

INTERIM REPORT OF THE OPTN/UNOS PEDIATRIC TRANSPLANTATION COMMITTEE

24 March 2010
Chicago, Illinois

The OPTN/UNOS Pediatric Transplantation Committee (the Committee) met on March 24, 2010, and considered the following items:

Review and Consideration of Public Comment Proposals

Proposed Modifications to Data Elements on Tiedi® forms (referred to in the past as OMB forms)

The Committee reviewed a summary of proposed changes for the following Tiedi® forms: Transplant Candidate Registration (TCR), Transplant Recipient Registration (TRR), Transplant Recipient Follow-up (TRF), Living Donor Registration (LDR), Living Donor Follow-up (LDF), Deceased Donor Registration (DDR), Histocompatibility Form (HF), and a new Explant Pathology Form for liver recipients. The Committee's review focused on the proposed changes as they would appear on the pediatric version of these forms. The Committee did not review the living donor and recipient histocompatibility forms.

The Committee first reviewed the co-morbidity factors added to the TCR and TRR for every organ. Before reviewing each individual field, a Committee member asked if there were recommendations made as to how these data are to be collected accurately. The Committee concurred that the proposed data elements would be good information to have, but serves no value if the data are not reliable. For example, it would be challenging to collect accurate data regarding cigarette use for pediatric candidates. To this point, Committee members initially recommended removing smoking questions from pediatric forms. In response to this recommendation, other 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. Other factors that are not very prevalent in children for every organ group were reviewed (e.g. liver candidates with myocardial infarction), but ultimately the conversation returned to the notion that answering "No" is still an option. Considering that answering these questions is mandatory and that the Committee pointed out a number as predominantly being answered with "No", the Chair, Simon Horslen, MB, ChB, questioned the Committee if the expectation to answer these questions is reasonable. 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 was confused by the usage and meaning of the term "total". The Committee commented that in its experience laboratory results usually don't report "total". It is important that the questions posed on the data collection forms reflect the same information as what is being tested and reported by laboratories analyzing the blood samples. The Committee strongly felt that the role of a data coordinator is not to interpret reported results.

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. Additionally, “is the candidate listed for multiple organs?” is another question also on the TCR, seemingly rendering this information duplicative. 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. [After the meeting it was clarified that these questions were added to help identify those candidates/recipients who received a pancreas for technical reasons – so that they can be excluded from the SRTR Program’s Specific Reports. Upon providing the clarification, no additional comment was provided as to the ongoing validity of the Committee’s original concerns regarding these multi-visceral questions.] Reviewing the TRR for these organs, the Committee voiced concerns regarding the “average daily insulin unit” question. The Committee expressed that this question was too broad considering the variety of possible insulin treatments. 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 element should instead read “portopulmonary hypertension?”

OneLegacy and Region 2 Split Liver Alternative Allocation Systems

Considering the similarity of these two proposals the Committee addressed both simultaneously. The Committee first focused on its understanding that both proposals included the possibility of adult-adult split liver procedures. Committee members indicated they are only aware of small, single center data sets that show comparable results for adult-adult splits. This lack of robust data led the Committee to believe that this proposal’s potential to increase the number of adult-adult splits could very possibly yield numerous bad liver transplants. Committee members also raised concerns that the number of pediatric liver transplants could decrease with an increase in adult-adult splits. This is because of the 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 use 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 these variances validated their concerns. Accordingly, the Committee recommends that these proposals should only include left lateral segment and right tri-segment splits.

Focusing on left lateral segment and right tri-segment splits, the Committee expressed concerns regarding the determination as to who gets the left lateral segment in Region 2’s proposal. The Region 2 proposal indicates the remaining segment would be transplanted into “any other medically suitable

listed patient at that institution or an affiliated pediatric institution.” The Committee feels that this language is too broad and could result in less urgent patients being transplanted. Deviating from the match run to allocate organs could turn into a public relations issue. Acknowledging 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 a transplant.

Regarding the evaluation of this variance, Committee members felt that right lobes imported into CAOP/Region 2 should also be included in the analysis.

Another concern raised by the Committee pertains to hospitals that are not affiliated with an adult liver program. The Committee is concerned that exclusion of these stand alone pediatric programs from the proposals 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.

A final concern voiced by the Committee surrounds consent procedures. In particular, the Committee was concerned about possible coercion and persuasion for the intended candidate to consent to accepting a split at the time of transplant. There is nothing in either 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 even for the current policies and split liver transplants (exemplified by a Committee member’s account of a surgeon who has performed a number of these transplants and reports no one has yet to decline consent) the Committee feels these proposals do have the potential to increase the frequency of these split liver transplants, and thus the likelihood of this concern. 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.

Discussion of these proposals segued into a conversation about the concept that the Committee has been working on recently to increase split liver transplants nationally. The concept would provide priority to candidates that would only accept a left lateral segment, and the remaining portion of the liver would then be allocated according to the match. In light of these proposals, more split liver transplants being performed, and an increased comfort in transplanting the right lobe only, the Committee agreed that now is a good time to address details, build consensus, and pursue its idea to modify and promote split liver allocation.

Throughout the discussion, Committee members acknowledged the numerous benefits that would result from these AASs. In particular, an increase in the number of split liver transplants performed. But, the Committee felt its expressed concerns outweighed the benefits. The Committee voted on whether or not to accept the proposals as written, and ultimately opposed this motion (0-support, 12-oppose, 4-abstain). The Committee stated it could not lend its support for these variance proposals until the concerns stated above are addressed.

Proposal to Develop an Efficient, Uniform National Pancreas Allocation System

As a result of the Pancreas Transplantation Committee reaching out to build consensus, the Committee has discussed this proposal on numerous occasions at the Working Group level, as well as with the full Committee. The Committee reviewed the finalized proposal and continues to be concerned that children have the potential to be disadvantaged with proposed modifications. Pediatrics have a good chance at transplant when two kidney's are available, but this access decreases significantly when only one kidney is available which would more often be the case with the approval of this proposal. Considering this proposal along with multi-organ transplants including a kidney, zero antigen mismatches, and paybacks- especially if the pediatric candidate is located in a DSA with a large number of outstanding paybacks- it is reasonable to forecast that pediatric candidates would not receive kidney offers from a number of donors that would otherwise be ideal for this population . Furthermore, the Committee indicated that it is an assumption and not a guarantee that the volume of pancreas transplants will not increase as a result of this proposal. This possible change in behavior could result in less kidneys being offered to isolated pediatric potential transplant recipients than anticipated.

In light of these concerns, several Committee members expressed their sentiments that Run 14, the single kidney contingency, is a better option. The Committee opined that the single kidney contingency represents a good compromise for pediatric candidates and SPK candidates. The increased complexities of the single kidney contingency are minor, but regardless, the Committee feels it is a better option because it is the right thing to do from the perspective of pediatric kidney candidates. A motion was made to oppose the proposal as written and to instead recommend option 14, this motion was unanimously supported (18-support, 0-oppose, 0-abstain). The Committee concluded this discussion commenting that it supports a consistent, national kidney-pancreas policy, but feel a single kidney contingency is a better option to protect the interests of pediatric kidney candidates.

Proposed Ohio Alternative Local Unit (ALU)

The Committee briefly discussed the proposed Ohio ALU. Todd Astor, MD, of Nationwide Children's Hospital led the discussion and provided some background and historical perspective. The Committee did not believe this proposal directly affected pediatric candidates, but noticed that the intended evaluation plan will track pediatric deaths on the waiting list, to be reviewed annually. If this proposal is approved, the committee would be like to review the following data elements included in the annual evaluation:

- 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 groupings.

Status of Kidney Allocation Policy Review

- *Evaluation of Modifications to OPTN/UNOS Policy on Pediatric Priority for Kidneys from Deceased Donors under Age 35*

Wida Cherikh, PhD, UNOS Research support staff for the Committee, presented data related to the Committee's ongoing evaluation of modifications to policy that gave pediatric potential transplant recipients priority to kidneys from deceased donors under the age of 35 (Share 35). These changes were implemented in September 2005. 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 pt 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 Sep 2005 vs. 768 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.

In response to these data, Committee members indicated it is hard to extract definitive conclusions without comparing to the adult population- so as to observe overall trends. Others stated that comparisons to adult data have limited value as well as small differences would go unnoticed in the adult population, but would appear as large differences in pediatric population as a function of sample size. In reviewing the data, Committee members also thought it to be important to observe trends prior to implementation of policies as that may give a better insight of the overall changes.

Discussion of these modifications led to the contemplation of a donor profile index (DPI) to be included in the new kidney allocation policy. The Committee would like to investigate a range and median DPI describing the deceased donors from which pediatrics are currently receiving kidneys. The Committee was reminded that this analysis had been reported in April 2008, and reviewed again recently in the summer of 2009. Considering the desire to have the most recent data possible to be included in the cohort for analysis, Committee members agreed it was not necessary to rerun the analysis immediately. It will be important to have this information ready when more detailed conversations regarding DPI and pediatrics are had with the Kidney Transplantation Committee (Kidney Committee).

A final point made cautioned against too much serum creatinine data analysis as it is affected by a lot more than the donor quality.

- *March Teleconference- Pediatric and Kidney Committees: Highly Sensitized Pediatric Kidney Candidates*

Eileen Brewer, MD, at large member of the Committee and cross over representative to the Kidney Committee, led the discussion and provided background on the Committee's ongoing efforts to determine what can be done to improve the access to transplantation for highly sensitized adolescents. Based on modeling that has been done thus far, the Committee feels the best solution would be a prioritization of these potential transplant recipients over highly sensitized adult potential transplant recipients, combined with regional sharing of kidneys for the highly sensitized pediatrics. The Kidney Committee has expressed some concern with this approach. The Monday prior to the Committee's meeting, members of the Committee's Kidney Working Group met with the leadership of the Kidney Committee to discuss the Committee's perspectives and strategies for moving forward.

During the teleconference, 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 pediatrics 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. That is not to indicate a lack of support for making changes to benefit the highly sensitized pediatrics; rather, the Kidney Committee would be very interested in addressing these matters with the implementation of a new system.

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. The Committee had looked at data investigating a possible DPI at its meeting in April 2008. The Committee had more recently reviewed these analyses, and felt that the results were still appropriate but that more recent data analysis should occur closer to the Kidney Committee's development of a proposal. During the Committee's discussion at this meeting, there was a brief dialogue as to whether or not the Committee's proposed DPI should try to capture an abundant pool of donors, or if the priority should only focus on extremely high quality donors. The tone of the Committee during this discussion was to err on the side of a higher DPI, to make sure adequate access for pediatric kidney candidates is achieved. This is something that will need further discussion at the Working Group level, to frame the argument for the DPI value that the Committee ultimately decides to recommend.

Another concept discussed during the teleconference was the idea of regionally sharing kidneys for pediatrics as 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. It is thought that the volume of pediatric candidates on the waiting list would make that group an ideal starting point.

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 to ponder and address these pursuits. The Working Group's next teleconference will focus on pertinent issues that should be included in a memorandum sent to the Kidney Committee seeking their input as to what is needed to make progress towards these initiatives.

Status of Liver and Intestinal Organ Allocation Policy Review

- *February 24th Teleconference- ABO-incompatible Liver Transplants: Requirements and Allocation*

Heung Bae Kim, MD, at large member of the Committee and cross over representative to the Liver and Intestinal Organ Transplantation Committee (the Liver Committee), led the discussion and updated the Committee on the outcome of this teleconference. Call participants discussed the current requirements to be eligible for an ABO-incompatible liver transplant. This conversation evolved in response to concerns expressed by members of the Committee and Liver Committee that certain candidates, who would be appropriate for an ABO-incompatible liver transplant, do not appear on match runs due to screening as a result of the current policy requirements. Committee members on the teleconference felt that these patients should appear on the match, and this should be achieved in as simple a manner as possible. Accordingly, the Working Group unanimously supported eliminating the status requirements for an ABO-incompatible liver transplant. 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. There were no objections to this approach from the remainder of the Committee, and it agreed with sending a memorandum to the Liver Committee to communicate this recommendation.

- *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*

Dr. Cherikh presented data to the Committee for 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 liver-intestine alone candidates aged 0-11 was significantly lower during the post-policy period (6/20/07-10/31/09) (Note that RR 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 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 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 liver-intestine alone recipients transplanted in PELD 25+ or status 1B increased.
- Percent of 0-11 liver-intestine recipients transplanted in PELD 25+ and status 1B increased, while percent of adult recipients transplanted in MELD 15-24 and 25+ increased.

There was little follow-up discussion after the presentation of these data. The Chair did comment that the fall in the mortality rate on the waiting list for those in need of a liver and intestine may be related to advances and changes in clinical practice.

- *Number of Deceased Donors between 18 and 21 Years of Age*
 During its December 2009 meeting, the Committee discussed a suggestion to establish a donor age cut-off at which livers could be split and prioritized for young pediatric recipients. In order to help the Committee determine an appropriate age cut-off, the Committee requested data on the number of donors between 18 and 21 years old. Dr. Cherkh presented this information based on OPTN data as of November 27, 2009. To summarize:
 - There were 2,086 deceased donors, 1,907 deceased liver donors and 1,805 transplanted deceased liver donors aged 18-34 recovered in 2008.
 - During the same period, there were 662 deceased donors, 613 deceased liver donors and 592 transplanted deceased liver donors aged 18-21 recovered.

The Committee felt that the number of potential liver donors 21 years of age or less would provide a large enough pool of potentially splittable livers if pediatric candidates willing to accept a left lateral segment were prioritized after regional Status 1 potential transplant recipients. Donors 21 years of age and less is also the age range of donors that the Liver Committee had agreed would be acceptable and appropriate when it discussed the concept of this split liver policy modification. Accordingly, 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.

Status of Thoracic Organ Allocation Policy Review

- *Evaluation of Pediatric Heart Status 1A Criteria- Jan 29th , Feb 26th Teleconferences*

Steve Webber, MB, ChB, at large member of the committee and cross over representative to the Thoracic Organ Transplantation Committee (Thoracic Committee), provided the Committee with an update from these teleconferences. These meetings consist of the Committee’s Thoracic Working Group and the Thoracic Committee’s Heart Subcommittee. The problem being addressed is that a majority of pediatric candidates, infants in particular, are being transplanted at Status 1A. What has emerged is a system that was intended to be driven by urgency has now reverted to a system dependent upon waiting time. The three options were seen as 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.

Dr. Webber also mentioned discussions had during these teleconferences regarding ABO-incompatible heart candidates. When modifications (that are currently in the process of being implemented) were first approved, there was a significant level of apprehension regarding the long term success of these transplants, as the science at the time was relatively novel. As numerous years have passed, this procedure is proving to be a safe and effective treatment. Accordingly, the data indicate that appropriate pediatric candidates would stand to benefit from an increased priority for ABO-incompatible hearts as compared to the current system where they fall at the end of the match run. There was some desire to include an increased priority for ABO-incompatible potential transplant recipients within the implementation of the current project; however, this would completely remove this project from the current schedule of work. Instead of indefinitely delaying any changes, the Pediatric and Thoracic Committees thought it was prudent to complete the current project and try to incorporate modifications reflecting more recent science after its implementation.

A Committee member asked if there were any discussions occurring regarding heart/lung allocation. Dr. Webber informed the Committee of a discussion had a day earlier at the Thoracic Committee meeting addressing this exact topic. The Thoracic Committee is concerned with the ambiguity in policy regarding multi-organ allocations, particularly heart/lung allocations. There is a desire on the Thoracic Committee's part to address this matter in the immediate future, and representation from the Committee should be included in those discussions. Dr. Horslen interjected that this is an issue not exclusive to the Thoracic Committee, but touches the majority of the Committees. Dr. Webber indicated that for the heart/lung issues in particular, the Thoracic Committee should drive the effort, but it will be imperative that this Committee provides its thoughts and insights. Considering hesitancy in the past to address these matters because of the impression that other Committees were, and the lack of any proposed modifications, the Thoracic Committee feels this issue can no longer be ignored. Members of the Committee concurred, and wanted to express that it feels this is an important issue that needs to be addressed. A Committee member suggested asking the Board if it could advise whether or not multi-organ transplantation is actively being pursued by any Committee and what the timeline is for it to be addressed as the Committee is unaware of any progress on this effort and it is an ongoing concern. Another recommendation suggested also including the Policy Oversight Committee on such a memorandum. Committee members only provided support of such a communication; no Committee member expressed any disagreement.

- *Review proposed changes to Pediatric Status 1A form*

The Committee reviewed mock-up screen shots based on conversations had regarding modifications to the Pediatric Status 1A form. The main change from the current form is

collection of a few more data elements related to mechanical circulatory support (MCS) devices. Not only will the type of MCS be collected, but also the implant date and device type (no device type for ECMO). The Committee agreed that these changes reflected what had been discussed in previous teleconferences, and there were no additional recommended edits.

New Pediatric Specific Data Elements

In March 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. To summarize the data presented by Dr. Cherkh:

- 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.

Dr. Horslen said it’s hard to imagine how those following up pediatric candidates do not have developmental assessments. He wondered if it was a case of the development not being explicitly commented upon, and data coordinators assume it is not available accordingly. It might be helpful to look at center response rates to see if there is an educational opportunity to address this lack of data. Another Committee member indicated that some of these data are not necessarily readily accessible considering source document for follow-up. “Not assessed” is commonly entered if there is no explicit note in the source documentation, e.g. when certain developmental aspects are normal and not denoted accordingly.

Pediatric Experience Requirements for Primary Physicians and Surgeons at Pediatric Programs

The Committee was made aware of an anonymous memo in which the Chair was copied. The memorandum called into question the experience and qualifications of a recently appointed director of a transplant program at a children’s hospital. This memorandum was used to illustrate to the Committee that the bylaws lack requirements with regard to pediatric experience for leadership positions at pediatric centers. The Committee liaison has been made aware that the Membership and Professional Standards Committee (MPSC) is interested in investigating and working towards establishing some sort of pediatric experience requirements for primary surgeons/physicians at transplant programs that predominately serve pediatric patients. The MPSC is interested in this issue as it has received numerous applications for these positions at predominately pediatric

centers; however, the applicant has little to no pediatric experience. As this specificity is not indicated in the bylaws, these applications are approved assuming all other requirements are met. There is an underlying concern regarding the lack of pediatric experience in these leadership positions at some pediatric transplant programs. Although the memo addresses a program director (of which there is no immediate plan to develop requirements for adults or pediatric programs) the memorandum was shared with the Committee to introduce this matter, and so Committee members could begin to think of experience requirements or other possible solutions for this issue. More in depth conversations are anticipated as the MPSC engages the Committee.