

OPTN/UNOS Pediatric Transplantation Committee
Report to the Board of Directors
November 16-17, 2009
Orlando, FL

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)
 - Liver Allocation Policy Review (Item 1b, Page 5)
 - Kidney Allocation Policy Review (Item 1c, Page 9)
- The Committee considered modifications to the OMB data collection forms. (Item 2, Page 12)
- The Committee considered policy and bylaws proposals distributed for public comment. (Item 3, Page 12)

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Simon Horslen, M.B., Ch.B., Chair
David Campbell, M.D., Vice Chair

The following report presents the OPTN/UNOS Pediatric Transplantation Committee's deliberations and recommendations on matters considered during its July 16, 2009 meeting.

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

1a. Thoracic Organ Allocation Policy Review

Policy Language Modifications for the Broader Sharing of 0-11 Year Old Pediatric Lungs and the Establishment of Priority Categories for Pediatric Lung Candidates of the Same Age The Committee liaison updated the group on the outcome of the Executive Committee's review of the modifications to Policies 3.7.6.2 (Candidates Age 0-11), 3.7.9 (Time Waiting for Thoracic Organ Candidates), 3.7.9.3 (Waiting Time Accrual for Lung Candidates Less than 12 Years of Age), 3.7.11 (Sequence of Adult Donor Lung Allocation), and 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation). The Board of Directors (BOD) passed the original policy modifications at its June 2008 meeting. The Committee proposed these modifications, retaining the original intent, to allow for a more efficient and less complex and risky implementation. The Executive Committee unanimously supported the proposed changes at its June 2009 meeting. Incorporating the approved changes, the project is on task to be implemented during the second quarter of 2010.

Programming update: Modifications to Policies 3.7.8 (ABO Typing for Heart Allocation) and 3.7.8.1 (Heart Allocation to Pediatric Candidates Eligible to Accept a Donor Heart of Any Blood Type) The liaison informed the Committee on the progress of its other approved proposals that UNOS is currently working to implement. On May 6th, UNOS implemented the broader sharing of pediatric hearts proposal that the BOD passed at its June 2008 meeting. Implementation did not result in any reported or unforeseen issues.

The ABO-independent pediatric heart proposal that the BOD first approved in September of 2006, with modifications approved by the Executive Committee in December of 2007, is now in the execution phase. The implementation of this proposal is on a very strict timeline, with the potential to affect other projects if not adhered to. Steven Webber, MB, ChB, At Large member of the Committee and a crossover representative from the Thoracic Organ Transplantation Committee, commented that the document is clear and well organized. He continued that feedback from the community will likely be that the current language is obsolete because the policy has taken so long to implement. He added that this is unfortunate considering the level of work exerted thus far. The science driving these policy changes was relatively new when this project began. Accordingly, the community had substantial reservations due to the lack of follow-up data. As time has elapsed since the policy's approval, significant data have been reported that indicate this procedure is not as risky as once thought. Risk adjusted outcomes of patients who receive ABO-independent heart transplants are comparable to those who receive ABO-compatible transplants. Accordingly, the question may be raised as to why those willing to accept an ABO-incompatible transplant are stratified at the end of a match run when the science indicates these patients could be inter-dispersed throughout the match. The 1:4 isohemagglutinin titer level is another element that was appropriately conservative at the time, but medicine and science have evolved so that eligibility of

candidates with higher titer levels is likely safe and appropriate. Dr. Webber made clear that he understood that the approved policy language is what is to be implemented and he believes it is worthwhile as an improvement upon what is currently in place; however, he felt it necessary to point this out as a problem that arises with the significant delay of any programming/implementation of an approved proposal. This is especially the case for pediatric transplantation, in which some aspects are growing and developing at a rapid pace.

In response, Eileen Brewer, MD, At Large member of the Committee and a crossover representative from the Kidney Transplantation Committee, reiterated the value of continuing to pursue the already approved modifications. She commented that in her opinion amending a policy is an easier process than completely developing a policy. It is her hope that later policy revisions upon implementation, considering new science and data, will be a faster process than the current implementation. The Committee's discussion made it apparent that these policies will need to be reevaluated in the near future.

Thoracic Working Group Update- June 29 Teleconference: Medical Currency of Pediatric Heart Policy David Campbell, MD, Region 8 representative and Committee Vice-Chair, updated the Committee on a recent teleconference had with the Thoracic Working Group of the Pediatric Committee and the Heart Working Group of the Thoracic Organ Committee. The call allowed for a preliminary discussion outlining the issues that need to be addressed in an overall review of the pediatric heart allocation policies. The ultimate goal is to improve upon policy in an effort to prioritize heart allocation to the sickest of those pediatric patients. Before entering into a policy modifications discussion, those participating on the call requested some data to evaluate the current policies and potential avenues for improvement. Those data requests are as follows:

- Waiting list mortality for pediatric heart candidates before and after the implementation of sharing policy for Status 1A on July 12, 2006, stratified by age group (0-<1, 1-10, 11-17) and status;
- Waiting list mortality in Status 1A for pediatric heart candidates before and after the implementation of sharing policy for Status 1A on July 12, 2006, stratified by age group and each of the following factors:
 - Criteria met for Status 1A
 - Broad diagnosis category of congenital vs. non-congenital
 - Hospitalized vs. not hospitalized at time of listing (Note: this field is no longer required on 3/1/08);
- Post-transplant survival for pediatric heart transplant recipients performed before and after the implementation of sharing policy for Status 1A on July 12, 2006, stratified by age group (0-<1, 1-10, 11-17) and status;
- Post-transplant survival for Status 1A pediatric heart transplants performed before and after the implementation of sharing policy for Status 1A on July 12, 2006, stratified by age group and each of the following factors:
 - Criteria met for Status 1A
 - Broad diagnosis category of congenital vs. non-congenital
 - Hospitalized vs. not hospitalized at time of transplant.

At the July meeting, Dr. Campbell provided some historical perspective on the original development of these pediatric Status 1A heart policies. In particular, the lack of a hospitalization requirement was an effort to eliminate in-hospital infections and other resulting stresses. At that

time very few pediatric patients were placed on a ventilator or ECMO. As time has passed, these procedures have become more common. Therefore, the current 1A requirements are yielding a significant number of patients being listed at that status. This results in allocation driven by waiting time and not urgency. The current system should be modified and improved so that heart allocation is more dependent upon a patient's urgency, but not at the expense of higher mortality.

Dr. Webber noted that it is particularly challenging in today's environment, especially considering the small numbers of pediatric patients, to make any major overhauls in the allocation system. As an example, he alluded to the relatively minor addition put forth in the Thoracic Organ Transplant Committee's bilirubin proposal and the resulting BOD discussions. Accordingly, the best approach may be to use the data available to redefine which patients are eligible for the different statuses in an attempt to differentiate candidate urgency.

Dr. Horslen agreed that this is reasonable for addressing just the Status 1A questions. Looking at the bigger picture, he indicated that he finds it difficult to accept that there would be organizational concerns regarding an allocation system that the transplant community believes would result in a more equitable distribution of hearts across all age groups- pediatric and adult. Ultimately, if major changes are what the data and transplant community support, then resources will need to be set aside to improve the system. In response, Dr. Webber wanted to clarify his comments: he thought both efforts could be done in parallel. He believes a better heart allocation scheme needs to be developed, possibly a heart allocation score, but this would likely take multiple years to come to fruition. His hope is that addressing the status definitions will improve the system in the short term, while continuing to consider larger modification efforts.

Pirooz Eghtesady, MD, PhD, Region 10 representative, agreed that the current heart allocation system could be improved. In particular, he suggested further analyzing the outcomes of those sickest of patients receiving transplants to help develop allocation modifications or a completely new system. The point was reiterated that the sickest patients must be the priority in heart allocation, but these patients must also have reasonable outcomes so as not to waste the scarce resources as they become available.

In moving forward, Dr. Horslen took an opportunity to express apprehension in using hospitalization as criterion for status eligibility. Hospitalization is not necessarily an indicator of severity of illness as practices vary dramatically from hospital to hospital.

1b. Liver Allocation Policy Review

Split Liver Discussion Findings from the data request submitted at the Committee's March meeting were presented. **[Exhibit A]** The data request explored how many livers were first offered to pediatric patients that were deemed splittable according to those stipulations in policy implemented within UNetSM in November 2007 (donor less than 40 years of age, on a single vasopressor, transaminases no greater than 3 times normal, BMI of 28 or less). The analyzed data included donors from one year pre- and post- the implementation of the splittable liver criteria policy.

The major findings from this data analysis are:

- Of the deceased liver donors recovered, the number and percent that met all the splittable criteria were 710 (10.2%) during one year pre- and 713 (10.5%) during one year post-policy.

- Of the livers meeting splittable criteria, the number and percent of donors where two liver segments were recovered increased from 19 (2.7%) to 28 (3.9%) during one year post-policy.
- The number of times both segments were transplanted when two liver segment were recovered increased from 17 to 24 during the post-policy period, however, the percent out of the number of times two liver segments were recovered did not increase (89.5% vs. 85.7%).
- 48% of the times, the deceased livers donors that met the splittable criteria were offered to pediatric candidates.
- 40% of the times, the deceased livers donors that met the splittable criteria were offered first to pediatric candidates.
- The number of times these deceased livers donors that met the splittable criteria were offered to pediatric candidates decreased as the donor age increased.

Dr. Brewer commented that even though the number of splittable livers only slightly increased in percentage, it leads to a greater impact on the number of patients receiving transplants considering the potential that two patients could receive a transplant from one liver. She indicated that more substantial conclusions from the data could be made if you focus on the number of segments available rather than the total pool of donors. Dr. Horslen responded that approach strengthens the original argument of the number of lives that could be saved, but to analyze the policy's effect you have to compare the number of donors. He went on to say that he did not feel the policy changes have made any impact, rather those programs willing to split livers became more active. Accordingly, he was curious in gathering and analyzing data that explored how many times both segments stay at the same center or at least a sister program. John Magee, MD, SRTR principal liaison to the Pediatric Transplantation Committee, added that other forces are at work (e.g. OPO's can consider a split as two transplanted organs) that may be driving increases more so than the policy language changes.

Carmen Cosio, MD, Region 4 representative, noted a potential problem with the data/policy in deeming a liver splittable based on the number of ionotropic agents. She stated that sometimes these agents are used for purposes other than ionotropic agents. Presently, UNetSM does not allow for a description of why each agent is used, making the current assessment of a donor liver's potential to be split less than ideal. Therefore, the pool of suitable donor livers that would be splittable may very well be higher than the data indicate.

Another Committee member asked- how many livers were split with both segments transplanted that did not meet the criteria outlined in policy? Wida Cherikh, Ph.D, UNOS Senior Biostatistician indicated this had not been analyzed but was data that could be compiled.

As the discussion continued, Heung Bae Kim, MD, At Large member of the Committee and Liver and Intestinal Transplantation Committee ("Liver Committee") crossover representative, asked how many times was the liver offered to an adult recipient first, and split? He contended that if the liver is offered to a pediatric patient first, it will be split- so this is not an issue. Dr. Kim requested data on how many livers were split that were first offered to an adult potential transplant recipient, and whether or not the split liver criteria were met. If there is a difference comparing these data pre- and post- policy implementation, then maybe this policy has had an effect; but, based on his experience that is not to be expected.

Dr. Kim also pointed out the large number of donors that are 18 years old or greater that met the split liver criteria (958 over the two years analyzed), yet only 22.4% were initially offered to pediatric patients. Dr. Kim proposed giving small pediatric patients that would only use the left lateral segment some priority to this large number of donors (similar to Share 35 for kidneys). Such a modification has the potential to increase the number of livers that are split and greatly reduce the number of pediatric liver patients on the waiting list. Multiple Committee members commented that adults will consent to and accept split livers for transplant, but these same adults do not want to split the organ when they receive whole liver offers.

Dr. Horslen summarized the discussion stating that it is apparent there is opportunity to increase the number of split liver transplants. This will be actively pursued in conjunction with the Liver Committee through a joint subcommittee.

MPSC MEMO- ICU as a Surrogate for Severity of Illness Dr. Horslen reviewed the memorandum and explained the requirement that patients, adult and pediatric, must be in a hospital's intensive care unit (ICU) to qualify for Status 1A. The concern arises considering different institutions' varying definitions of ICU. Dr. Horslen provided examples of urgent candidates who may not necessarily be admitted to a hospital's ICU. He also elaborated on internal challenges within hospitals that result because of this policy requirement. Ms. Strichartz shared her experiences, stating that unless a patient is ventilated, it is very difficult to get that patient admitted to the ICU at her institution. To continue to list Status 1A/B patients appropriately, the center applied for exceptions for those that met at least one of the outlined criteria, requesting that the intermediate intensive care unit be accepted as a substitute for the ICU. These exceptions have received repeated approvals.

Dr. Webber provided his perspective from a thoracic standpoint. He indicated that years ago the Thoracic Organ Transplantation Committee was urged to remove any hospitalization as representation of the patient's illness. He recommended making these changes for liver status proactively; otherwise, he anticipated these modifications would be a mandate in the future.

Dr. Kim provided an update from the discussions at the Liver Committee meeting that occurred the previous day. There were varying opinions during the discussion of this topic, but ultimately the Liver Committee decided that if the patient meets the 1A/B criteria, but is not in the ICU, an exception should be submitted explaining why the patient is not in the ICU. The Liver Committee reached this decision so as to avoid altering policy language that has been updated recently

In response to questions from Committee members, Drs. Horslen and Kim explained the varying steps and outcomes of the exception process. After no further discussion, the question was posed if the Committee was in agreement with the Liver Committee's approach? Nissa Erickson, MD, Region 7 representative, responded by asking what value does the ICU designation still hold considering the additional, stricter criteria that have been implemented? Of those exceptions reviewed by the Liver Committee how many were in or out of the ICU, and how did that impact the determination as to whether or not the Status 1A exception was appropriate or not? ICU admittance in and of itself is not physiologic. To echo this point, Todd Astor, MD, At Large member, stated that admittance to the ICU is ultimately a physician's decision. In that light, he asked what is the difference between asking the physician, "Is the patient in the ICU?," as compared to, "Is the patient critically ill?" The consensus of the Committee's discussion of this point was that if ICU admittance is not critical in determining the severity of a patient's illness and therefore their status, then language requiring ICU admittance as a requisite for status should be removed. The Committee reviewed the exact verbiage of the policy language for listing pediatric liver patients. The Committee focused its attention on the first sentence of the Status 1A/1B

criteria in Policy 3.6.4.2 (Pediatric Candidate Status), which states: “A pediatric candidate listed as Status 1A or 1B is located in the hospital's Intensive Care Unit (ICU).” Discussing the policy language, the Committee unanimously supported (18-0-0) responding to the MPSC that it would be appropriate, and the Committee would recommend, to remove the sentence quoted above from Policy 3.6.4.2. To support this recommendation, the Committee requested data on the number of Status 1A/AB exception cases where the sole reason that the candidate did not meet the Status 1 criteria in policy 3.6 was “candidate not in the ICU.”

Pediatric Deceased Donor Liver Program Specific Report Models For the benefit of the Committee, Dr. Horslen succinctly reviewed the information presented by the SRTR related to those elements in the program specific reports (PSR) for pediatric liver programs. During the teleconference, SRTR representatives presented what elements had been removed and what elements had been added for each PSR. **[Exhibit B]** The modifications of the elements in the PSRs are solely based on reported data. Therefore, there is some variation from year to year as to what elements are significant and what are not. This is particularly true for pediatric PSRs considering the smaller sample sizes. Differences in variables between the 1-, 3-, and 5- year PSRs can be explained by different cohorts being examined for each report, rendering different results. To increase the robustness of the models, teleconference participants discussed increasing the current 2-year cohorts for each report to 5-year spans for pediatric centers. Considering nominal changes in practice in pediatric transplantation over the past 10 years, the group felt analyzing a larger set of data would provide a stronger model that is still accurate.

Allocation of Incompatible ABO Livers Ms. Strichartz introduced for preliminary discussion the possibility of modifying policy to make incompatible ABO liver transplants more accessible for pediatric patients in light of some encouraging data she reviewed, and the overall mission of the Committee to eliminate pediatric deaths on the waiting list. One particular question she raised is how the committees established the current MELD/PELD threshold of 30. Dr. Horslen addressed this question stating that ultimately the desire was to make compatible organs available first to those that need them, and that it was felt that patients willing to accept an ABO-incompatible liver would rarely fall below a MELD/PELD of 30. Admittedly though, the score of 30 was an arbitrary decision. Ms. Strichartz asked if data could be collected to analyze the outcomes of these ABO-incompatible liver transplants in children. Dr. Magee responded it is possible, but the numbers are extremely low. Further complicating matters is that a significant number of these patients require transplant as a function of fulminant liver failure which often complicates the analysis due to the nature of this condition.

Dr. Kim interjected that the Liver Committee also discussed this same matter the previous day. They outlined two questions related to this issue that needed to be addressed:

- Should there be a lower limit for patients to be able to accept an incompatible liver transplant?
- Should pediatric patients be so low on the list? That is, for patients younger than one year old, should there be any ABO requirement?

Dr. Cherikh indicated that UNOS Research staff has produced some descriptive data (due to small numbers in the sample set) for the Liver Committee investigating this issue. This information could be used to begin exploring possible modifications. Dr. Kim made a motion to strike the MELD/PELD requirement of 30 as a qualification to be eligible to receive an ABO-incompatible liver transplant. The Committee unanimously (18-0-0) supported this motion, and this

recommendation will be provided and discussed with the Joint Subcommittee and Liver and Intestinal Committee.

Programming Update: Pediatric LI/IN Broader Sharing The Committee liaison provided an update regarding the LI/IN Broader Sharing Proposal that the BOD approved at its June 2008 meeting. Currently, the project is in the Execution phase, testing is to begin shortly, and it is on schedule to be released at the end of January 2010.

Stage IV Hepatoblastoma Policy Review Dr. Kim provided a final update from the Liver Committee meeting that will be addressed further with the Joint Subcommittee. A Liver Committee member introduced for discussion a proposal regarding Stage IV hepatoblastoma and whether the non-metastatic language is still relevant and should remain. Some Committee members indicated that this is something that may receive pushback from the adult programs. The discussion concluded that the Joint Subcommittee would be an appropriate place to begin to address this matter.

1c. Kidney Allocation Policy Review

Highly Sensitized Pediatric Kidney Candidates Priority Sharon Bartosh, MD, At Large member, began discussion by giving some historical context of Share 35 and the Committee's review of the effects of Share 35. The Committee's current efforts have been focused on those highly sensitized pediatric kidney patients. The benefit observed for these patients is not of the same magnitude as the remaining pediatric population which has benefitted greatly from Share 35. Dr. Bartosh, with the assistance of SRTR representatives, then reviewed the different data requests and results that examined possible modifications to work toward minimizing variation in benefit resulting from Share 35. **[Exhibit C]** Considering the background discussed, the Kidney Working Group determined that KPSAM "Run 2" (add regional sharing for pediatric PRA $\geq 80\%$) would not hurt adult patients' access to transplant but still aid the highly sensitized children's access. Accordingly, Dr. Brewer took this suggestion to be discussed at the Kidney Transplantation Committee's May meeting. The Kidney Transplantation Committee expressed concern with "Run 2" due in part to the model's inability to factor in unacceptable antigens. As a result, it felt the number of discards would be higher in reality, and therefore the impact resulting from modifying the allocation would be negligible. Another concern the Kidney Transplantation Committee expressed is that regional sharing of kidneys has not worked very well to date. Mechanisms are not currently in place to facilitate timely transport of kidneys around some regions. The resulting cold ischemia time often makes it more agreeable to wait longer for a local kidney with less ischemia time that will result in a better outcome. To summarize, the Kidney Transplantation Committee's (the Kidney Committee) perspective, Dr. Brewer stated that it would like to do something to support better access for highly sensitized children, but it did not feel that "Run 2" was the best way to accomplish this.

In response to the Kidney Committee's feedback, questions were raised as to why it is feasible to share livers regionally but not kidneys. Committee members indicated this has to do with the traditional transportation means of livers as compared to kidneys: livers are often flown in private charter jets, where kidneys are usually flown via commercial airlines. Even discounting flight arrangements, vast geographies of some regions combined with a lack of cooperation between OPO's and programs not within their DSA also make the regional sharing of kidneys difficult. Again, processes are not currently in place to accommodate regional sharing. This discussion led to another observation related to cold ischemia time that regional sharing would be very challenging without local backup inclusive only of those patients at the center originally accepting the kidney. Vast geographies of some DSA's make it difficult to ship a kidney from one center to

the next without accruing significant amounts of cold ischemic time. Cost and usage of resources must also be a consideration. Another Committee member stated that although there are these concerns, the transplant center ultimately has the final say. Considering the small number of patients and thus the small number of instances a center would be placed in this situation, it may be reasonable to continue with the suggestion and let the transplant centers make the final decision as to whether the offer, considering the related logistics, is appropriate for their candidate.

Dr. Bartosh posed the question: is regional sharing worth pursuing considering the resistance expressed thus far? Dr. Horslen responded that if the argument for change is based upon these data, then the approach likely needs to be rethought. All the concerns with the data make it difficult to rely on as a predictive measure. This is combined with the notion that sharing kidneys regularly over a significant distance seems to be a complicated task to achieve. Dr. Brewer echoed Dr. Horslen's comment by reiterating that the Kidney Committee's main concern was the validity of the data, and implementing a policy change based upon these data. Kathryn Meyer, MS, SRTR Representative, brought to the Committee's attention that modifications to the acceptance model within the KPSAM are currently being made that may strengthen the validity of the data. This new model will likely be ready by the next Committee meeting.

Dr. Bartosh outlined three paths to move forward from her perspective: continue to be persistent with the current regional sharing pursuits with respect to the small number of patients, devise an alternative path which has yet to make itself apparent after much pondering and deliberation, or drop the topic altogether. The third choice being undesirable considering the current placement of highly sensitized pediatric patients amongst those highly sensitized adults, and therefore the lack of access these patients encounter as compared to less sensitized pediatric patients. Kathy Jabs, MD, Region 11 representative, asked if it would be worthwhile to wait for the modifications to the KPSAM and review the data at that point. Dr. Magee indicated that although the data will be improved, those concerns raised by the Kidney Committee will still be valid. Acknowledging that logistics will vary from region to region, Dr. Savo asked if any regions had tried regionally sharing of kidneys and if their results could be further analyzed for some insight. In response, Dr. Horslen mentioned New York/Region 9. Dr. Kim then proposed looking at zero-antigen mismatch kidneys that are shared regionally. If the number of regionally shared zero-antigen mismatch kidneys is large, then adding 20-30 more for pediatric benefit shouldn't be as challenging as earlier indicated. In moving forward, Dr. Horslen also thought it would be prudent to strengthen the argument as to why highly sensitized patients need this priority.

Dr. Brewer stressed that further conversations with the Kidney Committee need to include new data for it to consider. It would also be beneficial to give the Kidney Committee significant time to incorporate this matter into its agenda, so as to allow sufficient time for discussion of these pediatric matters. The Committee concluded the discussion of this topic planning for the Kidney Working Group to review the regionally shared zero-antigen mismatch data well in advance of the Kidney Committee's November meeting. The hope is that the data will provide greater insight to support the logistics of kidney regional sharing, and that this can be brought back to the Kidney Committee.

Kidney Committee Memo: Donor Profile Index as a Substitute for Donor Age in Assigning Allocation Priorities Just prior to the Committee's meeting, the Kidney Committee sent a memo for review. The memo indicates that the Kidney Committee would like to explore donor profile index (DPI) as a substitute for donor age in assigning allocation priorities. The Committee explored using DPI for pediatric patients at its April 2008 meeting, and preliminarily established a DPI range that it felt was appropriate for pediatric patients. To assure the DPI characteristics are still applicable and current, the Committee agreed to review the data again with particular focus on

this aspect. Further, the Committee agreed to respond to the Kidney Committee that it has done preliminary work analyzing this topic, is interested in principal in pursuing DPI as tool for allocation, and would request that it involve the Committee in its future efforts to this point once some framework for allocation has been established and the Kidney Committee seeks more detailed recommendations.

Inactive Pediatric Kidney Candidates In hopes of better understanding the trend of inactive pediatric kidney candidates, Dr. Bartosh introduced the idea of supplying a more exhaustive list of options in UNetSM for transplant centers to indicate more accurately why their patient is listed as inactive.

Dr. Horslen replied that the real question here for pediatric patients is whether or not it is appropriate for patients to be listed immediately as inactive because it is shortly before their 18th birthday, they are being worked up for a living donor, they are searching for suitable insurance, etc. The number of inactive pediatric kidney patients is initially striking; however, it is his sense that the current system is serving pediatric patients well. How the system is serving the pediatric population is ultimately the Committee's main concern.

Committee members commented that an unexpectedly high number of inactive candidates is not an issue exclusive to pediatric patients. It is a trend also seen at many adult transplant centers. Committee members responded that too much time should not be spent on this matter. A Committee member suggested that the high number of inactive patients is a subject that each individual transplant program should address on its own by reviewing their lists. Another member asked who is being harmed by the current practice? Unless this can be definitively answered, it is probably not appropriate at the moment to introduce any "fixes." The Chair concluded the discussion of this item with the assessment that the Committee does not support pursuing this issue further at this time.

2. Discussion of OMB Data Collection Forms

Dr. Cherikh reviewed data items suggested by other committees, and asked the Committee to opine whether or not these data elements are applicable to pediatric patients. Those elements and the Committee's response can be found in **[Exhibit D]**.

During the discussion of these data elements, a Committee member questioned if all the efforts to update these forms are reasonable considering the current fiscal environment. Dr. Horslen asked how the Kidney Committee is justifying the additional elements. Dr. Cherikh responded that the Kidney Committee's intent is that collecting these data will help develop better allocation policy and/or assist in evaluating member performance. Ms. Strichartz, speaking from her experience as someone who completes these forms, indicated that they are arduous already. She continued that there should be attempts to simplify the forms so they only require questions to collect data that is absolutely pertinent and necessary. Dr. Horslen then reminded the group of past goals in reviewing OMB forms of minimizing the data collection burden.

3. Review of Policies and Bylaws for Public Comment Issued on July 10, 2009.

Proposal to Include Non-Directed Living Donors and Donor Chains in the Kidney Paired Donation
The Committee liaison briefly reviewed the proposal and its intent. One Committee member highlighted that the proposal gives pediatric patients 100 "priority points." The member noted that all pediatric patients are given the same number of points, where traditionally those patient younger than 12 are separated from the adolescents and given a slightly greater priority in allocation. She proposed

requesting that 12-17 year olds receive 100 points as indicated and increasing the number of priority points to 125 for those 11 and younger. The Chair cautioned that this suggestion may result in the number of points being lowered for adolescents. Other Committee members shared this same concern. Accordingly, a Committee member motioned to accept the proposal as written, and the Committee voted unanimously in support. (18 support, 0 oppose, 0 abstentions)

Proposal to Improve the ABO Verification Process for Living Donors After the liaison reviewed the proposal, the Committee indicated it felt this proposal was a good measure, something that most centers already do, and obviously in the best interest of patient safety. The Committee unanimously voted to support the proposal as written. (18 support, 0 oppose, 0 abstentions)

Proposed Guidance for the Medical Evaluation of Living Liver Donors After a review of the proposal, multiple Committee members had concerns with the “guidelines” label transforming into policy/a document that would dictate medical practice. The Committee also expressed concern with lawyers using these guidelines in litigation. Committee members requested additional time to review this particular proposal in greater detail before commenting further. Considering the Committee’s review occurred at the beginning of the public comment it elected to defer its vote. The Committee agreed to respond to a later email sent by the liaison requesting its feedback on this proposal.

OPTN Notification Requirements for OPOs, Transplant Hospitals, and Histocompatibility Labs When Faced With an Adverse Action Taken by Other Regulatory Agencies The Committee briefly reviewed the proposal, and the general tone of the Committee was that this proposal is beneficial for transplant centers. The Committee unanimously voted to support the proposal. (16 support, 0 oppose, 0 abstentions)

Proposal to Change the UNOS Bylaws to Reconcile Discrepancies in Patient Volume Requirements for Full and Conditional Program Approval When Qualifying Kidney, Liver and Pancreas Primary Transplant Physicians The Committee liaison reviewed the proposal and after minimal discussion a member motioned to approve the proposal as written. The Committee voted unanimously to support the proposal. (18 support, 0 oppose, 0 abstentions)

Proposal to Add Language to the Bylaws Requiring Transplant Center and OPO Members to Follow State Law Regarding Anatomical Gifts After the initial introduction and review of the proposal, a Committee member stated that this proposal is redundant if there are state statutes already in place. Shouldn’t states be enforcing their laws and not UNOS? Another Committee member responded that it seems wise to have a clear statement that regarding the avoidance of a conflict of interest. Discussion around this point proceeded to a unanimous vote in support of the proposal. (18 support, 0 oppose, 0 abstentions)

Proposal to Change Requirements for Labeling and Packaging Organs Procured by Visiting Transplant Center Teams and for OPO Labeling of Tissue Typing Materials After the liaison introduced the proposal, a Committee member raised question about the use of the phrase “shared responsibility” and what that actually meant. The member continued that OPO staff are well trained and perform these tasks on a regular basis, and they should continue to be responsible for the labeling and packaging. The urgency and errors of some junior fellows should not be a factor behind changing the process. Committee members did not feel it was appropriate to make policy modifications to accommodate bad behavior. Multiple Committee members stressed the importance of having organs properly packaged and labeled. The Vice-Chair suggested that if the policy is modified, it should be modified to clarify the mandate that appropriate steps for packaging and labeling must be taken by the OPO. The party that causes an impediment to or a deviation from these established processes should be reviewed and acted on by the MPSC. He also suggested that an alternative solution to a policy

modification would be an educational effort outlining the appropriate packaging and labeling procedures, as well as stressing the importance of these procedures.

Ultimately, the Committee felt it understood the OPO Committee's intent for the proposal, but it thought the wording of the proposed language was problematic and may cause more issues than what it solves. Accordingly, the Committee unanimously voted to reject the proposal as written. (0 support, 18 oppose, 0 abstentions) The Committee recommends an educational effort to achieve the desired intent without altering established and well-meaning procedures, and/or modifications to policy that retain the OPO's responsibility in the packaging and labeling, but establishes language for the MPSC to follow-up and review those parties whose actions result in the OPO not following established procedures.

OPTN/UNOS Pediatric Transplantation Meeting
 July 16, 2009
 Chicago, IL

Pediatric Transplantation Committee		
Name	Committee Position	In Person
Simon Horslen MB, ChB	Chair	x
David Campbell MD	Vice Chair	x
Scott Elisofon MD	Regional Rep.	x
George Mazariegos MD, FACS	Regional Rep.	x
Rene Romero MD	Regional Rep.	
Carmen Cosio MD	Regional Rep.	x
Debra Strichartz RN, BA, CCTC	Regional Rep.	x
Andre Dick MD	Regional Rep.	
Nissa Erickson M.D.	Regional Rep.	x
David Campbell MD	Regional Rep.	x
Manuel Rodriguez-Davalos MD	Regional Rep.	x
Pirooz Eghtesady MD, PhD	Regional Rep.	by phone
Kathy Jabs MD	Regional Rep.	x
Todd Astor MD	At Large	x
Sharon Bartosh MD	At Large	x
Eileen Brewer MD	At Large	x
Michael Chobanian MD	At Large	
Sam Davis	At Large	x
LeeAnna Hungerford MHA	At Large	x
Heung Bae Kim MD	At Large	x
Kenny Laferriere BSW	At Large	x
Thomas Nakagawa MD	At Large	
Anthony Savo MD	At Large	x
Steven Webber MBChb	At Large	x
Monica Lin Ph.D.	HRSA	x
Elizabeth Ortiz-Rios MD, MPH	HRSA	by phone
Mary Guidinger MS	SRTR Liaison	x
William Harmon MD	SRTR Liaison	
John Magee MD	SRTR Liaison	x
Kathryn Meyer MS	SRTR Liaison	by phone
Jeff Moore MS	SRTR Liaison	
Nadirah Pitts	SRTR Liaison	
Chad Waller	Committee Liaison	x
Wida Cherikh Ph.D	Support Staff	x