

## INTERIM REPORT OF THE OPTN/UNOS PEDIATRIC TRANSPLANTATION COMMITTEE

July 16, 2009  
Chicago, Illinois

*The OPTN/UNOS Pediatric Transplantation Committee met on July 16, 2009, and considered the following items:*

Simon Horslen, MB, ChB, chair of the Pediatric Transplantation Committee (the Committee) called the meeting to order. After a few opening remarks, all participating Committee members introduced themselves. Following this, the Committee liaison, Chad Waller, MS, alerted the Committee of the upcoming UNOS orientation sessions that would be broadcast via LiveMeeting, and the expectation that all Committee members attend. The Committee chair and liaison proceeded to review the Committee's "2009-2010 Annual Committee Goals", as well as the Committee's current efforts. Continuing the Committee's introduction, Wida Cherikh, PhD, UNOS Biostatistician for the Committee, explained data requests during the policy development process. Dr. Cherikh reviewed the context of requests, their need to be relevant to the committee's goals, that the OPTN Research staff does descriptive data analysis (what *actually* happened), and that the Scientific Registry for Transplant Recipients (SRTR) support staff investigate inferential data (what may be *expected* to happen). Following this presentation, John Magee, MD, SRTR principal liaison to the Pediatric Committee, concluded the introduction by presenting some background on the SRTR. Dr. Magee discussed the SRTR's roles in organ transplantation, the flow of the information analyzed (where it comes from, goes, etc.), some of the statistical methods the SRTR uses, and the SRTR's overall approach in providing analytic support for OPTN committees.

### Update Regarding Actions from the June 22-23, 2009 Board of Directors Meeting

Following the introduction, the liaison provided an update on the June Board of Directors (BOD) meeting, focusing on those items pertinent to the Committee. The liaison reported the BOD's resolution to approve a modification to Policies 3.6.4.3 (Pediatric Liver Transplant Candidates with Metabolic Diseases) that will reinstate the "no appeal/no withdraw" button in UNet<sup>SM</sup> for rejected exception cases; however, before a center may use that option, it will be required to appeal the case and participate in a conference call with their regional review board. The BOD approved similar modifications for all situations in which the liver Regional Review Boards presides.

The liaison also made the Committee aware of the discussions and outcomes at the BOD meeting regarding the Thoracic Organ Transplantation's proposal to include bilirubin in the Lung Allocation Score (LAS), and the Liver and Intestinal Transplantation Committee's proposal to standardize MELD/PELD exceptions. The liaison reported on modifications by the BOD to those proposals (in particular their implementation), due in part to BOD's aim of being fiscally responsible. Once the BOD reached the decision that the implementation could be achieved in a more cost efficient manner, it began to modify the policy language during the meeting. The BOD modified language modifications yielded numerous implementation questions after the fact. The message for the Committee is to be

aware that the financial implication of executing a proposal is a factor that will be considered in its, and all Committee's, future efforts. With that and the complete development of policy proposals in mind, it is also important for the Committee to thoroughly explore all avenues of the proposal before submitting it for public comment so that no proposal adjustments need to be done "on the fly."

A few Committee members had some thoughts to share in response to this update. Committee members stated adding the overlay of financial considerations is troubling, as everything will have some financial impact. Committee members questioned if such considerations are really its role, especially considering that it has never received any data regarding costs of anything up to this point. If committees are expected to consider financial implications, this information needs to be provided for the committees to fold into its efforts.

Along these lines, another Committee member commented that committees should find out ahead of time whether or not the efforts they are pursuing are fiscally appropriate before significant work is done. He alluded to an example of the Liver Committee working on the standardized MELD/PELD exceptions proposal for over two years, only for it not to be completely passed. The Chair posed the question- Is the BOD giving Committees the opportunity to say they don't accept that this is of insufficient priority and that the policy should be reconsidered? The Chair concluded the discussion stating Committees can't always see the total impact a policy will have at the beginning of the development process, which would necessarily include the financial impact relative to the benefit of the change.

#### Discussion of the OPTN Final Rule Requirements for Organ Allocation Policy

##### ***Status of Thoracic Organ Allocation Policy Review***

- *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) for the allocation of lungs to pediatric candidates and from donors less than 12 years of age*

The Committee liaison updated the group on the deliberations and outcome of the Executive Committee's review of the modifications to the policy language 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 group passed at the June 2008 BOD meeting. The Committee had proposed these modifications, retaining the original intent, to allow for a more efficient and less complex and risky implementation. The Executive Committee unanimously supported these changes at its June 2009 meeting. Accordingly, the project is scheduled to be implemented during the second quarter of 2010. Currently, the business rules are being developed for the project, and the Committee will be asked for feedback upon completion.

- *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 updated the Committee on the progress of its other approved proposals that UNOS is currently working to implement. The broader sharing of pediatric hearts proposal that the BOD passed at its June 2008 meeting was implemented on May 6<sup>th</sup> with no issues to report.

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 an execution phase. The implementation of this proposal is on a very strict timeline, with the potential to affect other projects if not adhered to. Presently, the business rules are being developed and the project is scheduled to be completed in the first quarter of 2010. Committee members had been sent a draft of the business rules earlier in the week to provide their feedback. As a majority of the Committee was in participation at the meeting, the floor was opened for discussion if any members had feedback they wanted to share. Steven Webber, MB, ChB, At Large member of the Committee and a crossover representative from the Thoracic Organ Transplantation Committee, commented that the document in and of itself 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 that receive ABO-independent heart transplants are comparable to those that 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, and shouldn't be added at the end of the list as a last attempt not to waste organs. The 1:4 isohemagglutinin titer level is another element that was appropriately conservative at the time, but medicine and science has 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, commented that in her opinion it amending a policy is an easier process than completely developing a policy. It is her hope that amending the policy 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.

The Committee liaison concluded this item of discussion reminding the group to submit any other commentary it had, if they had not already done so.

- *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 Committee. UNOS staff organized the conference call in response to the Committees' deliberations at each respective spring meeting regarding a memorandum sent by the Membership and Professional Standards Committee (MPSC). The memorandum asked for clarification on pediatric 1A heart statuses. The call allowed for a preliminary discussion outlining the issues that needed to be address 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 delving 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:

1. 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
2. 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)
3. 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
4. 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

Dr. Campbell then gave the group some history 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 stresses resulting from a patient staying in the

hospital. At that time very few pediatric patients were placed on a ventilator or ECMO. As time has passed, things have changed and the current 1A requirements are resulting in a significant number of patients being listed at that status. This results in allocation driven by waiting time and not urgency, which is something that needs to be corrected but not at the expense of higher mortality. Dr. Campbell indicated he is hopeful that the requested data will provide some insight towards these pursuits.

In addition, 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. He alluded to the Thoracic Committee bilirubin proposal's relatively minor addition discussed earlier as an example of this. 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 UNOS would balk at an allocation system that the 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 have to be set aside to for to improve the system accordingly. In response, Dr. Webber wanted to clarify his comments, and that 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.

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. To this point, Dr. Horslen mentioned a memorandum received from the MPSC to be discussed later in the meeting. It asked for feedback regarding admittance to the ICU as a qualification for liver Status 1A/B in response to its observations of the varying definitions and practices of hospitals across the country.

Pirooz Eghtesady, MD, PhD, Regional 10 representative, added to the conversation his agreement that the current heart allocation system stood to 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 to not waste the scarce resources as they become available.

### ***Status of Liver and Intestine Organ Allocation Policy Review***

- *Split Liver Discussion*

Dr. Horslen began the discussion providing the Committee some background on the development of split liver transplants, the potential to increase the number of split liver transplants in the current allocation of livers, and context for the most recent data requests.

Dr. Cherikh presented the findings from data requests submitted at the Committee's March meeting. [Exhibit A] The data request explored how many livers that were deemed splittable according to those stipulations in policy implemented within UNet<sup>SM</sup> 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) were offered first to pediatric patients. The analyzed data included donors from one year pre- and post- the splittable liver criteria policy implementation.

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.

After the data presentation, 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 affect 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. Dr. Magee 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. Unfortunately, UNet<sup>SM</sup> does not allow for a description of why each agent is being used making the current assessment of eligibility 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? Dr. Cherikh 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 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 made a data request asking how many livers are split that were first offered to an adult potential transplant recipient, whether or not the splittable criteria was 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 splittable 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 this is worth pursuing considering 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 and Intestinal Transplantation Committee. A joint subcommittee comprised of members from both committees will be chaired by Dr. Kim. The following members of the Committee volunteered to work with this joint subcommittee: Tony Savo, MD, At Large member, George Mazariegos, MD, FACS, Region 2 representative, Manuel Rodriguez-Davalos, MD, Region 9 representative Debra Strichartz, RN, BA, CCTC, Region 5 representative and LeeAnna Hungerford, MHA, At Large member.

- *MPSC MEMO- ICU as a Surrogate for Severity of Illness*

Dr. Horslen led the discussion, reviewing the memorandum and explaining 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 or 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 s/he 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 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 and Intestinal Committee meeting that occurred the previous day. There were varying opinions during the discussion of this topic, but ultimately the Liver and Intestinal Committee decided that if your 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 and Intestinal Committee reached this decision so as to avoid altering policy language that has been updated recently. In response to this, a Committee member posed the question how this would affect those patients that are in the ICU and would be listed as Status 1A/B even though their need is not as dire. Committee members clarified that ICU admittance is never the only criterion, that it is only part of the requirement.

In response to some questions asked by a couple of 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 and Intestinal 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 and Intestinal 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, "over simply" stated that ultimately admittance to the ICU is the physicians decision. In that light, he posed the question 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 required ICU admittance 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.”

While reviewing the policy language, Dr. Kim observed the differences between the adult and pediatric hepatic artery thrombosis definitions in policy. After preliminary discussion, Dr. Horslen also pointed out the definition of fulminant hepatic failure is identical for adults and pediatrics which he indicated to be “wrong.” The Committee agreed that these issues should be communicated with the Liver and Intestinal Committee and further discussed with the Joint Subcommittee.

- *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 the data reported. 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 also 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 wanted to introduce 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 and Intestinal 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 less than one, should there be any ABO requirement?

Dr. Cherikh indicated that UNOS Research has produced some descriptive data (due to small numbers in the sample set) for the Liver and Intestinal Committee investigating this issue. This information could be used to begin exploring possible modifications. Upon the end of this discussion, 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.

- *Additional Discussion*

To complete the day's discussion of liver matters, Dr. Kim provided one last update from the Liver Committee meeting that will be addressed further with the Joint Subcommittee. A Liver and Intestinal 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.

### **Status of Kidney Allocation Policy Review**

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 (below) that examined possible modifications to work toward minimizing variation in benefit resulting from Share 35.

## Expected Number of KI Alone Transplants Mean and Standard Deviation of 3 runs

Transplant	Current Rules	1. OMM PRA ≥ 80% pediatric patients over PRA ≥ 80% adults	2. Add Regional sharing for pediatric PRA ≥ 80%	3. Regional sharing for adults PRA ≥ 80%
Total Pediatric KI:	584 (26)	603 (9)	641 (9)	581 (3)
Pediatric PRA ≥ 80%	39 (5)	42 (6)	67 (3)	74 (7)
OMM Pediatric PRA ≥ 80%	4 (2)	6 (3)	6 (2)	4 (1)
Total Adult KI:	7670 (43)	7692 (53)	7625 (34)	6482 (95)
Adult PRA ≥ 80%	988 (8)	1040 (19)	998 (46)	1649 (29)
OMM Adult PRA ≥ 80%	142 (9)	150 (16)	137 (2)	147 (1)
<b>Total KI:</b>	<b>8254(68)</b>	<b>8295(54)</b>	<b>8266(43)</b>	<b>7063(93)</b>

SRTR

Considering the background discussed, the Kidney Working Group determined that KPSAM “Run 2” (add regional sharing for pediatric PRA ≥80%) would not hurt adult patients’ access to transplant but still aide 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. Accordingly, it felt the number of discards would be higher, and therefore the impact resulting from modifying the allocation would be minimal or 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 Committee’s 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. This has to do with the traditional transportation means of livers as compared to kidneys: livers are often flown in private charters, 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, there are not processes in place currently 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. Again, 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.

After further discussion, 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 this 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 on it. 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 needed 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.

- *Additional Discussion: Memo from the Kidney Committee*

A few days prior to the Committee meeting, the Kidney Committee sent a memo to the Pediatric Committee for its review. The memo indicates that the Kidney Committee would like to explore donor profile index (DPI) as a substitute for age of donor in assigning allocation priorities. The Pediatric 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 principle 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.

- *Additional Discussion: Inactive Pediatric Kidney Patients*

Upon a request for any more pediatric kidney items to discuss, Dr. Bartosh brought forward to the Committee her ongoing concerns regarding inactive pediatric patients on the waiting list. In hopes of understanding this phenomenon better, Dr. Bartosh introduced the idea of supplying a more exhaustive list of options in UNet<sup>SM</sup> 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 18<sup>th</sup> birthday, they are being worked up for a living donor, searching for suitable insurance, etc. The number of inactive pediatric kidney patients is initially striking; however, it is his sense based on those he has spoken with that the current system is serving pediatric patients well. How the system is serving the pediatric population is the 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. Therefore, is the Committee interested in exploring the details of these inactive pediatric patients considering a possible inequity that may arise as result from the ability of transplant programs to list pediatric kidney patients at any time? 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 worth the effort or prudent to introduce any "fixes." Considering the Committee's comments and tone, the Chair concluded the discussion of this item with the assessment that there isn't much Committee support in pursuing this further at this time.

## OMB Forms

Dr. Cherikh provided the Committee with an update on the progress of the OMB form modification process. Considering the importance of these forms, and the desire to thoroughly and effectively work and think through the issues, the current forms will be submitted to meet the November 2010 deadline. Efforts to improve the form will continue, and they will be submitted upon completion.

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 are as follows:

DATA ELEMENT	APPLICABLE TO PEDIATRIC PATIENTS
<i>KI TCR/TRR- Diagnosis at listing/transplant</i>	
<ul style="list-style-type: none"> <li>Collect primary cause of ESRD and two other possible causes for ESRD</li> </ul>	Yes
<ul style="list-style-type: none"> <li>Add the following diagnoses from "other, specify" field as new diagnosis codes: Hepatorenal syndrome, lithium toxicity and HIV nephropathy</li> </ul>	Yes
<ul style="list-style-type: none"> <li>Codes should be standardized across kidney, pancreas and kidney-pancreas</li> </ul>	Yes
<i>KI TCR- Drug Treated Systemic Hypertension at Listing</i>	
<ul style="list-style-type: none"> <li>Hypertension question mandatory</li> </ul>	Yes
<ul style="list-style-type: none"> <li>Age of onset</li> </ul>	No
<i>KI TCR- Symptomatic Cerebrovascular Disease at Listing</i>	
<ul style="list-style-type: none"> <li>Change field label to "Diagnosis of CVA or TIA or surgical/percutaneous revascularization for cerebrovascular disease" (yes/no/unk), and make this field mandatory.</li> </ul>	Yes
<i>KI TCR and TRR- Recommended New Cardiovascular Comorbidity Data Collection for Adult Population</i>	
<ul style="list-style-type: none"> <li>Collect actual value and method of Ejection Fraction at Listing (<i>TCR</i>)</li> </ul>	No
<ul style="list-style-type: none"> <li>Sleep Apnea/Treatment at Listing/Transplant (<i>TCR and TRR</i>)</li> </ul>	No
<ul style="list-style-type: none"> <li>History or Current Use of Tobacco at Listing/Transplant (<i>TCR and TRR</i>)</li> </ul>	No
<ul style="list-style-type: none"> <li>Add Cardiac Troponin T at Listing/Transplant (<i>TCR and TRR</i>)</li> </ul>	No
<i>Histocompatibility suggestion: KI TRR- Desensitization Protocol</i>	
<ul style="list-style-type: none"> <li>Add "Was patient on pre-transplant</li> </ul>	Yes

desensitization protocol: Yes/No”	
<ul style="list-style-type: none"> <li>• Is patient part of a pre-transplant desensitization protocol? <ul style="list-style-type: none"> <li>○ Yes, high dose IVIG</li> <li>○ Yes, plasmapheresis (with or without low dose IVIG)</li> <li>○ Yes, other specify</li> <li>○ No</li> </ul> </li> </ul>	Yes

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.

Review and Consideration of Public Comment Proposals Released 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 fear. Accordingly, a Committee member motioned to accept the proposal as written, and the Committee voted unanimously in support. (18 support, 0 oppose, 0 abstention)

**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 abstention)

**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. Lawyers using these guidelines in litigation were one of the concerns expressed. 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 abstention)

#### **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 abstention)

#### **Proposal to Add Language to the OPTN/UNOS 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 statues are 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 abstention)

#### **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 of 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 abstention) 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.

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