

OPTN/UNOS Policy Oversight Committee
Report to the Board of Directors
November 17-18, 2008
St. Louis, MO

Summary

Action Items for Board Consideration

- None

Other Significant Items

- The Committee is using a new “Policy Development Scorecard” that is intended to provide a consistent framework for reviewing policies, and is aligned with the OPTN Strategic Goals and the Committee’s policy review charge (Item 3, Page 3).
- The Committee supports the Ad Hoc International Relations Committee’s proposal to add the factor “change in bilirubin” to the lung allocation score (LAS) (Item 4, Page 4).
- The Committee supports the Ad Hoc International Relations Committee’s proposal to verify that foreign agencies importing organs to the United States, or receiving organs exported from the United States, are legitimate and test organs for transplant safety (Item 5, Page 5).
- The Committee supports the Living Donor Committee’s proposal to improve the safety of living donation by restricting the acceptance and transplant of living donor organs to OPTN member institutions (Item 6, Page 6).
- The Committee supports the Membership and Professional Standards Committee’s proposal to modify the bylaws pertaining to conditional approval status for liver transplant programs that perform living donor transplants (Item 7, Page 7).
- The Committee supports the Membership and Professional Standards Committee’s proposal to change the OPTN/UNOS Bylaws to better define functional inactivity, voluntary inactive membership transplant program status, relinquishment of designated transplant program status, and termination of designated transplant program status (Item 8, Page 8).
- The Committee reviewed four proposals that were scheduled for public comment circulation in October 2008, and provided their recommendations (Items 9-12, Page 9).
- The Committee reviewed the Pancreas and Liver Alternative Allocation Systems (AAS), and supported the recommendations of the Pancreas Transplantation and Liver and Intestinal Organ Transplantation Committees (Item 13, Page 11).
- The Committee reviewed five proposals in development (Items 14-18, Page 14).
- The Committee conducted its annual data review, including analyses of linkage to non-OPTN sources of malignancy data (Item 19, Page 17).

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Edward R. Garrity, M.D., MBA, Chair

This report represents the deliberations of the Policy Oversight Committee during its July 16, 2008, and September 15, 2008, meetings.

1. Committee Orientations. The Committee received several orientations during the July 2008 meeting:

- Orientation to OPTN Committees and the Policy Oversight Committee (**Exhibit A**);
- An introduction to the OPTN and UNOS, and the OPTN Regulatory Framework (**Exhibit B**);
- OPTN/UNOS Policy Development Framework and Process: Strengthening Evidence-Based Health Policy Capabilities to Improve Transplantation (**Exhibit C**);
- Policy Implementation Technology Considerations (**Exhibit D**);
- Progress Toward Reaching the HHS Donor-Related Program Goals (**Exhibit E**); and
- An Introduction to the SRTR (**Exhibit F**).

Committee members asked how the HHS Program Goals were developed, and whether there is a process for input. Christopher McLaughlin, Chief of the Operations and Analysis Branch for the Division of Transplantation OPTN, agreed to provide a description of how the goals were developed at a future meeting.

2. Annual Goals. Edward Garrity, M.D., Committee Chair, reviewed the Committee Goals for 2008-2009, which have been aligned with the OPTN's Long-range Strategic Goals and Priorities (**Exhibit G**). The goals for the Committee are as follows:

- Review policies related to donor organ supply and make recommendations for needed policy development by other Committees (Relevant Goal: Maximum Capacity).
- Address geographic variation in organ supply and transplantation that may be influenced by organ allocation policy (Relevant Goals: Maximum Capacity, Equitable Access).
- Review policies related to living donation/paired kidney donation and make recommendations for needed policy development by other Committees (Relevant Goals: Maximum Capacity, Patient Safety).

3. Proposed Policy Review Scorecard. During both meetings, members were reminded of the Committee's charge with regard to policy review, which is to review existing and proposed policies to determine that policy goals (1) are objective and measurable; (2) further the mission, strategic plan and long term goals of the OPTN and HHS program goals; and (3) are scientifically based. The policy review scorecard concept was included in the OPTN contract proposal as a way to guide the Committee's deliberations and to form the basis for feedback to the Board of Directors and sponsoring Committees. The scorecard is also intended to streamline the Committee's very complex work and to lend transparency to the policy-making process.

The proposed scorecard integrates the OPTN Strategic Goals with the Committee's policy review charge and incorporates many of the principles embedded in the Final Rule (**Exhibit H**). It uses a modified Stapel Scale, which is a type of itemized rating scale originally developed to measure the direction and intensity of an attitude simultaneously. This type of scoring system is used when individuals are not being asked to make bipolar comparisons (good vs. bad, fast vs. slow). Rather, it is used to measure how closely a proposal meets each goal. Proposals receive a score ranging from -3 to +3 for each category listed. If a proposal is anticipated to harm patients, it might receive a -3 in the patient safety category, while if it has no impact on patient safety, the score would be zero (neutral). A proposal that would greatly increase patient safety would receive a score of +3 in that category. An overall score will be provided, as well as scores for each category. As the scorecard consists of two sections ("Goals" and "Policy Development"), aggregate scores could be provided for each section as well. The scorecard provides a consistent framework for reviewing policies, so that each policy is reviewed similarly, and committees know what criteria the Policy Oversight Committee will be evaluating.

Committee members discussed the timing of proposals as they are presented to the Committee, and noted that it would be beneficial if proposals were presented as early in the development process as possible, so that the scores could be provided to the sponsoring committee as feedback. The scores could also be used to prioritize a committee's work. One recommendation was that the committee liaisons should be prepared to describe how a committee's proposal addresses each of the categories. The scorecard should be distributed to the committees that are developing policies, with the caveat that the scorecard may continue to evolve as the Committee gains experience with the tool.

Committee members noted that the "impact" question was confusing, and asked whether this should reflect the impact on a specific group of patients versus patients as a whole, or whether it refers to impact in terms of consequences to the system. Most reviewers seemed to be using this category to assess the impact on a group of patients. It was suggested that this could be split into two categories: (1) the impact on the patients or specific circumstances that the policy is intended to address, and (2) the impact on the broader system. The significance and impact questions could also be taken out of the policy development section and put in a separate category.

Review of Proposals Circulated for Public Comment, June 2008 (Scores Provided in Table 1)

4. Proposal to add the factor "change in bilirubin" to the lung allocation score (LAS). The LAS is used to prioritize candidates who are 12 years of age or older on the lung transplant waiting list. The implementation of the LAS three years ago was a dramatic change from the former allocation method, which used time on the waiting list independent of disease process or severity. The LAS is based on medical urgency and transplant benefit. The Thoracic Organ Transplantation Committee ("Thoracic Committee") has been monitoring the impact of the LAS on the 4 diagnostic groups (Groups A, B, C, and D, as outlined in the lung allocation policy). While the death rate in the overall population has declined since the implementation of the LAS, the death rate for candidates in diagnosis Group B (primarily candidates with pulmonary hypertension) appears to have increased slightly.

Several analyses revealed an association between high bilirubin levels and waitlist mortality. This association was statistically significant for candidates in diagnosis Group B only. Further analyses

showed that an increase in a lung transplant candidate's bilirubin level that is 50% or higher than the value at listing, observed in 6-month period, increases the candidate's waitlist mortality. This proposal would add the change in bilirubin to the lung allocation score (LAS), with the intent to reduce deaths on the waiting list for candidates in diagnosis Group B. The current bilirubin value and the change in bilirubin were not significant predictors of post-transplant mortality. Mark Barr, M.D., Vice Chair of the Thoracic Committee, felt that this change will not adversely affect other diagnostic groups and may better predict the risk for patients that have been disadvantaged. The presentation outlined the statistical evidence used to support the proposal, as well as supporting literature and clinical observations. The proposal will require additional data to be collected on the lung waiting list, and programming changes to UNetSM.

The Committee discussed how this will be communicated to the public and potentially affected parties. Members of the Pulmonary Hypertension Association (PHA) (who would be affected by this change), made a presentation to the Thoracic Committee during the development of the proposal. UNOS staff will communicate with the PHA when the policy is approved. There is already a brochure that describes the LAS, which professionals distribute to their patients. This brochure will be updated with the change to the LAS if the policy is approved.

During the October meeting, the Committee used the proposed scorecard to assess this policy, and the proposal received an overall score of 15.3. The proposal received average scores of greater than 2 in the following categories: Best use of donated organs, statement of the problem, evidence, assessment, and impact. Thus, the policy scores highest in the policy development criteria, with lower scores for the strategic plan criteria. The Committee voted to support this proposal by a consensus vote.

5. Proposal to verify that foreign agencies importing organs to the United States, or receiving organs exported from the United States, are legitimate and test organs for transplant safety. The Ad Hoc International Relations Committee (AHIRC) is proposing this change to Policies 6.4.2 (Developmental Protocols in Organ Exchange) and 6.4.3 (Ad Hoc Organ Exchange). One of the annual goals for the AHIRC was to clarify policy language related to organ exchanges. The proposed modifications are intended to clarify and strengthen the existing policy language for importing and exporting deceased donor organs to and from the United States. Policy 6.4 (Exportation and Importation of Organs – Developmental Status) allows OPTN members to develop formal or ad hoc organ exchange agreements with foreign organizations. However, some of these foreign organizations may not have the same laws or organ procurement standards as the U.S. The AHIRC believes that it is necessary to verify the legitimacy of foreign organizations, as there are no organizations that credential organ procurement and transplantation organizations at an international level. In summary, the proposed changes address the following:

- Clinical (laboratory) safety of imported organs;
- Application of ethical practices in recovering deceased donor organs imported for transplant;
- Application of ethical practices in distributing organs exported from the US; and
- Legitimacy of the foreign organization engaged in importing an organ to an OPTN member or receiving an organ exported from an OPTN member.

The proposal requires that members who enter into formal exchange agreements with a foreign transplant center or OPO must develop protocols to address laboratory testing and safety of organs, legitimacy of the foreign participants, and ethical procurement and transplantation practices of the foreign participants. The AHIRC has already reviewed protocols between the Miami OPO and the Bahamas and between the New England Organ Bank and Bermuda. Committee members asked if the Miami OPO and the New England Organ Bank are the only OPOs that are impacted by this policy, and whether the OPOs in Canada or Mexico are handled differently from the Bahamas and Bermuda.

The policy stipulates that if a center participates in fewer than 6 exchanges with a foreign entity per year, these are considered “ad hoc organ exchanges” and do not require formal agreements. Above this number, the center must have a formal protocol. Committee members asked whether this means 6 times in total or 6 times per foreign entity. The policy implies that this is 6 times total. For example, if an OPO in the U.S. sends two organs to Canada, two to the Bahamas, and three to Bermuda, would a protocol be required for all of these entities, or just one? The Committee asked that the AHIRC clarify this policy. Committee members made several other comments:

- While the member is asked to obtain documentation, there is no requirement that the documentation be verified.
- Standards held by organizations in other countries may not be as stringent as those in the U.S., so that being recognized by their own government may not be an assurance of safety.
- The AHIRC should consider including isolated pancreatic islets shipped overseas to recipients and other cellular transplants in the policy.

As part of its evidence review, the AHIRC reviewed media reports about transplant tourism, as well as reports from the World Health Organization, and held a discussion with an expert on global transplant tourism. Most of these reports involve living donation. There is not much evidence available on which to base the policy changes.

During the September meeting, the Committee used the scorecard to assess this policy, and the proposal received an overall score of 15.3. The proposal scored highest for “Patient safety and transplantation oversight” and “statement of the problem.” The overall score was balanced between the strategic plan criteria and the policy development criteria. The Committee voted to support this proposal by a consensus vote.

6. Proposal to improve the safety of living donation by restricting the acceptance and transplant of living donor organs to OPTN member institutions. This proposal that would require that living donor organs must be recovered only from OPTN member institutions. A notice posted in the Federal Register on June 16, 2006 emphasized that living donor guidelines and policies developed by the OPTN should “promote the safety and efficacy of living donor transplantation for the donor and recipient.” Non-OPTN/UNOS facilities are not subject to the membership criteria required of OPTN member transplant programs that perform living donor transplants. Therefore, living donors recovered at non-OPTN member facilities may not be guaranteed the same protections provided at OPTN member institutions. The intent of the proposal is to offer the best possible protection to living donors. If a living donor experiences complications or dies after donating their organ at a non-OPTN member institution, UNOS would not be able to investigate the circumstances contributing to this adverse donor outcome.

A review of OPTN Living Donor Registration (LDR) forms revealed that 22 living donors donated their organ at a non-OPTN member hospital during the preceding five years. The Living Donor Committee discussed the possibility that donors may want to donate at a non-OPTN member hospital, but ultimately decided that the proposed requirement was necessary to offer the best possible protection to living donors. Committee members inquired whether UNOS had explored the reasons why the donors were procured at non-OPTN institutions in these 22 cases. It was reported that only 3 or 4 centers that performed the majority of these cases. However, during their discussions, Living Donor Committee members expressed the opinion that this practice should not occur, regardless of the reason. While this appears to be a limited issue now, the number of cases may increase with the implementation of a national kidney paired donation system. One member asked for the percentage

of these cases that involve donation to a pediatric recipient, theorizing that this could be a result of pediatric centers that are unable to recover adult donors.

Committee members discussed the possibility of a new membership category for institutions wanting only to perform living donor organ recoveries, as mentioned in the public comment proposal. This would enable the OPTN to modify its policies to require that the recovery center must be responsible for the donor follow-up. Members asked whether a parallel activity is planned with the Membership and Professional Standards Committee (MPSC), in order to facilitate this aspect of the proposal. The Living Donor Committee plans to review the public comment to determine if there is support for a new membership category prior to taking further steps. While several members felt that such a process must not pose an undue burden on centers, noting that a streamlined application process would be helpful, other members expressed concerns about making this process too easy for any hospital to become a donor center without some oversight. In general, Committee members felt that UNOS should have oversight over the donation process so that any adverse outcomes can be investigated thoroughly. The small numbers of centers receiving organs from non-OPTN members suggest that any unintended consequences of the proposed requirement (e.g., disadvantages to recipients, adverse impact on donation) should also be small. The Committee accepted the proposal in principle; a final vote will be done during a meeting or conference call in September.

The Committee received an update on this proposal during the September meeting. Since the proposal was released for public comment, one standalone center reported to UNOS that they had recovered four donor organs at a nearby non-OPTN center, and had been reporting the recoveries as if the organs had been recovered at the transplant center. If this proposal is approved by the Board, some transition plan may have to be developed for this center. The proposal received high scores in the patient safety and transplant oversight category, but concerns about potential negative impacts on donation led to negative overall scores in two categories: Best Use of Donated Organs and Maximum Capacity. One member noted that there were no data to show that there has been a problem with patient safety. The overall score was 5.8. The Committee voted to support this proposal by a vote of 9 in favor, 0 opposed, and 0 abstentions.

7. Proposal to modify the bylaws pertaining to conditional approval status for liver transplant programs that perform living donor transplants. The bylaws currently include the option of conditional approval for programs that do not have a second living donor liver surgeon who fully meets the criteria as specified in the Bylaws. However, the bylaws do not clearly delineate the path forward for programs that reach the end of the two-year conditional approval period and still do not meet the requirements for full approval. The proposed language will provide clear direction by stating the options available to a program when it reaches the end of its conditional approval term. Under the proposed change to the bylaw, the transplant center must inactivate or stop performing living donor liver transplants when transplant program personnel do not fully satisfy the criteria for full program approval by the end of the conditional approval period. This change was approved by the Board in June 2008, concurrent with public comment. This preliminary approval allowed UNOS to give more specific direction to 5 programs that fell into this category. The proposed changes would also allow centers applying for a living liver donor transplant program to understand what will be expected of them, which should help improve compliance with the bylaw. The Committee had no comments about this proposal.

In September, the Committee reviewed the key points of this proposal. The staff liaison noted that some negative comments on the proposal have been “off-topic,” in that they address the parts of the policy that are not included in the proposal. The proposal scored highest in the Patient Safety and Transplantation Oversight category, with an overall score of 7.9. The Committee voted to support this proposal by a vote of 9 in favor, 0 opposed, and 0 abstentions.

8. Proposal to change the OPTN/UNOS Bylaws to better define functional inactivity, voluntary inactive membership transplant program status, relinquishment of designated transplant program status, and termination of designated transplant program status. This proposal clarifies the definition of “functional inactivity” to include waiting list inactivation in UNetSM. The proposed language also defines short and long-term voluntary inactivation and specifies responsibilities for Member institutions that choose to inactivate a transplant program, including patient notification requirements. Currently, the bylaws define functional inactivity based on a lack of transplant activity, but do not specifically address waiting list inactivation. The MPSC reviewed data for several programs with inactive wait lists for greater than 14 days, with some inactive for more than 100 days. The MPSC was concerned that candidates were not notified of periods greater than 14 days during which the waiting list was set to “inactive” and therefore no organ offers would be made on their behalf. Under this proposal, candidates must be notified of these periods of wait list inactivation. The proposal also clarifies responsibilities for transplant programs that voluntarily inactivate and removes duplicative language from Attachment I of Appendix B. If the proposal is adopted, the MPSC will include waiting list inactivation as part of its functional inactivity review process. Programs that inactivate a wait list for greater than 14 consecutive days or 28 cumulative days in a year will be identified for MPSC Data Subcommittee review. Committee members asked why the threshold of 14 days was selected, and were informed that this time period is already used by the bylaws. The Committee had no further comments.

In September, the Committee reviewed the key points of this proposal. The proposal scored highest in the Patient Safety and Transplantation Oversight category, with an overall score of 7.0. The Committee voted to support this proposal by a vote of 7 in favor, 0 opposed, and 0 abstentions.

Table 1	Addition of Bilirubin to the LAS	Living Donors procured by OPTN Members	Foreign Agencies Exporting Organs	Living Donor Conditional Pathway	Waiting List Functional Inactivity
Patient Safety and Transplantation Oversight	1.2	2.6	2.7	2.2	2.3
Best Use of Donated Organs	2.5	-0.3	1	-0.1	0.1
Geographic Equity	0.7	-0.2	0.5	0.0	0.0
Maximum Capacity	0.3	-0.4	1.4	0.2	0.4
Operational Effectiveness	0.1	0.9	0.6	1.3	1.9
Statement of the problem	2.4	2	2.3	1.8	1.5
Evidence	2.7	0.2	1	0.8	0.8
Assessment	2.5	0.2	1.5	0.9	0.0
Impact	0.6	0	0.7	0.3	0.1
Significance/Innovation	2.3	0.8	0.8	0.4	0.0

Total	15.3	5.8	12.5	7.9	7.0
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Proposals Planned for Public Comment Submission, October 2008

9. Proposed changes to Policy 3.2.4 (Match System Access), Policy 3.1 – (Definitions), and Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates). Policy 3.2.4 requires recipients of deceased donor organs to appear on a match run. However, other policies (e.g. 3.5.2) prevent the member from complying with this requirement under some allocation scenarios, such as directed donations, compatible transplants intended to prevent organ wastage, and multiple organ allocation to a single recipient. In its review of potential policy violations, the MPSC has identified the need to provide instruction to members about what to do when a candidate does not appear on the match run. The MPSC intends to do this by modifying three policies as follows:

- Including a definition of directed organ donations in policy (Policy 3.1);
- Creating new requirements for allocating organs to candidates who do not appear on the match run (Policy 3.2.4); and
- Clarifying which match runs a multi-organ candidate must appear on (Policy 3.9.3).

The intent is to extend the same safety screening performed by the match run to candidates who cannot appear on the match run. The MPSC also hopes to promote a consistent understanding of (1) directed organ donations and (2) what “on a match run” means for a recipient of multiple organs from the same donor. This will improve the MPSC’s ability to assess potential policy violations by providing clear instruction to members in the form of policy language.

The proposed policy language includes a provision that, “if the transplant center deems it necessary to transplant a candidate who does not appear on a match run for the donor, such as in the event of a directed organ donation or to prevent organ wastage, the transplant center must maintain all related documentation and provide written justification to the OPTN upon request.” The proposal includes a list of items that must be included in the written justification. New proposed Policy 3.1.13 provides a definition of directed donation. Finally, proposed language for Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates) provides clarity for listing these candidates appropriately.

Committee members discussed the proposed policy modifications, and provide the following comments as feedback:

- Specify if there is additional documentation other than the routine documentation that the OPO must maintain for a directed donation.
- Make it clear, either through policy language or the Evaluation Plan document, how members are expected to submit documentation to the OPTN.

The Pancreas Transplantation Committee (“Pancreas Committee”) is developing a policy that would require centers that reallocate pancreas islets to send documentation directly to the Pancreas Committee. UNOS staff members were asked to ensure that these policies (once developed) are not in conflict with the proposed policy, so that transplant centers know where to send documentation if they reallocate islets.

During the September meeting, the Committee reviewed the summary and goals of the proposal. The Committee had some questions about the policy as it related to directed donation. The staff liaison explained that, if there is a directed donation to a candidate who is not yet listed, but the center knows

that the candidate will not appear on the match because of blood type compatibility or other reasons, there is no requirement to re-run the match. However, the preferable scenario is for the match to be re-run. The policy does stipulate that, if the candidate cannot appear on a match run, the Transplant Center must maintain documentation as to this occurred and ensure that the organ is safe and appropriate for the intended recipient. The Committee had no further substantive comments on the proposal, and supported the proposal by a vote of 7 in favor, 0 opposed, and 1 abstention.

10. Pancreas Listing for Technical Reasons (Pancreas Committee). In September 2007, the Department of Evaluation and Quality asked the Pancreas Transplantation Committee to consider changing the listing criteria for pancreas to include an option for candidates needing a pancreas for technical reason as part of a multivisceral transplant. Under current policy, a patient must be diagnosed with diabetes or have “pancreatic deficiency” to be added to the pancreas waiting list. However, the surgical procedure for the procurement of organs for a multiple organ transplant often includes the procurement of the pancreas regardless of whether the candidate has diabetes or pancreatic deficiency. This means that there are some circumstances where a candidate may need a pancreas to facilitate the procurement for a multiple organ transplant, but the policy does not have a mechanism for such candidates to be added to the pancreas waiting list.

Dixon Kaufman, M.D., Vice-Chair of the Pancreas Committee, reviewed data showing the increase in this practice over the last 5 years, and the distribution of diabetes status for multivisceral recipients who received a pancreas. Approximately 90% of patients who receive a multivisceral transplant do not have diabetes, and do not meet the current criteria. The Pancreas Committee is proposing to add language to policies 3.2.7 (Pancreas Waiting List Criteria) that would allow candidates who need the pancreas for technical reasons as part of a multiple organ transplant to be placed on the pancreas waiting list. The Pancreas Committee is also proposing changes to policy 3.2.9 (Combined Kidney-Pancreas Waiting List Criteria) intended to correct the terminology. The Committee supported the proposal by a vote of 8 in favor, 0 opposed, and 0 abstentions.

11. Proposal to Clarify the Islet Allocation Protocol. The Pancreas Transplantation Committee has been concerned that the current islet allocation policy language is ambiguous, as it does not define when a candidate is medically suitable for an islet transplant, and it allows a candidate to remain on the waiting list until he/she has had three islet infusions. This allows a program to accept an unlimited number of pancreata for islet infusion for a candidate without that candidate ever receiving a third islet infusion. A center that has a candidate listed with a lot of waiting time could potentially receive many offers that are subsequently re-allocated to other candidates on that center’s list. The proposed revisions are intended to:

- Define when a candidate is medically suitable for an islet transplant,;
- Set criteria for when a candidate can be listed as active on the pancreas islet waiting list;
- Increase efficiency and access for candidates on the islet waiting list to receive an offer;
- Clarify the process for re-allocating islets; and
- Explain what documentation a transplant center must maintain to demonstrate compliance with this policy.

Under the proposal, islet product medical suitability is defined as meeting the islet center’s investigational new drug (IND) product release criteria, as approved by the Food and Drug Administration (FDA). When islets are re-allocated, it must be to a medically suitable candidate covered by the same IND, based on waiting time. The proposed language provides definitions for active and inactive status. If the candidate is eligible for active status, the transplant center will need to document in the candidate’s record every six months either that the candidate is currently insulin

dependent, or that the candidate has had an HbA1c test in the past 6 months, that the most recent HbA1c test had a value of greater than 6.5%, and that the candidate is insulin independent. A candidate would not be eligible for active status if the he or she is insulin independent and has an HbA1c value of less than or equal to 6.5%. The criteria for active status are consistent with the American Diabetes Association's Standards of Medical Care in Diabetes (2008) and existing criteria in the IND for the NIH-funded Clinical Islet Transplantation Study (CIT) trials. The proposal has also been evaluated by the CIT consortium. The OPTN will monitor the activity of centers that accept pancreata for islets and the outcome of those acceptances.

The secondary committee reviewer stated that the proposal gave clarity to the criteria, would improve operational effectiveness, will facilitate the best use of the islets, and will provide equitable access for pancreas islet candidates. The Committee was supportive of the proposal by a vote of 7 in favor, 0 opposed, and 0 abstentions.

12. Proposed changes to Policy 2.0 (Minimum Procurement Standards for an OPO). Policy 2 sets forth the minimum standards that OPOs must adhere to for donor evaluation and management. The policy contains requirements for laboratory tests, verification of death, the type of documentation that OPOs must keep regarding donor management, etc. The policy was originally organized down by organ system. The intent of the proposal is to clarify the policy requirements to foster better and consistent donor management. The Department of Evaluation and Quality provided the OPO Committee with a list of the most common OPO infractions found on OPO audits. This list was used to help identify portions of policy that might be misinterpreted or confusing, or may be out of date. The proposal includes the following modifications:

- Reorganizes the content;
- Consolidates laboratory tests required for all donors into one list;
- Updates terminology;
- Eliminates repeated laboratory tests; and
- Tests that are not always available to OPOs or are not routinely conducted are no longer required.

These changes bring the policy in line with current practice. Further, clarification and reorganization of the policy should help OPOs better understand the requirements and may enhance compliance. A Committee member noted that a requirement for a basic metabolic panel would replace some of the tests that are named individually. The Committee supported the proposal by a vote of 7 in favor, 0 opposed, and 0 abstentions.

13. Review of Alternative Allocation Systems (AAS). The OPTN Final Rule states that any variance to the national system must be accompanied by a research design and include data collection and analysis plans. It also stipulates that these must be time limited. The OPTN contract also included a requirement that the OPTN review all AASs. (**Exhibit I**). This review began with an e-mail from Tim Pruett, MD, UNOS president, in March 2008 to all AAS participants notifying them that they must submit an application if they wished for the AAS to continue. The kidney AASs were put on hold while the new kidney allocation system is being developed. The application required that the participants address the following areas:

- The goals of the proposal;
- Why the current national system does not sufficiently address the needs of transplant professionals or candidates in the area;

- A research and evaluation plan;
- The target audience/population;
- The time period for the AAS;
- The data elements that will be used to evaluate it; and
- The predicted outcomes of the AAS.

Each organ-specific committee then made recommendations as to whether each AAS should be continued. The Committee's role is to assess the process and the supporting evidence for each AAS. There was not enough information about the new Thoracic AASs that were being considered by the Thoracic Committee.

Pancreas Alternative Allocation Systems

Tennessee Statewide (TNUK) Pancreas AAS. This AAS combines the state's simultaneous pancreas-kidney list with its solitary pancreas list. The AAS appears to improve the distribution of organs, especially in the group of individuals with diabetes and renal failure who receive a living donor kidney transplant who are then listed for a solitary pancreas. The Pancreas Transplantation Committee has discussed adopting this system nationally, and agreed that this AAS should be maintained. The application stated the anticipated benefits of the change, but there was no formal study design including objective measurable goals metrics or a time limit. The Committee discussed the difficulty of developing a rigorous study design with the small numbers under an AAS, and the lack of a control group. However, the Pancreas Committee felt that this system has advantages over the current system for certain individuals who may be disadvantaged by the current system. This AAS would also encourage living donation. Finally, since the outcomes for pancreas-alone transplants have improved, this will be examined by the Pancreas Committee for broader application. The Committee approved the recommendation to maintain this AAS by a vote of 9 in favor, 0 opposed, and 0 abstentions.

LifeSource (MNOP) (Allocation Sequence). There are two parts to this AAS: one involving solid pancreas organ allocation and one involving islet cells. The AAS assigns priority for well-matched isolated pancreas candidates because an analysis of MNOP's registry revealed that post-transplant outcomes are better with a higher degree of HLA match level. The application contained several published studies. MNOP selected a four year time for the AAS. The Committee noted that it is important to follow-up with each AAS to ensure that objectives are being met. The Committee approved the recommendation to maintain the pancreas allocation portion of the AAS by a vote of 10 in favor, 0 opposed, and 0 abstentions.

The Pancreas Committee did not support the continuation of the second part of the AAS, involving priority for pancreas islets. The current allocation policy for pancreata for islet transplantation prioritizes donors that are either older than 50 years of age or have a body mass index (BMI) of 30 or higher. This was established by studying whole pancreas allocation in these groups, which have a low rate of utilization. These donors also yield good islets for transplantation. The AAS uses a BMI cutoff of 28 and a donor age of 15 or higher. The Pancreas Committee did not support this as it is not in the best interest of patients awaiting a whole pancreas, and felt that the rationale was not compelling enough to support the AAS. The Committee agreed with the Pancreas Committee's recommendation to eliminate this portion of the AAS by a vote of 10 in favor, 0 opposed, and 0 abstentions.

Liver Alternative Allocation Systems

A subcommittee of the Liver and Intestinal Organ Transplantation Committee (“Liver Committee”) reviewed each of the liver AASs in detail and presented their recommendations to the full committee. The Liver Committee recommended that six AASs should continue, and the three should be discontinued. These are summarized as follows.

Region 1. This AAS has a region-wide list for Status 1A/1B patients without any local priority. The Liver Committee felt that this is in best interest of patients and is considering a proposal for regional sharing for Status 1A/1Bs as national policy. The Committee agreed to accept the Liver Committee’s recommendation to maintain this AAS by a vote of 9 in favor, 0 opposed, and 0 abstentions.

Region 9/New York State. This AAS is similar to the Region 1 AAS, in that there is a single Regional list for all Status 1A/1B and MELD/PELD candidates. The Liver Committee is also considering a proposal to adopt Regional sharing for MELD/PELD candidates as national policy. The Committee agreed to accept the Liver Committee’s recommendation to maintain this AAS by a vote of 9 in favor, 0 opposed, and 0 abstentions.

LifeGift (Houston). Under this AAS, a center performing a right and left lobe split is allowed to transplant both lobes into the institution’s “index patient” (an adult) and any other candidate on their waiting list. The Liver Committee felt that this is an experimental policy that should be encouraged, to determine whether it could be applied nationally. Current national policy says that the remaining segment must be offered to the local area, which may actually decrease splitting. This AAS has only been in place for a year. Committee members were concerned that only one split had occurred under the AAS. This may be because the organs are offered in order of highest MELD score, and candidates with high MELD scores have better outcomes with a whole liver rather than a segment. The trend towards older donors may also discourage splitting. The Liver Committee felt that the AAS should continue so that more data can be gathered. The Committee supported the continuation of this AAS by a vote of 10 in favor, 0 opposed, and 0 abstentions.

Region 10. Under this AAS, livers are shared regionally for Status 1A and 1B candidates. The Liver Committee supported the continuation of this AAS as it is in line with the Committee’s current proposal to share livers regionally. The Committee supported the continuation of this AAS by a vote of 10 in favor, 0 opposed, and 0 abstentions.

Region 8. Under this AAS, there is regional sharing for candidates with a MELD/PELD score of 29 or higher. This AAS has only been in place since May 2007, so the Region is still gathering data. The Liver Committee felt that the AAS should continue, and the Committee supported this recommendation by a vote of 9 in favor, 0 opposed, and 0 abstentions.

Hawaii. Hawaii’s AAS allows transplant programs to transplant deceased donor blood type O livers into blood type A and B recipients. Current national policy state that “With the Exception of Status 1A and 1B candidates, blood type O donors may only be allocated to blood type O candidates, or B candidates with a MELD or PELD score greater than or equal to 30. Any remaining blood type compatible candidates will appear on the match run list for blood type O donors after the blood type O and B candidate list has been exhausted at the regional and national level.” The rationale for the AAS is that, because of their location, Hawaii’s access to organs is limited, which puts blood type A and B patients at a disadvantage. The Liver Committee felt that blood type O organs in Hawaii should be offered first to Status 1A/B blood type O patients in the Region before local MELD/PELD candidates. The current proposal for Regional sharing for Status 1A/1B candidates would obviate this

request. The Committee was in favor of continuing the AAS (9 in favor, 0 opposed, 0 abstentions), but also recommended that blood type O livers should be offered to Status 1 candidates in Region 6 (9 in favor, 0 opposed, 0 abstentions).

Ohio Statewide. Under the Ohio AAS, livers are offered first to regional status 1 candidates, then to local patients with a MELD/PELD score of 35 or higher, then to patients in Ohio with a MELD/PELD score of 35 or higher. Ohio candidates with MELD/PELD scores lower than 35 are then offered the organ (local first, the state) before the organ is offered to MELD/PELD candidates in Region 10. The Liver Committee felt that the imposition of another layer between local and regional may disadvantage candidates within the region. The AAS has been in place since 1998, and there is no proposal to adopt this as national policy. Further, two organizations in the state that are subject to the AAS had indicated that they do not wish to continue to participate in the agreement. The Committee agreed with the Liver Committee's recommendation to eliminate this AAS, with 9 in favor of eliminating the AAS, 0 opposed, and 0 abstentions.

Tennessee Statewide. Tennessee has a statewide list for liver allocation, after which livers are offered to the Region. The Liver Committee felt there was value to the AAS in terms of patient access due to broader sharing. However, the AAS is not time limited, there was no research design, and there is no plan for statewide sharing for the national allocation system. The Committee agreed with the Liver Committee's recommendation to eliminate this AAS by a vote of 9 in favor, 0 opposed, 0 abstentions.

Florida Statewide. Under this AAS, livers are offered first locally and then to the statewide list prior to being offered to the region. This AAS has been in place for many years and is not time-limited. The Liver Committee did not feel that the AAS had applicability to the national allocation system. It was reported that other programs in the Region were not aware that this AAS existed. The Committee agreed with the Liver Committee's recommendation to eliminate this AAS by a vote of 9 in favor, 0 opposed, 0 abstentions.

Review of Proposals in Development

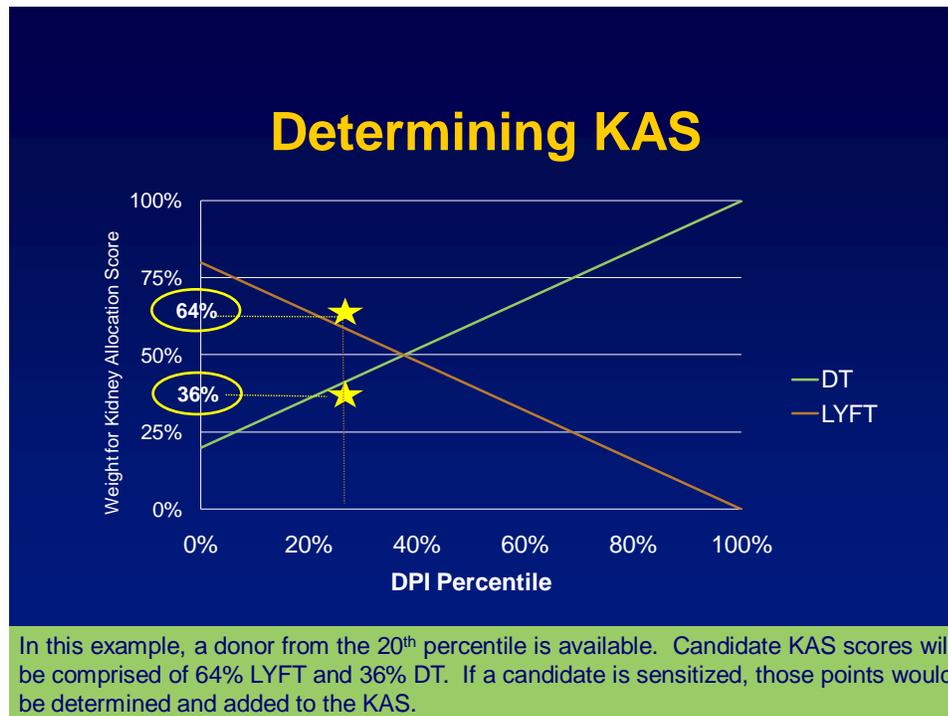
14. Update on Revisions to the Kidney Allocation System. Kenneth Andreoni, vice chair of the Kidney Transplantation Committee ("Kidney Committee"), provided an update on the status of the proposal during the July meeting. The OPTN is awaiting a final decision by Office of Civil Rights on the use of age in the Life Years Following Transplant (LYFT) score calculation. Dr. Andreoni outlined the major components of the proposal, which include:

- Ranking candidates based upon objective medical criteria (LYFT);
- Replacing standard- and extended criteria donor designations with donor profile index (DPI);
- Changing from time since listing to time on dialysis (DT); and
- These 3 components are combined into a Kidney Allocation Score (KAS).

Other items under consideration include: maintaining priority for pediatric candidates and prior living donors; including a sliding scale priority for sensitized candidates; eliminating absolute priority for 0-ABDR mismatch to unsensitized candidates; eliminating the kidney payback system; changes to simultaneous kidney-pancreas allocation; and incorporation of the A₂/A₂B system into the national system.

The KAS is based on LYFT, DT, DPI, and candidate sensitization level, and is calculated for each candidate when a donor becomes available. The factors included in each calculation were described for the Committee. The interactions between LYFT, DPI, and DT in determining the KAS are depicted in Figure 1.

Figure 1



Dr. Andreoni presented the impacts of the KAS on patients by race, blood type, diagnosis, sensitization level, and age, as modeled using LSAM. He also demonstrated a spreadsheet created by the SRTR that will allow individuals to calculate the LYFT, DPI and KAS based upon various patient and donor characteristics. The spreadsheet will also provide an estimate of how long a patient might wait in a given OPO for organs of varying quality.

A Committee member noted that patients might also want to know how long they might expect to live post-transplant for a given DPI. One potential unintended consequence of this level of detail may make “DSA-shopping” easier for candidates looking to shorten their waiting times. However, patients can list at multiple centers now, using existing data on USTransplant.org for guidance about waiting times and survival. Another member asked about transition plans for currently waiting patients. Dr. Andreoni noted that, upon implementation, waiting time will continue to dominate LYFT scores in many DSAs because of the weight given to time on dialysis in the KAS.

15. Allocation of Organs from Altruistic Donors. This proposal arose from an Annual Goal set for the Living Donor Committee for 2007-2008, which asked the Committee to consider if components of the Ethics Committee white paper on altruistic living donation should become policy. That white paper proposed that “*non-directed organs from living donors be allocated according to the existing algorithm governing the allocation of cadaveric organs within the appropriate sharing unit.*” The Living Donor Committee is recommending that centers complete a “test match run” of their waitlist candidates, and that the organ would be allocated according to that test match run. This would enable

UNOS to verify that the organ was allocated to most appropriate waitlist candidate. The Committee provided early feedback in January 2008, with several comments related to the potential impact on live donor exchange chains.

The Living Donor Committee noted that there are no data to support a requirement that the recovery center should also place the altruistic donor organ, and was unsure what the Policy Oversight Committee would recommend in such a situation. The Living Donor Committee was also seeking comment on whether these organs should be offered to the best candidate at the local, regional or national level. The Living Donor Committee noted that studies on the effects of cold ischemia time on kidneys do not support limiting allocation to the recovery center, but that there is a small risk of damage or loss of the organ if transported.

Committee members asked if donors usually prefer to donate to a specific hospital or to the general transplant pool. Individuals at the center paying for the donor work-up may feel that the center should be able to place the organ. Lori Brigham, MBA, Vice-Chair of the OPO Committee, explained that among the transplant programs in the Washington, DC area there is an agreement that the organ is a community resource. The donor chooses the recovery center, but the organ is allocated among the transplant centers in that area. Some Committee members asked why the local area was selected, versus regional or national allocation. These donors could also be used to start a chain within a wider area, thereby resulting in multiple transplants and making the most of the donation. The Committee asked that the Living Donor Committee provide the number of altruistic living donors that have donated each year, so that they might better understand the potential impact of this policy.

The Committee reviewed the requested data during the September meeting. There have been 511 non-directed living donors; these data were provided by donor age, ethnicity, and other factors (e.g., diabetes, hypertension). This practice could increase with paired donor exchange. The Living Donor Committee is asking the Policy Oversight Committee how it considers the development of Living Donor policies in cases of limited data/evidence. One approach would be to hypothesize what might happen, and monitor the effect of the policy change. One Committee member noted that, as we have a fair and equitable national allocation system, we would also want to ensure fair allocation for altruistic donation. If a person makes a directed donation to a center, that act may take the decision out of the realm of the national policy. However, a donor may donate to “the person who needs it the most.” One member suggested that that the Living Donor Committee could also try to identify where the organ should go (center, DSA, region, or nation) and who will pay for the costs if the organ leaves the center.

16. Proposal to Standardize MELD/PELD Exception Scores. Since MELD/PELD was implemented in 2002, transplant centers have had the opportunity to request higher MELD/PELD scores through their Regional Review Board (RRB). The Committee realized that there are substantial inconsistencies across regions regarding which diagnoses should be granted additional points, and how many points should be awarded. This proposal is intended to establish standard MELD/PELD exception scores to be used across all UNOS regions. The Liver Committee has taken the recommendations of the MELD Exception Study Group (MESSAGE) Consensus Conference which was held in March 2006 and the proceedings published in *Liver Transplantation* in December 2006. The proposal recommends criteria and MELD/PELD scores for seven diagnoses that account for 21% of all non-HCC exceptional point requests. Appropriate mortality risk scores for each diagnosis were determined using OPTN and SRTR analyses. By increasing the number of “standard exceptions,” this may also pave the way for the Committee’s charge to investigate a national review board. The Committee felt that the Liver Committee is on track with the development of this proposal.

17. Proposals to Create Regional Sharing of Livers for Status 1 and MELD/PELD Candidates. After the Region 8 AAS was implemented, the Liver Committee began to look at what the impact might be for a national policy that shared livers regionally for candidates with a MELD/PELD of 29 or higher. LSAM modeling of this system predicted a decrease in total deaths and an increase in the percentage of transplants performed using non-local organs in each region. However, the proportion of transplants by region would not change substantially, and the average distance traveled would only increase slightly. The Liver Committee is also proposing to regional sharing of livers for Status 1A/1B candidates. These proposals will be circulated separately, in case there is more support for status 1 Regional sharing than for sharing for candidates listed with a MELD/PELD score. Committee members asked why UNOS Regions are still being considered, as opposed to a system such as concentric circles, as used in thoracic organ allocation.
18. Proposed listing requirements for simultaneous liver-kidney (SLK) transplant candidates. Since MELD/PELD was implemented in 2002, there has been an increase in the number of candidates receiving combined liver-kidney transplants due to the priority given to creatinine and dialysis. The Liver and Intestinal Organ Transplantation and Kidney Transplantation Committees formed a joint subcommittee tasked with identifying those candidates who are unlikely to regain renal function after liver transplantation and to standardize allocation for SLK candidates. Data presented at consensus conferences held in 2005 and 2007 and in peer-reviewed literature, together with OPTN analyses, were used to determine the appropriate GFR and dialysis time cut-offs are for listing these candidates. The policy will include a “safety net” to give candidates additional priority if they that do not meet these criteria but are determined to need a kidney after the transplant.

Ongoing Committee Projects

19. Annual Data Review. As part of the data reduction project conducted in 2006, the Board asked that the Committee conduct an annual data review to (1) assess the impact of the reduction in data elements, and (2) to review requests for new data elements. As the data reduction project was not fully implemented until March 2008, the Committee did not conduct an annual review in 2007. Additionally, the Board approved the following resolution in June 2006: “The POC proposes to collect malignancy data for another 2 years, until the SRTR analyses of linkage to other sources have been completed, at which point the issue will be revisited by the POC and Board.”

The Committee reviewed a list of potential new data elements that committees either have requested or may be considering requesting (**Exhibit J**). Additional items may be identified during the organ-specific committees’ review of the SRTR center-specific report methodology. Four of the items identified may require modifications to the UNetSM forms, which cannot be modified until the forms are resubmitted to the Office of Management and Budget (OMB) for approval in 2010. Six items would involve changes to the waiting list, which was not part of the original Data Reduction project. The Pancreas Transplantation Committee may request forms for pancreas islets recipients, which currently have no forms. Once all of these requests are formalized, the Ad Hoc Data Managements Working Group will review the requests and report back to the Committee.

Robert Merion, M.D., presented slides from the Transplant Cancer Match Study (**Exhibit K**), which is a collaborative effort between the Division of Cancer Epidemiology and Genetics within the National Cancer Institute (NCI) and the SRTR, under contract to HRSA. The project links OPTN transplant registry data with multiple cancer registries in order to systematically identify cancers in transplant recipients, candidates and donors.

Dr. Merion explained that there is under-ascertainment of cancers due to reliance on OPTN data, as recipients are followed most closely in first years after transplant but may be less so in later years,

when the risk of cancer increases. Further, the cancers are often treated at non-OPTN institutions and the data are not reported back to the OPTN. In order to obtain more complete information, the SRTR has been working to link OPTN data with data from individual Surveillance Epidemiology and End Results (SEER) sites. Within the SEER coverage areas, there is a high ascertainment of cancer.

An initial study included data from four SEER sites covering 40,423 recipients. The SRTR identified 1,296 cancers from the OPTN data, and the SEER data identified an additional 776 cancers. The Transplant Cancer match study will expand this endeavor to all 18 SEERs. The objectives of the study are to quantify cancer risk in transplant recipients and transmission of cancer from donors. The cohort will include transplant recipients between 1987 and 2005 and donors from 1990-2005. The 18 registries represent slightly fewer than 50% of these recipients. Although the NCI approved the project in June 2006, issues related to protocol review, confidentiality and data security, and lack of a centralized process have slowed the project down.

Dr. Merion noted that the Transplant Cancer Match Study will miss some outcomes due to incomplete reporting to cancer registries, in particular early-stage post-transplant lymphoproliferative disorder and squamous cell skin cancer. Thus, the Transplant Cancer Match Study is not a substitute for continuing OPTN data collection on malignant outcomes. The SRTR would recommend that he OPTN continue to collect malignancy data.

20. Geography Study. In 2007, the Committee recommended to the Board that the OPTN conduct a study of the effects of geography on organ allocation. The Board approved this recommendation and assigned to the Committee. The Committee reviewed an inventory of all the projects that the Liver Committee is undertaking related to geography. The Committee received a similar list of projects that the Thoracic Committee has worked on related to geography (**Exhibit L**). The Committee will review these projects and assess whether there are other projects that the Thoracic Committee should undertake.
21. Policies Relating to Multiorgan Transplants. In October 2007, the Committee reviewed a letter from a member asking that the policies related to multiorgan transplants be reviewed. Upon review, the Committee indicated that the policies (primarily 3.9.3) are difficult to understand, and also use words such as of “may,” “should,” and “recommended,” which make them more confusing. At the time, the Committee recommended that “A small working group be established, with representation from the Liver, Kidney, and Thoracic Committees, to develop consensus on these policies.” The Liver and Kidney Committees have begun to address the issues surrounding liver-kidney allocation. The Pancreas and OPO Committees were also looking into these issues. In order to move the project forward in a unified fashion, UNOS staff recommended that a subcommittee consisting of the Vice Chairs of the Liver, Kidney, Pancreas, Thoracic, and OPO Committees, should be established.
22. Review of Specification Document for Policy 7.1.3. During the data reduction project, this Committee recommended a change to the requirement for post-transplant follow-up, which was approved by the Board in February, 2008. After review of SRTR analyses pertaining to ascertainment of death after graft failure, the Committee felt that the policy could be modified to require that each organ transplant must be followed until graft failure, rather than until death or retransplantation. Volunteers from the Committee will be needed to review Programming Specification Document.

Other Updates

23. Update on the Kidney Paired Donation (KPD) Proposal. Dr. Andreoni provided an update on the status of the KPD proposal during the July meeting. He noted that during the March 12, 2008

meeting, the Kidney Committee voted to send the proposal that had been circulated for public comment in 2006 to the Board, with the following revisions:

- Include three-way matching as well as two-way matching; and
- Allow donor and candidate preferences (travel, age, etc) to go into effect at the beginning of the program.

The proposal was approved by the Board in June 2008. It will be conducted as a pilot program and the Kidney Committee will evaluate the program every 6 months for the first three years of the pilot program and recommend appropriate adjustments to the system

Dr. Andreoni noted that the Kidney Committee has agreed to take a two-tiered approach to HLA. First, centers will be asked to list all unacceptable antigens for each candidate, even those with low levels of antibody. If the donor has none of the candidate's unacceptable antigens, then there is a high likelihood that there will be a negative crossmatch. The center can also list those antigens that have some level of antibody, but that the center feels that they are not truly 'unacceptable', as "undesirable." The candidate could receive offers for donors with these antigens, knowing that there may be a higher chance of a positive crossmatch. Dr. Andreoni reviewed the point assignments that will be used for HLA match level, prior living donor status, sensitization, age, waiting time, and geographic proximity. Both donors and recipients will be able to specify their choices with regard distance traveled, and recipients will be able to choose the nephrectomy type and donor characteristics. Additional elements (e.g., closed and open altruistic donor chains) will be circulated for public comment separately. The Financial and Education Subcommittees will continue to study the costs and develop educational materials. The Kidney Committee will also assess the need for central oversight of the process after the match results are sent to transplant centers.

**Attendance at the July 15, 2008 meeting of the
OPTN/UNOS Policy Oversight Committee
Chicago, IL**

Member	Position	Attended
Edward Garrity Jr., M.D., M.B.A.	Chair	X
Kenneth Andreoni M.D.	At-Large	By Telephone
Mark Barr M.D.	At-large	X
Lori Brigham M.B.A.	At-large	X
David Campbell M.D.	At-large	X
Laura Ellsworth	At-large	
Dixon Kaufman M.D., Ph.D.	At-large	X
Mary Kelleher M.S., C.I.P.	At-large	X
Henry Randall M.D.	At-large	X
W. Kenneth Washburn M.D.	At-large	X
Monica Lin Ph.D.	Ex-Officio	By Telephone
Christopher McLaughlin	Ex-Officio	By Telephone
UNOS Staff in Attendance		
Erick Edwards, Ph.D.	Assistant Director, Research	X
Mary D. Ellison, Ph.D., M.S.H.A.	Assistant Executive Director, Federal Affairs	X
Ann Harper	Policy Analyst/Liaison	X
Karl J. McCleary, Ph.D., M.P.H.	Director, Policy, membership, and Regional Administration	X
Sally Aungier	Liaison, MPSC	By Telephone
Lee Bolton, MSN, ACNP	Liaison, Living Donor Committee	By Telephone
Betsy Coleburn	Liaison, MPSC	By Telephone
Elizabeth Sleeman, MHA	Liaison, MPSC	By Telephone
Vipra Ghimire, MPH, CHES	Liaison, Thoracic Committee	By Telephone
Catherine Monstello, B.S., RRT,	Liaison, MPSC	By Telephone
Elizabeth Sleeman, MHA	Liaison, Pancreas Committee	By Telephone
SRTR Staff in Attendance		
Robert Merion, M.D.	SRTR Representative	X

**Attendance at the October 16, 2008 meeting of the
OPTN/UNOS Policy Oversight Committee
Chicago, IL**

Member	Position	Attended
Edward Garrity Jr., M.D., M.B.A.	Chair	X
Kenneth Andreoni M.D.	At-Large	
Mark Barr M.D.	At-large	By Telephone
Lori Brigham M.B.A.	At-large	X
David Campbell M.D.	At-large	By Telephone
Laura Ellsworth	At-large	X
Dixon Kaufman M.D., Ph.D.	At-large	X
Mary Kelleher M.S., C.I.P.	At-large	X
Henry Randall M.D.	At-large	X
W. Kenneth Washburn M.D.	At-large	X
Monica Lin Ph.D.	Ex-Officio	By Telephone
Christopher McLaughlin	Ex-Officio	By Telephone
Janis Orłowski, MD	Ex-Officio	By Telephone
UNOS Staff in Attendance		X
Erick Edwards, Ph.D.	Assistant Director, Research	X
Mary D. Ellison, Ph.D., M.S.H.A.	Assistant Executive Director, Federal Affairs	X
Ann Harper	Policy Analyst/Liaison	X
Karl J. McCleary, Ph.D., M.P.H.	Director, Policy, membership, and Regional Administration	X
Robert Hunter, MPA	Policy Analyst	X
Alex Miller, MPH	Policy Analyst	X
Sally Aungier	Liaison, MPSC	By Telephone
Lee Bolton, MSN. ACNP	Liaison, Living Donor Committee	By Telephone
Betsy Coleburn	Liaison, MPSC	By Telephone
Elizabeth Sleeman, MHA	Liaison, MPSC	By Telephone
Vipra Ghimire, MPH, CHES	Liaison, Thoracic Committee	By Telephone
Catherine Monstello, B.S., RRT,	Liaison, MPSC	By Telephone
Elizabeth Sleeman, MHA	Liaison, Pancreas Committee	By Telephone
SRTR Staff in Attendance		
Robert Wolfe, Ph.D.	SRTR Representative	X
Erik Roys	SRTR Representative	X