

OPTN/UNOS Pediatric Transplantation Committee
Report to the Board of Directors
June 22-23, 2009
Richmond, VA

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)
- The Joint Pediatric-Organ Procurement Organization (OPO) Subcommittee reviewed ongoing efforts to determine if the community might benefit from best practices for donor management. (Item 2a, Page 17)
- The Committee received an update on the discussions addressing multi-system organ failure. (Item 2b, Page 18)
- OMB forms (Item 3, Page 18)
- Member children's center concerns with the Scientific Registry of Transplant Recipients (Item 4, Page 19)
- The Committee considered policy and bylaws proposals distributed for public comment. (Item 5, Page 20)

This page is intentionally left blank.



OPTN/UNOS Pediatric Transplantation Committee
Report to the Board of Directors
June 22-23, 2009
Richmond, VA

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 17, 2008, November 20, 2008, and March 26, 2009 meetings.

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

1a. Kidney Allocation Policy Review

Kidney and Pancreas Working Group Update In July 2008, the Pediatric Transplantation Committee (the Committee) received an update regarding the Kidney and Pancreas Working Group's ongoing efforts to monitor the effects of Share 35 policy on pediatric candidates. Continuing this effort will require working with both the Kidney and Pancreas Transplantation Committees to determine how pediatric kidney and simultaneous kidney-pancreas candidates should be factored into the kidney allocation system (KAS) in development.

During the November 2008 meeting, Sharon M. Bartosh, M.D., Region 7 representative and Kidney and Pancreas Working Group chair, reported on the Kidney and Pancreas Working Groups' efforts analyzing the effect that Share 35 has had on kidney allocation to pediatric patients. There have been very positive effects as a result of Share 35:

- The number of pediatric kidney refusals has declined.
- Transplant rates for children (transplant rate per active patient years on the wait list) has improved for children except for those highly sensitized (PRA \geq 80%).
- Median waiting time for children has decreased for in all age groups.

The Kidney Working Group also reviewed whether or not there has been much utilization of donors above the age of 35 for pediatric patients. This does not appear to be an issue, thus the pediatric patients are receiving young, presumably healthy, deceased kidney donors. Dr. Bartosh reported that there has not been any detriment to graft survival in children post Share 35. In addition, the group has looked at graft survival for recipients of living donor transplants as compared to recipients of deceased donor transplants. Although members have not seen any decrease in graft survival for children, the data does reflect a decrease in the percentage of children who are receiving living donor transplants. The decrease in living donation transplants in children is being seen both in the absolute number and overall percentage, and spans across all age groups (with adolescents being affected the most).

Following Share 35, the data show no increase in the percentage of the highly sensitized children who are getting transplanted. The percentage of children receiving zero antigen

mismatched kidneys went from six percent before Share 35 to three percent following Share 35. The Kidney Working Group is searching for solutions to tweak the system to give highly sensitized pediatrics priority instead of simply debating reinstatement of priorities that had been taken away from pediatrics.

At the March 2009 meeting, an update was provided regarding a joint conference call held with the Living Donor and Kidney Transplantation Committees. This teleconference was organized to further discuss the observed decrease in living kidney donations to pediatric patients following the implementation of Share 35. The following conclusions were reached as a result of the teleconference call:

- Although the decrease in living donation in pediatric recipients post-Share 35 is receiving more and more attention, it is important to remember that Share 35 has benefitted pediatric patients in terms of receiving more transplants from quality deceased donors. This perspective must be kept in mind when discussing the effectiveness of Share 35 in general and this phenomenon in particular.
- Considering multiple conversations on this topic and the lack of clear and evident answers, it is unlikely that the absolute source of the decrease in pediatric kidney patients receiving living donor transplants will be completely sorted out. It is likely a combination of the overall decrease in living donation throughout the country and all the tangible and intangible aspects of Share 35.
- The discussion yielded three possible approaches to handle the decrease in living donation:
 - removal of disincentives for the living donation process (e.g. retaining some pediatric priority if a patient is in need of another transplant after having previously received a living donor kidney as a pediatric patient);
 - addition of incentives for the living donors (e.g. assurance of future, comprehensive, medical insurance); and
 - providing thorough and balanced educational opportunities regarding the value of living donation for all of those in the transplant community.

Evaluation of Policy Modification to Pediatric Priority for Kidneys from Deceased Donors under Age 35 At the July 2008 meeting, Wida S. Cherikh, Ph.D., UNOS Research representative to the Pediatric Transplantation Committee, presented an analysis (Exhibit A) focused on the number of pediatric living donor kidney transplants across regions and the number of inactive pediatric candidates on the waiting list by age group.

Dr. Cherikh noted that the trends of living donor kidney transplants in pediatric recipients seemed to vary by age group and region. In summary, there have not been substantial changes for 0-5 and 6-10 year-old recipients. Adolescents appear to have an increase in deceased donor transplants and a decrease in living donor transplants. These changes are more prominent in certain regions. Alternatively, some regions have maintained a stable number of living donor transplants.

When considering the number and percentage of registrations on the waiting list at the end of each month from January 2005 through May 2008, the data illustrated:

- Although the number of inactive candidates aged 0-5 was less than the number of active candidates in the beginning of the study period, this number started to increase even before Share 35 implementation, and since October 2007, the number of inactive candidates exceeded the number of active candidates. For example, in October 2005, there were 35 (34%) inactive and 69 (66%) active candidates, whereas in May 2008, there were 91 (59%) inactive and 64 (41%) active candidates.
- The number of inactive candidates aged 6-10 also started out less than the number of active candidates and it seemed to increase around Share 35 implementation. The number of inactive candidates exceeded the number of active candidates during June 2007 – September 2007. In the more recent months, however, the number of inactive candidates was slightly less than the number of active candidates. For example, in October 2005, there were 43 (36%) inactive and 77 (64%) active candidates, whereas in May 2008, there were 64 (49%) inactive and 67 (51%) active candidates.
- The number of inactive candidates aged 11-17 was less than the number of active candidates, and this number seemed to increase before Share 35 implementation. The gap between active and inactive candidates has narrowed in the more recent months. For example, in September 2005, there were 159 (27%) inactive and 426 (73%) active candidates, and in May 2008, there were 258 (49%) inactive and 272 (51%) active candidates.

Dr. Cherikh then presented a brief slide set (Exhibit B) of work done by Ruth A. McDonald, M.D., former Pediatric Transplantation Committee Chair, considering whether younger deceased donor kidneys had better graft survival rates than older living donor kidneys. The cohort reviewed was from 1994 through 2005, prior to Share 35 implementation. A multivariate analysis of allograft survival comparing living donor and deceased donor groups to the 18-34 year-old deceased donor group in all recipients indicated that three of the living donor kidneys age groups (18-34, 35-49, 50-54) had a higher graft survival rate than deceased donor kidneys from any age group.

Continuing to discuss Share 35 and the resulting data and trends at the March 2009 meeting, Dr. Cherikh presented data (Exhibit C) from an on-going evaluation of the modification to OPTN/UNOS policy on pediatric priority for kidneys from deceased donors under age 35. The most recent analysis compares the data three years prior to the policy implementation versus the data three years after the policy implementation. To summarize the data presented:

- After Share 35, there has been an increase in absolute numbers of all kidney transplants in children (from 2,349 during 3-yr pre to 2,471 during 3-yr post) as well as an increase in the number of deceased donor transplants for all pediatric age groups (from 1,093 to 1,552).
- Very few children are receiving transplants from donors over the age of 34 since Share 35.
- There has been a decrease in the absolute number of living donor kidney transplants in children of all ages with a decrease of 337 comparing 3-yr prior to

Share 35 to 3-yr post Share 35.

- There has been an increase in the absolute numbers of deceased donor transplants in White, Black and Hispanic patients.
- There is an increase in the number and percentage of children who are receiving more poorly matched deceased donor kidneys.
- Total time on the wait list has gone down considerably and more patients are being transplanted preemptively.
- Transplant rate per 1,000 active pt years has increased for all blood groups and all age groups except for the 6-10 group with AB blood group (Note: very few number of patients (fewer than 20 registrations)).
- Transplant rate per 1,000 active pt years has increased for all PRA categories for all age groups, although the increase is not as pronounced for the highly sensitized adolescents (Note: For this group, transplant rate increased from 123.6 to 134.8).
- Although the number of pediatric registrations has not changed (812 vs. 815), the percent of children listed as inactive has gone from 24% on 1/31/05 to 47% on 1/31/09.
- Across all age groups the two most commonly reported reasons for inactive status were incomplete work up and temporarily too sick.
- Registrations that had been inactive for 181 days or more seemed to be less likely to have a deceased donor transplant.
- Registrations that were never active or active for 180 days or less seemed more likely to be still waiting in inactive status.
- Yearly, the number of living donor transplants done in all pediatric age groups during 1/1/00-11/30/08 continues to decrease.
 - This trend is also observed in adult population.
 - The number and percent of parents donating to their children has gone down from 899 (72%) during 3-yr pre-Share 35 to 623 (68%) during 3-yr post-Share 35.
- Despite more poorly HLA matched transplants after Share 35, pediatric graft and patient survival within 24 months of deceased donor transplants were not significantly different before and after the policy.
- There does not seem to be a significant increase in delayed graft function rates, 6-month or 1-year acute rejection rates, and median serum creatinine at 6-month and 1-year post-transplant for pediatric recipients transplanted after Share 35.

Analysis of Inactive pediatric Kidney Waiting List Registrations At the November 2008 meeting, Dr. Wida Cherikh presented data (Exhibit D) pertaining to the Committee's concerns with the increasing number of inactive pediatric registrations on the waiting list. The data are stratified by age at listing (<1, 1-5, 6-10, 11-17) and included reason for inactivity, length of inactive time and time on the waiting list, and removal status. To summarize the data:

- Of the 1,137 pediatric kidney registrations on the wait list in December 2007, 618 (54%) were inactive as of 12/31/07.
- The percentages of inactive registrations were higher than the active registrations in the 1-5 year (63%) and 11-17 year age groups (54%).
- The most common reasons for inactive status were incomplete work-up (31%) and temporarily too sick (19%).
- Nearly a third of the registrations that were on the kidney wait list for one year or more and were inactive on 12/31/07 had never been active.
- Of the 618 inactive registrations from 12/31/07, as of 10/17/08:
 - 359 (58%) were still waiting in inactive status.
 - 53 (9%) were still waiting in active status.
 - 140 (23%) had received a kidney transplant.
 - 10 (2%) had died.

Committee members opined with varying degrees of concern regarding the potential that patients are being disadvantaged due to prematurely listed inactive patients. The Committee's tone indicated that no patient should be waitlisted until their workup is complete, and that refining waitlist requirements may be beneficial to both pediatric and adult candidates.

Committee members also questioned the accuracy of the reasons given explaining a potential transplant recipient's inactivity. Those filling out the forms may be entering data solely for the sake of completion, as they may not know the complete reason a patient is inactive. The Committee agreed that forms gathering information about inactivity should be altered to include a serial estimate of renal function to determine if patients are actual transplant candidates or listed inappropriately. Ideas were presented that GFR at listing or dialysis dates could be investigated. The Committee also concurred that if the prolonged inactivity of pediatric patients could be better categorized, this would assist in developing beneficial policy changes. Along the lines of further analyzing these inactive patients, a Committee member proposed that the distribution of inactive pediatric patients be examined. In theory, there should be an even distribution across the country, but it would be telling if a significant number of inactive pediatric patients are only at a couple of transplant centers. The Committee hypothesized that some of the inactive patients could be a function of waiting for a living donor. Working up a living donor takes time, and certain situations arise which would extend those time frames. If this is a significant reason for pediatric inactivity, an idea was posed (in the spirit of more helpful data) that there be another category for "Inactive- Waiting for a Living Donor."

The discussion around this topic concluded with notion that the Committee should tread carefully in pursuing this topic. Simon P. Horslen, M.B., Ch.B., Chair of the Pediatric Transplantation Committee and Liver and Intestine Working Group, noted it must be considered that the current system may in fact be serving pediatric patients best. A Committee member cautioned bringing undue attention to the fact that patients who are waitlisted before their 18th birthday receive pediatric priority, regardless of how long they stay on the wait list. This is a great advantage for pediatric patients, but continually spotlighting it may bring questions and criticism that could ultimately disadvantage pediatric patients.

Kidney-Pancreas Simulated Allocation Model (KPSAM) Assessment of Kidney Transplants in Highly Sensitized Patients (PRA \geq 80%) – Consequences of Increased Pediatric Priority

The Committee requested that the Scientific Registry of Transplant Recipients (SRTR) use KPSAM to assess the impact of the following changes to the existing allocation policy on the number of transplants in pediatrics:

- Prioritize highly sensitized pediatric patients (PRA \geq 80%) over highly sensitized adults (PRA \geq 80%) in the kidney allocation algorithm for all deceased kidney donors, regardless of age.
- Regional sharing for highly sensitized pediatric kidney patients (PRA \geq 80%) for all deceased kidney donors, regardless of donor age.

SRTR representatives first reviewed these data at the July 2008 meeting (Exhibit E). The total number of pediatric kidney transplants in the first simulation run was larger in the first allocation change than under the current rules, but could be attributed to random variation. It was noted that the number of sensitized pediatric transplants was similar when comparing the current rules versus this first simulation.

In the second simulation with regional sharing, the increases in pediatric transplant (as compared to the first simulation run) were less explainable by random variation. The increase in priority for sensitized candidates resulted in 18 more transplants to PRA \geq 80% candidates and 17 more transplants to candidates with a PRA $<$ 80. A possible explanation for the additional 17 transplants in the PRA $<$ 80 group was that sensitized non-0MM adults only outrank pediatric candidates if they have more kidney points than the highest pediatric (whether sensitized or not) candidate. With regional sharing of sensitized pediatric candidates, it became harder for non-0MM adults to have more points than any pediatric candidate, and thus they would tend to rank below all pediatric (even non-sensitized) candidates.

The SRTR analyzed these data further and representatives reported on their findings at the November 2008 meeting. (Exhibit F) While discussing these data, a Committee member posed the question whether regional sharing was investigated for pediatric and adult highly sensitized patients, with preference given to highly sensitized pediatrics over highly sensitized adults. The concern is that regional sharing for pediatrics alone will likely be unpalatable within the kidney transplant community as a whole, and that some benefit for adults should be included in any proposal.

SRTR representatives presented the third requested run at the March 2009 meeting (Exhibit G) The third run modified run two to include regional sharing for highly sensitized adults ($PRA \geq 80\%$) by prioritizing highly sensitized local adults and then highly sensitized regional adults ahead of non-sensitized local adults, for non zero antigen mismatch standard criteria donors, and prioritizing local pediatric and regional sensitized pediatric candidates evenly with local adults and regional sensitized adult candidates for non-zero antigen mismatch kidneys from non-expanded criteria donors greater than 35 years of age. Upon reviewing these data, the SRTR representative stated that due to limitations of KPSAM there is reason to believe that the third run overestimates the number of discarded kidneys in this scenario as a result of assumptions built into the model. The SRTR representative contended the data is still showing inefficiency in allocating kidneys in a manner defined by those rules entered for run three. The challenge in this case is working with highly sensitized patients and predicting group behavior of broader sharing. For these highly sensitized patients the chance of a transplant being suitable is lower and this is corrected for in KPSAM; however, UNetSM and KPSAM don't deal with all unacceptable antigens in a way consistent with reality. Furthermore, the introduction of broader sharing of kidneys increases the likelihood of discard. These data highlight the inefficiency of such allocation scenarios possibly resulting in sending a kidney a long distance resulting in a positive cross-match, no other candidates are suitable, and the kidney is ultimately discarded. Whereas this may not happen often in reality, its possibility has been forced into the model. Accordingly, discards likely occur in the model more often than in reality, and the model therefore yields inflated discard numbers. The Chair pointed out that it is difficult to extract broad conclusions from the data with the noted inaccuracies- one cannot judge the magnitude of the effect of the inaccuracies on the data. Dr. Bartosh had emailed a list of thoughts pertaining to the KPSAM analysis as she was not able to participate in the March 2009 meeting. In the interest of time, and since Dr. Bartosh was not present, it was determined that her analysis and other thoughts could be further discussed during a teleconference call with the Kidney Working Group.

Calculated adjusted living donor graft outcomes pre- and post-Share 35 SRTR representatives presented a table of data at the November 2008 Committee meeting that investigated pediatric transplants from living donors before and after Share 35's implementation. (Exhibit H) The data show that while there are small differences, in no case does the difference approach a single standard deviation. Also, none are statistically significant. The Committee agreed that these data were not helpful in deciphering the decrease in living donors, and did not provide insight as to if pediatric decreases in living donors are the same reasons as a decrease in adult living donors.

Committee members hypothesized some explanations to the living donor decrease. One suggestion is that centers are becoming more stringent in who they will accept as a living donor, out of concern for the living donor. Another idea was that transplant centers are not pursuing living donation as much. The discussion of this topic concluded with the intentions of setting up a Joint Pediatric-Kidney-Living Donor Subcommittee to investigate further (as reported on earlier).

1b. Liver and Intestinal Organ Allocation Policy Review

Liver and Intestine Working Group Update In July 2008, Dr. Horslen outlined this group's recent activities as well as its ongoing efforts to work with the Liver and Intestinal Organ Transplantation Committee to consider broader sharing for adolescent donor livers and intestines, allocation based on net benefit, multi-organ transplantation concerns (i.e. liver-

lung, liver-kidney) and advancing the number of split liver transplants. Members were also made aware of a concern that will also be shared informally with the Liver and Intestinal Organ Transplantation Committee. UNOS Regional Administration has been contacted regarding several incidents of adolescent donor livers being offered to candidates less than 5 years-old where a split was agreed upon, but did not occur. The two programs willing to share the liver have run into conflict because the center accepting the original offer has repeatedly refused to travel to the donor hospital to split the liver. This center has requested that the whole liver be sent to its location to be split *ex vivo*. The remaining segment would then be flown to the second accepting center. None of the local centers have been willing to do this due to significant amount of cold ischemia time added with transporting the liver segments. Ultimately, this accepting center is cutting down the graft and discarding the remnants. As the Working Group prepares to continue its efforts to promote and incentivize split liver transplant in conjunction with the Liver and Intestinal Organ Transplantation Committee, members were asked to think about ways to address this and similar concerns.

During the Pediatric Transplantation Committee's November 2008 meeting, the Committee agreed that enough time has elapsed since the implementation of policy that identified livers to be split, and now there should be significant data to analyze. The Committee requested that the splittable liver policy implemented in late 2007 be evaluated with regard to how often both segments were actually transplanted or one segment was discarded when the livers met the splittable criteria. A Committee member suggested an idea that would essentially make splitting mandatory, by increasing the age that pediatrics received preference. For example, all pediatrics would receive priority for a donor aged <18, and 0-11 year old recipients would receive priority for all donors <35, similar to kidney. In this example, the pediatric patients that received priority from donors aged 18-34 would not use the whole liver, and this -in theory- would yield more splits. Committee members expressed concern that the anatomies of some livers render them unable to be split, not all pediatric centers split or are able to split livers, and an overall concern of the adult community's reaction to such an idea. To solve some of those problems, it could be included in policy that this allocation schema would only apply if a split liver transplant is to occur.

At the November 2008 meeting, the Committee also discussed the Liver and Intestine Working Group's teleconference review of the Membership and Professional Standards Committee's (MPSC) proposal to alter the bylaws pertaining to conditional status of living donor liver programs and its effects on pediatric programs. The Working Group supported the proposal, but had a lot of discussion around the set volume thresholds. Due to multiple other committees echoing a similar sentiment, the MPSC is interested in forming a joint subcommittee with multiple parties to address the concerns.

At the March 2009 meeting, the Committee discussed an update pertaining to the Liver/Intestine Working Group's teleconference call addressing cosmetic changes to the current split liver allocation policy language (Policy 3.6 (Allocation of Livers) & Policy 3.6.11 (Allocation of Livers for Segmental Transplantation)). The teleconference concluded with the following recommendations for the liaison to draft new potential language:

- Livers and liver segments from pediatric donors should be offered using the appropriate pediatric liver match run. Livers and liver segments from adult donors should be offered using the adult match run.

- If a liver segment is refused by a potential transplant recipient as a function of it not being a whole liver graft and it is later determined that the liver will not be split and is not suitable for the initial acceptor, then that liver must be re-offered as a whole graft beginning with the first potential transplant recipient that did not receive the whole liver graft offer and declined for the reasons listed above.

Through research and discussion, the Committee agreed that these changes are more than cosmetic but worth the effort to pursue. Committee members opined these policies were developed before MELD/PELD and pediatric preference which would justify its complete review.

Dr. Cherikh presented data the Committee requested at the November 2008 meeting to evaluate how often both segments were transplanted or one segment discarded when the liver met the splittable criteria as outlined in policy and as denoted on liver match runs of qualifying donors. (Exhibit I) The major findings of the study are as follows:

- Although the number of deceased liver donors went down slightly from 6,128 in the pre-policy period to 6,032 in the post-policy period, the number of donors where two liver segments were recovered increased from 66 to 81 during one year after the policy was implemented.
- The number of times both segments were transplanted increased from 55 to 66 during the post-policy period; however, the percent out of the number of times two liver segments were recovered did not increase (83.3% vs. 81.5%).
- Of the livers that met the splittable criteria, 55 (2.4%) resulted in two split liver transplants during the pre-policy period, whereas 66 (2.9%) resulted in split liver transplants during the post-policy period.
- Discard reasons for segments that were not transplanted included anatomical abnormalities, vascular damage, size/recipient too small, "liver split segment 2 not transplantable," organ trauma, and too old on ice.

Upon the conclusion of Dr. Cherikh's presentation the discussion focused on what else can be done to increase the number of livers that are split for transplant. The nature of the current system which prioritizes the sickest patients first may, by default, hinder attempts at increasing split liver transplants. This is because those whom are first offered the organ are not likely to transplant anything but a whole liver. The dilemma faced is that there are many centers and patients that would accept a right lobe if the liver is offered as a right lobe. These same centers and patients are unlikely to split the liver and remove the left lateral segment for a pediatric patient if it is allocated the whole liver. The Committee readdressed the idea discussed at the November 2008 meeting of increasing the age priority of liver allocations to facilitate livers being allocated to recipients who would be apt to receiving a split liver transplant. In theory, this would drive livers into the population that will require splitting, and generate more isolated right lobes for transplant that someone will use. There was consensus at the meeting that it may not be the next person on list, but the right lobe will usually be transplanted. Another similar solution would be to alter allocation so a liver suitable for splitting is offered first to a patient that will just need left

lateral segment. Again, this will allow the right lobe to be allocated and transplanted. Considering those suggestions, a Committee member noted that since the potential transplant recipients that could accept a left lateral segment are probably no older than 11, it would be prudent to include an age limit for that pool of candidates that would receive priority for the whole liver offers. Another Committee member proposed a final consideration under the premise that it is sometimes difficult to allocate the right lobe to a particular patient, and that could be a factor limiting the number of split liver transplants. He suggested for consideration that the right lobe be offered to transplant centers so they may evaluate the right lobe and then determine which candidate would be the most suitable and appropriate.

The Committee's split liver discussion at the March 2009 meeting then shifted to preparing for the broader politics that would result in submitting such a proposal. The Committee agreed that uncovering and understanding the potential that is currently unattained in the existing pool of pediatric livers that are available to be split is valuable data. If this potential is significant, as the Committee surmised, then it would be reasonable to focus initial policy changes on it. An underlying sentiment throughout this part of the discussion was the lack of data detailing split liver transplants and the need for it to proceed with informed analysis, discussion, and policy development.

A final consideration made regarding split liver allocation policy introduced the possibility that the center controlling the vessels may affect the number of livers being split. A Committee member commented that any policy considerations should make sure that left lateral segment recipients do not take more vasculature than necessary. The Chair then concluded the split liver discussion at the March 2009 meeting with the notion that the Pediatric Committee will continue to work on this effort and will appeal to the Liver Committee for it to convene a split liver subcommittee comprised of Pediatric and Liver/Intestinal Committee members. The Committee unanimously supported this direction.

Evaluation of Liver Allocation Policies (MELD/PELD Share 15 Policy; Refinement of Status 1 into 1A and 1B, and Regional Sharing of Pediatric Donors; and New Liver-Intestine Allocation for Donors Aged 0-10): Waiting List Death Rates and Number of Transplants Liver and intestinal organ allocation policy review continued at the March 2009 meeting with Dr. Cherikh's presentation of data pertaining to the on-going evaluation and analysis of recent modifications that affect the allocation of pediatric donor livers. (Exhibit J) Dr. Cherikh first reviewed analysis of Waiting List data. Careful analysis of the data yielded the following findings:

- No increased risk of death in any status or PELD categories for the 0-11 age group in most recent period.
- No increase in overall risk of death in the 0-11 age group in the most recent period.
- No increased risk of death in any status or MELD categories for the 12-17 age group.
- No increase in overall risk of death in the 12-17 age group in most recent period.

- Multiple organ system failure was most common cause of death for those without exception.

Dr. Cherikh proceeded to review findings from her analysis of transplant data from the same cohorts. Dr. Cherikh tabulated the deceased donor liver transplants performed in each of the transplant cohorts by age group, and calculated the number and percent of split liver transplants (defining a split transplant as one when there are two recipients of the same donor liver). The following summarizes the highlights of the data presented:

- Percent of transplants done in Status 1B for 0-11 recipients seemed to increase, while percent of transplants done in PELD <15 seemed to decrease in the most recent period.
- Percent of transplants in Status 1A or 1B seemed to increase slightly in 12-17 recipients, and percent of transplants in MELD 15+ seemed to decrease slightly in most recent period.
- There does not seem to be much change in split liver transplants.
- Approximately 80% of adolescent livers are being transplanted into adults and presumably are not being split.

Programming Update- Pediatric LI/IN Broader Sharing At the Committee's March 2009 meeting, UNOS staff provided a status update of the pediatric donor liver/intestine broader sharing proposal that the Board of Directors approved at its June 2008 meeting. The programming effort is currently in redesign. During a review following the development phase of the project, UNOS staff revisited the original project assumption that one single national allocation algorithm for pediatric liver donors would be created, and that the new allocation would replace (rather than be integrated with) existing approved alternate liver allocation agreements. As this was not made clear during the public comment process, UNOS leadership ultimately decided that the pediatric liver allocation changes and the pediatric liver-intestine allocation changes should be integrated with each of the existing approved liver alternate allocation systems. As a result, an additional 10 new allocation systems will have to be developed and tested. Production will resume for a tentatively scheduled release at the beginning of the third quarter 2009.

1c. Thoracic Organ Allocation Policy Review

Heart-Lung Working Group Update At the July 2008 meeting the Chair of the Heart and Lung Working Group outlined this group's recent activities and ongoing efforts. This group will continue to focus on doing more with available donors and increasing access to transplant. The reporting of pediatric donor outcomes is also being considered in light of the Collaborative, and the Committee hopes to see OPOs being held accountable for pediatric metrics for conversion rates. Pediatric rates were higher than that for adults prior to the Collaborative, but did not enjoy the same increase that was seen in the adult donor population as a result of the Collaborative's efforts. The Working Group will also explore opportunities for facilitating organ procurement and recovery. It may be unnecessary for the transplant surgeon to go out to procure organs. The Chair of the Heart and Lung Working Group suggested the possibility of a regional pilot program to see if this might be a practical and acceptable change in practice. It was also noted that this group will need to

be involved in the Thoracic Committee's upcoming project to consider net benefit for heart allocation, and its effects on the pediatric population

The Heart and Lung Working Group met with the MPSC's Data Subcommittee regarding post-transplant outcomes for lung recipients aged 12-17 years. The Lung Allocation Score (LAS) System created an artificial divide in the pediatric population in the outcomes assessment process used by the MPSC. After a review of data requested to determine the impact of changing the age cutoff for pediatric programs (Exhibit K), the Joint Subcommittee determined that when the adult cutoff was changed to 18 years of age, adult programs that transplanted adolescents were being flagged for poor outcomes. A review of a larger cohort group indicated that there was significantly increased hazard ratio (2.2 with a significant p value) for adolescents transplanted in adult transplant programs. For the first time, there is data to indicate that transplanting children in adult programs may not warrant as successful an outcome as transplant at a pediatric program.

The Joint Subcommittee agreed that the MPSC should consider how it looks at lung programs for outcomes review. The Joint Subcommittee suggested that pediatrics be considered from birth up to 18 years of age and adults are considered as 18 years and older. The Joint Subcommittee was disbanded, but the MPSC will contact the Committee should it need any suggestions or guidelines for a new review process.

At the Committee's November 2008 meeting, the Vice Chair of the Committee provided an update of the group's September conference call that addressed the implementation of the broader sharing of heart and lungs, and the status changes that are coming for <12 year old heart-lung and lung candidates. Much of the conversation dealt with housekeeping issues and addressing questions from UNOS IT. At the full Committee meeting, UNOS staff explained difficulties that had been recently uncovered with the Board of Directors approved broader sharing of pediatric lungs policy. UNOS IT staff indicated the policy as written is relatively prescriptive as to how the design of the system should work. Accordingly, if programming were to proceed it would be extremely resource intensive, not efficient, and introduce future risk into the system. Fortunately, it is believed that changes that need to be made will be relatively minor from a policy perspective, and should be able to go through the Executive Committee for approval. The Heart-Lung Working Group and UNOS staff participated in a conference call on December 4, 2008 to address the necessary questions. At the March 2009 meeting, the Committee discussed the minutes and decisions of December 4th conference call. The two major decisions reached are:

- Eliminate tracking the total time spent at a particular status as a tie breaker and replace it with the most recent amount of time spent at the candidate's current status.
- Distinguish candidate lung priority from organ status for the purposes of programming and user clarity.

The ongoing goal will be to bring the updated, detailed policy language change to the working group, then to the Committee as a whole, and finally to the Executive Committee for their review. There is a desire to only go through this process once; therefore the policy language will be edited after there is a complete understanding of the necessary programming and other work involved.

Programming updates - Pediatric Committee Thoracic Proposals Approved in June 2008

At the March 2009 meeting, the Committee liaison gave an update on the programming status of the broader sharing of pediatric hearts and pediatric lungs proposals approved at the June 2008 Board of Directors meeting. The liaison reported that the broader sharing of pediatric hearts project is currently in testing and scheduled for release during 2nd quarter 2009. Alluding to the previous update on the broader sharing of pediatric lungs, the liaison communicated that the policy is currently in planning and is scheduled to be completed in the first quarter of 2010.

Memo: Pediatric 1A Downgrades to 1B Upon Discharge, from the Membership and Professional Standards Committee The Pediatric Committee addressed the pediatric status 1A heart listing practices memo it received from the MPSC (Exhibit L) at its March 2009 meeting. After comprehensive discussion, the Committee's consensus is that it is of the utmost importance that centers give their patients every opportunity to be transplanted; however, this should not be achieved by mandating certain listing priorities. Further, educating the transplant community on OPTN Policy 3.7.4 (Pediatric Candidate Status) would be a worthy effort.

The consensus of the Committee was that members should be allowed discretion in listing/upgrading/downgrading their patients. The Committee concurred it would not be appropriate to mandate certain listings based on definitions. These requirements would effectively ignore transplant physicians' expertise and eliminate a center's latitude that results from its working knowledge of the patient. Rather, the Committee agreed that it is better to analyze outcomes retrospectively through the MPSC's waiting list and post-transplant outcome review process that holds programs accountable to established outcome standards. If any programs' "discretion" yields poor results, these programs will be highlighted by the MPSC's outcome reviews and can be addressed individually as necessary. Regarding the current policy's appropriateness and whether it needs to be modified, multiple Committee members indicated that they were content with the policy as it is written. Concerning the Status 1B justification form, the Committee agreed that relying on the narrative entered in the "other" option is not ideal for querying and analyzing data; however, it did not think it is necessary or prudent to modify the form. It reached this conclusion considering the possibility that incorporating these scenarios on the form would yield the perception of legitimizing this listing behavior. Further, the Committee felt the likelihood of similar downgrades is small in number. Modifying the Status 1B justification form would not be the best use of resources, especially considering the current list of projects awaiting programming.

Multiple times throughout the discussion Committee members suggested developing educational opportunities for transplant programs and professionals. Some members of the Committee were incredulous that a program would not list a patient at the highest status that they qualified by policy. Accordingly, these members hypothesized that some, if not the majority, of these listings/downgrades/upgrades are a function of an incorrect or incomplete understanding of Policy 3.7.4 (Pediatric Candidate Status). The educational efforts could also make centers aware that if they are not taking advantage of the priorities provided in policy, the center may be looked at negatively – by the MPSC or the public – if their patients are not being transplanted and/or having poor outcomes.

Data update on Waiting List Outcomes for Adolescent Cystic Fibrosis Patients after Implementation of Lung Allocation Score Dr. Cherikh presented data on the evaluation of waiting list outcomes for adolescent cystic fibrosis (CF) patients after implementation of

the LAS System, stratified by age (<12 versus 12-17 years of age). (Exhibit M) This data request was initiated after reviewing public comment feedback from the Committee's proposal for broader sharing of lungs. A commenter raised concerns that adolescent CF candidates may be disadvantaged by the broader sharing of 0-10 year old donor lungs to candidates aged 11 and under. The cumulative probabilities for transplant and death for patients with a primary diagnosis of CF at 3, 6, and 12 months after listing, stratified by listing period (pre- and post-LAS) and age group (<12, 12-17, and 18+ years of age) are:

- The cumulative probability of receiving a transplant at 12 months increased in the <12 candidates from 27.8% to 31.8% after the LAS system, while the probability of death on the waiting list increased from 11.1% to 27.3%.
- The cumulative probability of receiving a transplant at 12 months increased in the 12-17 candidates from 28.9% to 52.2% after the LAS system, whereas the probability of death on the waiting list increased from 10.3% to 13.9%.
- The cumulative probability of receiving a transplant at 12 months increased in the 18+ candidates from 31.9% to 61.9% after the LAS system, while the probability of death on the waiting list decreased from 14.7% to 9.4%.

Data update on the Lung Allocation Score System for Thoracic Committee & Data Update on the Heart Allocation System for Adolescent Donors for Thoracic Committee-At the March 2009 meeting, Dr. Cherikh summarized data to be presented at the Thoracic Organ Transplant Committee meeting that would be relevant to the Pediatric Transplantation Committee. There were two summaries, the first with data focusing on the LAS system and the second focusing on the heart allocation system for adolescent donors. To summarize the lung allocation data:

- Waiting List data
 - Since the implementation of LAS there has been a major decline in the total number of waitlist candidates
 - The number of active candidates 12+ years has remained relatively stable since January 2006 (~1000-1100)
 - The distribution of LAS at listing has shifted towards higher scores every year since implementation
 - Overall waiting list mortality has declined since LAS was implemented
- Transplant data
 - The percentage of lungs transplanted has increased from pre- to post-LAS
 - There was a huge increase in the number of transplants from pre-LAS to post-LAS but since then has remained relatively stable.
 - There has been a substantial shift in the distribution of diagnosis from pre-LAS (>50% group A) to post-LAS (>50% group D).
 - Post-transplant survival is comparable pre- and post-LAS, overall and by diagnosis grouping.

To summarize the heart allocation data

- There are no major changes in the waiting list with regard to:
 - Total number of candidates
 - Total number of active candidates
 - Distribution of status
 - Distribution of age group
 - Distribution of region
 - Center volume
- Waiting list mortality in Status 1A and Status 1B appears to have decreased
- The number of transplants has remained essentially flat over the past three years
- The distribution of status at transplant has changed: Status 1A- increase, Status 2- decrease
- There is no significant change in post-transplant survival within one year.

1d. Pancreas Allocation Policy Review

At the July 2008 meeting, the Committee received a brief update on the modeling that was requested during a joint subcommittee call to consider how both pediatric and combined kidney-pancreas allocation should be handled in the new kidney allocation system. The Committee also received a brief overview of the Pancreas Committee's survey results. The Committee was interested in learning more about barriers to pancreas placement- specifically how OPOs determine whether to offer a combined SPK or allocate the pancreas and/or kidneys separately. This was an informational item for committee members. Some later revisions had been made to the data (Exhibit N) and notice of this was given at the November 2008 meeting.

2. Joint Pediatric-Organ Procurement Organization (OPO) Subcommittee Update

2a. Donor Management Guidelines

At its July 2008 meeting, the Pediatric Transplantation Committee briefly reviewed the ongoing efforts to determine if the community might benefit from best practices for donor management (as related to concerns relayed to the committee regarding thoracic organ quality being damaged due to pre-recovery drugs administered to prepare the intestine for recovery) for the benefit of new members. A Joint Pediatric-OPO Subcommittee met in January 2008 to discuss this issue. The OPO Committee discussed this matter during its June 26, 2008 meeting; however, a report was not available on the outcome of this discussion at the time of this committee's meeting. At the November 2008 meeting, the Committee discussed the response received from the OPO Committee. The OPO Committee reported that it does not feel best practices guidelines for conflict resolutions in the OR are necessary. The Committee's discussion highlighted that the few instances that have come up seem to be individual and isolated- not a common issue that can be legislated. The Committee's OPO representatives indicated that it is every OPO's goal to recover and transplant as many organs as possible; to do something counterproductive just doesn't make sense. Furthermore, the issue at hand could be a result of coordinator inexperience. The Committee concluded this conversation by ultimately deciding to wait and see if similar situations occur before it pursues the matter further.

2b. Multi-System Organ Failure

At the July 2008 meeting the Committee received an update on the discussions addressing multi-organ transplant issues. The Committee was informed that the OPO Committee is currently addressing these concerns, and this Committee will receive feedback on this process. At the November 2008 meeting, the Committee discussed a memo from the OPO Committee which asked:

- Are there specific criteria that you would like to propose to classify organs as failed?
- Is there a specific definition of organ failure from the perspective of pediatric practitioners?

A Committee member suggested that good definitions can be found in text books and that attempting to recreate those definitions is unnecessary, and will not ultimately help to achieve the OPO Committee's objectives. Furthermore, multiple Committee members indicated that each scenario is different, therefore rendering it difficult to form an absolute and useful definition of specific organ failure. The Committee concluded the discussion of this item without a formal response to the questions posed for consideration. The Committee sent a memo to the OPO Committee in response indicating that if the OPO Committee would like to provide a representative to explain its goals what type of feedback it seeks, then the Pediatric Committee will conduct additional discussion to provide further feedback.

3. OMB Forms

Near the conclusion of the November 2008 meeting, Dr. Cherikh presented a slide set that introduced the timeline for the upcoming review of OMB forms that are set to expire in November 2009. The Chair indicated that since the forms were categorized recently to include pediatric fields, unless there are glaring omissions (possibly guided by intuition) then changes would probably be minimal. Discussion continued that there isn't a great deal to be gained by reviewing all the forms that were recently implemented. It was thought to be more prudent to wait for a year to eighteen months of data to be compiled and then analyzed for questions and issues that UNOS Research and/or the UNOS Help Desk have encountered. The Committee concluded the conversation agreeing to participate in conference calls to discuss this matter further and provide any of the current forms' glaring omissions.

Conference calls were conducted and Dr. Cherikh had a list of questions at the March 2009 meeting that required the Committee's attention, including clarification of suggestions made by the Committee's organ specific work groups and feedback from the Committee pertaining to changes suggested by the organ specific committees. The first issue that needed addressing pertained to the "renal dysfunction?" question that is currently on the thoracic 1-5 years follow up form. Currently, if the renal dysfunction question is answered in the affirmative, then three other questions are posed which would all be answered with yes, no, or unknown: serum creatinine > 2.5 mg/dl, chronic dialysis, renal transplant since thoracic transplant. The thoracic working group of the Committee had decided to pose these as four independent questions. A subcommittee of the Thoracic Committee suggested deleting the renal dysfunction question due to confusion that results from a lack of clarity and varying definitions of renal dysfunction. Another recommendation was made to collect

an actual serum creatinine value in hopes of collecting more valuable data and make the follow-up forms more consistent. The Committee unanimously voiced their support for these recommendations and there were no comments of apprehension.

The next item for discussion pertained to questions on the adult and pediatric TCR and TRR forms that inquired about previous cardiac or lung surgery (depending on the transplant received) other than previous transplant. The Thoracic Organ Transplantation Committee suggested striking “other than previous transplant” from this data collection question. Committee members responded it didn’t matter, and was worthwhile if it is the desired path of the Thoracic Organ Transplantation Committee and would yield more consistent data.

Another item that required attention pertained to differing opinions by members of the pediatric thoracic working group about collecting pan-resistant bacteria lung infection information. Currently this is a yes/no question. One Committee member recommended deleting this question as it is not helpful without more details. Another Committee member countered with the suggestion of providing a list of organisms to select to completely answer the question, and provide more details. When asked for the Committee’s feedback, the Chair pointed out two problems with keeping the question and collecting the name of organism: who will be collecting the information and where are they getting it from? Can it be assured that this information will be entered accurately all the time? Further, the names of the organisms are constantly changing. Committee members agreed with this sentiment and that this data would be collected unreliably. Accordingly, the Committee agreed to delete the pan resistant bacteria question.

More edits needed discussion; however, the allotted time for the meeting had essentially been exhausted. The Chair, the Committee liaison, and Dr. Cherikh decided to address the remaining questions via email with the Committee, and if need be, a conference call.

4. Member Children’s Center SRTR Concerns

Days prior to the November 2008 meeting, the Committee received a letter from an OPTN member children’s hospital bringing its attention to a recent interaction with SRTR. The letter stated that pediatric centers were expected to pay for sample risk adjustment data; however, adult programs could receive these reports free of charge. The Chair suggested that the letter be given to the Committee’s SRTR representatives to review, investigate, and provide a response. The Committee’s SRTR representatives provided an update at the March 2009 meeting regarding the response given. Directors from the SRTR responded in writing (Exhibit O) to the original letter explaining the concerns as a misunderstanding. Further, the SRTR representative stated he personally spoke with the author of the original letter. The response letter explained the spreadsheets posted on its website are intended for sample usage and do not contain any actual data for any center. The SRTR does provide pre-populated versions of these spreadsheets only after a program has made the request and payment has been received. The SRTR works equally with pediatric and adult centers to fulfill these requests. The SRTR representative went on to say that during the next data release the SRTR has decided to provide every center with its downloadable data sets. This will allow each center to compute its own center specific reports with all cutting and pasting already complete.

5. Review of Policies and Bylaws Issued for Public Comment

5a. Proposals Issued on June 30, 2008 The Committee reviewed the five proposals out for public comment, and provided the following feedback during its July 2008 meeting:

- i. *Proposal to add the factor “change in bilirubin” to the lung allocation score (LAS). Policy affected: 3.7.6.1 (Candidates Age 12 and Older) (Thoracic Organ Transplantation Committee)*

Discussion yielded the suggestion that retrospective bilirubin values should also be considered to ensure that a candidate is receiving the appropriate benefit. Members agreed that a candidate’s historical bilirubin values should be entered at listing if this candidate has met this criterion before presenting to the transplant center. A member also questioned whether this change would benefit candidates with intrinsic but not life threatening liver disease who may need a lung. The Thoracic Committee did not specifically consider this, but the Committee thought that monitoring may be required- especially in cases of candidates listed for combined liver-lung transplant. Concern was noted because there is a small but possibly significant portion of the population with unconjugated hyperbilirubin due to either low grade or drug-induced hemolysis or Gilbert’s syndrome that would also benefit, perhaps unfairly, with this new factor in place. The Committee voted in favor of this proposal with the suggestions that (1) retrospective bilirubin values be included to ensure that all candidates with a significant increase are receiving the appropriate benefit; and (2) the Thoracic Committee consider the exclusion of candidates with intrinsic liver disease or modifications to the scoring system for candidates with this added diagnosis to avoid unfairly advantaging these candidates with a high LAS score based on bilirubin. (Committee vote: 16 in favor, 0 opposed, 1 abstention)

- ii. *Proposal to verify that foreign agencies importing organs to the United States, or receiving organs exported from the United States, are legitimate and test organs for transplant safety. Policy affected: 6.4.2 (Developmental Protocols in Organ Exchange) and 6.4.3 (Ad Hoc Organ Exchange) (Ad Hoc International Relations Committee)*

Upon review, members voiced concerns that the verification of these foreign organizations would be essentially left to the importing OPO. Members were concerned that OPO personnel would have no way of knowing whether the exporting OPO’s accreditation process would be equivalent to the expectations for American quality criteria for organ procurement. Members were not aware of any documentation that requires foreign governments to approve their specific organ procurement systems in the same manner as OPOs in the United States are held responsible. A member questioned whether existing import/export relationships (i.e. Canada) would be in compliance with the proposed language, or whether such current relationships could be potentially damaged- potentially affecting organ offers on both sides of the border. A member questioned whether such changes may create pressure on OPOs to import organs from greater distances in order to find foreign programs that were able to meet specific criteria. The Committee voted to support this proposal, suggesting that transparency in the process of accreditation for foreign organ procurement agencies should be considered if available. If such transparency exists, then this information could be evaluated to determine whether an exporting OPO is a legitimate and safe alternative organ source. Members agreed that this proposal should be amended to include specific language to address this suggestion. (Committee vote: 17 in favor, 0 opposed, 1 abstention)

- iii. *Proposal to improve the safety of living donors by restricting the acceptance and transplant of living donor organs to OPTN member institutions. Policy affected: Add Policy 3.3.7 (Center Acceptance of Organs from Living Donors) (Living Donor Committee)*

Committee members noted that the 22 recoveries completed at non-OPTN/UNOS member centers did not involve any stand-alone pediatric center transplants. Recognizing that it is possible that a living donor may benefit most from access to a specific hospital and acknowledging that this may become a larger issue when kidney paired donation is utilized more aggressively on a national level, the Committee supported this proposal with the suggestion that the procuring hospital should be expected to assist the transplant center in ensuring that adequate follow-up for the living donor is maintained. Members believe that until living donor follow-up is a requirement for the procuring center, this must be considered a shared responsibility. (Committee vote: 16 in favor, 0 opposed, 1 abstention)

- iv. *Proposal to modify the bylaws pertaining to conditional approval status for liver transplant programs that perform living donor transplants. Bylaw affected: Attachment I, Appendix B, Section D, (4) Liver Transplant Programs that Perform Living Donor Liver Transplants of the Bylaws (Membership and Professional Standards Committee)*

Upon review, the Committee was concerned that the number of required procedures is somewhat arbitrary, as there is no specific data to support it. Members noted that pediatric programs will be affected and that cutting down the number of living donor programs will make it harder for candidates to have access to technical variants. The Committee requested data on the number of pediatric centers that are currently performing living donor transplants but will not be able to meet the criteria (as evidenced by those who have requested conditional approval but are now withdrawing their applications). A member questioned whether the MPSC might entertain changes to its requirements based on the number of left lateral segment versus right lobe procedures completed by a center. Members agreed that relatively arbitrary standards may impair the pediatric community from offering living related donor transplant, a key component to both managing candidates and the waiting list. The Committee agreed to request the desired data from the MPSC for review by the Liver Working Group. A conference call will be held to review this data and determine whether pediatric programs with existing living donor programs will be negatively impacted and whether a compromise can be sought that will not impact living donor or living donor recipient safety. The Committee voted unanimously to authorize the Liver Working Group to submit a public comment response on its behalf before the September 24 deadline. (Committee vote: 16 in favor, 0 opposed, 0 abstentions)

- v. *Proposal to change the Bylaws to better define functional inactivity, voluntary inactive membership transplant program status, relinquishment of designated transplant program status, and termination of designated transplant program status. Bylaw affected: Appendix B, Section II, C of the Bylaws (Membership and Professional Standards Committee)*

After discussion, a member questioned whether small programs with a surgeon on vacation requiring temporary inactivation should even be transplant programs. Members felt strongly that small programs that could be in this situation must be very clear with candidates at the time of listing regarding coverage plans and the option of multiple listing to avoid inactivation on the wait list due to provider who is unavailable for up to 14 days. Equally, members agreed that there must be protection for candidates hospitalized in a

center that is inactivated. What should be done with a Status 1 candidate when a program must inactivate suddenly (i.e. the surgeon dies, etc.) and arrangements cannot be made for transfer, as noted in Appendix B, Section II, C, 3b (6) and (7)? A suggestion was made to revise the policy language to include initiate transfer to reflect that a program may be working in good faith to accomplish the transfer, but still be unsuccessful in its efforts due to patient volume or other issues. It was acknowledged that a candidate's lack of insurance, for example, may make transfer difficult if not impossible in some instances. After discussion, the Committee supported the proposal in principle, including notification of all transplant candidates and recipients of temporary and/or permanent inactivation as well as good faith efforts to these patients in reasonable time and according to medical status. The Committee requested that the MPSC consider modifications to the proposed bylaw language to ensure that expectations regarding the transfer of candidates can be met. (Committee vote: 16 in favor, 0 opposed, 0 abstentions)

5b. Proposals Issued on October 10, 2008 The Committee reviewed the four proposals out for public comment, and provided the following feedback during its November 2008 meeting:

- i. *Proposal to allow candidates who need a pancreas for technical reasons as part of a multiple organ transplant to be listed on the pancreas waiting list – Policies Affected: Policy 3.2.7 (Pancreas Waiting List Criteria) and Policy 3.2.9 (Combined Kidney-Pancreas Waiting List Criteria) (Pancreas Transplantation Committee)*

The Committee's discussion of this proposal focused on follow up and forms that would need to be completed for the recipients of a pancreas for technical reasons. The Committee had concerns that the proposal does not fully address how graft outcomes are to be followed after classifying these patients as pancreas transplant recipients. The expectation as the proposal currently stands is that these forms will likely be completed as "lost to follow up." A Committee member proposed that upon a pancreas being denoted as transplanted for technical reasons, that the requirement for follow-up forms for that pancreas is eliminated. In response, a SRTR representative indicated that one would want to be able to capture the pancreatic graft loss. Conversation focused on when to indicate the pancreas is lost, and the Committee elicited that it would be best for a pancreas transplanted for technical reasons to be considered lost at the time of the transplant. In terms of multi-visceral transplants, discussion indicated that it is likely necessary to include the classifications: transplanted for technical reasons-function not required and transplanted for technical reasons- function required. The Committee approved a motion to support the proposal as written, but suggests when it is time to make changes to the follow-up forms that revisions are made to minimize the impact on transplant centers that are taking the pancreas solely for technical reasons. The revision of the forms should also include questions which will give some meaningful data as current forms do not provide any questions that can be answered for a pancreas used for technical reasons. (Committee Vote: 14 in favor, 0 opposed, 0 abstentions)

- ii. *Proposal to clarify islet allocation protocol – Policy Affected: Policy 3.8.1.6 (Islet Allocation Protocol) (Pancreas Transplantation Committee)*

The Committee briefly reviewed this policy proposal and agreed that although this is an interesting topic for discussion, it has no pediatric relevance. Accordingly, there was no further discussion and no vote.

- iii. *Proposal to increase the safety of allocations to candidates who do not appear on the match run – Policies Affected: Policy 3.1 (Definitions), Policy 3.2.4 (Match System Access), and Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates) (Membership and Professional Standards Committee)*

The Committee discussed this policy proposal, and conversation focused on the multi-organ implications of this proposal. The Committee had concern that this policy will add a layer of complexity to an already complex process, likely yielding inefficiencies in the system. It is felt that a bigger, all inclusive perspective is necessary to analyze multi-organ transplant listings and matching from top to bottom. Rather than put band aids on the system to make it more complex, the Committee suggested that UNOS should look at multi-organ transplants and redesign the system to solve these problems more clearly. The Committee voted to support the proposal, making note that it believes a complete analysis and redesign of multi-organ listing, matching, and allocation needs to be approached. (Committee Vote: 14 in favor, 0 opposed, 0 abstentions)

- iv. *Proposal to clarify, reorganize and update OPO policies to align with current practices – Policy Affected: Policy 2.0 (Minimum Procurement Standards for an Organ Procurement Organization) (Organ Procurement Organization Committee)*

The Committee briefly reviewed the proposal. There were no comments or vote as the Committee did not feel this was necessarily a pediatric issue.

5c. Proposals Issued on February 6, 2009 The Committee reviewed the eight proposals out for public comment, and provided the following feedback during its March 2009 meeting:

- i. *Proposed listing requirements for simultaneous liver-kidney transplant candidates – Policies Affected: Policy 3.5.10 (Simultaneous Liver-Kidney Transplantation) (Kidney Transplantation Committee and the Liver and Intestinal Organ Transplantation Committee)*

The Committee's initial discussion of this proposal indicated support, and those regional representatives whose meetings had already been conducted (1, 2, 6, 10) echoed this sentiment. An at large member of the Committee expressed concern that this proposal would disadvantage pediatric isolated kidney patients. The concern being that liver-kidney patients come before all isolated kidney pediatric patients for donors under the age of 35. She continued that in her area they are seeing a lot of repeat pediatric liver transplants that include a kidney transplant the second time. The Committee Chair responded that he felt this is the exact reason that this proposal is being submitted; to tighten protocol and provide some regulation for placing patients on the waitlist for a simultaneous liver and kidney transplant. Another Committee member commented that if the data later shows this proposal does disadvantage isolated kidney pediatric patients, a possible solution would be to prioritize these disadvantaged patients above the simultaneous liver-kidney transplant candidates in terms of kidney allocation. The at large member raised a second question whether any consideration was given to repeat liver transplants that need a simultaneous kidney. The Chair indicated this had not been exhaustively reviewed as re-transplant rates have remained relatively static; however, he added that repeat transplants are a concern and important to monitor. In particular, what percentage of livers re-transplants are simultaneous liver-kidney transplants compared to primary liver transplants. Another Committee member alluded to the second part of the proposal, the "safety net" for those that did not receive a kidney transplant initially but are still in need. He introduced into

discussion if this bulky addition was necessary with respect to an expected behavioral change as a result of this policy. For numerous reasons, multiple Committee members commented they felt the “safety net” was necessary.
(Committee Vote: 15 in favor, 0 opposed, 0 abstentions)

- ii. *Proposal to create regional distribution of livers for Status 1 liver candidates – Policy Affected: Policy 3.6 (Allocation of Livers) (Liver and Intestinal Organ Transplantation Committee)*

The Chair introduced and briefly reviewed the proposal. Regional representatives of the Committee initiated discussion, some with strong support and others with multiple concerns. The concerns being that the change would likely lead to regional patients being transplanted at the expense of local patients’ mortality, and this proposal would allow more aggressive centers to accept more livers thereby decreasing access for patients at other centers within the region. Committee members addressed the concern with aggressive centers indicating that in theory this would result in some livers being transplanted that otherwise would be discarded. Therefore, under these assumptions, the total number of livers in the organ pool would increase, mitigating the presented risk. Further, the Committee’s region 9 representative (which already participates in a sharing arrangement similar to what is being proposed), stated these same concerns were present when region 9 initiated these discussions; however, in reality, region 9 has not seen these concerns come to fruition. (Committee Vote: 14 in favor, 1 opposed, 0 abstentions)

- iii. *Proposal to create regional distribution of livers for MELD/PELD candidates (Policy affected 3.6 - Allocation of Livers)(Liver and Intestinal Organ Transplantation Committee)*

The Chair introduced and reviewed the proposal, and then reported the strong opposition expressed at the region 6 meeting. In particular, the large geographic distribution of region 6 would make this proposal a logistical and financial burden for the OPOs. The tone of the Committee’s discussion echoed these concerns, highlighting the minimal decrease in waitlist mortality at a high financial cost for OPO’s. After brief discussion of this proposal, the Chair questioned if Committee members had identified any specific pediatric issues with the proposal. The Committee did not provide any feedback to this question; due in part to the OPTN Board of Directors recently passing a proposal to regionally share livers from pediatric donors aged 0-11. Accordingly, the Committee had no further discussion on this proposal and no vote.

- iv. *Proposal to standardize MELD/PELD exception criteria and scores (Policy affected: 3.6.4.5 - Liver Candidates with Exceptional Cases) (Liver and Intestinal Organ Transplantation Committee)*

The Committee reviewed each diagnosis individually and discussed those likely to affect pediatric patients. The resulting discussion and votes transpired as follows:

- Cholangiocarcinoma- Not applicable to pediatrics.
- Cystic Fibrosis - The Committee reviewed the details and accepted the proposal as written. (Committee Vote: 15 in favor, 0 opposed, 0 abstentions)

- Familial Amyloid Polyneuropathy – Not applicable to pediatrics.
 - Hepatopulmonary Syndrome – Occasionally pediatrics are diagnosed with hepatopulmonary syndrome. Although the criteria for the automatic exception are high for pediatric patients, a transplant center may still submit an application for exception (as is the case currently) if their patient’s do not qualify for the automatic exception and their MELD/PELD score does not accurately reflect that patient’s condition and need. (Committee Vote: 15 in favor, 0 opposed, 0 abstentions)
 - Portopulmonary Syndrome - Occasionally pediatrics are diagnosed with portopulmonary syndrome. Although the criteria for the automatic exception are high for pediatric patients, a transplant center may still submit an application for exception (as is the case currently) if their patient’s do not qualify for the automatic exception and their MELD/PELD score does not accurately reflect that patient’s condition and need. (Committee Vote: 14 in favor, 0 opposed, 0 abstentions)
 - Primary Hyperoxaluria – The Chair briefly reviewed the proposal for primary hyperoxaluria and its relevance with respect to the diagnosis. A comment from a Committee member echoed the significance as indicated by the chair, and the Committee proceeded to approve the proposal. (Committee Vote: 15 in favor, 0 opposed, 0 abstentions)
- v. *Proposal to add the factors current bilirubin and change in bilirubin to the lung allocation score (LAS) (Policy affected: 3.7.6.1 (Candidates Age 12 and Older)(Thoracic Organ Transplantation Committee)*

The Chair started the Committee’s discussion raising the question which bilirubin measurement is being used? How does the policy handle those in the population with Gilbert's syndrome if total bilirubin is being used? In response, a Thoracic Organ Transplantation Committee crossover representative indicated that this has not been specifically written in the proposal and asked for the Chair’s recommendations. Dr. Horslen felt the least contentious value to be used is conjugated bilirubin. Which values used in the data for the proposal dictate what value is being supported by the proposal, be it total bilirubin, conjugated bilirubin, or a combination of the two. A Committee member voiced concern with the ambiguity, contending that centers will use whichever value is most helpful at the time. The Committee agreed it would be helpful to clarify which measurement is to be used to assure consistency in the proposal’s application and future data. A motion was made to support the proposal with the recommendation that a clear distinction is made as to which bilirubin measurement is to be used. The recommendation’s intent is to minimize the effect of exogenous increases in bilirubin that do not reflect a change in clinical status, and assure consistency in the proposal’s application. (Committee Vote: 15 in favor, 0 opposed, 0 abstentions)

- vi. *Proposal to modify the high risk donor policy to protect the confidential health information of potential living donors (Policy affected: 4.1.1 - Communication of Donor History) (Living Donor Committee)*

The Chair introduced and briefly reviewed the proposal. Committee members discussed the necessity of this policy considering its alignment with HIPAA, redundant nature, and the notion that centers are already doing this. A Committee member pointed out that although these things may be true, the Living Donor Committee is submitting this proposal to assure that a living donor's privacy is considered and an additional safeguard is in place to achieve that. With that, a motion was made to approve the proposal as written. (Committee Vote: 14 in favor, 1 opposed, 0 abstentions)

- vii. *Proposal to change the Bylaws to clarify the process for reporting changes in key personnel (Bylaw affected: Appendix B, Section II,E (Key Personnel); Appendix B, Attachment 1, Section III (Changes in Key Personnel) (Membership and Professional Standards Committee)*

The Committee's initial discussion focused on the time limits dictated by the bylaw proposal. Committee members commented that the bylaw's 30 days time limit prior to the end of an individual's active participation is difficult for pediatric programs. Pediatric programs traditionally do not have multiple staff members that would meet OPTN/UNOS qualifications, making successors of key personnel not inherently obvious. Acknowledging the MPSC's individual considerations in case of unanticipated events, a Committee member commented that too many things could happen that would put a center in potential violation of the bylaw; thereby forcing the center to go through the process of resolving the potential violation. The Committee also had some confusion and concerns pertaining to the 15 day time limit associated with key personnel's inactivity. The confusion stemmed from the 15 day time limit and whether it applied to departures which would result in the program's inability to function or a temporary absence by the primary transplant surgeon or physician. If key personnel were to go on sabbatical or take a 16 day vacation, must this be reported to UNOS and must work be suspended even if the program is staffed well enough to continue activity with no challenges? A Committee member reminded the group that this proposal is not changing the intent of the current bylaws. All agreed with the intent of the proposal, those members with concerns indicated the wording is what is problematic.

Committee members raised other concerns with the application process itself. The amount of paperwork necessary is not a trivial exercise and at times becomes frustrating. Also, UNOS staff's ability to process the applications within the same time limits was discussed. An at large member of the Committee posed the question could a statement be added that would prioritize a current program's key personnel applications ahead of others to assure this is not an issue? Another Committee member proposed a possible solution of converting the paper requirement to an electronic medium to expedite and ease submissions of these data for all parties involved.

Committee members agreed the bylaw proposal is missing a clear statement advising and encouraging programs to have a succession plan in place to avoid any repercussions set by the bylaws. Also, a clearer message highlighting retention and organization of the necessary documentation throughout one's career will simplify their approval process in the future. This applies to all transplant physicians and surgeons, but especially those starting their careers, and they should anticipate eventually becoming the primary transplant surgeon or physician at a program. Another reminder was entered into the discussion that the bylaw intent is not changing, just some of the details. The group's conversation then shifted to what the MPSC could do to operationalize the bylaw to assist members in compliance. The Chair noted that he felt the solution is a case of the

administration in each transplant program keeping staff's information and documentation up to date so submissions can be made promptly. If a program has no forethought, it will likely encounter trouble. To encourage this forethought, and also to work towards a well staffed program's ongoing activity even during a primary transplant physician/surgeon's 15 or more day absence, the MPSC should consider developing a classification to the effect of a secondary or associate primary physician. This would cause the majority of necessary information to be supplied in advance, making it a less onerous process for all parties. An alternative approach suggested to achieve those same two points was to approve individuals and not programs.

A Committee member motioned to support the intent of the proposal with the recommendations that the MPSC consider altering the proposal to:

- include less stringent time limits,
- include a statement or develop protocol that prioritizes key personnel changes/applications for staff review,
- include clear messages advising and encouraging program succession plans and progressive collection and organization of necessary documentation for individuals throughout their careers, and
- consider a way to operationalize the bylaw proposal. A suggestion made was to develop secondary/associate/ other named key personnel classifications for staff at the program other than the primary transplant physician/surgeon. These secondary classifications could also be a means to keep well staffed programs active in the event of a 15 day or greater absence of the primary transplant physician/surgeon.

The Committee unanimously accepted the motion. (Committee Vote: 15 in favor, 0 opposed, 0 abstentions)

- viii. *Proposal to clarify, reorganize and update policies on OPO and transplant center packaging, labeling and shipping practices (Policy affected: 5.0 (Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials)(Organ Procurement Organization Committee)*

The Chair briefly introduced the proposal, and after no further questions or commentary, the Committee unanimously voted to support it. (Committee Vote: 15 in favor, 0 opposed, 0 abstentions)

PEDIATRIC TRANSPLANTATION COMMITTEE		MONTH	JULY	NOVEMBER	MARCH
		DAY	17	20	26
		In Person	In Person	In Person	
NAME	COMMITTEE POSITION				
Simon Horslen MB, ChB	Chair	X	X	X	
David Campbell MD	Vice Chair/Region 8 Rep.	X	X	X	
Michael Chobanian MD	Region 1 Rep.	X	X	phone	
Anthony Savo MD	Region 2 Rep.	X	X	X	
Rene Romero MD	Region 3 Rep.	X	X	X	
Anthony Sebastian MD	Region 4 Rep.				
Christine Mudge RN, MS, CNS/PNPc	Region 5 Rep.	X	X	X	
Patrick Healey MD	Region 6 Rep.	X		phone	
Sharon Bartosh MD	Region 7 Rep.	phone	X		
Steven Lobritto MD	Region 9 Rep.	X		X	
Pirooz Eghtesady MD, PhD	Region 10 Rep.			X	
Kathy Jabs MD	Region 11 Rep.	X	X		
Eileen Brewer MD	At Large	X		X	
Philip Carlson RNP, CPTC	At Large		X		
Carol Conrad MD	At Large				
Mark Fox MD, PhD	At Large				X
LeeAnna Hungerford MHA	At Large	X	X	X	
Heung Bae Kim MD	At Large	X	X	X	
Robert Mazor MD	At Large			X	
Victor Morell MD	At Large			X	
Veronica Munson RN, CCTC	At Large				
Biagio Pietra MD	At Large	X	X	X	
Elizabeth Roach RN, BSN	At Large	X	X		
Stuart Sweet MD, PhD	Ex. Officio	X	phone	X	
Monica Lin PhD	Ex Officio		X	phone	
Elizabeth Ortiz-Rios MD, MPH	Ex Officio	X	X	phone	
Mary Guidinger MS	SRTR Liaison				
William Harmon MD	SRTR Liaison				
John Magee MD	SRTR Liaison	X	X	X	
Kate Meyer, MS	SRTR Liaison	X		X	
Jeff Moore MS	SRTR Liaison		X		
Shandie Covington BS	Committee Liaison	X	X		

Chad Waller MS	Committee Liaison		X	X
Wida Cherikh PhD	Support Staff	X	X	X
Mary D. Ellison PhD, MSHA	UNOS Staff	X		
Karl McCleary PhD, MPH	UNOS Staff	X	X	
Paula Bryant MBA	UNOS Staff	X		
Aaron Powell PMP	UNOS Staff	X	X	