally, programs will no longer be permitted to list in utero candidates, which is no longer clinical practice. This project is currently being prioritized for programming and implementation.

Implemented Committee Projects

4. **Evaluation of Kidney Share 35 Policy: Inactive Status and Refusal Reasons among Pediatric Registrations**

   The Committee continues to monitor the Share 35 Kidney Policy, which was implemented on September 28, 2005. Under this policy, candidates less than 18 years old at listing receive local priority for non-zero HLA mismatch kidneys from donors less than 35 years old. Data presented at the April 9, 2014 meeting showed that pediatric candidates 0-5 years old at listing had a higher percentage of inactive candidates as compared to those 6-10 or 11-17 years old at listing. The Committee requested

additional data on inactive pediatric candidates, including reason for inactivity, length of inactivity, and whether the candidate was waiting for a primary or repeat transplant. This data was reviewed at the following in-person meeting on September 26, 2014.

The Committee learned that of the 1,425 pediatric, kidney-alone registrations waiting on July 18, 2014, 59% were inactive. Registrations aged 0-5 years old at listing continued to have the highest proportion of inactivity at 64%, followed by 11-17 years old at 59% and 6-10 years old at 57%. The most common reason for inactivity among all pediatric registrations was incomplete work-up (46%), followed by temporarily too well (19%) or temporarily too sick (13%). More than 75% of inactive pediatric registrations were waiting for a primary transplant. Most registrations (68%) that were currently inactive had been waiting for less than 2 years, and most had been inactive for the same length of time as they had been on the list.

The Committee discussed varying listing practices responsible for these trends, including listing pediatric candidates prior to completion of the work-up so they can begin accruing waiting time. However, they acknowledged while there may be legitimate reasons to inactivate a candidate, some of these trends could be due to poor waiting list management or difficulty transferring a pediatric candidate to an adult program. The Committee has requested an update of this analysis to include additional organs (liver, heart, and lung) as well as inactive adult candidates for comparison.

Other Significant Items

5. Evaluation of Open Variance for Segmental Liver Transplantation

At the recommendation of the Board of Directors in March 2011, the Committee tabled discussion on their proposed split liver policy in favor of monitoring data from OPOs and Regions participating in the Board-approved segmental liver variance. The Committee routinely reviews match run data to identify the number of pediatric candidates prioritized above the second recipients of split livers but who did not receive the livers on the original match run within the OPO or Region. They most recently reviewed this data at their in-person meeting on August 26, 2014.

From the beginning of program approval to participate in the variance through April 30, 2014, 42 deceased donors were transplanted as splits at four OPOs and one region. After limiting the analysis to split liver transplants where one segment was transplanted into an adult recipient and the other into a pediatric recipient at the same or an affiliated center, there were 20 donors. An examination of the match run data for these 20 donors found the following:

- For 16 donors, the pediatric candidate was the index patient and allocation of the remaining segment appeared to follow *Policy 9.6.A: Segmental Transplant and Allocation of Liver Segments*.
- For the remaining 4 donors, where the adult candidate was the index patient, only one remaining segment appeared to follow *9.8.A: Open Variance for Segmental Liver Transplantation*. In this instance, 7 pediatric candidates were bypassed above the pediatric acceptor. Of these, six were not waiting at the same or an affiliated center and one required a multi-organ transplant at the same center.

The Committee acknowledges that although some research indicates that a higher MELD is not associated with split liver graft failure, surgeons are still hesitant to split or accept segments for adult candidates with high MELD scores. Due to geographic disparity, adult candidates are transplanted at increasingly high MELD scores. The Committee will continue to monitor the segmental liver variance and will be vigilant of the impact of liver redistricting on the future of this policy.

Upcoming Meeting

- September, 2014