

INTERIM REPORT OF THE OPTN/UNOS PEDIATRIC TRANSPLANTATION COMMITTEE

December 3, 2009
Chicago, Illinois

The OPTN/UNOS Pediatric Transplantation Committee met on December 3rd, 2009, and considered the following items:

Update Regarding Actions from the November Board of Directors Meeting

The liaison to the Pediatric Transplantation Committee (the Committee) provided an update on those items relevant to the Committee that the Board of Directors (BOD) discussed during its November meeting. The update focused on the approval of the resolutions the Committee submitted to be considered by the BOD: substituting the general classifications for pediatric heart allocation in policy 3.7.10.1 (Sequence of Pediatric Heart Allocation) with the actual classifications as they appear on the match run; and the inclusion of pediatric Priority 1 lung candidates as an urgent status in policy 3.2.1.8.1 (Waiting Time Modification for Urgent Status Candidates). The BOD did not discuss these items as they were included on the consent agenda.

Discussion of the OPTN Final Rule Requirements for Organ Allocation Policy

Status of Kidney Allocation Policy Review

- *Discard Rates for Shared Zero-Antigen Mismatched Kidneys*
Wida Cherikh, PhD, UNOS Research support staff for the Committee, presented data describing discard rates for shared zero-antigen mismatched kidneys. The Committee requested these data in response to logistical concerns regarding its idea to increase access for highly-sensitized (PRA/CPRA $\geq 80\%$) pediatric kidney candidates through regional sharing. To summarize the data presented:
 - During 1/1/05-6/30/09, 1% (64) of all 6,181 zero-antigen mismatched kidney transplants were performed in pediatric recipients
 - Of the 64 zero-antigen mismatched kidney transplants done in children, 81% resulted from national sharing, 11% from local and 8% from regional sharing.
 - For adult zero-antigen mismatched transplants, 74% resulted from national sharing, with local and regional sharing accounting for 16% and 10%, respectively.
 - In 2009, there was a decrease in the zero-antigen mismatched transplants from regional and national shares due to limited zero-antigen mismatched sharing policy for adults implemented on 1/21/09.
 - None of the kidneys allocated to pediatric candidates as zero-antigen mismatched transplants were discarded
 - The discard rate of kidneys allocated to adult candidates as zero-antigen mismatched transplants was very small (1.5% overall, 0.3% for local share, 0.9% for regional share, and 1.8% for national share)

With these additional data, Committee members opined that this provides support for the feasibility of regionally sharing kidneys for highly-sensitized pediatric kidney candidates. Another concern expressed to the Committee pertained to the model's validity. Some of these validity concerns will likely be addressed in the newest iteration of the kidney and pancreas simulation allocation model (KPSAM) which will include unacceptable antigens. The model runs that the Committee has analyzed had not yet been completed, but have been requested. SRTR representatives stated this would probably be complete prior to the Kidney Transplantation Committee's (the Kidney Committee) meeting on February 1, 2010. This will allow the Pediatric Kidney/Pancreas Working Group time to analyze the data before the next discussions with the Kidney Transplantation Committee.

The Committee discussed additional arguments that will likely be brought forth. Previous discussions have yielded objections to putting highly sensitized pediatrics above highly sensitized adults, citing this will necessarily place all children above all the highly sensitized adults. This is something that has been interjected in past discussions, but no one on the Committee could understand why this has to be the case. The Committee felt it would be best to get an explanation detailing this point so that it can specifically address these concerns. Eileen Brewer, MD, At Large member of the Committee and the Kidney Transplantation Committee, volunteered to make efforts towards unraveling this matter.

Another expected counterpoint is that accepted zero antigen mismatched kidneys are usually ideal kidneys expected to have a relatively short travel/ischemic time. The majority of kidneys are transported by commercial airlines, and therefore bound to those flight schedules. Considering this, an increase in regional sharing will lead to an increased dependency on commercial flights to transport the kidneys, which may lead to greater cold ischemic times, and thus a greater number of discards, than what is currently seen. To this point, Committee members responded that these types of shares are successfully happening. Whatever the logistical dilemmas that may be present, centers receiving offers would ultimately have the final say as to whether or not they want to accept the kidney. Additionally, kidneys accepted for pediatric patients likely wouldn't be discarded if the intended recipient could not be transplanted. Considering the quality of organs accepted for pediatric potential transplant recipients, reallocation at the local level would find another suitable recipient in most situations.

The number of antigen-mismatched kidney offers for pediatrics is a small. The Committee felt this should be focused on in ongoing discussions of possible modifications. Additional attention should highlight that regional sharing is supported, not national sharing. Alluding to the rationale for Share 35, the Committee made the argument that these pediatric candidates will eventually get transplanted. Similarly, the modifications being discussed now are to put these candidates forward on the match runs to expedite their access, but in a manner that does not significantly affect the total number of transplants.

The Committee's next steps will be to review the new KPSAM analysis prior to the Kidney Committee's next meeting. After this discussion, and also prior to the Kidney Committee meeting, the Kidney/Pancreas working group will attempt to schedule a call with a small group of the Kidney

Committee to address this matter. If this is not possible, Dr. Brewer will contact the Kidney Committee Chair and immediate past chair, to make them aware of the Committee's discussions and intents prior to their meeting.

- *November 3rd Teleconference- Pancreas Transplantation Committee Concept for Simultaneous Pancreas and Kidney Allocation*

Sharon Bartosh, MD, At Large member of the Committee, reviewed information representatives from the Pancreas Transplantation Committee (the Pancreas Committee) presented to the Kidney/Pancreas Working Group regarding the concept it is developing to address simultaneous pancreas and kidney (SPK) allocation. The Committee appreciated the Pancreas Committee's consideration of the potential impact on pediatric candidates and involving the Committee before submitting a proposal. The Kidney/Pancreas Working Group recognizes that the model indicates that pediatrics would not be significantly affected; however, there is still concern stemming from the model's "global" allocation analysis. Based on the local experience of a member that participated in a similar arrangement, members were apprehensive that the modeled results would not necessarily be the reality at a number of OPOs/transplant centers. In particular, an active SPK program could significantly impact the number of offers received by pediatric potential kidney transplant recipients in that same donation service area. This concern is highlighted by the notion that SPK candidates and pediatric kidney candidates would, in most circumstances, be accepting organs from donors of similar demographics.

The Committee addressed possible elements to assure pediatric access remains unchanged that were discussed during the teleconference. Those being a SPK yearly volume threshold, that once met, would initiate a change in allocation so that pediatric candidates had initial priority; and, a willingness to continually monitor a modifications impact on pediatrics so that additional changes could be made to address any trends of declining access for pediatric kidney candidates. The Committee had little support for either of these potential solutions. The Committee saw the threshold as difficult to implement and logistically challenging. With respect to modifying the system as access issues become apparent, the Committee referenced the time it takes for adjustments to be implemented and was uncomfortable with a reactive approach.

The Committee Chair, Simon Horslen, MB, ChB, shared with the Committee a recent conversation he had with the Pancreas Committee Chair. Dr. Horslen echoed the desire and willingness of the Pancreas Committee to work with the Committee to attain some consensus in whatever proposal is put forward. That conversation ended with the suggestion that a working group comprised of members from both committees come together to discuss these matters in detail. Volunteers to participate in this working group include: Dr. Brewer; Dr. Bartosh; Kathy Jabs, MD, Region 11 representative to the Committee; and Sam Davis, At Large member of the Committee.

A member of the Committee proposed another alternative could be to assure that at least one kidney should be allocated by the kidney match, which would result in pediatric candidates getting at least one offer. This is assuming the kidney isn't accepted by any zero antigen mismatches, which

one Committee member indicated would be a large assumption for her OPO. Before spending too much time considering alternative solutions, other Committee members responded that it would be important to review the data requested by the Pancreas Committee regarding modeling of pediatrics having priority over SPK candidates. There is hope that this model will serve the interests of both committees.

Regardless of what is ultimately decided upon, the Committee appreciates the Pancreas Committee's effort to address the nationwide variability in how these organs are allocated. In that light, it is important that the Committee is involved with any proposed change to assure that pediatric kidney candidates are not negatively impacted.

Status of Liver and Intestinal Organ Allocation Policy Review

The Joint Liver and Intestinal and Pediatric Subcommittee have been meeting. A number of data requests resulted from the items that the group is reviewing:

- ***Incompatible ABO Transplants***

Dr. Cherikh presented information that had been presented to the Liver and Intestinal Transplantation Committee (the Liver Committee) in March 2009. The Liver and Intestinal Committee had requested this data in response to one of its members desire to modify existing liver allocation policy requirements regarding incompatible ABO transplants. To summarize the data:

- The analysis considered OPTN data on deceased donor liver transplants from 1/1/2003 – 10/31/2008. Survival analysis is based on deceased donor liver transplants from 1/1/2003 – 12/31/2006.
- During that time, 118 ABO incompatible liver transplants were performed
 - Accounts for 0.3% of deceased donor transplants
 - About 50% in adults, 50 percent in pediatrics
 - About 80% in Status 1/1A/1B
- These recipients had the lowest graft/patient survival, followed by compatible ABO and identical ABO, respectively
 - Lowest graft survival for >30 lab MELD/PELD
 - Patient survival similar for <30 vs ≥30
- Survival in pediatrics was better than adults.

Heung Bae Kim, MD, At Large member of the Committee and Liver Committee, led the group in discussing these data. Currently, there is a requirement that a candidate have a MELD/PELD of 30 before being eligible to receive offers for an ABO-incompatible liver. If the candidate did not meet this requirement, then they would not appear on the match run. The Liver Committee member initiating this effort suggested that this requirement be removed so that those that do not meet this requirement could at least appear at the very end of the match run. The Committee agreed that it is reasonable to remove the MELD/PELD 30 requirement, particularly for pediatric liver candidates.

The second matter related to ABO-incompatible liver transplants involves where some groups of candidates willing to accept these organs appear on match runs. In particular, those groups of urgent candidates that are less than one or two years of age (or older depending on what is determined to be most appropriate) that could benefit from improved access resulting from greater priority. Considering the liver is not as immunological sensitive as the heart, Committee members alluded to the ABO-incompatible heart policy and felt it would be a good starting reference. This may be a way to reduce waitlist mortality for the sickest of infant liver candidates. Committee members indicated that those centers actively caring for and working closely with pediatric recipients that receive an ABO-incompatible transplant have outcomes that are comparable to ABO-compatible/identical transplants. These successful protocols would be important to disseminate with any policy modification.

Moving forward with this issue, the Liver/Intestine Working Group needs to address the following questions:

- 1) What is the appropriate age limit for eligibility? All pediatrics?
- 2) Should there be additional eligibility requirements? If so, what are they?
- 3) Where in the allocation schema should these potential transplant recipients appear?
- 4) Should this apply to all donors, or only donors that are less than 11 years of age?

Once this Working Group has answered these questions, a draft proposal can be presented to the Pediatric/Liver Joint Subcommittee, and then ultimately to the Liver Committee.

A Committee member interjected a final consideration on this topic. Based on experiences at her center, she feels that those patients with a PELD in the 20's are hindered the most by the current policy. These are often very sick patients that do not meet the current requirements for an ABO-incompatible liver. Accordingly, the numbers of suitable offers they receive are not as high as they could be. Her hope is that any modifications are not exclusively limited to Status 1A and 1B patients.

- *Evaluation of Liver Status 1A Definition and Hepatoblastoma Requirements*

Dr. Cherikh presented data that the Joint Pediatric/Liver Subcommittee requested during its September 2, 2009, meeting. The request resulted from the Subcommittee's discussion about Liver Status 1A definitions, and separately, the current hepatoblastoma requirements. For the Status 1A analysis, all pediatric Status 1A/B candidates that did not meet the policy criteria between 9/1/2005 – 7/31/2009 were included. To investigate the hepatoblastoma requirements, pediatric candidates who were added to the waiting list between 8/24/2005 – 7/31/2009, who ever had an approved exception for hepatoblastoma were included. To summarize the results:

- Of the 266 Status 1A/B listings, 25 (9.6%) did not meet criteria solely because they were not in the ICU (10 were Status 1A, 15 were Status 1B).
- A little over half (53%) of the registrations where the ever had an approved exception for hepatoblastoma were removed for deceased donor liver transplant at Status 1B and 44% were removed for deceased donor liver transplant at MELD/PELD of 30.

- 64% of registrations removed for deceased donor liver transplant at Status 1B were removed within 50 days.
- 91% of registrations removed for deceased donor liver transplant at MELD/PELD of 30 were removed within 30 days.

The Committee initially focused on the ICU requirements for Status 1A pediatric liver candidates. Committee members expressed concern regarding any status being associated with a patient's location, in the hospital or otherwise. These concerns are based on the varying definitions of, and requirements for admission to, ICUs. The Committee felt statuses should be assigned based on medical criteria and a patient's degree of illness, not physical location.

The Committee reviewed Policy 3.6.4.2 (Pediatric Candidate Status) in detail. For those criteria defining pediatric Status 1A outlined in (i)-(iv), Committee members indicated that they described a patient that would likely be in a hospital's ICU, but not necessarily. The Committee unanimously supported (19- support, 0-oppose, 0-abstentions) a motion to eliminate ICU requirements for Status 1A as outlined in Policy 3.6.4.2 (i)-(iv).

The Committee then discussed the requirements for Status 1B for pediatric liver candidates, defined in Policy 3.6.4.2 (v). Committee members stated that the same logic from its discussion minutes prior should be applied to Status 1B candidates as well. Additionally, the current requirements offer a significant level of stringency, even with the removal of the ICU requirement. Considering this discussion, the Committee revised the motion it just supported and voted on it. The Committee unanimously supported (19- support, 0-oppose, 0-abstentions) a motion to eliminate ICU requirements for Status 1A and Status 1B as outlined in Policy 3.6.4.2 (i)-(v).

A Committee member raised a question if the group was comfortable with the following from Policy 3.6.4.2:

“Extensions for Status 1B candidates indicating a gastrointestinal bleed as the initial Status 1B upgrade criteria must have had another bleed in the past 7 days prior to upgrade in order to remain in Status 1B.”

The Committee member questioned whether or not this is appropriate in the case of candidates that have received aggressive treatment to control their bleeding. Committee members pointed out that status renewal every seven days is also required for other conditions. Compared to the example given, Committee members were more apprehensive about a patient that only had one bleed and is then indefinitely qualified for Status 1B.

The Committee then addressed the second part of the presentation investigating hepatoblastoma data. Dr. Kim provided an update from the Liver Committee's discussions pertaining to this topic. He stated that the Liver Committee supported a motion to remove the 30-day waiting period at PELD 30 requirement- all hepatoblastoma patients awaiting a liver transplant would be listed as Status 1B. A Committee member made an identical motion during the meeting: for hepatoblastoma candidates, policy should be revised to remove the initial 30-day waiting period at PELD 30, allowing

these candidates to be listed as Status 1B while on the waitlist for this condition. The Committee unanimously supported this motion (19- support, 0-oppose, 0-abstentions).

- *Evaluation of Split Liver Allocation*

Dr. Cherikh presented data requested for the Committee's ongoing efforts to develop new policies for split liver allocation. The analysis reported on the following requests asked by either the Committee or the Joint Pediatric/Liver Subcommittee:

- Distribution of deceased donor liver transplants (all and split), by recipient and donor age.
- For split liver transplants, determine the number of times the primary recipient was an adult and the number of times the primary recipient was a child, overall and by region.
- Determine the number of donors under 35 who met the criteria for splitting.
- Total number of all split livers and the number that met splittable criteria.
- Number of livers from donors 18+ that were split for recipients <18.

To summarize the data:

- Most livers from young pediatric donors went to younger recipients, most adolescents received livers from donors aged 4-17, and most adult recipients received a transplant from adult donors.
- About 50% of the times, livers from donors aged 14 and above were split for 0-11 and 18+ recipients.
- The number of split transplants done in pediatrics age 12-17 was relatively small compared to the number done in the 0-11 or adult recipients.
- The primary recipients of split liver transplants were pediatrics (age <18) 90-93% of the time.
- About 87% to 89% of the liver donors who met the splittable criteria were <35.
- More than 90% of the times livers from adult donors went to pediatric and adult recipients for split liver transplants.

These data confirm the Committee's notion that livers offered primarily to adults are rarely split, even if these adults had earlier consented to being transplanted with a split liver. To this point, Dr. Kim shared the main points from the Liver Committee's split liver discussions. The Liver Committee discussed two separate approaches. They discussed the possibility of increasing the pediatric preference for small liver recipients only in need of the left lateral segment. Priority for livers from donors ages 35 and younger was initially proposed, referencing the Share 35 proposal that has been applied for pediatric kidney potential transplant recipients. The Liver Committee opined that age 35 was too high of a cutoff, due in part to the number of potential donor livers from this cohort being many more than necessary. The Liver Committee felt donors 21 years of age or younger would be more appropriate, and still provide a suitable number of livers that could be split. This number could be eased upwards if later analysis proved this cutoff to be ineffective. Consequently, the Committee requested to tabulate the number of donors by donor age to get a better assess the real volume of donors.

The Committee indicated that it felt 35 year old donors is a reasonable cutoff. Committee members felt the size of the pool pediatric candidates received priority from was irrelevant. The same number of candidates that would receive a split liver, and therefore number of livers that are going to be split, is the same regardless of what donor age is established for priority. If priority is established for donors 35 years of age and younger as compared to 21 years, one could assume that some livers from donors in the 22-35 age range would be split. This would leave more whole livers from donors younger than 22 years for adults. To that point, a Committee member stated that it seems more reasonable to focus on potential livers that pediatricians would accept for splits, instead of just focusing on an age. Additionally, current data do not delineate a difference in the frequency of acceptance of right lobes from donors 35 and under as compared to donors 21 and under.

A Committee member observed that a relatively small percentage of livers that are split actually meet the splittable criteria outlined in policy. This would suggest these criteria are not as effective as intended. As a whole, increasing the donor age for which small pediatric candidates receive priority would increase access to livers that could be split, likely rendering the current criteria unnecessary.

Ultimately, the Committee desires change and wants to work with the Liver Committee to accomplish this. Upon reviewing the requested numbers of donors tabulated by age group, the Liver and Intestine Working Group of the Committee will finalize the details of what it thinks is most appropriate and share these sentiments at the next Liver Committee meeting.

The Liver Committee also discussed an alternative allocation system application involving split liver allocation that Region 2 submitted for consideration. Region 2 proposed having a system where if a liver is allocated to an adult, then that center may elect to split the liver to allocate the second segment to a candidate also located at that center. With a few stipulations for potential termination, the Liver Committee supported this alternative allocation system. There is some concern that this goes against the Final Rule, in that an organ segment would not be allocated by a match run. Viewed from another perspective, this supports one of the main premises of the Final Rule to increase organ donation (two transplants from one organ). Dr. Kim communicated that the Liver Committee felt that in these instances some deviation from the match run would be tolerable if it resulted in two transplants.

A Committee member from Region 2 explained some of the rationale behind the proposal. One thought is that the allocation of the second segment could be seen as an altruistic measure by the primary recipient. Additionally, those that are prioritized higher on the match run than the selected second-segment recipient at a different center would not receive an offer anyway because the liver has been primarily accepted by an adult and unlikely to be split. Therefore, one could say that they are not being disadvantaged.

Numerous Committee members balked at the idea of deviating from the match run to allocate organs. There is appreciation for the attempt to increase the volume of these transplants; however, it should follow that what is good for a patient at one's own center, should be good enough for a

patient at another center as well. To promote the use of split liver transplantation to benefit patients nationwide, and not just a center's own patients, is an educational issue as well. Furthermore, this type of allocation conflicts with the mission of the OPTN to allocate organs nationwide considering equity and utility. An OPO representative made the point that more organs transplanted do not necessarily equate a better system. He continued that if the national system allowed organs to be sent where is most convenient, then OPO's would be able to place a significantly higher number of organs. This proposal would also limit the number of livers that could be split considering centers that do not transplant pediatrics or were not affiliated with a pediatric hospital would unlikely split livers allocated to it. Accordingly, this would yield access disparity for those pediatric candidates listed at stand-alone pediatric centers.

In response to these points, a Committee member argued that what is being discussed is ideal, but is not resulting in a higher number of split liver transplants. These procedures produce some logistical hurdles that centers may be more willing to undertake knowing that their patients stand to benefit. Increasing the frequency of these procedures through whatever appropriate means, could be the inertia needed to grow and further develop split liver transplantation.

Further discussion to these points reinforced the Committee's decision to pursue the left lateral segment priority alternative discussed. A portion of the Committee believed that it should formally share its opinions on the Region 2 alternative allocation system with the Liver Committee.

Ultimately, the Committee decided to provide formal feedback if this proposal is distributed for public comment, or if it is explicitly asked of the Committee.

Status of Thoracic Organ Allocation Policy Review

- *Evaluation of Pediatric Heart Status 1A Criteria & Corresponding October 20th Conference Call*
David Campbell, MD, Vice-Chair and Region 8 representative of the Committee, provided some background for the Committee's current review of the pediatric heart Status 1A criteria. The effort was initiated after the Committee received a memo from the Membership and Professional Standards Committee (which was also sent to the Thoracic Organ Transplantation Committee (the Thoracic Committee)) asking for clarification of the pediatric heart Status 1A criteria, and whether or not hospitalization should be required for this status. After both committees separate discussions, it was determined that representation from both Committees should further analyze the policy for improvements. The Heart Subcommittee of the Thoracic Committee and the Thoracic Working Group of the Committee met and requested some preliminary data to begin the analysis. The following data was requested:
 1. Waiting list mortality for pediatric heart candidates before and after the implementation of sharing policy for status 1A on July 12, 2006, stratified by age group (0-<1, 1-10, 11-17) and status
 2. Waiting list mortality in status 1A for pediatric heart candidates before and after the implementation of sharing policy for status 1A on July 12, 2006, stratified by age group and each of the following factors:
 - Criteria met for status 1A

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

Dr. Cherikh presented the data resulting from these requests. To summarize:

- Across different pediatric age groups, status 1A had the highest death rates, followed by status 1B and status 2.
- For all status categories combined, death rate seemed to be the highest for pediatric candidates <1, followed by pediatrics aged 1-10 and 11-17.
- Across most of the different pediatric age groups and status categories, death rates during post-policy seemed lower compared to death rates during pre-policy period.
- Across status 1A pediatric age groups, death rates while in different criteria varied.
- For pediatrics <1 at listing, death rate was higher in criteria B than A, whereas for pediatrics aged 1-10 and 11-17 at listing, death rate was higher in criteria A than B.
- Across different status 1A pediatric age groups, death rates seemed higher for those with congenital as compared to all other diagnoses.
- Death rate for status 1A pediatric candidates who were hospitalized at listing tended to be higher compared to those not hospitalized.
- Across status 1A pediatric age groups, death rates while in different criteria varied.
- For pediatrics <1 at listing, death rate was higher in criteria B than A, whereas for pediatrics aged 1-10 and 11-17 at listing, death rate was higher in criteria A than B.
- Across different status 1A pediatric age groups, death rates seemed higher for those with congenital as compared to all other diagnoses.
- Death rate for status 1A pediatric candidates who were hospitalized at listing tended to be higher compared to those not hospitalized.
- One-year patient survival seemed to be lower for status 1A recipients with congenital disease compared to non-congenital in the <1 and 1-10 age groups.
- For all status 1A pediatric recipients, one-year patient survival seemed lower in those hospitalized compared to those not hospitalized at transplant.

These data have already been presented to the representatives from the Pediatric and Thoracic Committees that requested the data. The group indicated a desire to use these and additional data to stratify candidates that currently all fall under Status 1A so those that are more ill would be given

greater priority. For example, the data suggest those candidates that are ventilated, or on a ventricular assist device or ECMO have higher waitlist mortality. It would appear that these candidates would stand to benefit from greater priority. Unfortunately, the data is somewhat limited in that Status 1A criteria (b) does not differentiate between therapies nor does it require documentation of the length of time on any mechanical assist device. A possible solution discussed is to approach the Pediatric Heart Transplant Study to see if it would be willing to assist with some analysis. This is currently being pursued. Critical to this assistance will be to define exactly what questions need to be asked. These questions are something that will continue to be developed with the Thoracic Committee.

Committee members suggested the ELSO Registry as another database that could potentially be accessed to assist in the analysis. Committee members indicated that a lot of the information that is not collected by UNOS could likely be accessed here.

A Committee member asked if it were possible to adjust for time on the waiting list with regard to survival data. The point of the question being that it isn't entirely accurate to compare a child on a ventilator for one month to a child that has been on a ventilator for one week, even though they are listed at the same status. Dr. Cherikh replied that currently the date of device implant is not included on pediatric heart justification form, unlike the adult form. It was suggested during the working group call that the pediatric heart justification form be modified to include this information.

Unfortunately, it is difficult to extract definitive meaning from some of the data because of the small volume of patients being discussed. If significant data cannot be attained, a possible alternative would be a consensus conference to allow all experts in this field to come together and determine improvements to better serve these sick, pediatric heart recipients. The Chair encouraged the Committee to continue pursuing these modifications and not let the lack of numbers be dissuasive. There will likely never be a large enough volume, and Committee members should use what data are available along with their own expertise and experiences to most appropriately allocate these scarce resources.

- *Future Descriptive Analysis of Broader Geographic Sharing of Pediatric Donors for Status 1A Pediatric Candidates*

Regarding the new heart allocation sequence for pediatric that UNOS implemented in May 2009, Dr. Cherikh asked the Committee to make a formal data request so that the policy changes' impact could be assessed. The following data will be collected and evaluated every six months:

- Waiting list death rates by age group and status before and after the policy change
- Waiting list transplant rates by age group and status before and after the policy change
- Number and percent of hearts under each organ disposition by age group before and after the policy change
- Distribution of heart transplants by donor and recipient age groups, location, and status before and after the policy change

- Post-transplant patient survival by donor and recipient age groups and status before and after the policy change. (Note: this will be provided when there is sufficient post-transplant information, i.e., after the policy has been in place for 18 or 24 months.)

OMB Form Updates

There were still some outstanding questions related to the OMB forms that required the Committee's input. In particular, of those items that the Committee has added to the forms in the past, what should now be reviewed for utility? Committee members opined that it would be worthwhile to evaluate whether or not real data is being entered into the fields, as compared to "not done" or "unknown". If these fields have a high response rate with no real data, that would indicate that these fields are not serving their purpose and are unnecessary. Considering the volume of the data that will be reviewed, the Committee agreed that Dr. Cherikh should first gather all the data and the Committee will then determine the best way for this data to be broken down for presentation and discussion. This will allow additional time for this matter to be thought through.

Dr. Cherikh also asked for the Committee's feedback on a matter brought forth by representatives from the organ specific committees. The age cut-off to display questions pertaining to academic progress and academic activity has been set for candidates that are less than 19 years of age. This results in these questions appearing on forms for 18 year old patients (adult forms). Even though this affects a relatively small number of patients, the organ specific committees requested these questions be removed from the adult forms. The Committee stated that it would be reasonable to delete these questions from the adult forms. Ideally, the Committee would like to have information on pediatric transplant recipients well into their 20's; however, the Committee appreciates the effort that goes into these forms. Accordingly, it is agreeable to limit questions directed for pediatric patients exclusively to pediatric forms (younger than 18 years of age).

Transplant Center Memo: Documentation of Donor Weight on DonorNetSM

The Committee reviewed a blinded memo sent to Dr. Horslen from a transplant center. The memo requested that the Committee consider supporting a measure that would add dry weight and a weight at time of donation to the donor weight field in DonorNetSM. The Committee liaison reviewed the available details of the case to provide context for the memo. The Committee responded that it would be difficult to expect OPOs to attain an absolute dry weight. This is especially true in the case of a trauma victim where attending to the person in a critical condition is the primary focus. Even if an eventual donor was weighed upon being admitted to the hospital, there would still be some question as to whether that is the absolute dry weight. The Committee felt that the situation in question likely could have been averted with better communication between the transplant center and OPO. Considering those points, the Committee indicated it is content with the donor weight field as it is currently displayed in DonorNetSM.

Review and Consideration of Public Comment Proposals

Proposal to Improve the Variance Appeal Process

The Committee reviewed the Policy Oversight Committee's proposal and had minimal discussion about it. The Committee voted unanimously to support it as written. (19-support, 0-oppose, 0-abstentions)

Proposal to Add a Valuable Consideration Disclosure to the Bylaws

The Committee reviewed the Living Donor Committee's proposal. Some Committee members were concerned that this requirement could lead to legal implications for a transplant center in a case where it is later determined that organs were bought/sold. Other Committee members felt the opposite, indicating that this measure would be a protection. To this point, a number of Committee members indicated that they already provide similar awareness and disclosures at their centers.

Committee members recommend that some of the language of the proposal be modified. In particular for (iv)(8), regarding the word "understands" the Committee felt it would be difficult to determine and document if someone truly understands. Accordingly, it suggested that the word "understands" be replaced with "has been informed". Additionally, the Committee recommended using more plain language (e.g. replace "valuable consideration") considering these bylaw modifications impact laypeople, some of who do not speak English as their primary language.

Ultimately, the Committee voted to support the proposal and communicate its suggestions to the Living Donor Committee. (18-support, 0-oppose, 1-abstention)