

## **OPTN/UNOS Pediatric Transplantation Committee Summary**

### **Action Items for Board Consideration:**

- The Board is asked to grant approval of new Policy 2.6.1 (Mandatory Match Run for All Consented Organs), which would require a match run to be generated for every organ for which an OPO receives consent for donation. (Item 1, Page 3)

### **Other Significant Items:**

- The Committee considered the Organ Specific Working Groups' continued work on developing a proposals to address the Committee charge of reducing death on the pediatric wait list (Item 2, Page 3)
  - Heart-Lung Working Group (Item 2A, Page 3)
  - Kidney-Pancreas Working Group (Item 2B, Page 6)
  - Liver-Intestine Working Group (Item 2C, Page 7)
- The Committee reviewed progress made on the proposal to revise the pediatric data collection forms. (Item 3, Page 8)
- The Committee discussed OPTN Final Rule requirements for organ allocation policy development. (Item 8, Page 12)
  - Thoracic organ allocation (Item 8A, Page 12)
  - Liver and intestinal organ allocation (Item 8B, Page 13)
  - Kidney allocation (Item 8C, Page 17)
  - Pancreas allocation (Item 8D, Page 17)
- The Committee considered policy proposals distributed for public comment (Item 4, Page 9)
- The Committee heard plans for the upcoming Pediatric Summit on Organ Donation and Transplantation. (Item 5, Page 11)

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**REPORT OF THE  
OPTN/UNOS PEDIATRIC TRANSPLANTATION COMMITTEE  
TO THE BOARD OF DIRECTORS**

**St. Louis, Missouri  
March 23, 2007**

**Stuart C. Sweet, MD, PhD, Chair  
Simon Horslen, MD, Vice Chair**

*The following report presents the OPTN/UNOS Pediatric Transplantation Committee's deliberations and recommendations on matters considered during its January 19, 2007, meeting.*

1. Request for Mandatory Match Runs. The Committee reviewed data detailing a number of instances across all organ groups where no match run was generated for various pediatric organs that were ultimately not transplanted. Charged with minimizing or eliminating death on the pediatric wait list, the Committee questioned why UNet<sup>SM</sup> was not utilized to provide potential recipient information for every consented organ, and whether some transplant programs may have considered these organs for transplant into the sickest candidates had an offer been made, avoiding unnecessary discard. The Committee understood that circumstances such as positive serologies and/or organ trauma may ultimately require a match run to be closed without allocation, but felt strongly that the generation of a match run for every consented organ be a required step for initiating organ procurement and placement of all donor organs.

After discussion, the Committee voted unanimously to submit the following for consideration by the Board of Directors. Committee vote: 14 in favor, 0 opposed, 0 abstentions.

\*\*\* **RESOLVED, that new Policy 2.6.1 (Mandatory Match Run for All Consented Organs) shall be approved for implementation as set forth below, pending distribution of appropriate notice to Organ Procurement Organizations.**

**2.6 INITIATING ORGAN PROCUREMENT AND PLACEMENT.** In order to maximize the number of transplantable donor organs; tissue typing and crossmatching of an organ donor shall commence as soon as possible, ideally pre-procurement. Tissue typing is initiated only after the consent of either the donor by previous designation or the next of kin.

**2.6.1 Mandatory Match Run for All Consented Organs.** An OPO must generate a match run for every donor organ for which it has received consent for donation.

2. Organ Specific Working Groups. Each of the Committee's Organ Specific Working Groups provided the full Committee with an update on data related to Dr. Sue McDiarmid's charge to eliminate death on the pediatric wait list. Dr. Sweet suggested that the number of pediatric candidates removed from the wait list for death or too sick for transplant without receiving an offer is the most powerful data considered because it proves that the current system is inefficient in delivering offers to potential recipients. When considering the number of organs that do not get placed alongside the number of deaths on the wait list without receiving offers, the data are quite compelling. Changes must be made to improve the system. Historically, an argument has been made that there are not enough organs available for smaller children, but the data suggest that this may not be the case.
  - 2A. Heart-Lung Working Group. Dr. Sweet, Working Group Chair, provided an overview of the data requested during its November 8, 2006, conference call and reviewed by this group during its January 16, 2007, conference call.

Mr. Jeff Moore, SRTR Analyst, presented modeling data requested to demonstrate the effects of removing geographic barriers for heart candidates <12 years of age (Exhibit A). He reviewed ten TSAM simulations for each of three allocation scenarios:

- The current, implemented, heart allocation system;
- The current system modified such that there is a national sharing system for hearts from age 0-11 donors to age 0-11 candidates; and
- The current system modified such that there is a national sharing system for hearts from all pediatric donors (0-17) to age 0-11 candidates.

In the two modified scenarios above, all children (age 0-11) were given priority before adults within the same status regardless of geographical constraints. Traditional geographic priorities (e.g. Zone A (including local), Zone B, etc.) were still utilized when allocating to these children. The intent of the modeling was to provide the maximum probability of allocation to children where the probability of organ acceptance is based on both the distance between the donor and candidate as well as the number of times an organ was previously declined. It was noted the scenarios ignore cold ischemic time in the mortality model.

As expected, adult and adolescent transplants declined as the number of children transplanted increased. This decline was noted as minimal. In contrast, transplants in children increased and waiting list deaths in children decreased approximately 10%. However, deaths on the wait list more than doubled in children from Zone C when comparing the current allocation system to the most liberal sharing, even with the number of transplant increasing substantially within this zone. This result was consistent within the ten simulations that were generated. It is difficult to explain these results at greater distances due to the small numbers when dividing them into groups by status. Mr. Moore will recheck the modeling to provide a more detailed explanation of these results to the Working Group at their next meeting. When considering waitlist deaths by pediatric age group, a stair step pattern appeared, reflecting a decline in death as more organs were made available to children. Adolescents, as expected, reflected an opposite effect as more organs were directed to younger children in this modeling.

Dr. Sweet explained that this data was requested to determine what the results of removing geographic barriers would be in transplanting children. While recognizing the numbers are small, he suggested that some aspect of this modeling may be a starting point for the Working Group to consider when suggesting modifications to the current allocation system to benefit younger heart transplant candidates without severely disadvantaging other populations.

Dr. Sweet and Dr. Wida Cherikh, UNOS Senior Biostatistician, reviewed select data (Exhibit B) that the Working Group requested for review during its January 16, 2007, meeting. The request included:

1. *The number of candidates with ECMO versus non-ECMO life support and VAD use, including a summary of wait times and causes of death.*  
Upon review, the Working Group determined that the results of this request regarding mechanical support did not yield any significant information that will be useful in decreasing pediatric wait list death.
2. *Acceptance of pediatric donor organs, stratified by organ, recipient age and donor age.*  
The Working Group requested this data as a means to determine what organs may be utilized for younger candidates without significantly impacting adolescents and adults. Offer acceptance as a percentage by candidate and donor age was reviewed. This data reinforced the Working Group's idea that 0-10 year old donor organs could be allocated first to 0-10 year old candidates without impacting older candidates.
3. *Examination of pediatric donors that are not being utilized (i.e. donors organs not recovered, recovered but not for transplant, and recovered for transplant but not transplanted) by organ and donor age.*  
The disposition of pediatric donor hearts and lungs, broken down by age, indicated that there were a number of hearts not recovered. Reasons where consent was obtained but 241

pediatric donor hearts were not recovered included: poor organ function, no recipient located, ejection fraction <50%, organ refused by all national programs, and other (please specify). Dr. Sweet noted many of these reasons that 50 of these organs were not utilized could potentially be overcome, preventing discard and transplanting a child.

A similar review of reasons why 1030 consented pediatric donor lungs were not recovered included: poor organ function, no recipient located, other (please specify), organ refused by all national programs, PO<sub>2</sub> <200 on O<sub>2</sub> challenge, trauma to organ, donor medical history, infection and medical examiner restricted. Again, Dr. Sweet noted potential for some of these donor organs if an appropriate candidate could have been located.

Concerns were raised regarding multiple instances where match runs were not generated for pediatric donor hearts and lungs when consent was given for recovery but organs were not recovered. Members acknowledged that there is a substantial number of legitimate cases where OPO staff recognizes that an organ will not be placed, and do not spend time attempting to allocate. However, Dr. Sweet raised concerns that current policy does not hold OPOs accountable for that decision. Members agreed the decision to pursue placement is often made after a call to an OPO's local center to determine interest. Unfortunately, the response is often dependent on this center's waiting list, acceptance criteria and whether or not they have a critical candidate waiting on the list. This may not take into account other centers that would consider this organ based on what may be very different circumstances. Dr. Sweet encouraged members to consider ways to overcome this barrier. After discussion, the Committee proposed new policy language requiring a match run be generated for every consented donor organ. (See Item #1 of this report).

A Member questioned if there were problems nationwide where programs may be too conservative. He offered the static number of hearts transplanted as an example, noting that the Organ Transplantation Breakthrough Collaborative efforts do not appear to be increasing heart transplant numbers at all while the numbers of other organs transplanted have increased. It was noted that there appears to be fewer cardiac physicians and surgeons participating in Collaborative events than for other organ specialties, raising the question of whether this may be an indicator that conservative views remain in this specific community.

Dr. McDiarmid noted the SRTR is currently working on acceptance rate modeling for kidney, liver and heart. She predicted that this information will be far more relevant to the adult population. She noted small programs, small patient numbers and practice issues as the main concerns for pediatrics. How do you seek out best practices in the pediatric transplant community? How do you determine what programs are safely aggressive versus conservative to the point of potentially harming patients when reviewing these small numbers? The MPSC monitors outcomes of small programs (adult and pediatric). Dr. Sweet noted that it is challenging to develop metrics to measure this type of performance. These numbers do not promulgate best practices. It appears that education will be the key—publishing and sharing recommendations and successes in professional meetings. Dr. Sweet agreed that education will be essential to the Committee's success in meeting its charge to eliminate pediatric wait list death. While this group can propose policy change, it must also provide data to support changing the current dogma. Would it be possible to transmit outcomes data that may parallel comparable organs that have been transplanted? The data must be available and widely to convince the more conservative parts of the transplant community to change their practices.

Continuing to review the data, Dr. Sweet pointed out the current system is still not as efficient as it could be. Data indicated that pediatric donor heart lung match runs are still being closed before being exhausted, without making offers to potential candidates who may have considered these organs that were ultimately discarded. Match location for these potential recipients not receiving an offer ranged from Zone A Status 1A ABO Primary to Zone D candidates for hearts. Lungs showed a similar spread, but in much lower numbers.

4. *Summary of organs declined by pediatric candidates who died on the wait list.*  
While sharing this data with the Committee, Dr. Sweet expressed frustration that 68% of the 0-5 year olds and 62% of the 5-10 year old heart candidates waiting never received a heart offer before removal from the wait list for death or too sick for transplant. The numbers are small, but the results are troubling. Lung results were similar, but involved smaller numbers.

In summary, Dr. Sweet suggested these data reinforce the theory that there is a pool of organs that could potentially be transplanted into younger children without affecting adolescents or adults, and that there are missed opportunities to place organs and instances where candidates are dying without receiving these offers. The challenge is to determine how to modify current allocation policies to offer organs more broadly to a selected group of candidates in a way that is palatable to the transplant community as a whole. Education is critical to ensure success. Confirming all OPOs are working to place every organ every time without focusing on distance and time constraints is the first step in meeting this goal.

This Working Group will meet again prior to the March 2007 Board meeting to review all the data requested alongside current allocation policy to determine if there may be simple opportunities to propose change to the current system that will make a positive change for these younger candidates.

- 2B. *Kidney-Pancreas Working Group.* Dr. Albin Gritsch, Working Group Chair, provided an overview of the data requested during the November 8, 2006, conference call and reviewed by this group during its January 17, 2007, conference call (Exhibit C) analyzing:

1. *Characteristics of pediatric kidney candidates who died on the wait list as inactive candidates.*

Overall, there are very few pediatric kidney candidate deaths on the wait list. Roughly half of the candidates who died on the wait list during the review period were active at the time of death. A larger percentage of older pediatric candidates died on the wait list as compared to younger children, with roughly half of these candidates noted as highly sensitized. It was noted that there is great variation in listing practices from center to center. Some programs list candidates immediately as inactive. This makes it difficult to determine if a candidate is not quite ready for transplant or not eligible for transplant. Conversely, there is reluctance by some centers to change candidates from active to inactive status in cases of infection, etc. when the physician or surgeon might consider an ideal match for a candidate (i.e. a zero antigen mismatch offer). There are a few children on the kidney wait list that die before receiving an offer, 17 in this specific review period. The key question to resolve here is why these children are dying. A member questioned whether these 17 candidates were ever appropriate for transplant. Would they have benefited from transplant? Dr. Sweet expects that it will be difficult to discern these answers out of the OPTN data. A suggestion was made to review mortality on dialysis to determine which candidates are dying for other reasons (i.e. pulmonary hypoplasia, etc.).

2. *Transplant outcomes of deceased donor kidney transplants (double and single) from donors age <6, stratified by recipient age.*

Dr. Gritsch noted current policy does not preclude from transplanting kidney from donors <2, but the data does indicate that survival results do tend to be slightly less than using kidneys from older pediatric donors. It may be appropriate to use kidneys from 2-6 year old donors for pediatric candidates, while <2 donor en-bloc kidneys may be appropriate for candidates with few remaining options that will otherwise not survive.

3. *Wait list death rates and post-transplant outcomes for pediatric patients waiting for liver alone, kidney-heart and kidney-liver transplant.*

Data was requested to determine whether there was competition between pediatric kidney recipients and multi-organ transplant recipients. Size or age matching is not necessary for kidneys. The Committee hoped to determine the number of pediatric donor kidneys utilized for multi-organ transplant that may have taken the opportunity for transplant away from pediatric kidney alone candidates and the outcomes of these multi-organ transplants. The results of this data did not address the Subcommittee's original question, and additional work will need to be done with the cooperation of the organ specific committees to consider this issue in more accurate detail.

Again, concerns were raised regarding multiple instances where match runs were not generated for pediatric kidneys where consent was given for recovery but organs were not recovered. Though numbers were small, there are still organs to be gained for transplant if every effort is made to place organs. The data reflects a large number of potential recipients for kidneys that were recovered where match runs were not exhausted, potentially one quarter of the entire pediatric population waiting for a kidney. Anecdotally, Dr. Gritsch noted that his center and others have accepted and traveled for en-bloc kidneys, cautioning that OPOs should not necessarily give up on placement when there is no local interest in these smaller organs. Education of transplant programs and sharing of survival data may be helpful to encourage acceptance of organs that they may not otherwise consider.

2C. Liver-Intestine Working Group. Dr. Simon Horslen provided an overview of the data requested during the November 9, 2006, conference call and reviewed by this group during its January 19, 2007, meeting (Exhibit **D**), analyzing:

1. *Wait list death rates for candidates on the liver alone wait list by status or MELD/PELD score, age and diagnosis.*

Dr. Horslen noted a significant increase in death rate as MELD/PELD increased, with the highest rate noted for Status 1 as expected. It was noted that death rates for pediatric candidates were lower than that of adults at all given scores. Members questioned whether the higher death rates in adults might be the result of other co-morbidity factors. This group would like to see additional data broken down for adults incrementally to consider this further. It would also like to separate Status 1s out to determine if lower mortality in Status 1Bs might be influencing death rates in this larger Status 1 category.

Upon review of death rates by age and diagnosis, adolescents were found to have significantly lower death rates as compared to younger children with the exception of acute hepatic necrosis. Children age 0-11 were noted as having higher death rates than adults in the cases of cholestatic liver/cirrhosis and malignant neoplasms.

2. *Death rates for candidates awaiting a liver re-transplant by age.*

Children experience fewer deaths on the wait list than adults when waiting for a first transplant, but wait list mortality rates certainly approach that of adults while waiting for a re-transplant. Dr. Horslen hypothesized that this may be the result of technical issues resulting from a more acute condition when a second organ is required (i.e. primary non-function, hepatic artery thrombosis, etc.)

3. *Death rates for adolescent candidates waiting for liver alone transplant by MELD score after the 2/27/02 MELD system implementation.*

Adolescents were noted as having a higher death rate than younger pediatric candidates listed as Status 1. It was suggested that this may be because there is a smaller proportion of Status 1B and exceptions included. The next analysis will reflect changes to the Status 1 policy, offering a clearer picture of this group. Additionally, the differences between MELD and PELD may be outlined here when looking at deaths in the 30+ MELD/PELD score. Dr. McDiarmid questioned how the policy change bypassing adolescents for younger PELD candidates in the case of pediatric donors has affected these death rates. This is something that the Committee will be monitoring as more data is collected. Acknowledging the pediatric community's concerns that adolescents are not being transplanted in as timely a fashion as they

used to, the data suggests that listing practices have changed and younger children are not listed as early as they were pre-MELD/PELD. Results show they appear to be transplanted after a shorter period on the wait list.

4. *Calculated death rates for pediatric candidates on liver alone wait list by number of pediatric partial and split liver transplant relative to the total number of pediatric liver transplants.*

Center practices and wait list deaths were compared to determine if there is a correlation between death rates and the how aggressive programs are in performing split liver transplants. Dr. Horslen noted that the next iteration of this data will include living related donor transplants for further comparison. Larger programs that pursue higher numbers of technical variants have consistently lower death rates than more conservative programs. This may be an opportunity for these more conservative programs to expand their services and improve their survival numbers. Dr. Horslen suggested that this may be a future variability analysis tool to compare and provide best practices for programs looking to improve their wait list death rates, though encrypted data of this type will be challenging to develop. Considering the number of offers per candidate received by a center will also be useful in future analyses.

5. *Number and percentage of deaths for candidates waiting for a combined liver-intestine transplant by status or MELD/PELD, age and weight.*

Data indicated that 30-40% of all candidates listed for a combined liver-intestine are removed from the wait list due to death or too sick to transplant. This is especially true for the youngest candidates, decreasing with age. This is an issue that the Committee hopes to address with upcoming changes to policy by the Liver and Intestinal Organ Transplantation Committee that were approved by the Board in December 2006. Members agreed that these numbers are significant, and this concern must be stressed to the Liver-Intestine Committee.

Again, concerns were raised regarding multiple instances where match runs were not generated for pediatric livers where consent was given for recovery but organs were not recovered. Dr. Horslen noted that numbers for liver, approximately 10%, are smaller than that for hearts and kidneys, but still present. He suggested that even <3 month old donors are still worth the effort for placement when the wait list is considered, noting that if intestines are also present, both organs would most certainly be utilized. Data indicated that there were many candidates on match runs that were closed without being exhausted that may have accepted these organs if offers were made. Though a smaller number of liver candidates died on the match run without receiving an offer as compared to other organs, this is still troubling data.

Members agreed that adult wait list mortality on the liver list is significant, and that diverting any organs to pediatric candidates may be difficult to persuade the Liver-Intestine Committee to accept. A closer look must be taken to determine if wait list death of Status 1A 0-1 year old children may be as high if not higher than Status 1 adults. Careful thought must be put into determining how to redirect a cross section of appropriate organs to these younger candidates without having a negative impact on the adult wait list.

Dr. McDiarmid thanked the Working Group members for all of their work and progress made on meeting her Committee charge. She emphasized to all that there is no need to apologize for the small numbers associated with pediatric transplant. The numbers are small, but when looked at as a whole will make a tremendous difference to the pediatric transplant community.

3. Update Regarding Selected Revisions to Pediatric Data Collection. Dr. Estella Alonso updated the Committee on progress made by the Data Revision Subcommittee as it finalizes its proposed revisions to the Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR) and Transplant Recipient Follow-up (TRF) forms for pediatric candidates and recipients. She reported that subcommittee members concentrated on review of the adult deletions to determine what would also be appropriate for children and adolescents. This group also worked to develop several data fields to capture information regarding growth and development that are critical indicators of a child's progress both pre- and post-transplant. Subcommittee members agreed that growth and mental development are

crucial for children and may be more pertinent indicators of patients' progress, both on the wait list and post-transplant, acknowledging that the current forms were designed predominantly with the adult population in mind.

For each form, data elements common to all organ types were reviewed, followed by data elements specific to individual forms by organ type. All recommendations to retain or add data were supported with one or more of the Principles of Data Collection:

- Develop transplant, donation and allocation policies;
- Determine if Institutional Members are complying with policy;
- Determine Member-specific performance
- Ensure patient safety when no alternative sources of data exist; and
- Fulfill the requirements of the OPTN Final Rule

The Committee reviewed worksheets detailing this subcommittee's suggested deletions, additions and revisions (Exhibit E) to the current TCR, TRR and TRF forms.

As noted in the discussion related to the POC's public comment proposal below (See Item 4, page 9), the Committee considering the POC's proposed modifications to adult transplant recipient follow-up. Members stressed the importance of following children for as long as possible to better understand the physical and development effects of transplant on children as they continue to grow, transitioning into adulthood. Committee members agreed that following the growth and development of these children is vital. It was acknowledged that children are not fully formed at five years post-transplant, and some consequences related to transplant may not even occur within the first five years after transplant. Members noted that although they agreed to eliminate many of the same fields to be deleted for adults, it was not done with the understanding that collection time would be dramatically truncated.

After discussion, the Committee unanimously agreed (15 In Favor, 0 Opposed, 0 Abstentions) to approve all recommendations as developed by the Data Revision Subcommittee, and allow this group to recommend a plan for following pediatric transplant recipients beyond five years. A final review of revisions to current forms and post transplant follow-up will take place during an upcoming conference call, with this proposal being released for public comment in March 2007.

4. Policy and Bylaw Proposals Distributed for Public Comment. The Committee reviewed the following proposals issued for public comment on November 20, 2006, and offered comments during its January 19, 2007, meeting.

1. **Proposed Modifications to OPTN/UNOS Policy 3.5.9 (Minimum Information/Tissue for Kidney Offer) (Organ Availability Committee)** This proposal is a modification of the original proposed modification to Policy 3.5.8 and is intended to support a decrease in discards of procured deceased donor kidneys. This modified proposal supports the comments/recommendations of the OPTN/UNOS Operations, Pediatric, Organ Procurement and Kidney Committees, and Regional comments during the previous public comment period, ending October 27, 2006. It requires standardization in the methodology and reporting of renal biopsies.

After review and discussion of this updated proposal, members agreed that recommendations previously made by this Committee have been incorporated; noting that this policy change will not affect many pediatric recipients due to its focus on expanded criteria donors. As a result, the Committee voted unanimously to support this proposal (14 in favor, 0 opposed, 0 abstentions).

2. **Proposed Modifications to OPTN/UNOS Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials) (Operations Committee)** The aim of the proposed policy modifications is to address live donor organ packaging and transporting. The proposed policy modifications will provide procedures for packaging and transporting of donated organs not addressed by current policy.

After discussion of the proposal, the Committee determined there was no pediatric issue requiring specific comment.

- 3. Proposed Modifications to OPTN/UNOS Policy 3.1 (Organ Distribution: Definitions) (Operations Committee)** The objective of the proposed policy modifications is to improve patient safety by requiring verification of UNOS Donor ID number of all organs prior to transplant.

After discussion of the proposal, the Committee determined there was no pediatric issue requiring specific comment.

- 4. Proposed Modifications to Data Elements on UNet<sup>SM</sup> Transplant Recipient Follow-up (TRF) Form (Policy Oversight Committee)** The proposal would significantly reduce the number of data elements that transplant centers will be required to submit on the Transplant Recipient Follow-up (TRF) form after five years post-transplant.

Recognizing that it is still in the process of completing its own proposed revisions to all data collection forms (TCR, TRR and TRF), the Pediatric Committee would like to consider the POC's recommended modifications to long term data collection specifically in relation to its own recommended changes to the TRF. Committee members agreed that following the growth and development of these children is vital. It was acknowledged that children are not fully formed at five years post-transplant, and some consequences related to transplant may not even occur within the first five years after transplant. Dr. Estella Alonso, Chair of the Pediatric Data Revision Subcommittee, noted that although this group agreed to eliminate many of the same fields to be deleted for adults, it was not done with the understanding that collection time would be dramatically truncated. As a result, the Subcommittee will reconsider its recommendations for pediatric collection on the TRF, focusing specifically on data fields related to growth and development. This group will complete its review in terms of which items are acceptable for collection up until five years post-transplant, and which fields are seen as critical for long term collection (i.e. height, weight, motor and cognitive development). The results of this discussion will be submitted to the POC as part of the Committee's proposed changes to all data collection forms for pediatric candidates and recipients.

Additionally, aspects of the interrelation of graft and recipient as related to growth and development were discussed as important for potential collection. Lungs were offered as an example for organs that grow along with a child. It was suggested, as an example, that it may be beneficial to collect FEV<sub>1</sub> and FVC as markers of lung growth, supported with the Principles of Data Collection. This type of information could be useful in modifying allocation policy to promote successful graft and recipient pairing. Members also suggested that closer follow up of pediatric recipients during transition to adult care might help us understand medical and psychosocial factors contributing to graft loss. From a practical standpoint, such information may create a useful subset of data that could be captured in other pediatric databases as a study for consideration. This is an idea that may be pursued by HRSA and UNOS leadership to determine its feasibility.

As a result of discussion, the Committee voted unanimously in favor (15-0-0) of charging the Pediatric Data Revision Subcommittee with formalizing a list of data elements related to pediatric growth and development to be collected beyond the POC's proposed five year period. The Committee feels strongly that the responsibility of this long term data collection should ultimately be moved away from the OPTN and to the various organ specific pediatric registries for organ transplantation as long as the registries can accurately represent a subset of the pediatric transplant community. The proposed elements for long term follow-up will be included in the Committee's upcoming March 2007 public comment proposal to revise all data collection forms for pediatric candidates and recipients.

5. Pediatric Summit on Organ Donation and Transplantation. Dr. Sue McDiarmid attended the Committee meeting as a guest, inviting all Committee members to attend the March 28-29, 2007, Pediatric Summit on Organ Donation and Transplantation in San Antonio, Texas. She reported that pediatric transplant physicians and surgeons, pediatric intensivists, organ procurement professionals, and other clinicians working in pediatric organ donation and transplantation will have the opportunity to work together for the first time to share the best strategies for identifying and converting eligible, deceased pediatric donors, and the allocation and utilization of deceased pediatric organs with the objective of decreasing death on the pediatric wait list.

The meeting will have two tracks: pediatric transplant physician/surgeon and pediatric intensivist. Clinicians will meet as a group to discuss topics and then separate into these breakout groups as appropriate to begin more detailed discussions based on each participant's specialty. Organ procurement professionals may attend seminars in either one of the tracks. Dr. McDiarmid shared details regarding the transplant/physician surgeon track, which will center around this Committee's Organ Specific Working Group data detailing death on the pediatric waiting list, and discussions about how practices and allocation policies might be changed to most effectively utilize organs available to pediatric recipients. She suggested that this event provides an essential opportunity to share this Committee's work with others in the pediatric transplant community to educate them on what has been done, hear additional suggestions and build support for future policy proposals to move improvements to the allocation of pediatric organs forward. The intensivist track will focus on identification, conversion and management of eligible pediatric donors, and will also include a session devoted to the new JCAHO rules on DCD, including strategies to overcome institutional barriers to successful implementation of pediatric DCD protocols. Additionally, all meeting attendees will come together at the end of the first day to consider DCD as they listen and offer reflections regarding the planned "town meeting" discussion panel to be led by Dr. Bill Harmon.

Dr. McDiarmid noted she was working with UNOS and the Transplant Alliance to offer assistance with registration and rooming expenses for members who would already be in San Antonio for the March 27, 2007, Committee meeting. Additional details and a meeting agenda will be circulated to members upon completion.

Committee members commented on the importance of sharing this information with the pediatric sections of critical care organizations such as the Society of Critical Care Medicine and the American Academy of Pediatrics to ensure the participation of intensivists. Dr. Robert Mazor, an intensivist on the Committee, noted the importance of making this population a part of the DCD protocol process to build trust and support for this practice.

6. Update Regarding Actions from the December 2006 Board of Directors Meeting. Dr. Sweet reported the highlights of the Board's meeting in Tucson, Arizona (Exhibit F). Of specific interest to this Committee was the Board's decision to move forward with the January 1, 2007, implementation date for mandatory donation after cardiac death (DCD) protocols. He noted that the Board considered this Committee's concerns regarding this requirement in pediatric centers, but did not honor the request to delay the deadline. Dr. Sweet was optimistic that the upcoming Pediatric Summit on Organ Donation and Transplantation may benefit attendees, as DCD will be a central part of the discussion. Dr. Sweet reported that HRSA offered to provide support or assistance to those centers needing resources for putting DCD protocols into place. Additionally, the Committee reviewed the Principles of Data Collection as approved by the Board (See Item 3, Page 8). It was recognized that specific populations, including pediatrics, may fall outside of these Principles. Other sources of information, such as the Studies of Pediatric Liver Transplantation (SPLIT) and North American Pediatric Renal Trials Clinical Studies (NAPRTCS) databases, should be considered as alternate resources for information when proposing additional data collection fields to avoid added expense and effort.
7. HHS Program Goal Update. Ms. Shandie Covington, UNOS Policy Analyst, offered the Committee an update on the importance of the Program and Strategic Goals as policy is considered and developed

(Exhibit G). An updated report on the current progress in meeting these Program Goals will be provided in March 2007.

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

8A. Status of Thoracic Organ Allocation Policy Review.

*Lung Allocation Score System Data Update.* Dr. Wida Cherikh provided the Committee with an update of the most recent Lung Allocation Score (LAS) System data (Exhibit H). Dr. Sweet noted that the Thoracic Committee continues to monitor this data and consider how modifications to the LAS might better serve candidates with Pulmonary Hypertension, who may be underserved in the current allocation algorithm as compared to other diagnosis groups. Listing practices have changed since the implementation of the LAS, and as a result there is no significant change in death rates when pre- and post-LAS deaths are compared. Drs. Sweet and Mallory agreed that 0-11 age group appears to have benefited from LAS as well. Even though this age group does not receive an LAS score, it appears that these younger children are now receiving organs more quickly than they under the previous allocation system.

The number of lung donors, lungs transplanted and lung transplant rates have increased since LAS implementation. Data indicated more of the young pediatric donors (0-11) are now being directed toward adolescent recipients than under the previous allocation system. This was one of the goals of the LAS system which incorporated additional priority for pediatric organs into pediatric recipients. The distribution of adolescent donor organs has also shifted more towards adolescent recipients and away from adults, though not the same extent as the 0-11 donor organs. Dr. Sweet noted that it is difficult to compare the cumulative probability of wait list outcomes from pre- and post-LAS periods due to the substantial differences in listing practices. He suggested that there is a substantially smaller percentage of candidates still waiting for lungs at the end of the year under the LAS system, and questioned how this could be assessed. Review of this data for adults demonstrated that adults were transplanted at the highest rate among all age groups and death rates were the smallest across age groups.

Probability of survival from time of listing including post-transplant survival was reviewed by the Committee for the first time. This data suggested that the 0-11 year olds reflected the lowest survival rate at both six months and one year of listing. Members agreed that this information will prove useful when determining the best path forward to address Dr. McDiarmid's charge to reduce pediatric wait list death. Establishing criteria to serve these younger children is essential to address the disparity, and the Committee continues to consider a way to address this concern. It was suggested that post-transplant survival analyses by diagnosis group comparing pre- and post-LAS cohorts might be beneficial to review alongside the probability data also considered. Dr. Sweet noted that the differences in listing practices after the implementation of LAS may make these comparisons difficult to interpret.

Mr. Moore stated that updated coefficients for LAS factors will be introduced at the upcoming Thoracic Organ Transplantation Committee meeting. Diagnosis groups have changed substantially, and he cautioned against moving forward with this now. The SRTR believes that a selection bias has been created where transplantation is no longer random. It is thought that a weighting system may resolve this situation, but more data is required to determine how to develop such a system. If sicker patients are transplanted with worse outcomes, this may not be the best use of available resources. The Committee will continue to receive regular updates on this data at future meetings, focusing on post-transplant survival and wait list mortality.

*Discussion of Center-Specific Outcomes Reporting for Lung Transplantation.* Several members on the Committee have voiced concern regarding the Membership and Professional Standards Committee's (MPSC's) interpretation of information reported on lung programs. Because 12-17 year-old pediatric patients are modeled by the SRTR in a different manner than 0-11 year-olds, adolescents are treated differently when reviewing patient outcomes. In pediatric centers, this can

lead to the possibility that a program is judged by a subset of patients when quality criteria are reviewed by the MPSC. A similar situation has arisen in the heart community, when adult congenital heart disease candidates are treated at pediatric centers because this is an area of expertise for pediatric surgeons. Centers reviewed for poor outcomes in older patients raised concerns regarding selective interpretation of data. The MPSC suggested that such scenarios in heart programs should be considered on a case-by-case basis before formal referral to the MPSC.

Dr. George Mallory noted that a single death or severe graft dysfunction in a recipient under 12 years of age can trigger such a review in smaller programs. A single death in 8-10 pediatric lung recipients should not, in his opinion, trigger such a formal review. A member questioned whether centers may choose to be less aggressive in transplanting sicker candidates for fear of incurring MPSC referral.

Dr. Sweet suggested lung programs be afforded this same opportunity for case-by-case review before referral. He recommended the formation of a Joint Subcommittee with the MPSC to consider this concern and develop an appropriate path forward. Drs. George Mallory, Pasala Ravichandran and Craig Lillehei will join Dr. Sweet in representing the Pediatric Committee in these discussions.

UNOS Staff noted the MPSC will be revisiting how members are flagged for review, with an eye to capturing cases that need to closer examination. Likewise, the SRTR is working on improved methods for flagging centers with low transplant numbers and adverse outcomes that fall out of a normal range. Dr. McDiarmid noted that it is difficult to determine how to review small volume programs, noting that the MPSC is sensitive to these concerns, and looked forward to receiving input on this process from her pediatric colleagues.

*Discussion of Pediatric Lung Listing Practices.* Since the implementation of LAS, it is no longer necessary to list adults before they are ready for transplant. Because lung allocation is still based on waiting time for 0-11 year-olds, pediatric programs still frequently list candidates as active prior to actually needing transplant to allow them to accumulate enough time on the list to begin receiving offers as their conditions become more critical. An OPO raised concern regarding this listing practice due to what it felt was an excessive number of turned down offers for pediatric lung candidates that it felt was slowing down the allocation process. The Thoracic Committee referred this issue to this Committee for consideration. The Thoracic Committee suggested allowing pediatric candidates to accrue time when listed as inactive on the wait list. Thoracic Committee members felt that this would be acceptable as long as specific listing criteria were met so as not to allow for gaming of the system.

Dr. Sweet suggested that this topic be incorporated in the Heart-Lung Working Group's upcoming proposal for decreasing pediatric wait list death. Dr. Mallory agreed that this would affect a very small number of candidates and supported the idea of flagging centers with high turndown numbers.

#### 8B. Status of Liver and Intestinal Organ Allocation Policy Review.

*Recalculate PELD Coefficients.* Dr. John Magee provided the Committee with updated data analyses on recalculating PELD coefficients (Exhibit I). Results of these analyses indicated that the new calculated PELD would have a very small impact on the overall ranking of candidates on the wait list as compared to the current PELD equation. The new calculated PELD could, however, impact the ranking of candidates who are at higher current PELD scores. The variables studied that are not in the current PELD equation (creatinine, ascites, encephalopathy) were not significant predictors of mortality on the wait list. Additionally, there were no significant interactions between variables. Final conclusions from these analyses indicated:

- Using coefficients from a model that best captures the relationship between mortality on the wait list and its predictors has a rank correlation coefficient of 0.59 compared to the overall ranking of the list based on the current PELD equation;

- The rank correlation drops to 0.37 for candidates with currently used PELD  $\geq 15$ .
- Candidates transplanted at PELD 0-18 benefit from a liver transplant. This benefit diminishes as PELD becomes lower than 0 or greater than 18; however, there is no evidence of harm to candidates at very high PELD scores;
- Due to the low number of subjects and events included in the analysis, the results are highly unstable; and
- The results are quite sensitive to minor changes in the study population or methods employed.

Dr. McDiarmid noted reviews of similar data by Studies of Pediatric Liver Transplantation (SPLIT) noted that death on the liver wait list is not so much renal function as measured by creatinine or GFR, but being on dialysis or any form of renal replacement therapy. She suggested that adding this into the PELD calculation may be a strong predictor. A scatter plot was also suggested to determine the change in specific patient's PELD scores, capturing the net change in PELD score based on which equation was utilized.

Dr. Sweet questioned what steps would be required to move forward programmatically to change the PELD calculation by collecting similar data but altering the coefficients in the existing equation to generate a PELD score. UNOS Staff noted that programming a testing would be difficult in light of commitment to the upcoming system redesign.

Dr. Sweet sees the next step in this process as getting a better understanding of how this new scoring system will alter the allocation to the current population, including how current PELD scores will change. He questioned whether more simulation modeling would be practical due to the small numbers involved. If wait list mortality goes down and the number of transplants also go down, will this be acceptable? Dr. Shepherd suggested modeling one year survival after listing, including transplant. If this is found to be improved with the new system, the Committee will consider proposing a changed PELD equation to the Board.

*Request for Consideration on Whether a 22 year-old Should Receive a Pediatric Liver Due to Size.* The Committee reviewed a request (Exhibit J) to modify the liver allocation system, allowing a 22 year-old adult candidate who is the height and weight of an 11-12 year old to be considered as part of the pediatric recipient pool for liver allocation to allow her access to an appropriate sized graft. The center provided recent labs reflecting her chronic autoimmune hepatitis and reported her MELD score as 23. Information was not provided regarding how long she had been waiting or whether her condition was progressing rapidly. A member pointed out that the letter did not address whether living related, right or a large left lobe, or other technical variants had been considered. Based on these concerns, he did not personally advocate offering this specific candidate a pediatric liver or modifying policy in general to allow smaller sized adults to be considered for pediatric organs. He stated that pediatric candidates are constantly faced with technical variance and recommended that adult programs facing this situation might also consider this option. Members agreed that this would be a troubling precedent to set.

*Concern Regarding Adolescent Liver Candidates and the Impact of Recent Allocation Policy Changes on Transplant and Wait List Mortality Rates.* The Committee considered an email detailing concerns about adolescent candidates receiving MELD scores who might require a pediatric donor. It was suggested that these adolescent candidates may be disadvantaged because they often wait an extended period of time for a suitable organ. The Committee has reviewed data on this topic, but found no specific proof that these older children are disadvantaged. Dr. Horslen agreed this patient group is especially challenging to care for due to related morbidity (including bone disease, small for age, depression, and missing great quantities of school) without rapidly progressing liver disease. Dr. McDiarmid reported her center had lost two Status 1B teenagers because appropriate organs could not be located. Currently, she has a teenager with a MELD score of 40 for the past year that has still not been transplanted. Her concern was that pediatric donors are offered preferentially to younger pediatric candidates <12 before offers to adolescents

are made, regardless of PELD score. She questioned that whether there is enough data to determine the effects of this recent policy change and whether this is a real or perceived concern.

Dr. Sweet questioned whether breaking down the adolescent data further by recipient weight would help determine the effects of this policy change. It was acknowledged that numbers are small and may not prove to be helpful. It was also acknowledged that the community seems reluctant to consider partial livers for these teenagers when they are offered to younger children without question. There is awkwardness about the small size of these adolescents. It was suggested that moving adolescents with higher MELD scores to appear before 0-11 pediatric candidates by PELD may be beneficial to this populations. Dr. McDiarmid noted that it is difficult to establish a threshold for the MELD score because there is not distinct cut off where there is loss of benefit. Dr. Horslen acknowledged that this Committee's original intent was to benefit the entire pediatric population with the policy change, but concessions had to be made to ensure acceptance within the adult community. It is difficult to get the right size organ at the right time for these teenager candidates. Similar problems have been noted with Cystic Fibrosis candidates waiting for lungs. Is there a way to target adolescents with a specific MELD score and create a threshold for moving them above 0-11 PELD candidates to ensure transplant in a timely fashion?

A member questioned whether the adolescent donor livers allocated to younger children could be split with adolescent candidates receiving offers before adults for the remaining lobe or segment? This was seen as a possibility that will be palatable to the adult community and increase utilization of split livers.

The Committee requested data detailing:

- Wait list death rates for pediatric candidates aged 0-11 and 12-17, stratified by status or MELD/PELD score as well as overall wait list death rates. Tabulate causes of death for pediatric candidates who died on the waiting list.
- Number of liver transplants by donor age (0-11, 12-17, 18+), recipient age (0-11, 12-17, 18+), and status at transplants.
- Number and percent of split liver transplants relative to all liver transplants, stratified by donor age (0-11, 12-17, 18+), and recipient age (0-11, 12-17, 18+).

The above reports should be stratified by the following periods:

- Prior to MELD/PELD Share 15 policy implementation;
- After MELD/PELD Share 15 policy implementation but prior to the 8-24-05 policy implementation;
- After the 8-24-05 policy implementation.

After discussion, the Committee voted (13 In Favor, 0 Opposed, 1 Abstention) to submit a request to the Liver and Intestinal Organ Transplantation Committee that all pediatric candidates with a MELD or PELD  $\geq 25$  (regardless of age) receive organ offers prior to pediatric candidates 0-11 in descending order of mortality risk scores as outlined in the draft policy language below to better serve more critical adolescent candidates. In addition to this change, the Committee proposed that preference be given to adolescent candidates for the right lobe of any pediatric donor liver that is split.

### **3.6 ALLOCATION OF LIVERS...**

#### **Pediatric Donor Liver Allocation Algorithm**

##### **Local**

1. Pediatric Status 1A candidates (age 0-17) in descending point order

##### **Regional**

2. Pediatric Status 1A candidates (age 0-17) in descending point order

**Local**

3. Adult Status 1A candidates in descending point order

**Regional**

4. Adult Status 1A candidates in descending point order

**Local**

5. Pediatric Status 1B candidates (age 0-17) in descending point order

**Regional**

6. Pediatric Status 1B candidates (age 0-17) in descending point order  
7. Pediatric candidates (age 0-17) with MELD or PELD of 25 or greater  
7.8. Pediatric Candidates age 0-11 with PELD score of 24 or less in descending order of mortality risk scores (probability of candidate death)

**Local**

- 8.9. Pediatric candidates age 12-17 with MELD scores of 15 or greater greater than or equal to 15 and less than or equal to 24, in descending order of mortality risk scores (probability of candidate death)  
9.10. Adult candidates with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

**Regional**

- 10.11. Pediatric candidates age 12-17 with MELD scores of 15 or greater greater than or equal to 15 and less than or equal to 24, in descending order of mortality risk scores (probability of candidate death)  
11.12. Adult candidates with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

**Local**

- 12.13. All other pediatric candidates age 12-17 in descending order of mortality risk scores (probability of candidate death)  
13.14. All other adult candidates in descending order of mortality risk scores (probability of candidate death)

**Regional**

- 14.15. All other pediatric candidates age 12-17 in descending order of mortality risk scores (probability of candidate death)  
15.16. All other adult candidates in descending order of mortality risk scores (probability of candidate death)

**National**

- 16.17. Pediatric Status 1A candidates in descending point order  
17.18. Adult Status 1A candidates in descending point order  
18.19. Pediatric Status 1B candidates in descending point order  
19.20. All other pediatric candidates age 0-11 in descending order of mortality risk scores (probability of candidate death)  
20.21. All remaining pediatric candidates in descending order of mortality risk scores (probability of candidate death)  
21.22. All remaining adult candidates in descending order of mortality risk scores (probability of candidate death)

[No further Changes to Policy 3.6]

#### 8C. Status of Kidney Allocation Policy Review.

KARS Update and Public Forum Announcement. Dr. Gritsch provided the Committee with an update of the most recent discussion related to KARS (Exhibit K). He noted that data indicating the relative rate of kidney graft failure for recipients by donor and recipient age reflects adolescents as having a relative risk of graft failure that is greater than the adult reference. Pediatric priority currently applies to all candidates <18 years of age, with a goal of receiving a good quality kidney in a short period of time due to growth issues and long life expectancy for children. Current policy directs all kidneys from donors <35 be offered preferentially to pediatric candidates before offers are made to adults. It is anticipated that this will not change in the new proposed system for standard criteria donor (SCD) kidneys. This new system is expected to utilize a survival benefit model using variables including:

- Age
- Time exposed to end stage renal disease
- Albumin
- BMI
- Diagnosis (hypertension, polycystic, diabetic, other)
- Previous transplant
- Peak PRA

The goal of this new system is to transplant candidates who will derive the greatest benefit from receiving a SCD kidney by:

- Limiting the associated wait list mortality (such as that experienced by young diabetics); and
- Realizing the maximum survival of the SCD kidney (that is possible in relatively young to middle aged candidates)

This was adjusted for graft survival and renamed Quality Adjusted Estimated Net Lifetime Survival Benefit, or QENLSB. Benefit scores are affected by age. A slight increase in the number of kidneys going to children is expected as well as an increase in kidneys going to young adults. This modeling reflects a decrease in kidneys allocated to older adults. Expanded criteria donor (ECD) kidneys are seen as an alternative for this older population. Overall, the KARS proposal is expected to retain pediatric priority for donors <35, allocate SCD kidneys by benefit and then wait time, continue to allocate ECD kidneys by wait time, and address geographic variability after three years of data have been collected utilizing the new allocation system. Overall, Dr. Gritsch anticipates a benefit to pediatric and young adult candidates who are currently disadvantaged by the expanding kidney wait list.

A public forum will be held on February 8, 2007, in Dallas, Texas, to share this data with the public and solicit feedback from both the transplant community and the public. Dr. Gritsch will provide an overview of what takes place at the Forum during the March 27, 2007, Committee meeting and spend more time updating this group on the developing proposal.

#### 8D. Status of Pancreas Allocation Policy Review.

There were no issues for discussion by the Committee regarding pancreata during this time.

9. IT Status Update. Mr. Berkeley Keck provided the Committee with a brief update (Exhibit L) on the status of the DonorNet pilot conducted in Region 2, started on December 11, 2006. He was pleased to share with the Committee that feedback has been positive. Members reported greater efficiency in offering and placing organs with this new technology. He will share more detailed data regarding this process in March, 2007. At that time, he will also provide Members with an overview of the upcoming System Redesign project expected to have dramatic positive effects on the transplant community as a whole for data collection. He requested members consider serving on the Steering Committee as Pediatric Representatives.

## Pediatric Transplantation Committee

	Format	In Person
		1/19/2007
Name	Position	
Stuart Sweet M.D.	Chair	X
Simon Horslen MD	Vice Chair	X
Craig Lillehei MD	Region 1 Rep.	X
Thomas Fishbein MD	Region 2 Rep.	
Ian Carmody MD	Region 3 Rep.	
John Goss MD	Region 4 Rep.	
H. Albin Gritsch MD	Region 5 Rep.	x
Patrick Healey MD	Region 6 Rep.	x (via teleconference)
Sharon Bartosh MD	Region 7 Rep.	x
Ross Shepherd MD	Region 8 Rep.	x
Morris Schoeneman MD	Region 9 Rep.	
Joanne Dupuis RN	Region 10 Rep.	x
Debra Dodd MD	Region 11 Rep.	x
Estella Alonso MD	At Large	x
Kathie Collins RN, CCTC	At Large	x
Sharon DiSano MS, ARNP	At Large	x
Susan Dunn MBA, RN, BSN	At Large	
George Mallory Jr, MD	At Large	x
Robert Mazor M.D.	At Large	x
Amy Palermo	At Large	
Pasala Ravichandran M.D.	At Large	x
Jorge Reyes MD	Ex Officio	
Elizabeth Ortiz-Rios MD, MPH	Ex Officio	x (via teleconference)
Jade Perdue MPA	Ex Officio	x (via teleconference)
Sue McDiarmid, MD	Guest	x

### **UNOS Staff in Attendance:**

Wida S. Cherikh, PhD, Senior Biostatistician/Team Leader, Department of Research  
 Shandie Covington, Policy Analyst, Department of Allocation Policy  
 Mary D. Ellison, PhD, MSHA, Assistant Executive Director for Federal Affairs  
 Berkeley M. Keck, RN, MPH, Assistant Executive Director for Information Technology  
 John F. Lombardi, Applications Systems Analyst & Programming Supervisor, Department of IT  
 Development (via teleconference)  
 Catherine B. Monstello, IT/Policy Analyst, Department of Evaluation and Quality (via teleconference)  
 Leann Marcucci, Business System Analysis, Department of IT Development  
 Stephen Miklandric, Business System Analysis, Department of IT Development

### **SRTR Staff in Attendance:**

Laura Christensen, MS, Analyst (via teleconference)  
 Mary K. Guidinger, MS, Analyst (via teleconference)  
 William E. Harmon, MD  
 John C. Magee, MD  
 Jeff Moore, MS, Analyst