OPTN/UNOS Pediatric Transplantation Committee
Summary

Action Items for Board Consideration

- The Board is asked to approve modifications to Policies 3.7.5 (Allocation of Adolescent Donor Hearts to Pediatric Heart Candidates) and 3.7.10.1 (Sequence of Adolescent Donor Heart Allocation), which incorporate all pediatric donor hearts into the current adolescent algrothim and share these hearts more broadly to the sickest candidates to reduce pediatric waiting list mortality. (Item 1, Page 3)

- The Board is asked to approve modifications to Policies 3.7.6.2 (Candidates Age 0-11), 3.7.11 (Sequence of Adult Donor Lung Allocation), and 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation), which will allow the creation of a stratified allocation system for 0-11year-old lung candidates to improve access to organs for the sickest candidates by more broadly sharing young pediatric donor lungs to reduce pediatric waiting list mortality. (Item 2, Page 5)

- The Board is asked to approve modifications to Policies 3.6 (Allocation of Livers) and 3.11.4.2 (Combined Liver-Intestinal Organs from Donors 0-10 Years of Age), which will extend offers nationally to all 0-11 year old Status 1A pediatric liver and combined liver-intestine candidates before making local adult Status 1A offers for the 0-10 donor age group in order to reduce pediatric waiting list mortality. (Item 3, Page 17)

Other Significant Items

- The Committee discussed OPTN Final Rule requirements for organ allocation policy development. (Item 4, Page 24)
    - Thoracic organ allocation. (Item 4a, Page 24)
    - Liver and intestinal organ allocation. (Item 4b, Page 24)
    - Kidney allocation. (Item 4c, Page 28)
    - Pancreas allocation. (Item 4d, Page 35)

- The Committee reviewed the ten proposals out for public comment and provided feedback. (Item 5, Page 36)

- The Committee received an update regarding the Joint Pediatric-OPO Subcommittee Call held in January 2008. (Item 6, Page 37)

- The Chair acknowledged committee member participation in addressing the charge to reduce pediatric waiting list deaths. (Item 7, Page 38)

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

Richmond, Virginia
June 19-20, 2008

Stuart C. Sweet, MD, PhD, Chair
Simon Horslen, MB, ChB, Vice Chair

The following report presents the OPTN/UNOS Pediatric Transplantation Committee's deliberations and recommendations on matters considered during its March 6, 2008, and April 24, 2008, meetings.

1. Request for Broader Sharing of Pediatric Donor Hearts. The Committee's joint proposal with the Thoracic Organ Transplantation Committee for broader sharing of pediatric donor hearts was offered for public comment in February 2008. This proposal was one of a series related to the Committee's 2006 charge to reduce the number of deaths on the pediatric organ transplant waiting lists. In keeping with the Final Rule, the common theme is to allocate organs from young pediatric donors more broadly to facilitate offers first to candidates at the highest risk of waiting list mortality, without negatively impacting adolescents or adults. The intent of the policy change is to incorporate all pediatric donor hearts into the current adolescent algorithm and share all pediatric donor hearts more broadly by combining local and Zone A offers for Status 1A candidates and for Status 1B candidates respectively. The Committee began preliminary review of the public comment feedback during its April 24, 2008, meeting. The proposal, all comments, and the Committee's responses are included in the briefing paper, attached as **Exhibit A**.

   A single motion was made during the April 24 Committee meeting to authorize the appropriate organ specific working group in conjunction with the Joint Pediatric-Thoracic or Joint Pediatric-Liver-Intestine Subcommittee to address all public comments and make any necessary modifications to proposed policy language for each of the three proposals (heart, lung and liver/liver-intestine) prior to final review by the sponsoring committees. The Committee voted unanimously in support of this motion (16 in favor, 0 opposed, 0 abstentions).

   The Pediatric Committee's Heart-Lung Working Group and members of the Thoracic Committee's Heart and Lung Subcommittees met as a Joint Subcommittee by teleconference for a final review of all submitted feedback on May 22, 2008. Overall feedback regarding this proposal was positive, and the Policy Oversight Committee (POC) was supportive of the proposal. A POC member noted that, in general, the terms "pediatric" and "adolescent" are defined differently across all of the organ allocation policies. He questioned why a pediatric organ donor is defined as an individual who is 0-17 years of age, and noted that changing the definition to 'an individual who is less than 18 years of age' would be more precise. The sponsoring committees appreciated this feedback and accepted the POC's suggested changes to language in Policy 3.7.5 that define a pediatric organ donor as an individual who is less than 18 years of age. This is an issue that will be addressed more broadly in the policy re-write project managed within the UNOS Department of Policy, Membership and Regional Administration.

   The Committees received an extensive individual comment, outlining concerns regarding the local impact on broader sharing within a region that loses a number of pediatric donors due to Medical Examiner or Coroner turndowns. The Committees appreciated the concerns regarding the importance of working with Medical Examiners and/or Coroners to ensure a higher yield of pediatric donor organs; however, these concerns were seen as parallel but not directly related to the issue of broader sharing in order to reduce waiting list deaths. The Committees welcomed the information provided

and will use this feedback to address the medical examiner/coroner concerns separately. Joint Subcommittee members agreed with the idea of taking every occasion to ensure opportunities for transplant, but do not believe that the potential benefit of the changes in this proposal should be delayed while a plan is developed to reduce organ loss due to medical examiner/coroner concerns.

The AST Pediatric Community of Practice Executive Committee and the AST Executive Committee reviewed the proposal and supported it as written without additional comment.

Upon completion of its review of the public comment feedback, Joint Subcommittee members voted unanimously (10 support, 0 oppose, 0 abstentions) to send the proposal to the Board of Directors for consideration in June 2008.

The Committee, therefore, offers the following recommendations for consideration by the Board of Directors:

****RESOLVED, that the following modifications to Policies 3.7.5 (Allocation of Adolescent Donor Hearts to Pediatric Heart Candidates) and 3.7.10.1 (Sequence of Adolescent Donor Heart Allocation) having been distributed for public comment, and subsequently recommended by the Pediatric and Thoracic Organ Transplantation Committees, shall be approved and implemented pending distribution of appropriate notice and programming in UNet^{SM}:**

3.7.5 Allocation of ~~Adolescent~~ Pediatric Donor Hearts to Pediatric Heart Candidates. Within each heart status, a heart retrieved from a~~n~~ ~~adolescent~~ pediatric organ donor shall be allocated to a pediatric heart candidate (i.e., less than 18 years old at the time of listing) before the heart is allocated to an adult candidate. For the purpose of Policy 3.7, a~~n~~ ~~adolescent~~ pediatric organ donor is defined as an individual who is ~~11 years of age or older, but less than 18~~ ~~0-17~~ less than 18 years of age.

3.7.10.1 Sequence of ~~Adolescent~~ Pediatric Heart Allocation. ~~Donor~~ ~~h~~Hearts recovered from ~~adolescent~~ pediatric donors shall be allocated in the following sequence in accordance with Policies 3.7.3, 3.7.4, 3.7.5, 3.7.7, 3.7.8, and 3.7.9:

1. Combined Local **and** Zone A Status 1A Pediatric candidates
~~2.~~ ~~Zone A Status 1A Pediatric candidates~~
~~3.~~2. Local Status 1A Adult candidates
~~4.~~3. Combined Local **and** Zone A Status 1B Pediatric candidates
~~5.~~ ~~Zone A Status 1B Pediatric candidates~~
~~6.~~4. Local Status 1B Adult candidates
~~7.~~5. Zone A Status 1A Adult candidates
~~8.~~6. Zone A Status 1B Adult candidates
~~9.~~7. Local Status 2 Pediatric candidates
~~10.~~8. Local Status 2 Adult candidates
~~11.~~9. Zone B Status 1A Pediatric candidates
~~12.~~10. Zone B Status 1A Adult candidates
~~13.~~11. Zone B Status 1B Pediatric candidates

~~14.~~12. Zone B Status 1B Adult candidates
~~15.~~13. Zone A Status 2 Pediatric candidates
~~16.~~14. Zone A Status 2 Adult candidates
~~17.~~15. Zone B Status 2 Pediatric candidates
~~18.~~16. Zone B Status 2 Adult candidates
~~19.~~17. Zone C Status 1A Pediatric candidates
~~20.~~18. Zone C Status 1A Adult candidates
~~21.~~19. Zone C Status 1B Pediatric candidates
~~22.~~20. Zone C Status 1B Adult candidates
~~23.~~21. Zone C Status 2 Pediatric candidates
~~24.~~22. Zone C Status 2 Adult candidates
~~25.~~23. Zone D Status 1A Pediatric candidates
~~26.~~24. Zone D Status 1A Adult candidates
~~27.~~25. Zone D Status 1B Pediatric candidates
~~28.~~26. Zone D Status 1B Adult candidates
~~29.~~27. Zone D Status 2 Pediatric candidates
~~30.~~28. Zone D Status 2 Adult candidates
~~31.~~29. Zone E Status 1A Pediatric candidates
~~32.~~30. Zone E Status 1A Adult candidates
~~33.~~31. Zone E Status 1B Pediatric candidates
~~34.~~32. Zone E Status 1B Adult candidates
~~35.~~33. Zone E Status 2 Pediatric candidates
~~36.~~34. Zone E Status 2 Adult candidates

2. Request for Broader Sharing of Pediatric Donor Lungs and a Stratified Allocation System for 0-11 year-old Candidates. The Committee's joint proposal with the Thoracic Organ Transplantation Committee for broader sharing of pediatric donor hearts was offered for public comment in February 2008. This proposal was one of a series related to the Committee's 2006 charge to reduce the number of deaths on the pediatric organ transplant waiting lists. In keeping with the Final Rule, the common theme is to allocate organs from younger pediatric donors more broadly to ensure that they are offered first to candidates at the highest risk of waiting list mortality, without negatively impacting adolescents or adults. The Committee began preliminary review of the public comment feedback during its April 24, 2008, meeting. The proposal, all comments, and the Committee's responses are included in the briefing paper, attached as **Exhibit B.**

   A single motion was made during the April 24 Committee meeting to authorize the appropriate organ specific working group in conjunction with the Joint Pediatric-Thoracic or Joint Pediatric-Liver-Intestine Subcommittee to address all public comments and make any necessary modifications to proposed policy language for each of the three proposals (heart, lung and liver/liver-intestine) prior to final review by the sponsoring committees. The Committee voted unanimously in support of this motion (16 in favor, 0 opposed, 0 abstentions).

   The Pediatric Committee's Heart-Lung Working Group and members of the Thoracic Committee's Heart and Lung Subcommittees met as a Joint Subcommittee by teleconference for a final review of all submitted feedback on May 22, 2008. Overall feedback regarding this proposal was positive. The POC observed this policy to be clearly written, well-organized, and meeting several of the objectives of the Final Rule. Though no modeling was used in its development, the Committee considered a great deal of data during the policy development process. The POC supported the proposal, but noted that it would impact a very small number of candidates.

The AST Pediatric Community of Practice Executive Committee and the AST Executive Committee reviewed the policy proposal and made several recommendations for improvement. The Joint Subcommittee appreciated this feedback and provided the following responses to each comment outlined:

- Add arterial blood pH as addition criteria to blood pCO_2 for Status 1 qualification.
  - Language to include venous blood pH will be added as a third option alongside arterial or capillary PCO_2 for Status 1 qualification. See revised policy language at the end of this document.

- Suggest that centers be mandated to update the candidate's information within 72 hours of any significant change in the candidate's clinical condition to prevent a patient in TEMPORARY deterioration from staying at Status 1 even when improved.
  - The sponsoring committees agreed that a requirement for updating status information within 72 hours of any clinically significant change in condition is not consistent with other areas of thoracic policy, particularly the LAS. The Thoracic Organ Transplantation Committee is scheduled to work with the Policy Oversight Committee on reviewing and revising all thoracic policy language as a whole in November 2008. This issue will be addressed as part of the rewrite for all lung policy; a requirement (for all thoracic policies) to update patient information between 24 and 72 hours following change in condition is anticipated. In the interim, the Joint Subcommittee is supportive of following the model set forth in the Lung Allocation Score (LAS) policy for adolescents and adults (i.e. allowing programs to update their candidates' clinical data at any time they believe a change in candidate medical condition warrants such modification but requiring updates at least once every six months). If at any time, more than six months have elapsed since the last six-month "anniversary" date of the candidate's initial listing without an update, then the candidate's status will automatically revert to Status 2. This will be clearly stated in the revised policy language.

- Where the proposal states "2 drugs" for status classification, we suggest a better definition for what constitutes a "drug" for antipulmonary hypertensive therapy number (i.e. is supplemental oxygen considered a drug?) and clearly delineate if there are restrictions on route of administration. Alternatively, since there is not a preponderance of good evidence to suggest that combination therapy in this age group is necessarily beneficial, the wording could state "maximal attempts at medical therapy." This should then be accompanied by some more detailed guidelines for what maximal might mean as it is fairly unlikely that a candidate with pulmonary hypertension, with the myriad of good agents now available, would actually go to transplantation prior to having been tried on various therapies.
  - The sponsoring committees discussed concerns related to refractory pulmonary hypertension (PH) and maximal medical therapy at length and agreed with the concerns raised about the "2 drug" language. This clause has been revised in the proposed policy language (see below), and the committees agreed that the implementation plan would require centers choosing this criteria for Status 1 to support an assertion that PH is refractory by identifying on the form one or more of the medical therapies that the patient has received. (If no therapies on this list have been tried but the center still wishes to list at Status 1, the center will be required to submit an exceptional case request for prospective approval by the Lung Review Board).

- Outline how and when to re-evaluate the new system to ensure that goals are met and if any unintended consequences are occurring.
    - The Pediatric Transplantation Committee will review data every six months to evaluate the policy changes with the following questions in mind to determine whether or not the proposal is meeting its intended goals:
        - Have pediatric death rates on the lung waiting list decreased since policy change?
        - Have adolescent and adult death rates on the lung waiting list increased since policy change?
        - Have pediatric transplant rates on the lung waiting list increased since policy implementation?
        - Have adolescent and adult transplant rates on the lung waiting list decreased since policy change?
        - Are there more 0-11 lungs being utilized after policy change?
        - Have number and percent of 0-11 lung transplants increased since policy change?
        - Have number and percent of adult or adolescent lung transplants decreased since policy change?
        - Has post-transplant survival changed since policy change?

UNOS' Department of Evaluation and Quality submitted a memo seeking clarification from the Pediatric and Thoracic Organ Transplantation Committees regarding the proposed language for Status 1 candidates to make certain that requirements are monitored in a way that is consistent with the Committees' intent (**Exhibit C**). The Joint Subcommittee considered the three questions specifically posed during its May 22 conference call.

1. To qualify for Status 1 under Respiratory Failure, the candidate may be on supplemental oxygen > FiO_2 50% to maintain oxygen saturation levels > 90%. How should staff interpret this requirement if the candidate is on a nasal cannula or partial non-rebreather and the output has not been analyzed?

   If staff apply the formula previously recommended by the Thoracic Committee to convert FiO2 to LPM, 50% would convert to 9.6667 LPM [(50% - 21%) / (3% per liter) = 9.6667 LPM]. Does the Committee intend for candidates to receive 10 LPM or greater in order to qualify as a Status 1?

   - ➢ The Joint Subcommittee supported staff using the formula recommended by the Thoracic Committee to convert LPM to a %. If the % were > 50% the candidate would qualify.

2. To qualify for Status 1 under Respiratory Failure, the candidate may have an Arterial or Capillary PCO2 > 50 mmHg. How should staff interpret this requirement if the candidate has a venous blood gas drawn? Would a venous PCO2 > 56 mmHg meet the requirement to qualify as a Status 1?

   - ➢ The Joint Subcommittee supported the inclusion of venous blood gas results as an option for Status 1 qualification. (This issue was also raised by the AST.)

3. To qualify for Status 1 under Refractory Pulmonary Hypertension, the candidate may have treatment failure while on 2 or more drugs for pulmonary hypertension. Can the Committees clarify what is considered a drug in this instance? Would oxygen be considered a drug?

   - This issue was resolved as noted above in the response to the AST, with the suggestion to require centers choosing the "Refractory Pulmonary Hypertension" criteria for Status 1 to provide supportive evidence by identifying on a form one or more of the medical therapies that the patient has received. DEQ staff will work with the heart/lung working group to create a list of appropriate medical therapies for the justification form.

The Joint Subcommittee also briefly discussed how tie breakers would be held for candidates with identical status. Acknowledging the precedent set in Policy 3.7.9.1 (Waiting Time Accrual for Heart Candidates), the Joint Subcommittee agreed that Status 1 lung candidates would be stratified by determining who has been listed as a Status 1 the longest. Total active waiting time accrued would be used as a tie breaker between Status 1 candidates who have been listed as Status 1 candidates for the same amount of time. Joint Subcommittee members were supportive of this approach.

The Transplant Coordinators Committee supported the proposal unanimously, but suggested monitoring of older cystic fibrosis candidates with disease-related growth retardation to ensure that allocation is fairly handled. As a result, the Committee requested data to assess outcomes for 12-17 year old lung candidates with cystic fibrosis versus younger candidates with the same diagnosis both pre- and post lung allocation system implementation. Information regarding rate of transplant and waitlist mortality was requested for each of these two age groups.

Based on feedback received from public comment and DEQ Staff, several minor changes were made to the Policy 3.7.6.2 modifications that were submitted for public comment. Additional policy language was also created under Policy 3.7.9 (Time Waiting for Thoracic Organ Candidates) to specifically outline how tie breaker situations should be handled for candidates with the same amount of time accrued at Status 1 at the time of an offer. No additional changes were made to the Policy 3.7.11 modifications as a result of public comment.

Upon completion of its review of the public comment feedback, Joint Subcommittee members voted unanimously (9 support, 0 oppose, 0 abstentions) to send the proposal to the Board of Directors for consideration in June 2008. Final policy language will be shared with both the Pediatric and Thoracic Organ Transplantation Committees prior to the Board meeting.

The Committee, therefore, offers the following recommendations for consideration by the Board of Directors:

****RESOLVED, that the following modifications to Policies 3.7.6.2 (Candidates Age 0-11), 3.7.11 (Sequence of Adult Donor Lung Allocation) and 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation) having been distributed for public comment, and subsequently recommended by the Pediatric and Thoracic Organ Transplantation Committees, and the addition of Policy 3.7.9.3 (Waiting Time Accrual for Lung Candidates Less than 12 Years of Age) shall be approved and implemented pending distribution of appropriate notice and programming in UNet^{SM}:**

3.7.6.2 <u>Candidates Age 0 - 11</u>. Candidates 0 – 11 years old are assigned priority for lung offers ~~based upon waiting time.~~ <u>according to the status</u>

categories defined below. (See Policy 3.7.6.1 for lung allocation to candidates 12 years of age and older.) Within each status, candidates will be ranked by ABO according to Policy 3.7.8.2 and then by waiting time. Status 1 candidates will be ranked in descending order according to the length of time waiting at that status. For Status 2 candidates, total active waiting time (defined for this purpose as beginning when the candidate was added to the waiting list and ending when the lung match run was generated) will be used to rank candidates on the match run.

Clinical data used to justify a candidate's status may be updated at any time a program believes a candidate's medical condition warrants such modifications. Programs must update every candidate variable, except those candidate variables that are obtained only by heart catherization, for Status 1 candidates, at least once every six months after initial listing on the lung waiting list. If at any time, more than six months have elapsed since the last six month "anniversary" date of the candidate's initial listing without an update, then the candidate's status will automatically revert to Status 2.

If multiple candidates have accrued the same amount of time waiting as Status 1, these candidates' total active waiting time will be used to determine priority on the match run for receiving lung offers. The total waiting time is the amount of time spent waiting as a Status 1 *and* Status 2.

Status 1: candidates with one or more of the following criteria:

- **Respiratory failure, defined as:**
  - Requiring continuous ~~Full time~~ mechanical ventilation;

  or,
  - Requiring supplemental oxygen delivered by any means to achieve FiO_2 greater than 50% ~~necessary~~ in order to maintain oxygen saturation levels greater than 90%;

  or,
  - Having an arterial or capillary PCO_2 greater than 50 mmHg, or a venous PCO_2 greater than 56mmHg.
- ~~**Refractory**~~ **Pulmonary hypertension, defined as:**
  - ~~Medical treatment failure (any~~ Exhibiting any of the following, in spite of medical therapy: suprasystemic PA pressure on cardiac catheterization or by echocardiogram estimate, cardiac index less than 2 L/min/M^2, recurrent syncope, or hemoptysis~~) while on 2 or more drugs for pulmonary hypertension~~

    Examples of accepted medical therapy for pulmonary hypertension will be listed in UNet^{SM}. Transplant centers must indicate which

of these medical therapies the candidate has received. If the candidate has not received any of the listed therapies, the transplant center must submit an exception request to the Lung Review Board for prospective consideration.

or,

- ~~Candidates with~~ Having pulmonary vein stenosis involving 3 or more vessels.

- **Exceptional cases by prospective submission to the Lung Review Board**

Status 2: ~~all c~~Candidates who do not meet the criteria for Status 1 ~~will~~ must be listed as Status 2.

3.7.9.3 Waiting Time Accrual for Lung Candidates Less than 12 Years of Age. Candidates listed as a Status 1 or Status 2 will accrue waiting time within each status. When waiting time is used for thoracic organ allocation, a candidate will receive a preference over other candidates who have accumulated less waiting time within the same status category (see Policy 3.7.9). However, a candidate's waiting time accrued while listed as Status 2 will not be used in prioritizing the candidate for lung allocation if the candidate is upgraded to Status 1.

If multiple candidates have accrued the same amount of time waiting as Status 1, these candidates' total active waiting time will be used to determine priority on the match run for receiving lung offers. The total accrued waiting time is the amount of time spent waiting as a Status 1 *and* Status 2.

3.7.11 **Sequence of Adult Donor Lung Allocation.** Candidates age 12 and older awaiting a lung transplant whether it is a single lung transplant or a double lung transplant will be grouped together for adult (18 years old and older) donor lung allocation. If one lung is allocated to a candidate needing a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from adult donors will first be offered to candidates age 12 and older, and then to candidates 0 – 11 years old. Lungs from adult donors will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D and finally to candidates in Zone E. In each of those six geographic areas, candidates will be grouped so that candidates who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical type,

they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor.

In summary, the allocation sequence for adult donor lungs is as follows:

~~i.~~ 1. ~~First locally to~~ Local ABO identical candidates age 12 and older according to Lung Allocation Score in descending order;

~~ii.~~ 2. ~~Next, locally to~~ Local ABO compatible candidates age 12 and older according to Lung Allocation Score in descending order;

~~iii.~~ 3. ~~Next, locally to~~ Local ABO identical Status 1 candidates 0 – 11 years old according to length of waiting time;

~~iv.~~ 4. ~~Next, locally to~~ Local ABO compatible Status 1 candidates 0 – 11 years old according to length of waiting time;

~~v.~~ 5. Local ABO identical Status 2 candidates 0 – 11 years old according to length of waiting time;

~~vi.~~ 6. Local ABO compatible Status 2 candidates 0 – 11 years old according to length of waiting time;

~~vii.~~ 7. ~~Next, to~~ ABO identical candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;

~~viii.~~ 8. ~~Next, to~~ ABO compatible candidates age 12 and older in Zone A according to Lung Allocation Score in descending order;

~~ix.~~ 9. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone A according to length of waiting time;

~~x.~~10. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone A according to length of waiting time;

~~xi.~~11. ABO identical Status 2 candidates 0 – 11 years old in Zone A according to length of waiting time;

~~xii.~~12. ABO compatible Status 2 candidates 0 – 11 years old in Zone A according to length of waiting time;

~~xiii.~~13. ~~Next, to~~ ABO identical candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;

~~xiv.~~14. ~~Next, to~~ ABO compatible candidates age 12 and older in Zone B according to Lung Allocation Score in descending order;

~~xv.~~15. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone B according to length of waiting time;

~~xvi.~~16. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone B according to length of waiting time;

~~xvii.~~17. ABO identical Status 2 candidates 0 – 11 years old in Zone B according to length of waiting time;

~~xviii.~~18. ABO compatible Status 2 candidates 0 – 11 years old in Zone B according to length of waiting time;

~~xix.~~19. ~~Next, to~~ ABO identical candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;

~~xx.~~20. ~~Next, to~~ ABO compatible candidates age 12 and older in Zone C according to Lung Allocation Score in descending order;

~~xxi.~~21. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone C according to length of waiting time;

~~xxii.~~22. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone C according to length of waiting time;

~~xxiii.~~23. ABO identical Status 2 candidates 0 – 11 years old in Zone C according to length of waiting time;

~~xxiv.~~24. ABO compatible Status 2 candidates 0 – 11 years old in Zone C according to length of waiting time;

~~xxv.~~25. ~~Next, to~~ ABO identical candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;

~~xxvi.~~26. ~~Next, to~~ ABO compatible candidates age 12 and older in Zone D according to Lung Allocation Score in descending order;

~~xxvii.~~27. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone D according to length of waiting time;

~~xxviii.~~28. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone D according to length of waiting time~~.~~;

~~xxix.~~29. ABO identical Status 2 candidates 0 – 11 years old in Zone D according to length of waiting time;

~~xxx.~~30. ABO compatible Status 2 candidates 0 – 11 years old in Zone D according to length of waiting time;

~~xxxi.~~31. ~~Next, to~~ ABO identical candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;

~~xxxii.~~32. ~~Next, to~~ ABO compatible candidates age 12 and older in Zone E according to Lung Allocation Score in descending order;

~~xxxiii.~~33. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone E according to length of waiting time; and

~~xxxiv.~~34. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone E according to length of waiting time.

~~xxxv.~~35. ABO identical Status 2 candidates 0 – 11 years old in Zone E according to length of waiting time;

~~xxxvi.~~36. ABO compatible Status 2 candidates 0 – 11 years old in Zone E according to length of waiting time;

3.7.11.1 **Sequence of Pediatric Donor Lung Allocation**. Candidates 0 – 11 years old awaiting a single or double lung transplant will be grouped together for allocation purposes. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant

Candidates 12 – 17 years old awaiting a single or double lung transplant will be grouped together for pediatric (0 – 17 years old) donor lung allocation. If one lung is allocated to a candidate waiting for a single lung transplant, the other lung will be then allocated to another candidate waiting for a single lung transplant.

Lungs from donors 0 – 11 years old will first be offered to candidates age 0 – 11; then to candidates age 12 – 17; then to candidates 18 years and older. ~~Lungs will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D, and finally to candidates in Zone E. In each of those six geographic areas, c~~Candidates will be grouped so that ~~candidates~~ those who have an ABO blood type that is identical to that of the donor are ranked according to applicable allocation priority; the lungs will be allocated in descending order to candidates in that ABO identical type. If the lungs are not allocated to candidates in that ABO identical

type, they will be allocated in descending order according to applicable allocation priority to the remaining candidates in that geographic area who have a blood type that is compatible (but not identical) with that of the donor.

- Offers for 0-11 year-olds will first be made to **combined** local, Zone A and Zone B candidates by status and waiting time. After adolescent and adult offers are completed through Zone B, offers will continue to these younger candidates in Zones C, D and E prior to adolescents and adults within in each zone.

- Offers for 12-17 year-olds will first be made to **combined** local and Zone A candidates according to lung allocation score in descending order after the completion of 0-11 year-old offers through Zone B. Once adult Zone A offers are completed, offers will continue to adolescent candidates in Zones B, C, D and E after the younger 0-11 candidates and before the adult candidates within each zone.

- Offers to adult candidates (18 years and older) will be made after the completion of 0-11 year old offers through Zone B and adolescent offers through Zone A. After local and Zone A adult offers are completed, offers will continue in Zones B, C, D and E after the completion of all pediatric offers within each zone.

In summary, the allocation sequence for lungs from donors 0-11 years old is as follows:

~~i. First locally to ABO identical candidates 0 – 11 years old according to length of time waiting;~~
~~ii. Next, locally to ABO compatible candidates 0 – 11 years old according to length of time waiting;~~
1. Combined local, Zone A and Zone B ABO identical Status 1 candidates 0-11 years old according to length of waiting time;
2. Combined local, Zone A and Zone B ABO compatible Status 1 candidates 0-11 years old according to length of waiting time;
3. Combined local, Zone A and Zone B ABO identical Status 2 candidates 0-11 years old according to length of waiting time;
4. Combined local, Zone A and Zone B ABO compatible Status 2 candidates 0-11 years old according to length of waiting time;
5. Combined local and Zone A ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;
6. Combined Local and Zone A ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;
~~iii. Next, locally to ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;~~
~~vii. Next, locally to ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;~~

~~viii.~~7. ~~Next, locally to~~ Local ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;

~~ix.~~ 8. ~~Next, locally to~~ Local ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;

~~vii. Next, to ABO identical candidates 0 – 11 years old in Zone A according to length of time waiting;~~

~~viii. Next, to ABO compatible candidates 0 – 11 years old in Zone A according to length of time waiting;~~

~~ix. Next, to ABO identical candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;~~

~~x. Next, to ABO compatible candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;~~

~~x.~~9. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;

~~xi.~~10. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;

~~xiii. Next, to ABO identical candidates 0 – 11 years old in Zone B according to length of time waiting;~~

~~xiv. Next, to ABO compatible candidates 0 – 11 years old in Zone B according to length of time waiting;~~

~~xii.~~11. ~~Next, to~~ ABO identical candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;

~~xiii.~~12. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in Zone B according to Lung Allocation Score in descending order;

~~xiv.~~13. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;

~~xv.~~14. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;

~~xvi.~~15. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone C according to length of time waiting;

~~xvii.~~16. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone C according to length of time waiting;

~~xviii.~~17. ABO identical Status 2 candidates 0-11 years old in Zone C according to length of waiting time;

18. ABO compatible Status 2 candidates 0-11 years old in Zone C according to length of waiting time;

~~xx.~~19. ~~Next, to~~ ABO identical candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;

~~xxi.~~20. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in Zone C according to Lung Allocation Score in descending order;

~~xxii.~~21. ~~Next, to~~ ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;

~~xxiii.~~22. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;

~~xxiv.~~23. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone D according to length of time waiting;

~~xxvi.~~24. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone D according to length of time waiting;

25. ABO identical Status 2 candidates 0-11 years old in Zone D according to length of waiting time;

26. ABO compatible Status 2 candidates 0-11 years old in Zone D according to length of waiting time;

~~xxvii.~~27. ~~Next, to~~ ABO identical candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;

~~xxviii.~~28. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in Zone D according to Lung Allocation Score in descending order;

~~xxix.~~29. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and

~~xxx.~~30. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.

~~xxxi.~~31. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone E according to length of time waiting;

~~xxxii.~~32. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone E according to length of time waiting;

33. ABO identical Status 2 candidates 0-11 years old in Zone E according to length of waiting time;

34. ABO compatible Status 2 candidates 0-11 years old in Zone E according to length of waiting time;

~~xxxv.~~35. ~~Next, to~~ ABO identical candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;

~~xxxvi.~~36. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;

~~xxxvii.~~ 37. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order; and

~~xxxviii.~~38. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order.

Lungs from donors 12 – 17 years old will first be offered to candidate~~-~~s age 12 – 17 years old; then to candidates age 0 – 11; then to candidates 18 years and older. Lungs will be allocated locally first, then to candidates in Zone A, then to candidates in Zone B, then to candidates in Zone C, then to candidates in Zone D and finally to candidates in Zone E.. In each of those six geographic areas, candidates will be grouped so that candidates who have an ABO blood type that is identical to that of the compatible (but not identical) with that of the donor.

In summary, the allocation sequence for lungs from donors 12 – 17 years old is as follows:

~~i.~~1. ~~First locally to~~ Local ABO identical candidates 12 – 17 years old according to Lung Allocation Score in descending order;

~~ii.~~2. ~~Next, locally to~~ Local ABO compatible candidates 12 – 17 years old according to Lung Allocation Score in descending order;

~~iii.~~3. ~~Next, locally to~~ Local ABO identical Status 1 candidates 0 – 11 years old according to length of time waiting;

~~iii.~~4. Local ABO compatible Status 1candidates 0 – 11 years old according to length of time waiting;

5. Local ABO identical Status 2 candidates 0 – 11 years old according to length of time waiting;

6. Local ABO compatible Status 2 candidates 0 – 11 years old according to length of time waiting;

~~vi.~~7. ~~Next, locally to~~ Local ABO identical candidates 18 years old and older according to Lung Allocation Score in descending order;

~~vii.~~8. ~~Next, locally to~~ Local ABO compatible candidates 18 years old and older according to Lung Allocation Score in descending order;

~~viii.~~9. ~~Next, to~~ ABO identical candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;

~~vix.~~10. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in Zone A according to Lung Allocation Score in descending order;

~~x.~~11. ~~Next, to~~ ABO identical Status 1candidates 0 – 11 years old in Zone A according to length of time waiting;

~~xi.~~12. ~~Next, to~~ ABO compatible Status 1candidates 0 – 11 years old in Zone A according to length of time waiting;

~~xii.~~13. ABO identical Status 2 candidates 0 – 11 years old in Zone A according to length of time waiting;

14. ABO compatible Status 2 candidates 0 – 11 years old in Zone A according to length of time waiting;

~~xiv.~~15. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;

~~xv.~~16. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone A according to Lung Allocation Score in descending order;

~~xvi.~~17. ~~Next, to~~ ABO identical candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;

~~xvii.~~18. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in zone B according to Lung Allocation Score in descending order;

~~xviii.~~19. ~~Next, to~~ ABO identical Status 1candidates 0 – 11 years old in Zone B according to length of time waiting;

~~xix.~~20. ~~Next, to~~ ABO compatible Status 1candidates 0 – 11 years old in Zone B according to length of time waiting;

21. ABO identical Status 2 candidates 0 – 11 years old in Zone B according to length of time waiting;

22. ABO compatible Status 2 candidates 0 – 11 years old in Zone B according to length of time waiting;

~~xxii.~~23. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;

~~xxiii.~~24. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone B according to Lung Allocation Score in descending order;

~~xxiv.~~25. ~~Next, to~~ ABO identical candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;

~~xxv.~~26. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in zone C according to Lung Allocation Score in descending order;

~~xxvi.~~27. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone C according to length of time waiting;

~~xxvii.~~28. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone C according to length of time waiting;

29. ABO identical Status 2 candidates 0 – 11 years old in Zone C according to length of time waiting;

30. ABO compatible Status 2 candidates 0 – 11 years old in Zone C according to length of time waiting;

~~xxx.~~31. ~~Next, to~~ ABO identical candidates 18 years old and older old in Zone C according to Lung Allocation Score in descending order;

~~xxxi.~~32. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone C according to Lung Allocation Score in descending order;

~~xxxii.~~33. ~~Next, to~~ ABO identical candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;

~~xxxiii.~~34. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in zone D according to Lung Allocation Score in descending order;

~~xxxiv.~~35. ~~Next, to~~ ABO identical Status 1candidates 0 – 11 years old in Zone D according to length of time waiting;

~~xxxv.~~36. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone D according to length of time waiting;

37. ABO identical Status 2 candidates 0 – 11 years old in Zone D according to length of time waiting;

38. ABO compatible Status 2 candidates 0 – 11 years old in Zone D according to length of time waiting;

~~xxxviii.~~39. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order; and

~~xxxix.~~40. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone D according to Lung Allocation Score in descending order.

~~xxxx.~~41. ~~Next, to~~ ABO identical candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;

~~xxxxi.~~42. ~~Next, to~~ ABO compatible candidates 12 – 17 years old in Zone E according to Lung Allocation Score in descending order;

~~xxxxii.~~43. ~~Next, to~~ ABO identical Status 1 candidates 0 – 11 years old in Zone E according to length of time waiting;

~~xxxxiii.~~44. ~~Next, to~~ ABO compatible Status 1 candidates 0 – 11 years old in Zone E according to length of time waiting**;**

45. ABO identical Status 2 candidates 0 – 11 years old in Zone E according to length of time waiting;

46. ABO compatible Status 2 candidates 0 – 11 years old in Zone E according to length of time waiting;

~~xxxxvi.~~47. ~~Next, to~~ ABO identical candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order; and

~~xxxxvii.~~48. ~~Next, to~~ ABO compatible candidates 18 years old and older in Zone E according to Lung Allocation Score in descending order.

3. Request for Broader Sharing of Pediatric Donor Livers and Combined Liver-Intestine. The Committee's joint proposal with the Liver and Intestinal Organ Transplantation Committee for broader sharing of pediatric donor livers and combined liver-intestine was offered for public comment in February 2008. This proposal was one of a series related to the Committee's 2006 charge to reduce the number of deaths on the pediatric organ transplant waiting lists. In keeping with the Final Rule, the common theme is to allocate organs from young pediatric donors more broadly to ensure that they are offered first to candidates at the highest risk of waiting list mortality, without negatively impacting adolescents or adults. The intent of these policy modifications is to extend offers nationally to all 0-11 year-old Status 1A pediatric liver and combined liver-intestine candidates before

making local adult Status 1A offers for the 0-10 year old donor age group. These changes were meant to build upon the 2005 policy improvements (pediatric Status 1A/1B definitions and regional sharing of pediatric livers). The 0-10 donor age group was specifically chosen because, historically, only 1% of all adults received a liver transplant from donors less than 12 years of age. Most committee, public and regional feedback was favorable for this proposal and the Committee began a preliminary review of comments received up to the date of the meeting. The proposal, all comments, and the Committee's responses are included in the briefing paper, attached as **Exhibit D**.

The POC was supportive of the proposal during its review. A suggestion to clarify which policies must be followed specifically for liver, intestine, or combined liver-intestine should be considered. Staff indicated that a rewrite of all policies is in the early stages with the intent of making them consistent with one another and clearer to the reader.

The AST Pediatric Community of Practice Executive Committee and the AST Executive Committee also reviewed this policy. The AST was supportive, but offered the following comments:

- There is a potential disincentive to the center or region that may also have Status 1A candidate of their own. It was suggested that a liver graft from a 0-11 year old donor should be offered to 1A candidates locally, regionally and nationally in that order so that no 1A candidates dies anywhere in the U.S.
- National sharing of donors aged 0-10 years old should be carried out in the sequence:
    - Pediatric 1A (local-regional-national)
    - Pediatric 1B (local-regional-national)
    - Pediatric liver/liver-intestine by PELD >15
    - Only then to adult recipients

Dr. Sue McDiarmid attended the April 24 Committee meeting as a guest, and applauded members for their work in developing this proposal that will likely reduce the death rate of children on the liver waiting list. She urged the Committee to consider a further modification to the proposed allocation sequence (**Exhibit E**). Dr. McDiarmid suggested that national sharing for older pediatric Status 1A, Adult 1A and Pediatric 1B (12-17 years old) be moved up in the algorithm for 0-10 year old donor livers. These three categories of patients all have a known high risk of death waiting and she suggested that a larger pediatric donor of 10 years old might be suitable for a small adolescent or adult. In keeping with the idea of the broadest possible sharing of pediatric donors into the sickest pediatric and small adult candidates, she suggested similar priority for 11-17 year-old donors. She noted the importance of remembering that on any given day the actual number of candidates listed as Status 1A or 1B is in the order of 15-20 (adults and children).

Dr. McDiarmid continued, suggesting that national sharing of the 0-10 year old pediatric donors to any pediatric candidate aged 0-11 years of age by PELD score, once offers to all pediatric and adult 1A and 1B candidates are exhausted nationally, but before these small donor livers are offered to older children and adults. She suggested that this may outline a more efficient allocation sequence, exhausting small liver donor offers to small recipients nationally. She suggested that she planned on submitting these ideas as a public comment and would also like to share them during the upcoming Region 5 meeting.

Drs. Horslen and Sweet thanked Dr. McDiarmid for her thoughtful consideration and noted that they would take her comments to the Joint Subcommittee for review and consideration. Dr. Horslen suggested engaging the Liver and Intestinal Organ Transplantation Committee in developing this proposal rather than taking it to this group for consideration. A face-to-face joint subcommittee

meeting may be beneficial for this group to discuss. Members believed that it may be easier to come to consensus around a table rather than on the phone.

This proposal focused on 0-10 year old organs. The Committee was uncomfortable with extending the proposal to include 11-17 year old donors. Members advocated working with the Joint Subcommittee to take an active role in developing additional policy modifications for these young children and even adolescents to benefit all Status 1 candidates. Dr. Horslen suggested that addressing the needs of the Status 1A and 1B candidates will then leave the Committee with time to work within the Joint Subcommittee to address the PELD candidates who are competing with adults for organs. He would ultimately like to see more of these children transplanted before rising to the more critical Status 1A or 1B designation.

As authorized by unanimous vote of the full Committee (17 in favor, 0 opposed, 0 abstentions), the Joint Pediatric-Liver and Intestine Subcommittee met by teleconference on May 13, 2008, to review public comment feedback. The Joint Subcommittee agreed that the changes proposed by the AST, Dr. McDiarmid and Region 5 could not be incorporated into the proposal without more careful analysis. Therefore, the committee agreed to recommend to the Board approval of the proposal as written, and suggested exploration of the additional suggestions via the joint subcommittee (the discussion focused on ensuring equal access by standardizing criteria for PELD exceptions) and the Liver and Intestine Committee's subcommittee on broader sharing (specifically in regard to the recommendation for broader sharing of adolescent livers).

The Committees also received an extensive individual comment outlining concerns regarding the local impact on broader sharing within a region that loses a number of pediatric donors due to Medical Examiner or Coroner turndowns. The Committees appreciated the concerns regarding the importance of working with Medical Examiners and/or Coroners to ensure a higher yield of pediatric donor organs; however, these concerns were seen as parallel but not directly related to the issue of broader sharing in order to reduce waiting list deaths. The Committees welcomed the information provided and will use this feedback to address the medical examiner/coroner concerns separately. Joint Subcommittee members agreed with the idea of taking every occasion to ensure opportunities for transplant, but do not believe that the potential benefit of the changes in this proposal should be delayed while a plan is developed to reduce organ loss due to medical examiner/coroner concerns.

The Committee, therefore, offers the following recommendations for consideration by the Board of Directors:

****RESOLVED, that the following modifications to Policies 3.6 (Allocation of Livers) and 3.11.4.2 (Combined Liver-Intestinal Organs from Donors 0-10 Years of Age) having been distributed for public comment, and subsequently recommended by the Pediatric and Liver and Intestinal Organ Transplantation Committees, shall be approved and implemented pending distribution of appropriate notice and programming in UNet^{SM}:**

3.6 ALLOCATION OF LIVERS

[…]

<u>0-10 year-old</u> Pediatric Donor Liver Allocation Algorithm

<u>Combined</u> Local <u>and Regional</u>

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

National

2. Pediatric Status 1A (age 0-11) in descending point order

~~**Regional**~~

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

Local

3. Adult Status 1A candidates in descending point order

Regional

4. Adult Status 1A candidates in descending point order

Combined Local and Regional

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

Regional

~~6. Pediatric Status 1B candidates (age 0-17) in descending point order~~

~~7.~~6. Pediatric Candidates age 0-11 in descending order of mortality risk scores (probability of candidate death)

Local

~~8.~~7. Pediatric candidates age 12-17 with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

~~9.~~8. Adult candidates with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

Regional

~~10.~~9. Pediatric candidates age 12-17 with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

~~11.~~10. Adult candidates with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

Local

~~12.~~11. All other pediatric candidates age 12-17 in descending order of mortality risk scores (probability of candidate death)

~~13.~~12. All other adult candidates in descending order of mortality risk scores (probability of candidate death)

Regional

~~14.~~13. All other pediatric candidates age 12-17 in descending order of mortality risk scores (probability of candidate death)

~~15.~~14. All other adult candidates in descending order of mortality risk scores (probability of candidate death)

National

~~16.~~15. Pediatric Status 1A (age 12-17) candidates in descending point order

~~17.~~16. Adult Status 1A candidates in descending point order

~~18.~~17. Pediatric Status 1B candidates in descending point order

~~19.~~18. All other pediatric candidates age 0-11 in descending order of mortality risk scores (probability of candidate death)

~~20.~~19. All remaining pediatric candidates in descending order of mortality risk scores (probability of candidate death)

~~21.~~20. All remaining adult candidates in descending order of mortality risk scores (probability of candidate death)

11-17 year-old Pediatric Donor Liver Allocation Algorithm

*(Please note, **no changes** are proposed to current pediatric allocation algorithm for adolescent donors. This simply creates language to direct allocation if approval is received that will subdivide pediatric donors into categories for young children and adolescent categories.)*

Local

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

Regional

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

Local

3. Adult Status 1A candidates in descending point order

Regional

4. Adult Status 1A candidates in descending point order

Local

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

Regional

6. Pediatric Status 1B candidates (age 0-17) in descending point order
7. Pediatric Candidates age 0-11 in descending order of mortality risk scores (probability of candidate death)

Local

8. Pediatric candidates age 12-17 with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)
9. Adult candidates with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

Regional

10. Pediatric candidates age 12-17 with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

11. Adult candidates with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

Local

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

Regional

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

National

16. Pediatric Status 1A candidates in descending point order
17. Adult Status 1A candidates in descending point order
18. Pediatric Status 1B candidates in descending point order
19. All other pediatric candidates age 0-11 in descending order of mortality risk scores (probability of candidate death)
20. All remaining pediatric candidates in descending order of mortality risk scores (probability of candidate death)
21. All remaining adult candidates in descending order of mortality risk scores (probability of candidate death)

3.11.4.2 **Combined Liver-Intestinal Organs from Donors 0-10 Years of Age.** For donors 0-10 years of age, offers will be made using the liver match run with candidates prioritized as follows:

- ~~Pediatric Liver Status 1A or 1B~~
- ~~Regional Liver Candidates with a PELD > 20~~
- ~~National Intestine Candidates with a PELD score~~

Combined Local and Regional

1. Pediatric Status 1A Liver and Liver-Intestine Candidates (age 0-17) in descending point order

National

2. Pediatric Status 1A Liver and Liver-Intestine candidates (age 0-11) in descending point order
3. Pediatric Status 1A Liver-Intestine candidates (age 12-17) in descending point order

Local

4. Adult Status 1A Liver and Liver-Intestine candidates in descending point order

Regional

5. Adult Status 1A Liver and Liver-Intestine candidates in descending point order

Combined Local and Regional

6. Pediatric Status 1B Liver and Liver-Intestine candidates (age 0-17) in descending point order
7. Pediatric Liver and Liver-Intestine candidates (age 0-11) by PELD greater than 20

National

8. Pediatric Status 1B Liver-Intestine candidates (age 0-17) in descending point order
9. Pediatric Liver-Intestine candidates (age 0-11) by PELD greater than 20

Combined Local and Regional

10. Pediatric Liver and Liver-Intestine candidates (age 0-11) by PELD less than or equal to 20

Local

11. Pediatric Liver and Liver-Intestine candidates (age 12-17) by MELD greater than or equal to 15
12. Adult Liver and Liver-Intestine candidates by MELD greater than or equal to 15

Regional

13. Pediatric Liver and Liver-Intestine candidates (age 12-17) by MELD greater than or equal to 15
14. Adult Liver and Liver-Intestine candidates by MELD greater than or equal to 15

Local

15. Other Pediatric Liver and Liver-Intestine candidates (12-17) by MELD
16. Other Adult Liver and Liver-Intestine candidates by MELD

Regional

17. Other Pediatric Liver and Liver-Intestine candidates (12-17) by MELD
18. Other Adult Liver and Liver-Intestine candidates by MELD

National

19. Pediatric Status 1A Liver candidates (age 12-17) in descending point order
20. Adult Status 1A Liver and Liver-Intestine candidates in descending point order
21. Pediatric Status 1B Liver candidates (age 0-17) in descending point order
22. Other Pediatric Liver and Liver-Intestine candidates (0-11) by PELD
23. Remaining Pediatric Liver and Liver-Intestine candidates (0-17) by MELD/PELD
24. Remaining Adult Liver and Liver-Intestine candidates by MELD

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

4a. Thoracic Organ Allocation Policy Review

Post-Transplant Outcomes for Lung Recipients Aged 12-17 In April, the SRTR presented outcomes data for adolescent lung recipients based on whether they were transplanted at primarily adult or pediatric centers (**Exhibit F**). This data request stemmed from an ongoing Joint Subcommittee with the Membership and Professional Standards Committee's Data Subcommittee (MPSC-DS) to determine a better method for reviewing pediatric lung transplant outcomes. Mr. Jeff Moore indicated that there were 125 adolescent recipients available for the analysis, with 40% of these transplants taking place in pediatric centers. Twenty-five of these recipients died post-transplant. There were only 20 transplants and 5 deaths for adolescent recipients transplanted in centers doing less than 10 transplants per year. Center volume has been shown to be a significant predictor of post-transplant mortality in the larger, adult population.

A member suggested that a longer study period be considered to make sure there is no divergence further out post-transplant. Adjusting for only the type of center (pediatric or adult) the center effect hazard ratio was 1.20 (p=0.6782) based on a Cox analysis. Adjusting for LAS factors and center type, the hazard ratio was 2.02 (p=0.1796). It was recommended that the analysis be re-run starting from the year 2000 rather than 2002, but noting that listing practices have changed since LAS implementation in 2005.

This expanded data request will be shared with the MPSC-DS during a future Joint Subcommittee call to review and determine a path forward.

Lung and Heart Allocation System Updates The Committee was asked to review slides updating the lung and heart allocation systems (**Exhibits G** and **H** respectively) independently due to time constraints during the April 24 meeting.

Heart-Lung Allocation and DonorNet® - Where do Multi-Organ Candidates Fit into the Allocation Sequence? Dr. Sweet shared a letter he received from a center with the Committee (**Exhibit I**). With electronic offers, individual heart and lung offers extend regionally far faster than in previous allocation. As a result, combined heart-lung candidates may be missing out on opportunities, as policy does not address in how multi-organ candidates should be prioritized in the allocation process. This issue is relevant for all multi-organ placements. Currently, OPOs are left to develop their own internal policies for prioritizing multi-organ candidates. This specific letter will also be discussed by the Thoracic Committee. Members thought it may be useful to provide OPOs with guidance on how to prioritize offers for multi-organ candidates. It was suggested that the Board of Directors and/or the the OPO Committee be asked to consider this issue and provide guidance to OPOs on how to best prioritize offers to multi-organ candidates.

4b. Liver and Intestinal Organ Allocation Policy Review

Liver and Intestine Working Group Update Dr. Horlsen provided the Committee with an update from the Liver-Intestine Working Group teleconference, held on April 18, 2008. The Working Group reviewed feedback received at that time regarding its joint public comment proposal. The remainder of the call was spent developing a path forward to continue addressing the

Committee's charge of reducing the number of deaths on the pediatric waiting lists. Dr. Horslen summarized this discussion into three components:

- The Collaborative efforts have clearly demonstrated an increase in adult donor numbers. Pediatric numbers have remained static during this same time period. The Working Group would like to request that the Collaborative turn its focus and expertise toward increasing pediatric donor numbers using the same techniques that have proven so successful for adults.
- The Working Group would like to explore the possibility of extending broader sharing of pediatric donor organs even further in a stepwise process. Broader sharing has proven across all organs to reduce deaths on the waiting list. As the Liver and Intestinal Organ Transplantation Committee explores net benefit, the Working Group would like to model how this in conjunction with broader geographical sharing to PELD candidates may ultimately be used.
- Methods for incentivizing the use of split livers must be considered. This project has been underway for some time, but must be reinvigorated. Literature is indicating that outcomes can be quite good for both pediatric and right tri-segment recipients. Data from a group in Texas has been very promising, showing success with both recipients and a survey noting acceptance of the concept of sharing an adult donor liver with a child. Dr. McDiarmid cautioned against attempting to mandate this practice as a first step because many centers do not have enough experience in technical variants, but suggested that regions develop cooperative agreements on how to handle or manage candidates willing to accept split livers using the Texas papers as a model. This would initiate discussion and planning amongst regional colleagues and perhaps develop more comfort in pursuing this practice. The Working Group will address this in an upcoming joint subcommittee with the Liver Committee.

  Dr. McDiarmid suggested that the Committee also look at the success of split livers in Italy, where the accepting hospital is allowed to determine the recipient of the right tri-segment. Members discussed whether this might be an appropriate incentive for encouraging the use of split livers. These ideas will be reviewed by the Joint Subcommittee.

<u>Evaluation of MELD/PELD Share 15 Policy</u> Dr. Cherikh presented a quarterly update of data evaluating the MELD/PELD Share 15 policy (**Exhibit J**) during the April 24 meeting in Chicago. This presentation focused upon the refinement of Status 1 into 1A and 1B, and regional sharing of pediatric donor policy, and the new liver-intestine allocation for donors aged 0-10 in relation to waiting list death rates and the number of transplants. Results indicated that there was no increased risk of death in any status or PELD category for the 0-11 age group in the most recent period reviewed. Equally, there was no increased risk of death in the <15 and 15-24 MELD category for adolescents, aged 12-17. Overall there was no increased risk of death rates in the 0-11 and 12-17 age groups in the most recent study period. Dr. Cherikh noted that multiple organ system failure was the most common cause of death for those without exceptions.

A member questioned how the relative risk of death for those with exceptions greater than 25 compares to those candidates with an equivalent MELD/PELD score. This will help the Committee determine how the community is doing in assigning exceptions. The curve indicated that children receiving exception scores now are sicker and appear to have a higher relative risk. The Committee will look more closely at actual death rates of this population as compared to other groups of candidates (I.e. MELD/PELD 25) in a future analysis.

The percentage of recipients transplanted in the MELD/PELD 15+ category seemed to increase for both the 0-11 and 12-17 age groups while the percentage of transplants in the <15 category seemed to decrease for adolescents. Despite the small numbers, the Committee was pleased to see that the percentage of split liver transplants done in the 0-11 age group appeared to increase during this most recent study period. Based on the data, the Committee questioned whether data was being incorrectly entered into UNet^{SM}, perhaps categorizing reductions as split livers. The numbers may reflect miscoding or data entry. A participant noted that he too was confused by the form, suggesting that the Committee may want to review how this data is collected. A suggestion was made to track the split organs by reviewing the donor ID attached to each allocation. The Committee is optimistic that this will provide cleaner data. Dr. Cherikh will review the raw data for the July meeting to determine if a clearer picture of split liver usage can be identified.

Dr. Cherikh reported that the percentage of transplants in 0-11 recipients using 0-11 donors increased from 70% to 78% in the most recent review period. An increase was also reported for 0-11 recipients receiving adolescent donor livers, rising from 11% to 16%. Adult transplants using 0-11 donors decreased slightly, from 22% to 19% in the most recent study period. A larger decrease was noted for adults receiving adolescent donor livers, from 82% in the first study period to 77% in the current period.

Net Benefit Allocation Update In April, the SRTR presented an update on net benefit allocation as presented to the Liver and Intestinal Organ Transplantation Committee during its March 2008 meeting (**Exhibit K**). Net benefit is being considered more and more to direct allocation. It is currently used for lung allocation and is the foundation of the newly simulated kidney allocation system. The Thoracic Organ Transplantation Committee is also looking into this area to drive heart allocation. The Liver and Intestinal Organ Transplantation Committee continues to advance the model and will then begin to request modeling on how net benefit can be used to improve the current allocation system. As a result, how to use net benefit in modeling the pediatric population must be addressed in much the same way that DPI is being considered for children. The SRTR expects that separate models will exist for pediatric and adult candidates, and that these models will need to mesh together for modeling and eventually allocation.

For pediatric cases with PELD <15, rankings under PELD and a benefit-based system are comparable. For PELD scores $\geq$15, children are ranked considerably lower under the benefit-based system. Adding 0.5 years to the benefit score and using $B^* = PT - 0.85 \times WL$ as the score appear to be appropriate adjustments to reduce this ranking issue. It was noted that post transplant survival now excludes time after re-transplant.

The Liver and Intestinal Organ Transplantation Committee's next step will be to evaluate interactions between the wait list and post-transplant models for candidates age 12 and older. The SRTR will also begin generating LSAM runs to compare the results of benefit-based versus MELD/PELD for adult and pediatric candidates. Additionally, the analysts hope to project an estimated change in life-years saved due to the benefit-based system. The SRTR hopes to have this first run of LSAM models in July.

A member cautioned that risk of mortality alone cannot be used for the decision of whether or not to transplant a child. Some children do not carry a substantial risk of wait list mortality (i.e. Crigler Najar, metabolic diseases) but still receive great benefit from transplant. Ultimately, a member noted the fundamental issue is that mortality and survival benefit as criteria for transplanting children.

A member noted that by far, the most significant predictors of death are all related to surgical complications. This brings in center and surgeon expertise. She wondered how these aspects could be factored in to net benefit. The SRTR suggested that this area of technical complications cannot be corrected in such a model.

The Committee wishes to be kept abreast of this process as it continues. Members requested that at least one pediatric representative be included in any subcommittee work related to the development of net benefit for liver allocation.

Concerns Regarding Requirement for Height Measurement Every 7 Days to Fulfill PELD Recertification The Committee concerns regarding a requirement to enter a candidate's height measurement each time a PELD recertification is required. Members noted that though height is a component of the PELD score calculation, growth will not noticeably occur from week to week. Members suggested that they are generally entering previous heights from source documentation to meet this requirement. Is documentation required to match recertification data? A member suggested that this issue does come up on audits. Height measurements are extremely unreliable on non-ambulatory patients. Participants suggested that this requirement may be unreasonable, as these candidates are not expected to change dramatically in height.

The Committee voted unanimously (17 in favor, 0 against, 0 abstentions) to draft a memo to DEQ suggesting that, based on current pediatric practice, height measurement taken more frequently than every three months is unlikely to show a significant difference. For this reason, centers should not be cited for using height measurements less than three months old for the purposes of PELD recertification.

Number of DCD Transplants and Post Transplant Outcomes for Liver and Kidney Transplants with DCD Organs In April, Dr. Cherikh provided an update requested by the Committee in July 2007 regarding donation after cardiac death (DCD) transplants and outcomes in pediatric candidates (**Exhibit L**). She noted that the number of DCD donor transplants performed in pediatric recipients is still relatively small, but seems to be increasing- especially for kidney and liver. From 1995 through 2007, there were 102 DCD transplants performed in pediatric recipients as compared to 6601 in adult recipients during the same time period. Sixty-seven of these were kidney transplants and 29 were liver transplants. The highest proportion of these transplants was done at high volume centers. DCD transplants done in pediatric recipients utilized organs from the following age groups:

Donor Age Group (in Years)	Number of Organs Transplanted
0-10	31
11-17	22
18-34	34
35-44	9
45+	6

Dr. Cherikh noted that the characteristics of kidney and liver DCD transplants were different from those of brain dead transplants. The data indicated that there was a higher rate of delayed graft function in DCD kidney transplants as compared to those transplants using organs from brain dead donors; however, graft and patient survival for DCD kidney and liver transplants were not different from same rates for brain dead donors. Dr. Cherikh intends to continue this analysis as more DCD transplant and longer follow-up information becomes available.

Dr. Sweet suggested that these data would be greatly beneficial to the pediatric transplant community as a whole, and suggested that it be published in order to promote the use of DCD organs in pediatric candidates based upon the positive results seen so far.

4c. Kidney Allocation Policy Review

Update Regarding Kidney Allocation System and How it Will Affect Pediatric Candidates
During the Committee's March 2008 conference call, Dr. Peter Stock, Chair of the OPTN/UNOS Kidney Transplantation Committee, presented slides (**Exhibit M**) detailing the simulated changes to the kidney allocation system. He specifically addressed how these changes are expected to affect pediatric candidates. After providing a brief progress update on the current status of this proposal, Dr. Stock outlined major proposal's components for adults including:

- Ranking candidates based upon objective medical criteria using Life Years From Transplant (LYFT)
- Replacing standard criteria donor (SCD) and expanded criteria donor (ECD) kidney designations with a donor profile index (DPI)
- Changing from time since listing to time on dialysis (DT)
- These components (LYFT, DPI and DT) along with a candidate's sensitization level are combined into a kidney allocation score

In this new simulated allocation system, priority for pediatric candidates and prior living donors are maintained. While absolute priority for zero antigen mismatch offers will be eliminated for adults, a sliding scale priority for sensitized adults has been modeled. The kidney payback system is expected to be eliminated in this new allocation system.

Pediatric allocation is expected to continue utilizing waiting time (defined as time since listing) and points. Children will no longer compete with adults for zero antigen mismatch offers. The central difference between current and simulated allocation policy is that children will only receive offers for donors 35 years old and younger.

Dr. Stock posed several questions for the Pediatric Committee to consider:

- **Is there a need for pediatric access to donors ≥35 years of age?**

  Since the September 2005 implementation of Share 35, giving pediatric candidates priority on organ offers from donors ≤35 years of age, only 2% of pediatric transplants (n=30) have been from donors older than 35. The Kidney Transplantation Committee requested feedback from this Committee as to whether access to donors ≥35 is necessary in the proposed system and/or whether access to these organs should be considered for highly sensitized pediatric candidates.

- **Should sensitization points be awarded to pediatric candidates on a sliding scale in the same manner that has been modeled for adults?**

  Current policy awards four points to candidates with PRA ≥ 80%. Candidates with a PRA <80% do not receive any priority points. The simulated allocation policy would generate a sliding scale for priority so that even moderately sensitized candidates get improved access to organ offers.

- **Should pediatric priority be based upon DPI instead of donor age?**

  DPI is a continuous measure which provides more clinical information than the current ECD and SCD categories about a donor's kidney. More information about an organ is expected to improve clinical decision making at the time of offer. Elements included in the DPI calculation are:
  - Age
  - Gender
  - Race
  - Height
  - Weight
  - Creatinine
  - History of smoking
  - Donor after cardiac death
  - Hepatitis C virus
  - History of hypertension
  - History of diabetes
  - Cause of death (i.e., anoxia, stroke, CNS tumor, other)

  Would DPI be more indicative of donor quality than age for pediatric candidates? What analyses would be useful for assessing this?

  Dr. Stock noted that age may not be the best measure to guarantee a quality kidney for pediatric transplant.

- **What is the effect of multi-organ allocation (especially the simultaneous kidney-pancreas (SPK) priority) on pediatric transplantation?**

  Current policy allocates combined kidney-liver and combined kidney heart according to the liver or heart match run. SPK allocation varies by donor service area. The Kidney Committee is currently working with the Liver and Intestinal Organ Transplantation Committee to establish criteria for liver-kidney allocation. The proposed allocation of SPK will have the kidney following the pancreas.

  It was suggested that the Committee may want to discuss requesting <u>at least</u> one kidney from each $\geq$35 year old donor be allocated to a child to prevent both kidneys from being utilized for multi-organ allocation in adults.

  An OPO representative noted that current policy does not require sharing the second organ with a lifesaving organ, though it is suggested. Members noted that the choice between kidney and SPK allocation is not specifically directed in current policy, and OPOs have latitude in determining how they want to offer isolated kidney, pancreas, or SPK. Kidneys are expected to follow the pancreas in the kidney allocation score (KAS) simulation. SPK allocation is expected to follow pancreas allocation policy. Dr. Stock noted that local SPK offers will be made before pediatric offers are extended in the simulated system.

  The Kidney Transplantation Committee is currently working with the Liver and Intestinal Organ Transplantation Committee to establish criteria for combined liver-kidney allocation.

Dr. Stock reminded Committee members that pediatric candidates cannot be in the same allocation categories as adults because adults are expected to be allocated organs based on their kidney allocation score. Pediatric candidates will not utilize a kidney allocation score. (This is similar to current lung allocation for children ≤11 years of age as compared to adolescents and adults with lung allocation scores.)

A Kidney Working Group member questioned why zero antigen mismatch offers would no longer be made to adults as proposed in KAS. Dr. Stock explained that zero antigen mismatch offers for adults are not given absolute priority in the simulation because they are given biological priority within the LYFT calculation. Candidates with a PRA of 80% or greater will appear as local candidates on any donor match run nationally that is a zero antigen mismatch. With accurately defined donors, the frequency of kidneys available to these highly sensitized adult candidates is expected to increase without the impact of the current payback system.

In reviewing a number of simulated effects of implementing KAS, Dr. Stock noted that distribution of recipients by age indicated the 0-17 age group remained constant while the 18-34 age group rose from 18%, under the current system, to 22% under the proposed system. The donor/recipient age correlation is expected to increase from 10.2% using the current system to 32.3% using the proposed system.

After Dr. Stock's presentation, the Committee decided to defer discussion of the list of questions outlined by him until the next Kidney Working Group call. Dr. Ruth McDonald noted the importance of keeping the one point priority for pediatric candidates <11 years of age as a part of the new system. The Pediatric Committee is unaware of any plans to remove this point, but wants to ensure that this point remains. She also suggested allowing candidates listed at <18 years of age to maintain their absolute priority for zero antigen mismatch if they remain on the waiting list beyond their 18th birthday. These issues were to be discussed during the April 21, 2008, Working Group call.

To prepare for these discussions, the Committee requested the following data for consideration when the Kidney Working Group reconvenes:

- Donor and recipient characteristics of the 28 candidates listed before age 18 that received kidneys from donors ≥35 since implementation of the Share 35 policy.

- DPI for all pediatric and adult deceased donor kidney alone transplants from 1-1-05 though 12-31-07 by the following characteristics:
    - PRA percent: <10, 10-79, ≥80
    - Primary transplant versus re-transplant
    - HLA 0-ABDR mismatch
    - Donor age 0-17, 18-34, ≥35

- Distribution of DPI in all deceased donor kidney alone transplants by donor age (<35 versus ≥35) in the last two years

- Proportion of deceased donor transplants that are pediatrics and the corresponding DPI

The Working Group will consider this data as it formulates responses to the questions Dr. Stock outlined and then share their feedback with the Kidney Committee after final discussion at the April 24 full Pediatric Committee meeting in Chicago.

The Committee continued its discussions during the April 24, 2008 meeting. The Kidney Working Group Chair, Dr. Sharon Bartosh, reviewed the three questions posed by Dr. Stock for Committee consideration as an introduction to data that was requested during the March 6, conference call.

DPI Priority for Pediatric Candidates The SRTR presented data to aid the Committee in exploring the relationship between DPI versus the current donor age preference of <35 years old for pediatric candidates (**Exhibit N**). DPI for all procured pediatric and adult (age 18-65) procured and deceased donor kidney alone transplants from January 1, 2005, through December 31, 2007, were reviewed. Results indicated that donors younger than 35 years of age represented 39% of the procured kidneys and 42% of the kidney alone transplant from this study population. The data suggested that if pediatric candidates received priority based on DPI, they may be offered kidneys from donors greater than 35 years of age, but would be offered kidneys with factors that are associated with a lower risk of graft failure. Using the number of procured and transplanted kidneys with donor age less than or equal to 35 years, a corresponding DPI, between 0.31 and 0.39, can be found at which pediatric kidney candidates would have priority over a similar number of organs as they do under current Share 35 policy.

Dr. Bartosh asked members if they thought it would be beneficial to pursue DPI in place of age now in light of the apparent delay in KAS coming to pass. After reviewing the data, the committee felt comfortable proceeding with DPI in place of an age cut off in the future system. Dr. Sweet noted that upon review of the data, a DPI in the range of 0.23 and 0.32 as a threshold appears reasonable. He suggested tying this to the number of organs available to pediatric candidates and number of organs available so if dynamics change the DPI cut off will not disadvantage children in the long run.

Is there a risk at setting a DPI? Is there a risk of selecting a number that will give poorer quality kidneys to children than what they are already receiving with the age cut off? It was noted that clinical judgment will still play a role here. If the DPI threshold is set for a number of organs that is comparable to what is received now, this will provide a practical starting point that can be monitored for future changes. Offering centers too much latitude in changing individual candidate thresholds from day to day could be dangerous.

After discussion, the Committee was supportive of using DPI in place of the current age cut off if a DPI threshold is set similar to the total number of organs received with age threshold. Though members agreed that the number of kidneys transplanted into children from donors >35 years of age does not appear to warrant the added complexity of programming for offer access to children above whatever DPI threshold is finalized, highly sensitized children may benefit from access to higher DPI kidneys. It was recognized that highly sensitized children will receive offers prior to adults in KAS, and this should also aid in serving this population. Another member highlighted that local versus regional sharing must also be considered to address situations where there is no local child and a <35 kidney is allocated to a local adult rather than a regional pediatric candidate. This member feared that DPI may end up as a simple substitution for the current age threshold and no additional changes will be made to address the number of these kidneys that were meant to be offered first to children going into adults.

Concerns were raised that, based on the SRTR data reviewed, using a DPI threshold could reduce the pool of kidneys offered preferentially to children- 8263 in the study population using the <35 age cut off to approximately 6000 using a DPI of 0.3. While DPI is a good system for identifying ideal kidneys, there are still concerns related to allocation priority to children. Share 35 has not solved the problem of pediatric kidney allocation as intended. There are still significant waiting times for some children to receive transplant, resulting in cognitive and developmental delays. Raising the DPI threshold is one option, but a better one may be to keep a low DPI threshold and change the allocation algorithm to give children increased priority for receiving these kidneys. The problem is access to the quality kidneys, not the quality of the organs in this case.

This data and related discussion will be shared with the Kidney Transplantation Committee as a response to its specific question related to DPI. A Joint Subcommittee call will be scheduled for the two groups to further discuss this topic.

Additional Data for Evaluating Kidney Share 35 Policy During the April meeting, Dr. Wida Cherikh presented data (**Exhibit O**) looking at the number of kidney offers children received but turned down while in active status in order to see whether turndowns contributed to the low transplant rate for non-sensitized children at one year. The median number of refusals seemed to go down slightly across all PRA categories after Share 35 policy was implemented. Dr. Cherikh also presented data to determine transplant rate by sensitization level for pediatric candidates per 1000 chronological and active patient years when inactive time is removed. Transplant rate per 1000 active patient years seemed to increase during the second year after Share 35 policy implementation, especially for pediatric candidates with a PRA < 20%. The data indicated that, in general, post Share 35 the transplant rate increased for all except those highly sensitized candidates aged 0-5 and 6-10. The overall transplant rate for candidates with 80% or greater sensitization is much lower than for the other candidates. In general, pediatric candidates have benefited, but some highly sensitized candidates have been potentially harmed. This indicates that the Share 35 concept is sound, but sensitized pediatric candidates who now have no priority above adults are not being helped. If the allocation algorithm is revised to make offers to sensitized children before adults, this should be expected to have a positive effect. Several members agreed that the loss of priority points without a change in the allocation system has not served this group of children. A member questioned whether extending the priority for children before adults beyond the local offers will be necessary to ensure that children are receiving the kidneys intended for children. The Committee requested simulation modeling on the anticipated impact of offering preference to sensitized children before adults locally versus locally and regionally under current Share 35 policy.

Concerns regarding how highly sensitized children receive offers in the current system were discussed as well during the April 24 meeting. The Kidney Transplantation Committee considered these concerns during its December 3, 2007, meeting. Some of its members expressed concern that the Share 35 policy may have been implemented incorrectly or that this issue of prioritizing highly sensitized children had not been considered in its development. One member explained that the Committee had considered whether or not to provide additional priority to highly sensitized pediatric candidates and decided that such additional priority would not be necessary in light of the expanded donor pool to which pediatric candidates would have access. Currently, highly sensitized children are intermingled with adults on match runs. After discussion and review of data, the Kidney Committee voted to develop a policy to give sensitized children additional priority over sensitized adults for kidneys from all donors (regardless of age) at the local, regional and national levels. This proposal will need to go out for public comment prior to Board consideration. Committee members agreed that it is of the utmost importance to

pursue this change to the current system in light of the delay in KAS moving to the public comment phase.

The Committee believes that the Kidney Transplantation Committee's proposal should be a programming priority to address the current allocation system even before KAS is implemented and is prepared to share data with the Board outlining the need for prioritization of this discrete disadvantaged population.

Dr. Cherikh continued presenting data showing the number of SPK transplants and waiting times for pediatric kidney candidates by region. This request was designed to see if children are being adversely impacted (i.e. longer waiting times to transplant) in those regions with active SPK programs before proposing any changes to the allocation algorithm. Several regions were noted as having lower than average numbers of pediatric kidney transplants and higher than average SPK numbers. It seems that there may be a trend where regions with high SPKs may be affecting the number of pediatric kidney transplants. It was recognized that there are no specific policies that guide OPOs in determining whether to place SPK or kidneys. The Pancreas Transplantation Committee surveyed the 58 OPOs and will provide this Committee with feedback on how allocation is usually handled and whether there are any trends.

Additionally, she reported on the number of adult combined liver-kidney and adult combined heart-kidney transplants from donors under the age of 35. This is another are of concern where kidneys are being directed to adults and away from children. The increasing numbers of combined kidney-liver transplant are somewhat alarming, but the Liver and Intestinal Organ Transplantation and Kidney Transplantation Committees are working as a Joint Subcommittee to determine the best way to address these increased numbers. Overall, there has been an increase in the overall and yearly numbers of adult SPK, combined liver-kidney and heart-kidney transplants using <35 donors after the Share 35 policy was implemented. The Committee will follow this Joint Subcommittee's progress closely, and requested that there be pediatric representation involved if this is not already the case.

A member noted that living related donation rates have also been affected by Share 35. It is critical to keep in mind the benefits of living donation and work to keep these numbers up, though members acknowledged that there are factors outside of Share 35 including changing numbers in ethnicity, increasing age, and overall parent or other related donor health that are potentially affecting these numbers. The Committee requested that the adjusted living donor graft outcomes be calculated pre- and post-Share 35 by the SRTR. Members wish to examine which living donor characteristics have changed since Share 35 if a difference is observed in the adjusted analysis.

In responding to the Kidney Transplantation Committee regarding KAS, Dr. Sweet suggested that it is critical to think about how KAS will affect children in broader terms. Strategies will need to be modeled to see how children will be impacted by any changes related to PRA, multi-organ transplant, living related donation rates, etc. It is important for the Joint Pediatric-Kidney Subcommittee to consider all of these elements before KAS go forward as a final proposal, though it seems that there will still be time to address such concerns.

<u>Graft Failure Rates in Pediatric Kidney Recipients with FSGS, MPGN and HUS</u> In April, Dr. Bartosh summarized concerns related to re-transplant rates in children with FSGS, MPGN, and HUS diagnosis (**Exhibit P**). The data suggests that pediatric recipients with HUS and MPGN diagnoses do not appear to differ with statistical significance from pediatric or adult recipients in their risk of graft failure. The Working Group agreed that results were disappointing but not

unexpected and not poor enough to consider excluding this group from re-transplantation on a futility basis.

Characteristics of Kidney Transplants Performed in Pediatric Candidates Pre- and Post-Share 35 Implementation Dr. Cherikh provided the Committee with an ongoing update on the number of transplants by recipient and donor age and time to transplant as well as characteristics of recipients (such as PRA level, ABO blood group, HLA mismatch level ethnicity) and post-transplant outcomes before and after the Share 35 policy implementation (**Exhibit Q**) during the April 24 meeting. The following points were highlighted:

- Transplant rate increased during the post-policy period for A, AB and O blood groups.
- Overall, the rate of transplant for pediatric recipients remained about the same after policy implementation.
- For pediatric candidates aged 0-5 and 6-10 there was an increase in transplant rate for candidates with PRA $\geq$ 80%.
- Transplant rate increased for pediatric candidates age 11-17 with PRA of 0% - 19%.
- During the pre-policy period, 58% of removals for pediatric candidates were due to deceased donor transplant, and this percentage increased to 70% after the Share 35 policy was implemented.
- During the same time period, the percentage of pediatric candidates removed for living donor transplant decreased from 27% to 17%.
- The number of active pediatric registrations has decreased by 33%, from 589 on 9/30/2005 to 395 on 2/29/2008. The number of inactive registrations has increased by 82% from 227 to 414 in this same time period.

  This was especially concerning to the Committee. Members questioned whether centers are still listing candidates well before transplant is needed even though the time to transplant has greatly improved. Additional data was requested, looking at this data by age to determine if candidates are being listed just prior to age 18 as pediatric candidates to maintain their pediatric status. The Committee would also like to look at the ranges for periods of inactivity and the longest period that a candidate has maintained pediatric status after turning 18.

- Despite the higher percentage of deceased donor transplants with higher HLA mismatch level performed in pediatrics after the policy was implemented, the graft and patient survival rates do not seem to be negatively impacted.
- There was a significant improvement in graft survival of pediatric living donor transplant recipients.
- Graft and patient survival for adult recipients were comparable during pre- and post-policy periods for both living and deceased donors.
- Acute rejection rates for pediatric recipients of deceased donor transplants decreased during the post-policy period.
- Delayed graft function rates for pediatric transplant recipients decreased following Share 35 policy implementation for both donor types.
- There has been a decrease in delayed graft function rates for adult living donor transplant recipients during the post-policy period.

  The Committee questioned the significance of this. One possible explanation would be that previously, centers were using lesser quality living donors. It could also indicate that, after Share 35 implementation, those centers with more expertise continued to utilize living donation while other centers depended more on deceased donor organs.

The Committee suggested taking a closer look at center volumes for living donation pre- and post-implementation as well as the age of living donors during these time periods- was there a shift?

- Median serum creatinine was very similar between pre- and post-policy periods for all age groups of recipients.

4d. Pancreas Allocation Policy Review

SPK and Pancreas Allocation as Expected in KAS At the request of the Pancreas Transplantation Committee leadership, an informal discussion was held with the Committees' Chairs and Vice-Chairs as well as Dr. Bartosh, to discuss SPK and pancreas allocation for adults and kidney allocation for children as suggested in KAS and how these two groups might work together to find a mutually agreeable method of allocation to present to the Kidney Committee. Dr. Bartosh briefly summarized this call during the April 24 meeting. SPK allocation is expected to be driven by the pancreas locally rather than the kidney in KAS. Current policy leaves this decision to the OPO. This is an opportunity for this Committee to put something into place that will ultimately benefit children. A draft allocation scheme was shared (**Exhibit R**) for discussion on how these two groups might prefer to see allocation proceed under the new system. The Pancreas Committee is eager to hear other ideas of how allocation could be modeled in addition to this one as it continues this discussion in an upcoming call.

The alternative view from the OPOs was recognized- the pressure to maximize placement from donors, making SPK more desirable than trying to allocate a solitary pancreas. The impact of regional sharing of SKPs was questioned; though it was acknowledged that there is great variability in how frequently regional sharing of SPKs occurs. According to another member, access to solitary pancreas has also become problematic, and the result has been more candidates listed for SPK when they had a living donor kidney option but were not able to access offers for an isolated pancreas.

Some suggestions made for modeling by the Pancreas committee included:

- Local pediatric allocation to continue after pediatric zero antigen mismatch and highly sensitized candidates, but BEFORE local SPK offers
- Local SPK offers after pediatric zero antigen mismatch and highly sensitized candidates, but BEFORE local pediatric allocation
- Regional sharing for highly sensitized pediatric candidates
- One kidney from <35 donors always being directed to pediatric candidates.

Pediatric representation will be present on the upcoming Pancreas Committee call where this modeling will be formally requested.

Update Regarding How to Account for the Pancreas in Multi-Visceral Transplants Dr. Sweet provided a brief overview of the Committee's response to the Pancreas Committee's memo (**Exhibit S**) during the April meeting, requesting input on listing any candidate needing a pancreas, even if it is only for technical reasons, on a match run. The OPO Committee response conflicted with this Committee's opinions. It was acknowledged that this is a challenging set of issues, where the driving factors are primarily financial. The Committee will await feedback from the Pancreas Committee, and anticipates that this issue will ultimately have to go out for public comment before going to the Board of Directors.

5. Review of Policies and Bylaws Issued for Public Comment

The Committee reviewed the ten proposals out for public comment, and provided the following feedback during its March 2008 meeting:

1. Proposal to Limit Mandatory Sharing of Zero Antigen Mismatch Kidneys to Children and Sensitized Adult Candidates *(Modifications to Policy 3.5.3 (Mandatory Sharing of Zero Antigen Mismatch Kidneys))(Kidney Transplantation Committee)*

   After brief discussion, the Committee voted to support this proposal, noting that this change should be expected to benefit children waiting for a kidney. (Committee vote: 16-0-0)

2. Proposal to Allow an Additional Method for Waiting Time Reinstatement for Pancreas Recipients *(Modifications to Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients))(Pancreas Transplantation Committee)*

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

3. Proposal to Change the Bylaws to Require Written Notification (or Disclosure) to Living Donors from the Recipient Transplant Programs *(Proposed Modifications to Appendix B, Section II, (F) "Patient Notification" of the OPTN Bylaws and Appendix B, Attachment I, XIII, D (13) of the UNOS Bylaws) (Living Donor Committee)*

   The Committee noted that while on the surface this appears to benefit patient safety, there appears to be little direction regarding how the collection of living donor data is to be managed. Adult living donors for pediatric recipients and paired exchanges were raised as examples where follow-up can be challenging. The proposal does not outline any requirements for follow-up in centers, most likely because it is unclear who pays for this extended care. Members noted that follow-up care for living donors is generally left to clinical judgment. Follow-up care is not paid for beyond a limited number of post-operative tests. As a result, members suggested that it will be difficult for centers to collect this data, leaving many as potentially non-compliant with policy.

   The timing of sending contact information for living donors to report concerns or grievances to the OPTN was also questioned. Living donors are usually not feeling well and not focused on such information immediately after surgery. Members felt strongly that this information should be discussed and dispersed prior to donation.

   Due to these substantial concerns, the Committee was uncomfortable with supporting this proposal. Members suggested that as written, it may not achieve the Living Donor Committee's desired goals and ultimately may create paperwork without changing outcomes. As a result, the Committee voted unanimously to oppose the proposal as written (Committee vote: 16-0-0).

4. Proposal to Change the Bylaws: Restoration of Membership Privileges Following an Adverse Action (Proposed Changes to Appendix A, Section 3.01A Paragraphs (1) and (3) and Section 5.05A, Addition of Section 5.07A) (Membership and Professional Standards Committee)

   After discussion, the Committee agreed that the additions outlined in the proposal were reasonable. The Committee voted unanimously to support this proposal (Committee vote: 16-0-0).

5. Proposal to Change to Elector System for Histocompatibility Lab Members and Medical/Scientific Members: Bylaws Article I, Sections 1.9 and 1.12; Article II, Section 2.2 and 2.4; Article VI, Section 6.1 (Membership and Professional Standards Committee)

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

6. Proposal to Change Organ Time Limits to Organ Offer Limits for Zero Antigen Mismatched Kidneys; Pancreata and Kidney/Pancreas Combinations (Modifications to: Policy 3.5.3.5 (Organ Offer Limit). Policy 3.8.1.7.1 (Time Limit), and Policy 7.6.1.2 (Validation of Offers of Organs Placed Through the Organ Center)) (Operations Committee)

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

7. Proposal to Require Transplant Centers to Inform Potential Recipients about Known High Risk Donor Behavior (Proposed Revisions to Policy 4.0 (Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Recipient Diseases or Medical Conditions, Including Malignancies, of Donor Origin)) (Executive Committee)

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

8. Proposal to Change How 0-10 Year-Old Donor Livers and Combined Liver-Intestines are Allocated (Modifying Policies 3.6 (Allocation of Livers) and 3.11.4.2 (Combined Liver-Intestinal Organs from Donors 0-10 Years of Age)) (Pediatric and Liver and Intestinal Organ Transplantation Committees)

   The Committee sponsored this proposal and will consider it in light of comments received at its April 24, 2008, meeting.

9. Proposal to Change Allocation of Pediatric Lungs and Allow Creation of a Stratified Allocation System for 0-11 Year-Old Candidates (Modifying Policies 3.7.6.2 (Candidates Age 0-11), 3.7.11 (Sequence of Adult Donor Lung Allocation) and 3.7.11.1 (Sequence of Pediatric Donor Lung Allocation)) (Pediatric and Thoracic Organ Transplantation Committee)

   The Committee sponsored this proposal and will consider it in light of comments received at its April 24, 2008, meeting.

10. Proposal to Allocate Pediatric Donor Hearts More Broadly (Modifying Policies 3.7.5 (Allocation of Adolescent Donor Hearts to Pediatric Heart Candidates) and 3.7.10.1 (Sequence of Adolescent Donor Heart Allocation) (Pediatric and Thoracic Organ Transplantation Committee)

    The Committee sponsored this proposal and will consider it in light of comments received at its April 24, 2008, meeting.

6. <u>Follow-Up on Joint Pediatric-OPO Subcommittee</u>

   Dr. Sweet provided the Committee with a brief update regarding donor management and the administration of pre-recovery medications during the April meeting. The Joint Pediatric - OPO

Subcommittee convened by teleconference on January 28, 2008, to (1) discuss concerns regarding administration of pre-recovery medication for donors and to (2) determine whether the development of best practices for organ donor management may be beneficial (**Exhibit T**).

After a productive discussion, the Joint Subcommittee agreed that because this is not a specifically pediatric issue, it would be more practical to take the following ideas to the full OPO Committee for consideration and further elaboration:

1. Each OPO to make available its donor management protocols in the interest of early full disclosure of pre-recovery drugs or protocols that may affect organ function in the form of guidelines or policy for all OPOs. Ideally these would be available in advance of the decision to accept organs from that OPO.

2. Develop written guidelines to help OPOs adjudicate situations/disagreements occurring in the OR. If these guidelines were written as policy, UNOS Department of Evaluation and Quality input would be critical for monitoring and enforcement as infractions would ultimately be reviewed by the Membership and Professional Standards Committee.

3. Share these ideas with AOPO to request support or possible inclusion in the accreditation process.

The Committee will follow-up with the OPO Committee to ensure that these concerns are being actively addressed.

7. Acknowledgements and Next Steps for Addressing the Committee Charge

Dr. Sweet shared his appreciation for all the hard work done by Committee members over the last two years, developing organ specific proposals in response to the Committee's charge to reduce waiting list deaths. He applauded the efforts in allocating organs to younger children without negatively affecting adolescents and adults. He sees the next opportunity as one to increase donor availability and do more with the donors that are currently available. The efforts to increase use of split livers are a prime example of an area in which progress can be made. He suggested other opportunities within the community to look at how donors are considered. Can better partnerships be made with OPOs to better manage pediatric donors- an educational intervention? He recommended reinforcing with HRSA and the Collaborative the need for pediatric donor outcome metrics and establishing OPO accountability for pediatric donor performance. As an example, he cited barriers created by Medical Examiner involvement and the lack of consistency in how OPOs manage this situation as a prime opportunity to increase the availability of pediatric donors. Access to transplant remains a concern, and he hoped that the Committee will focus on one of the areas of importance- defining the best place for a pediatric candidate to be treated. Currently, the transplant community does not know whether there are significant differences in access to transplant or post transplant outcomes for children being transplanted in adult programs, small volume pediatric programs, or more experienced stand alone pediatric programs. This is an area that he believes the committee should consider in depth in the next two years. He thanked members for making the last two years a great experience and recognized outgoing members with a certificate and letter.

Dr. McDiarmid echoed Dr. Sweet's appreciation of all the time and effort that went into developing the current proposals. She noted that she will be exploring the idea of a second Pediatric Summit on Organ Donation and Transplantation with HRSA. She believes that it is

time for another event that will bring the pediatric transplant and OPO communities together to build upon the momentum gained in San Antonio in 2007, and she will begin gathering support for such a meeting.

8. Living Donor Follow-Up Requirements

The Committee talked briefly regarding the recent policy changes requiring that pediatric centers are now responsible for following adult living donors that are used to transplant pediatric candidates. It was noted that the Living Donor Committee is addressing this as a stepwise process. There are plans for a public comment proposal that will require living donor recovery surgeries to take place in an OPTN/UNOS member facility. If this passes, a second proposal is anticipated, and will require that the recovering be responsible for donor follow-up rather than the transplanting center. The Committee is supportive of this approach and looks forward to progress being made related to its concerns.

9. Review of Executive Summary of Minutes

Committee members were encouraged to review minutes (**Exhibit U**) from the February 20-21 Board of Directors meeting that were included in the April 24 meeting materials packet.

PEDIATRIC COMMITTEE			
	MONTH	MARCH	APRIL
	DAY	6	24
	FORMAT (select)	Live Meeting/ Teleconference	In Person
NAME	**POSITION**		
Stuart Sweet M.D.	Chair	X	X
Simon Horslen MD	Vice Chair	X	X
Michael Chobanian MD	Region 1 Rep.	X	x (by phone)
Anthony Savo MD	Region 2 Rep.		X
Ian Carmody MD	Region 3 Rep.	X	X
Anthony Sebastian MD	Region 4 Rep.	X	x (by phone)
Christine Mudge RN, MS, CNS/PNPc	Region 5 Rep.	X	X
Patrick Healey MD	Region 6 Rep.	X	x (by phone)
Sharon Bartosh MD	Region 7 Rep.	X	X
Ross Shepherd MD	Regional 8 Rep.	No longer on Committee.	Dr. Sweet acting Reg. Rep for term
Steven Lobritto MD	Regional 9 Rep.		X
Joanne Dupuis RN	Regional 10 Rep.	X	X
Debra Dodd MD	Regional 11 Rep.		X
Estella Alonso MD	At Large		X
Kathie Collins RN,CCTC	At Large	X	X
Carol Conrad M.D.	At Large	X	X
Sharon DiSano MS,ARNP,CCTC	At Large		X
Susan Dunn MBA,RN, BSN	At Large	X	X
Mark Fox MD, PhD	At Large	X	
Heung Bae Kim MD	At Large	X	
Robert Mazor M.D.	At Large		
Victor Morell MD	At Large		X
Amy Palermo	At Large		
Biagio Pietra MD	At Large	X	X
Elizabeth Roach RN, BSN	At Large	X	
Monica Lin, PhD	Ex Officio	X	X
John Magee, MD	SRTR Liaison	X	X
Kate Meyer, MS	SRTR Liaison	X	x (by phone)
Jeff Moore, MS	SRTR Liaison	X	X
Shandie Covington, BS	Committee Liaison	X	X
Wida Cherikh, PhD	Support Staff	X	X
Leann Harris	Support Staff	X	X
Ruth McDonald, MD	Guest	X	x (by phone)
Peter Stock, MD	Guest	X	
Eileen Brewer, MD	Guest	X	
Sue McDiarmid, MD	Guest		X
David Campbell, MD	Guest		X