OPTN/UNOS Pediatric Transplantation Committee
Report to the Board of Directors
November 8-9, 2010
St. Louis, Missouri

Summary

I. Action Items for Board Consideration

- None

II. Other Significant Items

- The Committee discussed OPTN Final Rule requirements for organ allocation policy development. (Item 1, Page 3)
    - Thoracic Organ Allocation Policy Review (Item 1a, Page 3)
    - Kidney Allocation Policy Review (Item 1b, Page 5)
    - Liver Allocation Policy Review (Item 1c, Page 7)

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David N. Campbell, M.D., Chair
Heung Bae Kim, M.D., Vice Chair

The following report presents the OPTN/UNOS Pediatric Transplantation Committee's deliberations and recommendations on matters considered during its September 23, 2010, meeting.

1. Discussion of the OPTN Final Rule Requirements for Organ Allocation Policy Development

1a. Thoracic Organ Allocation Policy Review

Evaluation of Policy Modifications for the Broader Sharing of Pediatric Heart Donors for Pediatric Status 1A/1B Candidates, Implemented May 2009- As indicated in the broader sharing of pediatric donor hearts policy proposal approved by the Board of Directors (the Board) in June 2008, Pediatric Transplantation Committee (the Committee) research support staff presented data to evaluate the policy modification that was implemented in May 2009. In summary, the preliminary results suggest the following:

- The majority (about 70 percent) of pediatric candidates were added on the heart waiting list in Status 1A.
- There seemed to be a slight decrease in the Status 1A waiting list death rate during the 10 months after the broader sharing of pediatric hearts policy was implemented, although transplant rate did not seem to change.
- Waiting list death rate in Status 1B decreased for pediatric candidates during post-policy period, but transplant rate did not increase.
- During post-policy period, there was no increase in the number and percent of hearts that were transplanted from pediatric donors.
- There was a slight increase in the number of Status 1A pediatric transplants from pediatric donors after policy implementation.
- There was a decrease in the number of Status 1B pediatric transplants from pediatric donors after policy implementation.

Committee members commented that even though the numbers are modest, negative consequences from more broadly sharing pediatric donor hearts are not seen in the data. Nevertheless, benefits resulting from broader sharing will likely be minimal as the majority of pediatric candidates are listed as Status 1A. That is, there will only be few hearts that would originally have been allocated to Status 2 candidates that will now be allocated to the sickest Status 1 candidates. This is especially the case for the infant population, which has significantly higher waitlist mortality. This sentiment highlights the necessity of the Committee's current efforts, in conjunction with the Thoracic Organ Transplantation Committee (the Thoracic Committee), to address pediatric heart status criteria and overall allocation to pediatric heart candidates.

Joint Heart-Lung and Heart Working Group of the Pediatric and Thoracic Organ Transplantation Committees Descriptive Data Request: Waiting List and Transplant Outcomes for Pediatric Heart Candidates and Recipients by Medical Urgency Status and Device Type- Committee research staff presented data requested during a joint Pediatric Committee Thoracic Organ Working Group-Thoracic Committee Heart Subcommittee teleconference. To summarize the data that have been compiled and analyzed thus far:

- For infants (<1 year), death rate per 100 patient years in Status 1A seemed to be the highest for criteria B, and the second highest for criteria A.

- For infants (<1 year), death rate per 100 patient years in Status 1B seemed to be the highest for criteria A.

- For pediatrics aged 1-10, Status 1A-criteria A had the highest death rates during the earlier period; and Status 1B-criteria A had the highest death rate during both periods.

- Among pediatrics aged 11-17, Status 1A-criteria A had the highest death rate during the earlier period, while Status 1B-criteria D seemed to have the highest death rate during the earlier period.

- One-year Kaplan-Meier patient survival was the lowest for infant (<1 year) Status 1A transplants with criteria B.

- One-year Kaplan-Meier patient survival was the lowest for infant (<1 year) Status 1A and Status 1B transplants.

- Candidates with ECMO at time of listing had the lowest probability of transplant and the highest probability of death within 6 months as compared to candidates with other or no devices.

- Candidates listed initially in Status 1A had the highest probability of death within one-year of listing.

- One-year Kaplan-Meier patient survival was the lowest in Status 1A recipients with ECMO as compared to recipients with other or no devices.

With respect to a less complex implementation solution, Committee members initially discussed the data in the context of shuffling the current pediatric heart status criteria. Because of the low numbers of candidates transplanted at Status 1B and Status 2, modifying allocation for those hearts to go to more urgent candidates likely will not demonstrate a significant impact on current trends. Further, Committee members indicated that current devices used as a bridge to transplant are relatively crude, and as improvements would be expected, the data reviewed today could be completely irrelevant in five years for the purpose of policy decisions.

Committee members also recognized that some of the more urgent patients (i.e. candidates on ECMO) do not fare as well post transplant. A shift in mortality from pre-transplant to post-transplant is not an improvement, and could be seen as detrimental in the context of wasting scarce organs. Committee members cautioned using policy to exclude, or disadvantage, certain candidate groups that data have shown do not do as well after transplant. Codifying these

exclusions in policy is risky, and allowing transplant centers to apply appropriate medical judgment prevents any unintended consequences that exclusionary policy may cause.

A few weeks prior, these data had been reviewed on a call with members of Thoracic Committee and a few representatives of the Committee. As a less complex approach to modifying the allocation of hearts to pediatrics is not inherently clear it was asked during that call- and subsequently at the Committee's meeting- that participants review and write a couple of paragraphs on their individual inferences, upon the analysis of the remaining data requested by the joint group. Committee liaisons will review the responses for themes with apparent consensus. These responses will then be distributed to the group and a teleconference will be scheduled for additional discussion. It may be the case that significant improvements cannot be easily achieved within the confines of the current system, and that a more sophisticated allocation system (e.g. heart allocation score) will be the best and most effective solution.

1b. Kidney Allocation Policy Review

Analyses for Data Requests from the Pediatric Transplantation Committee Teleconference of June 9, 2010: KPSAM of Suggested Modifications for Pediatric Candidates in the Current Efforts to Develop a New Kidney Allocation System- The Kidney Working Group of the Committee met in June via teleconference to discuss pediatric elements that it would like to see included in the new kidney allocation concept to be proposed. Discussion primarily focused on determining a suitable donor profile index (DPI) value to establish pediatric priority for kidney allocation that could be substituted for the current priority pediatric candidates are granted for all donors under the age of 35 (Share 35). Past analysis had revealed a DPI within the range of 0.31-0.39 would yield a number and quality of donors comparable to those donors that pediatric kidney candidates currently receive priority as a function of Share 35. The Kidney Working Group requested that the SRTR perform a KPSAM analysis substituting a DPI of 0.31 and 0.39 in place of the pediatric priority granted for donors less than 35 years of age within the modeling of the new kidney allocation concept. In summary, the KPSAM results indicated:

- The number of pediatric transplants was highest for the DPI < 0.39 run, but the differences between this number and the numbers for DPI < 0.31 run or the age < 35 run were not statistically significant.

- There were also no statistically significant differences in the numbers of pediatric recipients with PRA 10-79 or PRA 80+.

The Committee thought these results were encouraging, and felt comfortable proceeding with a DPI value in this range. Removing age as the only factor to dictate pediatric priority will eliminate offers to pediatric potential transplant recipients from younger donors with some less than ideal characteristics, while also allowing pediatrics to receive offers from ideal donors that are outside the age 35 cutoff. Considering no significant difference between the 0.31 DPI runs and the 0.39 DPI runs, and assuming that all values in between this range would yield similar results, the Committee suggested recommending to the Kidney Transplantation Committee (the Kidney Committee) via the committees' crossover representative that a DPI of 0.35 be included in the new kidney allocation concept. The Committee selected a DPI of 0.35 in hopes that it would be more readily accepted as it was less than the high extreme of DPI values representing comparable benefit, and that this change might be easier to remember and understand considering the same number is being used for pediatric priority today (0.35 DPI/donors less than 35).

The Committee discussed if a separate 0.35 DPI KPSAM should be requested, but ultimately decided it was not necessary because of the lack of significant difference between the 0.31 and 0.39 runs. Further, the Committee expects additional KPSAM runs in the ongoing development of the new kidney allocation concept, and the 0.35 DPI for pediatric preference could be included and evaluated in those future runs.

The Committee was also made aware that the Kidney Committee has some desire to include minimal listing criteria for pediatric kidney candidates in the new kidney allocation system. The Committee agreed that the Kidney Working Group would convene a teleconference to facilitate a preliminary discussion.

Evaluation of New Pediatric Specific Data Elements Added to the Kidney and Kidney-Pancreas Forms on 3/1/2008- The Committee is in the process of reviewing all the pediatric specific data elements that were added in March of 2008, and at its September 2010 meeting it reviewed those elements added to the kidney and kidney-pancreas forms. The following were added to these organs' pediatric Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), and Transplant Recipient Follow-up (TRF) forms:

1. Growth hormone therapy: Yes/ No/Unknown

2. Bone disease
    a. Fracture in the past year (or since last follow-up): Yes/No/Unknown
        If yes, check location and number of fractures:
        - Spine compression fracture ___ # of fractures: ___
        - Extremity ___ # of fractures: ___
        - Other ___ # of fractures: ___
    b. AVN (avascular necrosis): Yes/No/Unknown

To summarize the results of the analysis:

- Rate of unknown response seems to be the lower for TRRs as compared to TCRs and TRFs.

- Number of KP records is much smaller compared than KI records, but rate of unknown response also tends to be higher for KP as compared to KI records.

- Rate of unknown response tends to be higher for graft failure or death follow-up as compared to annual follow-up records where recipients were reported as alive and with a functioning graft.

- When fracture is reported, location and number of fractures were always reported.

- Presence of fractures and AVN was reported in a very small percentage of pediatric TCR, TRR and TRF records.

Upon reviewing these data, Committee members questioned if these additional data fields would provide any value in future allocation discussions and analysis. The Committee generally felt that this information would not be useful in future discussions, but was hesitant to recommend that these fields be deleted upon their initial review recognizing that past committee members had spent time evaluating and recommending these data elements. The Committee decided that the Kidney Working Group should take time to contemplate and discuss the merits of these data

elements, especially considering a desire to reduce the data burden placed on members, and bring its recommendations back to the full committee.

1c. Liver Allocation Policy Review

Prioritize ABO-i Candidates at the End of the Match Run: Additional Questions and Considerations- The Committee has recently discussed potential policy modifications to expand the eligibility for ABO-incompatible livers, so that candidates who do not meet the current criteria could at least appear on the match run. After a data analysis confirmed what was intuitively expected (ABO-incompatible liver transplants are not as successful as ABO-compatible and ABO-identical liver transplants), the Committee agreed that candidates not meeting the current criteria should not have an increased priority. So that these candidates could appear on the match run, the Committee had discussed the possibility of adding these candidates at the very end of the match. Although the Liver and Intestinal Organ Transplantation Committee (the Liver Committee) had given its support to this idea, the Committee readdressed whether this idea would provide any significant benefit. After reviewing how the system currently works with regard to ABO-incompatible liver allocation, and in response to comments made during a past teleconference, the Committee was asked what the likelihood would be that a center would accept an ABO-incompatible liver for a pediatric candidate with a MELD/PELD score less than 30 after everyone else on that liver match had declined the offer. Multiple Committee members indicated that this would be extremely unlikely. UNOS staff reminded the Committee that a preliminary analysis of the resources required to implement such a change indicated that this project would not be small in scope. Resulting discussion yielded a motion that the Committee table this item, unless and until a member institution presents additional concerns about this subject. The Committee unanimously (19 support, 0 oppose, 0 abstentions) supported this motion.

Development of Public Comment Proposals- Allowing Candidates with a Non-Metastatic Hepatoblastoma to be immediately listed as Status 1B, and Removing the ICU requirement for Status 1A and 1B Pediatric Liver Candidates- The Committee has been working on two concepts that it intends to submit for public comment during the Spring 2011 public comment cycle. The first proposal addresses policy 3.6.4.4.1 (Pediatric Liver Candidates with Hepatoblastoma). Currently, candidates with a non-metastatic hepatoblastoma are initially listed at a MELD/PELD score of 30, and if they have not been transplanted at that score within 30 days, the candidate may then be listed as a Status 1B. The proposal will recommend that these candidates are immediately listed at Status 1B. The second proposal will recommend a modification to policy 3.6.4.2 (Pediatric Candidate Status). Specifically, the Committee will propose to eliminate the requirement that all Status 1A and 1B pediatric liver candidates be in the hospital's intensive care unit. During the September 2010 meeting, the Committee reviewed draft public comment proposals for each concept. Committee members recommended a number of edits to clarify and strengthen both proposals. The Committee liaison is to incorporate these suggestions and then redistribute these drafts to the Committee's Liver and Intestine Working Group. After this group is satisfied with the drafts, the proposals will then be shared with the Liver Committee so that its feedback may be incorporated prior to public comment distribution.

2. OPO and Organ Availability Committees Potential Modifications to the DCD Model Elements

In response to a request by the OPO and Organ Availability Committees, the Committee reviewed potential modifications to be proposed by these committees pertaining to DCD model elements. The Vice Chair of the OPO Committee presented the proposed changes, and began with a change in nomenclature to "donation after circulatory death," which would still retain the DCD abbreviation. The Committee did not have any comment on this modification.

In reviewing other potential bylaw language changes, the Committee expressed particular concern about the wording of one of the elements included in the "Pronouncement of Death" section. The requirement as reviewed by the Committee stated, "The time proximate to the donor's pronouncement of death, defined by hospital policy, will incorporate a waiting period sufficient to ensure that cardiac function cannot autoresuscitate." The Committee had particular concerns with ambiguity resulting from the word "proximate," and recommended that statement be rephrased to, "The patient will be declared dead by cardiac criteria as defined by the hospital policy."

The majority of the Committee's discussion focused on an attempt to define warm ischemic time, as there is no formal definition but this is a required field on OPTN forms. The OPO Committee's Vice Chair explained that this definition would not be a part of the DCD guidelines; rather, it would be included in the OPTN definitions help section. Different definitions are used in the field and this is resulting in inconsistent data on those forms used by the OPTN (and approved by the Office of Management and Budget (OMB)). As this is required information on an OMB form, Centers for Medicare & Medicaid Services (CMS) is requesting that a definition of warm ischemic time be developed. The Committee rejected the systolic blood pressures proposed to help define the warm ischemic time. Numerous Committee members indicated that blood pressure, or any isolated vital sign or lab value, should not be used to define the onset of warm ischemic time as those isolated elements will not give an accurate reflection of the organs suitability for transplant. The variation of scenarios among all DCD donors makes it extremely difficult to evaluate an organ's suitability for transplant based solely on warm ischemic time initiated by the presentation of a single lab value. In response to this opposition, the Committee was asked to provide the OPO committee with comments for the development of objective criteria. Attempting to define suitable objective criteria, the Committee could not develop a definition that could be consistently applied to all cases and would accurately reflect the quality of a donor's organs. The Committee opined that proposing a suboptimal metric for warm ischemic time would show support for this concept, and it was not comfortable proceeding in that fashion. Ultimately, the Committee felt CMS should withdraw warm ischemic time as a required field, or modify it so that a numerical value was not required. Realizing that this effort ultimately stems from CMS's request, Committee members questioned how they could communicate their sentiment directly to CMS. The Committee's Health Resources and Services Administration (HRSA) representative indicated that HRSA has a bimonthly conference call with CMS, and that this would be requested as an agenda item for the next call. In light of this, the Committee unanimously agreed (19 support, 0 oppose, 0 abstentions) to send a memo to the OPO Committee that it thoroughly discussed this issue, it does not believe a valid metric for warm ischemic time that is directly associated with organs' suitability for transplant is currently available, and that the Committee has formally requested that HRSA discuss the Committee's concern with CMS.

3. Pediatric Experience Requirements for Primary Physicians and Surgeons at Pediatric Programs

The Committee has been asked by Membership and Professional Standards Committee support staff to consider if it is reasonable for a transplant program that predominately performs pediatric transplants to have a primary surgeon or primary physician with no pediatric case experience; or, if a program that predominately performs adult transplants has a primary surgeon or physician that only has pediatric transplant experience. The Bylaws are currently silent on this matter. The Committee preliminarily discussed these issues, and the general tone was that this is not ideal. As the scheduled meeting end time had been reached, the Committee was not able to debate and evaluate these matters to the extent that was necessary. Accordingly, it agreed to reconvene this discussion during its next scheduled meeting.

4. Approved Pediatric Policy Modifications- Programming Updates

The Committee liaison provided an update on those approved policy modifications that the Committee has been working with UNOS IT to implement. The broader sharing of lungs from donors aged 0-11 years/priority system for 0-11 year old lung candidates, approved by the Board in June 2008, was implemented on September 12, 2010. The broader sharing of pediatric livers from donors 10 years old or less, also approved by the Board in June 2008, is currently being worked on and is scheduled for implementation in the fourth quarter of 2010. Finally, implementation efforts for the ABO-incompatible heart policy modifications, approved by the Board in June 2006, are also near completion and scheduled to be released in the fourth quarter of 2010.

5. Additional Considerations

At the beginning of the Committee's September meeting, highlights from the OPTN/UNOS orientation and Committee-specific orientation were presented. This included reviewing the newly developed Committee Activity Early Evaluation Tool that is to be completed and submitted to the Executive Committee after preliminary discussion of new topics that committees would like to address. A few Committee members expressed concern with restricting discussion. They fear that concepts to address pediatric issues may be stifled and not given due consideration, possibly resulting in good ideas bred by continuing discussion not being realized. This opinion stems from those Committee members' perception that pediatric issues are often placed at a lower priority compared to the other issues faced by the OPTN, due in part to advocates for pediatric transplantation in those types of discussions always being out numbered. Further, Committee members question how practical it was to expect Committee members (who volunteer their time) to ignore an issue that the group was adamant about pursuing. UNOS staff reassured Committee members that this process was not enacted to limit ideas; rather, it is an effort to assure that all committee efforts are aligned with the OPTN's charge before a significant amount of committee time is invested in any particular concept. Nevertheless, to help prevent these concerns from coming to fruition, it was agreed that these apprehensions would be documented.

OPTN/UNOS Pediatric Transplantation Meeting
September 23, 2010
Chicago, Illinois

Pediatric Transplantation Committee		
NAME	**COMMITTEE POSITION**	In Person
David Campbell MD	Chair	x
Heung Bae Kim MD	Vice Chair	
Simon Horslen MB, ChB	Ex-Officio	x
Scott Elisofon MD	Regional Rep.	x
George Mazariegos MD, FACS	Regional Rep.	
Alfonso Campos MD	Regional Rep.	x
Carmen Cosio MD	Regional Rep.	x
Debra Strichartz RN, BA, CCTC	Regional Rep.	x
Andre Dick MD	Regional Rep.	x
Nissa Erickson MD	Regional Rep.	x
Jeffrey Lowell MD	Regional Rep.	x
Kishore Iyer, MD	Regional Rep.	x
Jeff Shuhaiber MD	Regional Rep.	x
Kathy Jabs MD	Regional Rep.	x
Todd Astor MD	At Large	
Sandra Amaral MD	At Large	
Eileen Brewer MD	At Large	Phone
Michael Chobanian MD	At Large	
Sam Davis	At Large	x
Shylah Haldeman RN	At Large	x
Manuel Rodriguez-Davalos MD	At Large	
Kenny Laferriere BSW	At Large	x
Thomas Nakagawa MD	At Large	
Anthony Savo MD	At Large	x
Steven Webber MB, Chb	At Large	x
Jerry Wright RN, CPTC	At Large	x
Mary Carpenter	Visiting Board Member	x
Monica Lin PhD	HRSA	x
Jon Snyder PhD	SRTR	x
Jodi Smith MD	SRTR	x
John Magee MD	SRTR	x
Keith McCullough MS	SRTR	x
Chad Waller MS	Committee Liaison	x
Wida Cherikh PhD	Support Staff	x