

OPTN/UNOS Pediatric Transplantation Committee
Report to the Board of Directors
June 21-22, 2010
Richmond, Virginia

Summary

I. Action Items for Board Consideration

- None

II. Other Significant Items

- The Committee discussed OPTN Final Rule requirements for organ allocation policy development. (Item 1, Page 3)
 - Liver Allocation Policy Review (Item 1a, Page 3)
 - Kidney Allocation Policy Review (Item 1b, Page 7)
 - Thoracic Organ Allocation Policy Review (Item 1c, Page 11)
- The Committee considered policy and bylaws proposals distributed for public comment. (Item 5, Page 14)
 - Proposal issued on October 15, 2009.
 - Proposal issued on November 13, 2009.
 - Proposal issued on March 5, 2010.
 - Proposals issued on March 19, 2010.

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

The following report presents the OPTN/UNOS Pediatric Transplantation Committee's deliberations and recommendations on matters considered during its December 3, 2009, and March 24, 2010, meetings.

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

1a. Liver Allocation Policy Review

Pediatric Transplantation Committee Liver and Intestine Working Group and Joint Pediatric/Liver and Intestinal Organ Transplantation Subcommittee Teleconferences Update- At its December 2009 meeting, the Committee was updated on a September 2009 teleconference where representatives from the Committee and the Liver and Intestinal Organ Transplantation Committee (the Liver Committee) met to preliminarily discuss strategies to address a number of pediatric liver issues. Topics of conversation included ABO-incompatible liver transplant requirements, hepatoblastoma policies, the intensive care unit (ICU) requirement for pediatric Status 1A/1B liver candidates, and split liver allocation. Call participants agreed on the general approaches discussed and made data requests. It was determined that the Committee's Liver and Intestine Working Group would review the data, discuss the details and confer with the Committee, and then propose recommended changes to the Liver Committee. The Committee discussed the following data requests at its December 2009 meeting:

Evaluation of Liver Status 1A/B Definition and Hepatoblastoma Requirements- Committee research support staff presented the data requested during the Joint Pediatric/Liver Subcommittee. For the Status 1A/B 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 they 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 of being in Status 1B.
 - 91% of registrations removed for deceased donor liver transplant at MELD/PELD of 30 were removed within 30 days of being in MELD/PELD of 30.

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 around the country. The Committee reviewed Policy 3.6.4.2 (Pediatric Candidate Status) in detail, and indicated that current criteria describe a candidate who would likely be in a hospital's ICU, but not necessarily. Considering the data showing that candidates meeting criteria outlined in policy except for the ICU location are deemed appropriate as Status 1A/B upon review, the varying ICU definitions and requirements among institutions across the country, the detailed policy criteria, and the Membership and Professional Standards Committee's (MPSC) original request to review the notion that a candidate's location may be a surrogate for severity of illness, 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).

The Committee then addressed the second part of the data report investigating hepatoblastomas. After discussing the data, a Committee member made the following motion: policy should be revised to remove the initial 30-day waiting period at MELD/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).

Both recommendations were included in a memorandum sent to the Liver Committee requesting its feedback.

Evaluation of Incompatible-ABO Liver Transplants- Also at the December 2009 meeting, Committee research support staff presented a data report that had been requested earlier by the Liver Committee, and originally presented at its March 2009 meeting. 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 % in pediatrics
 - About 80% in Status 1/1A/1B
- These ABO incompatible recipients had the lowest graft/patient survival, followed by compatible ABO and identical ABO, respectively
 - Lowest graft survival for ≥ 30 lab MELD/PELD
 - Similar patient survival for <30 , ≥ 30 , and Status 1/1A/1B
- Graft and patient survival in pediatrics was better than adults.

The Committee's Liver Committee crossover representative communicated that the main concern expressed by members of the Liver Committee is the current policy requirements' prevention of candidates who would be appropriate for an ABO-incompatible liver transplant from appearing on an ABO-incompatible liver match run and receiving those liver offers. The Committee echoed these sentiments, referencing very sick children with a PELD score in the high 20's who are currently ineligible for an ABO-incompatible liver transplant. The Committee also debated

whether or not these pediatric candidates who are willing to accept an incompatible-ABO liver should have an increased priority due to their lower risk with these types of transplants. To conclude this discussion at the December 2009 meeting, the Committee established a list of questions for the Committee's Liver and Intestine Working Group to address for the development of recommendations for the Committee's consideration at its next meeting.

At the Committee's March 2010 meeting, recommendations to modify Policy 3.6.2.2 resulting from the ABO-incompatible liver transplant teleconference were put forth. Specifically, the Working Group unanimously supported eliminating the status requirements for an ABO-incompatible liver transplant so that any candidate deemed appropriate for an ABO-incompatible liver transplant by their center could be listed for and receive such offers. This will permit transplant centers to use their medical judgment as to when it would be appropriate to transplant a candidate with an ABO-incompatible liver. The Working Group felt that additional modifications affecting the priority of these potential transplant recipients should not be addressed until more data are available (as a function of the proposed change), and in hopes of a quicker implementation by means of minimizing the modifications, and thus the corresponding resources. The Committee had no objections to this approach, and it agreed to send a memorandum to the Liver Committee soliciting feedback to this recommendation.

Evaluation of Split Liver Allocation- The Committee's research support staff also presented data requests from the Committee's ongoing discussions on how to promote split liver transplants and improve split liver allocation. To summarize the data presented:

- 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.
- Among split liver transplants, about 50% of the time, livers from donors aged 14 and above were split for 0-11 and 18+ recipients.
- The number of split transplants performed in pediatrics age 12-17 was relatively small compared to the number done in the 0-11 or adult recipients.
- For livers that were split, pediatrics were the primary recipients (defined as the first candidate who accepted the liver on the match run) 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 time 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 a split liver transplant. Discussion of these data segued into an update from the Committee's Liver Committee crossover representative on the Liver Committee's initial response to the split liver concept the Committee has been contemplating. The Committee's general idea is to give candidates willing to accept only the left lateral segment priority after Regional Status 1B potential transplant recipients. This priority would only be for donors younger than 35 years of age; and, if the left lateral segment is accepted, the remaining segment would be allocated following the match run. It was reported that the Liver Committee opined that donors aged 35 years or less was too high a cutoff, and that 21 years of age or younger

would be more appropriate. The Committee did not agree with this recommendation for numerous reasons including the belief that the number of livers to be split will be the same regardless of the age cutoff, that it is important for a significant number of livers suitable for splitting to be included, and citing the priority for pediatric kidney candidates from Share 35 as a similar situation. Nevertheless, the Committee wants and appreciates the necessity of having the Liver Committee's support and requested data on the number of deceased donors between 18 and 21 years of age.

Evaluation of the Number of Deceased Donors between 18 and 21 Years of Age- At its March 2010 meeting, the Committee reviewed data detailing the number of liver donors aged 18-21 to help evaluate these donors split liver potential. To summarize the data presented:

- During 2008, there were 662 deceased donors, 613 deceased liver donors and 592 transplanted deceased liver donors aged 18-21 recovered

Upon reviewing the data, the Committee felt that the number of potential liver donors 21 years of age or younger would provide a large enough pool of potentially splittable livers, if its concept is ultimately approved. Considering the data and the report that pediatric priority to donors aged 21 years of age and younger was recommended by the Liver Committee, the Committee agreed that it would be prudent to include donors 21 years of age or less as the age cut off for the development of this proposal. A formal presentation of the Committee's concept to modify split liver allocation nationally will be presented at the next Liver Committee meeting. The Liver Committee's feedback and general response will be reported back to the Committee in an effort to determine details that need to be decided and if any other data need to be analyzed for the development of a formal proposal.

Evaluation of Liver Allocation Policies (MELD/PELD Share 15 Policy; Refinement of Status 1 into 1A and 1B, and Regional Sharing of Pediatric Donors; and New Liver-Intestine Allocation for Donors Aged 0-10): Waiting List Death Rates and Number of Transplants- At its March 2010 meeting, the Committee also reviewed data as a part of its ongoing examination of the effects of the liver MELD/PELD Share 15 policy (implemented on 1/12/05), changes involving the refinement of Status 1 definitions into 1A and 1B (implemented on 8/24/2005), the regional sharing of pediatric livers (implemented on 8/24/2005), and the liver-intestine allocation for donors aged 0-10 years (implemented on 6/20/07). To summarize the data presented:

- There was no significant increase of death rates in the 0-11, 12-17 and adult liver alone candidates across the different periods.
- Multiple organ system failure was most common cause of death for those with or without exception.
- Risk of death for candidates aged 0-11 waiting for liver-intestine alone with no other organ(s) was significantly lower during the post-policy period (6/20/07-10/31/09) (Note that relative risk of death could not be computed for the 12-17 and adult candidates due to the number of candidates less than 10).
- For candidates waiting for liver-intestine with other organ(s), risk of death for the 0-11 candidates was significantly lower during the post-policy period (6/20/07-10/31/09).
- Risk of death for the adult candidates waiting for liver-intestine with other organ(s) was higher during 6/20/07-10/31/09, but this did not reach statistical significance.

- Percent of deceased donor liver transplants done in pediatric recipients with MELD/PELD <15 decreased and percent transplanted in Status 1B seemed to increase in most recent period.
- There was an increase in the number of 0-11 deceased donor liver transplants from pediatric donors during the most recent period.
- Although the number is still small, there appears to be a slight increase in the percentage of split liver transplants performed in the 0-11 and 12-17 recipients out of all liver transplants.
- Percent of 0-11 recipients of liver-intestine with no other organ(s) transplanted in PELD 25+ or status 1B increased.
- Percent of 0-11 liver-intestine recipients (with other organ(s)) transplanted in PELD 25+ and status 1B increased, while percent of adult recipients transplanted in MELD 15-24 and 25+ increased.

1b. Kidney Allocation Policy Review

Evaluation of 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 (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 supports 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 Committee brainstormed additional arguments that may likely be brought forth. An 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 the data indicates these types of shares are successfully happening now. 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. This leads one to believe that the number of discards reported in past KPSAM iterations is likely inflated. Alluding to the rationale for Share 35, the Committee reiterated that these pediatric candidates will eventually get transplanted. Similarly to Share 35, the modifications being discussed 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.

Update on January 28th & March 22nd Teleconferences: Highly Sensitized Pediatric Kidney Candidates- At the March 2010 meeting, the Committee was provided an update on recent teleconferences held to facilitate ongoing discussions pertaining to highly sensitized pediatric kidney candidates priority. The Committee's Kidney Working Group met January 28th via teleconference and reviewed the most recent results produced by the Scientific Registry of Transplant Recipients' (SRTR) updated KPSAM. (SRTR updated KPSAM to include more recent data cohorts and acceptance models, as well as candidate screening as dictated by unacceptable antigens as entered by the transplant programs.) The trends seen from these runs are very similar to those observed in the earlier versions. Call participants ultimately felt that it had examined the Kidney Transplantation Committee's (the Kidney Committee) concerns, and thought it would be appropriate to broach this subject with them again. Before having the entire Kidney Committee discuss this matter, participants thought it would be prudent to meet with a small group from the Kidney Committee.

In a later teleconference, the Committee's Kidney Working Group met with leadership from the Kidney Committee to discuss the Committee's perspectives on the priority for highly sensitized pediatric candidates, and strategies for moving forward. The Kidney Committee's leadership brought attention to the proposal for a new kidney allocation system that it is in the midst of developing. One element the Kidney Committee has agreed to include in its proposal is a separation of the highly sensitized potential transplant recipients, so that highly sensitized pediatric candidates are prioritized before highly sensitized adults. Representatives from the Committee expressed some concern with the delay that would result in waiting to include these changes with the implementation of a new kidney allocation system. The Kidney Committee leadership empathized with the concerns, but felt it would be extremely challenging to garner support for implementing any isolated changes to the kidney allocation system. This opinion is heavily rooted in the resource implications of making an isolated change, followed by a complete system overhaul. Representatives from the Kidney Committee were very clear that this does not indicate a lack of support for making changes to benefit the highly sensitized pediatrics; rather, it

is very interested in thoroughly addressing these matters with the implementation of a new system.

Another concept discussed during the teleconference was the idea of regionally sharing kidneys for pediatrics on a trial basis. The Kidney Committee had been pondering similar ideas for the entire population, but there are a number of concerns. To investigate the validity of these concerns, and the possible benefit of regional sharing, call participants discussed the possibility of regionally sharing kidneys for pediatric candidates on a trial basis.

Another major topic discussed during the teleconference was the incorporation of DPI into the new system. The Kidney Committee would like for the Committee to contemplate and investigate a suggested DPI to replicate the priority given to pediatrics for donors that are less than 35 years of age.

To move forward with these efforts, the Committee agreed that the Kidney Working Group should convene to discuss these matters. The Committee needs more details from the Kidney Committee describing exactly what they want/need from the Committee to address the pediatric kidney candidates within the new kidney proposal. In particular, the Committee is interested in pursuing an appropriate DPI and regionally sharing for pediatric candidates, and is curious what it can do to help the Kidney Committee in its consideration of these pursuits.

November 3rd Teleconference- Pancreas Transplantation Committee Concept for Simultaneous Pancreas and Kidney Allocation- At its December 2009 meeting, the Committee was updated on a teleconference the Committee's Kidney Working Group had with representatives of the Pancreas Transplantation Committee (the Pancreas Committee). In hopes of addressing any of the Committee's concerns in advance, the Pancreas Committee requested this discussion to review the simultaneous pancreas and kidney (SPK) allocation modifications that it was developing.

The Kidney/Pancreas Working Group recognized that the modeling done by the Pancreas Committee 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 Chair shared with the Committee a recent conversation he had with the Pancreas Committee Chair. The Pancreas Committee Chair expressed a desire and willingness 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. Before spending too much time considering alternative solutions, the Committee agreed that it would be important to review the

data requested by the Pancreas Committee modeling scenarios where pediatric kidney candidates would have priority over SPK candidates.

Evaluation of Modifications to OPTN/UNOS Policy on Pediatric Priority for Kidneys from Deceased Donors under Age 35- At the Committee's March 2010 meeting, the Committee's research support staff presented data pertaining to its ongoing investigation of modifications to policy that gave pediatric potential transplant recipients priority to kidneys from deceased donors under the age of 35 (Share 35). To summarize the data presented:

- After Share 35, there has been an increase in absolute numbers of all kidney transplants in children (from 3,078 during 4-yr pre to 3,310 during 4-yr post) as well an increase in the number of deceased donor transplants for all pediatric age groups (from 1,397 to 2,068).
- Very few children are receiving transplants from donors over the age of 34 since Share 35.
- There has been a decrease in the absolute number of living donor kidney transplants in children of all ages with a decrease of 439 from 1,681 during 4-yr before, to 1,242 during 4-yr after Share 35.
- There is an increase in the number and percentage of children who are receiving more poorly matched deceased donor kidneys.
- Total time on the wait list has gone down considerably and more patients are being transplanted preemptively.
- Transplant rate per 1,000 active patient years has increased for all blood groups and all age groups except for the 6-10 group with AB blood group (Note: relatively few number of patients).
- Likelihood of transplant across blood groups increased significantly, except for the 6-10 candidates with AB blood group.
- Transplant rate per 1,000 active patient years increased for all PRA categories for all pediatric age groups.
- Likelihood of transplant did not increase significantly for the 0-5 and 6-10 candidates with PRA of 21-79% and PRA 80%+; and for the 12-17 candidates with PRA 80%+ (Note: small number of candidates in PRA some categories).
- While the percentage of pediatric registrations has decreased by 6% (816 in Sep 2005 vs. 768 in Jan 2010), the percent of children listed as inactive has gone up from 28% on 9/30/05 to 51% on 1/31/10.
- While the yearly number of pediatric living donor transplants seems to decrease, it appears to have slightly increased through November 2009 (299 through November 2009 compared to 293 for all of 2008).
- The number and percent of parents donating to their children has gone down from 1,213 (72%) during 4-yr pre-Share 35 to 841 (68%) during 4-yr post-Share 35.
- Despite more poorly HLA matched transplants after Share 35, pediatric graft and patient survival within 36 months of deceased donor transplants were not significantly different before and after the policy.
- There does not seem to be an increase in delayed graft function rates, 6-month or 1-year acute rejection rates, and median serum creatinine at 1-year and 3-years post-transplant for pediatric recipients transplanted after Share 35.

1c. Thoracic Organ Allocation Policy Review

Evaluation of Pediatric Heart Status 1A Criteria & Corresponding Conference Calls- The Committee is continuing its review of the pediatric heart Status 1A criteria with the Thoracic Organ Transplantation Committee (the Thoracic Committee). 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 and yield an informed discussion. The Committee's research support staff presented the data resulting from these requests at the Committee's December 2009 meeting. To summarize the results:

- 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 the post-policy period seemed lower compared to death rates during pre-policy period.
- Status 1A pediatric recipients who were <1 year at transplant seemed to have the lowest one-year patient survival compared to the other groups.
- Overall one-year patient survival rate for all pediatric recipients seemed lower for status 1A than status 1B or status 2.
- One-year patient survival varied across age groups and criteria met for status 1A, with the lowest survival observed for criteria B in the <1 age group.
- 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.

At the Committee's March 2010 meeting, the Committee's Thoracic Committee crossover representative updated members on the conference calls and ongoing discussions investigating the Status 1A criteria. Along with the question regarding a candidate's physical location as it is related to status, the main problem is the current system's evolution from one being driven by urgency to

a system dependent upon waiting time. The three options noted were to do nothing (which wasn't seen as acceptable); modify the Status 1A/B definitions so as to move away from hearts predominately being allocated by waiting time; or the development of a heart allocation score, or some other similar, larger, and more complex change. It is understood that the third option is a more involved option and therefore a long term goal. To improve the current system with some definition changes, it was recognized that additional data would need to be collected and investigated. These data would also be helpful in working towards a heart allocation score. These two groups will be continuing to meet to review data and deliberate on possible modifications.

The group indicated a desire to use these and additional data to stratify candidates who currently fall under Status 1A so that those sicker, more urgent candidates would be given greater priority. For example, the data suggest those candidates who are ventilated, on a ventricular assist device, or on ECMO have higher waitlist mortality. It would appear that these candidates would stand to benefit from greater priority. Unfortunately, the data are somewhat limited in that Status 1A criterion (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 Group to see if it would be willing to assist with some analysis. This is currently being pursued. Committee members suggested the Extracorporeal Life Support Organization (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. 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.

Review Proposed Changes to Pediatric Status 1A Form- As a result of the recent discussions had among the Thoracic Working Group of the Pediatric Committee and the Heart Subcommittee of the Thoracic Committee, changes to the pediatric heart status 1A justification form for capturing mechanical circulatory support (MCS) data were proposed. At its March 2010 meeting, the Committee reviewed mock-up screen shots based on the recommendations made during the conference calls. The main change from the current form is collection of a few more data elements related to MCS devices. Not only will the MCS type be collected, but also the implant/cannulation date and device type (no device type will be collected for ECMO). The Committee agreed that the mockup screen shots reflected what had been discussed in previous teleconferences, had no recommended edits, and supported moving forward with the changes.

Future Descriptive Analysis of Broader Geographic Sharing of Pediatric Donors for Status 1A Pediatric Candidates- At its December 2009 meeting, the Committee's research support staff reminded the Committee of the new pediatric heart allocation changes' implemented on May 6, 2009, and the need to formally assess the policy in the near future. The following data have been requested for evaluation 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; and
- 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.)

Multi-Organ Allocation- Upon the end of conversations had at the March 2010 meeting regarding thoracic organ allocation, a Committee member asked the Committee's Thoracic Committee crossover representative if there were any discussions addressing heart/lung allocation. The Committee's Thoracic Committee crossover representative stated the Thoracic Committee is concerned about this issue, in particular the ambiguity in policy regarding heart/lung allocations, but all multi-organ allocations in general. There is a desire on the Thoracic Committee's part to address this matter in the immediate future, and it will be imperative that the Committee provides its thoughts and insights in those discussions. Alluding to past hesitancy to focus on these matters because of the understanding that other Committees were, and a corresponding lack of any proposed modifications, members of the Committee wanted to express its feelings that this is an important issue that needs attention. Committee members suggested communicating these sentiments to the Board and asking if there is a timeline for it to be addressed, as this is an ongoing concern. Another recommendation from the Committee suggested including the Policy Oversight Committee on such a memorandum. No Committee member expressed any concern and it agreed to proceed in this manner.

2. Discussion of OMB Data Collection Forms

At its December 2009 meeting, the Committee discussed outstanding questions surrounding the proposed modifications to the OMB data collection forms prior to their distribution for public comment. In particular, considering the pediatric-specific data elements that the Committee has added to the forms in the recent 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." With an anticipated large volume of data that needs to be reviewed, the Committee agreed that UNOS staff should first gather all the data. The Committee will then determine the best way for these data to be broken down for presentation and discussion.

The Committee was also asked for 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, resulting in these questions appearing on adult forms for 18 year old patients. 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 and to limit questions directed for pediatric patients exclusively to pediatric forms (younger than 18 years of age).

3. Transplant Center Memo: Documentation of Donor Weight on DonorNet®

At its December 2009 meeting, the Committee reviewed a redacted memorandum from a transplant center sent to the Committee Chair. The memorandum 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 DonorNet®. All of the Committee's responses ultimately pointed to the notion that it would be difficult to expect OPOs to attain an 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 DonorNet®, and agreed to write to the author of the memorandum to summarize the Committee's discussion and communicate its decision.

4. New Pediatric-Specific Data Elements

On March 1, 2008, various pediatric specific data elements were added to the data collection forms for pediatric recipients. Some of these elements were added to all forms across all organ types, others were added to specific forms and/or organ types. The Committee had requested that the responses to the newly added elements be tabulated for review. This particular report only focused on date of height and weight measurement, cognitive development, and motor development, and was presented at the March 2010 meeting. To summarize the data presented:

- Overall completeness rate of date of height/ weight measurement was pretty high, especially on TCRs and TRRs.
- Overall rates of "Not Assessed" response for cognitive and motor development questions were higher for TRFs, but they seemed to have gone down during the second period for TCRs, TRRs and TRFs.

The next step in evaluating these pediatric specific data elements will be to review the responses to the questions added to the kidney and kidney/pancreas forms (TCR, TRR and TRF): growth hormone therapy and bone disease.

5. Review of Policies and Bylaws Issued for Public Comment

5a. Proposal Issued on October 15, 2009

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

5b. Proposal Issued on November 13, 2009

Proposal to Add a Valuable Consideration Disclosure to the Bylaws- The Committee reviewed the Living Donor Committee's proposal and recommended 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 whom 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)

5c. Proposal Issued on March 5, 2010

Proposed Modifications to Data Elements on Tiedi® Forms- The Committee reviewed a summary of proposed changes to Tiedi® forms. The Committee did not review the deceased donor, living donor and histocompatibility forms.

The Committee first reviewed the co-morbidity factors added to the Transplant Candidate Registration (TCR) and Transplant Recipient Registration (TRR) for every organ. There are a number of suggested data elements that are rarely seen in pediatric candidates. In response to these recommendations, Committee members opined that transplant centers can always enter “No” to the questions- as is the case the majority of the time with similar types of questions on the current forms. Considering that answering these questions are mandatory and that the Committee pointed out a number as predominantly being answered with “No,” the Committee Chair questioned if the expectation to answer these questions is reasonable or if they should be removed for pediatric patients. Committee members opined that although some of these factors may rarely be seen in pediatric patients, they do occur on occasion. Committee members stated that later analysis to get an accurate, complete picture of these conditions and their prevalence and impact in pediatric transplantation will never be possible unless the questions are asked.

The Committee next reviewed the serology additions to the TCR and TRR for each organ. Regarding the “HBV Surface Antibody Total” and “CMV Total” additions, the Committee commented that in its experience laboratory results usually don’t report “total.” The Committee strongly felt that the role of a data coordinator is not to interpret reported results and collecting data with confusing, incongruent questions will ultimately lead to poor, inaccurate data. The Committee recommends that these fields reflect what is commonly reported by labs doing these serological tests, i.e. no “total” fields.

The Committee next provided feedback on the variables added to the kidney, pancreas, and kidney-pancreas TCRs. The Committee was curious about the question asking if the candidate is listed for a pancreas as part of a multi-visceral transplant. The Committee felt that this information could be extracted from multiple waitlist registrations. The Committee questioned why the collection of information seemingly accessible from other sources was added. The same concerns were expressed for the multi-visceral questions on the TRR. Reviewing the TRR for these organs, the Committee also voiced concerns regarding the “average daily insulin unit” question. Without knowing the type of insulin given, the Committee felt it would be difficult to compare and extract meaning from the answers provided to this question.

Finally, the Committee reviewed those variables to be added to the liver and intestine forms. Committee members stated that the nomenclature “portopulmonary syndrome” is not how this

condition is commonly referred to, and therefore is confusing. The Committee indicated that this question should instead read “portopulmonary hypertension?”

5d. Proposals Issued on March 19, 2010

OneLegacy and Region 2 Split Liver Alternative Allocation Systems- Considering the similarity of these two proposals the Committee addressed both simultaneously. The Committee voted on whether to accept the proposals as written, and ultimately opposed this motion (0-support, 12-oppose, 4-abstentions). Although the Committee acknowledged the proposals’ potential to increase the volume of split liver transplants, it could not lend its support until the follow concerns are addressed:

- The Committee is concerned with the possibility of an increase in adult-adult split liver procedures as a result of the lack of specificity in the proposed alternative allocation system. There is a lack of robust data showing comparable results for adult-adult split transplants versus whole liver grafts. An increase in these adult/adult split liver procedures could result in a greater number of poor outcomes for these adult recipients, and decreased pediatric access. The predicted decreased pediatric access is on account of an increased possibility of failing adult-adult segmental transplants, which could yield two adult candidates with fulminant liver failure resulting in a situation where three livers are used to transplant two adults. The Committee did acknowledge how rare these adult-adult splits occur, but felt the potential increase in volume as a result of the proposed system validated their concerns. Accordingly, the Committee recommends that the proposals should only include left lateral segment and right tri-segment splits.
- The Committee is concerned with the language in the Region 2 proposal stating that the remaining segment would be transplanted into “any other medically suitable listed patient at that institution or an affiliated pediatric institution.” The Committee is worried about less urgent patients being transplanted and public relations issues that could arise as a result of deviating from the match run to allocate organs. Considering the incentive element of keeping both liver segments at a single institution, the Committee opined that the second segment should be offered to potential transplant recipients at the same institution by their order on the match run. There needs to be documentation of refusal reasons for any higher priority potential transplant recipient that did not receive the transplant.
- The Committee is concerned with how stand alone pediatric centers will be affected by this alternative allocation system. The Committee believes that exclusion of these stand alone pediatric programs from the proposal will create a disparity in access to transplant for pediatrics across the OPO/region. Candidates listed at pediatric programs affiliated with adult programs will have an advantage as compared to those listed at pediatric only programs.
- The Committee’s final concern surrounds consent procedures and possible coercion. There is nothing in the proposal that addresses when or how candidates would be provided the necessary information to make an informed decision as to what would be best for them. Although this is a general concern for the current policies and split liver transplants, the Committee acknowledges this proposal has the potential to increase the frequency of split

liver transplants. Accordingly, the Committee feels that any future proposals addressing split liver allocation should at least consider this matter and make some attempt to mitigate its occurrence.

Proposal to Develop an Efficient, Uniform National Pancreas Allocation System The Committee supports a consistent, national kidney-pancreas policy, but is concerned that pediatric kidney candidates have the potential to be disadvantaged by the proposed modifications. The Committee unanimously voted (18-support, 0-oppose, 0-abstentions) to support a motion that rejected the proposal as written and recommended that the Pancreas Transplantation Committee instead pursue “Run 14” from the proposal, the “single kidney contingency.”

Proposed Ohio Alternative Local Unit (ALU) Upon review, the Committee did not believe the proposal directly impacted pediatric patients. If this proposal is approved, the Committee requests that it be provided for its review the following data elements that the proposal indicates will be collected and annually evaluated for monitoring the impact of the alternative local unit:

- Pediatric deaths on waiting list by program and status of patient and PELD score at time of death; and
- Waiting time to transplant by PELD categories.

Remaining Proposals The Committee did not review the remaining proposals distributed on March 29, 2010, as they did not appear to have a direct and significant impact on pediatric transplantation. Committee members were asked to review thoroughly the proposals not discussed and bring forward any proposals, or elements of certain proposals, that they felt the Committee should discuss to provide commentary. No Committee member requested discussion for any of those proposals not discussed at the meeting.

OPTN/UNOS Pediatric Transplantation Meeting
 December 3, 2009
 Chicago, Illinois

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

OPTN/UNOS Pediatric Transplantation Meeting
 March 24, 2010
 Chicago, Illinois

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