

OPTN/UNOS POLICY OVERSIGHT COMMITTEE SUMMARY

Action Items for Board Consideration:

- The Board is asked to consider a modification to Policy 7.1.3 (Reporting Definitions) that will require that each organ transplant must be followed until graft failure (Item 1, Page 3).

Other Significant Items:

- The Committee reviewed eleven policy and Bylaw proposals and made recommendations for the sponsoring committees to consider as the proposals are finalized (Item 2, Page 4).
- The Committee reviewed three policy proposals that are in development (Item 3, Page 8).
- The Committee completed its review of Policies 3.7 (Allocation of Thoracic Organs); 3.3 (Organ Distribution: Acceptance Criteria); 3.4 (Organ Distribution: Organ Procurement, Distribution and Allocation); and 6 (Transplantation of Non-Resident Aliens) (Item 5, Page 12).
- The Committee reviewed policies related to multiorgan transplants and recommended that a small working group be established, with representation from the Liver and Intestinal Organ, Kidney, and Thoracic Organ Transplantation Committees, to develop consensus on these policies (Item 6, Page 14).
- The Committee developed a path forward for its study of geographic variations in organ allocation (Item 7, Page 14).
- The Living Donor Data Task Force (LDDTF) has been established (Item 8, Page 16).

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**REPORT OF THE POLICY OVERSIGHT COMMITTEE
TO THE BOARD OF DIRECTORS
Orlando, Florida
February 20-21 2008
Janis M. Orlowski, M.D., Chair**

Framework for Committee Discussions

At the start of the October 15, 2007, and January 15, 2008, meetings, Janis M. Orlowski, M.D., Committee Chair, reviewed the charge to the Policy Oversight Committee (POC) and the proposed 2007-2008 Annual Goals for the POC (**Exhibit A**).

Items for Board Consideration

1. Modifications to Policy 7.1.3 (Reporting Definitions). In June 2006, the Committee recommended that Policy 7.1.3 should be modified to eliminate the requirement to follow patients after graft failure; this was approved by the Board. The intent was to discontinue follow-up after graft failure for kidney or kidney-pancreas recipients, as the death information for these patients can be ascertained from other sources. However, the policy as written would require that centers follow all patients until death. SRTR analyses (**Exhibit B**) demonstrated that almost all deaths are captured through non-OPTN sources, eliminating the need for the OPTN to follow these patients via follow-up forms. For the 4,008 kidney transplants performed in 2004, 202 were reported as having died on the day the graft failed, and 200 of those deaths were found using a source other than the OPTN data. Of the 55 recipients who were reported to have died within the first week after graft failure, all were found using a source other than OPTN data, and of the 579 reported as having died between the first week and 1 year, only 3 were identified in the OPTN database solely. Similar results were found for liver, lung, heart, pancreas, and intestine recipients. Thus, there are very few deaths after graft failure that are only known through OPTN data (i.e., cannot be found from another source). For liver recipients, graft failure is defined as either re-transplant or death, so graft failure should be captured by one of these two events. However, in 79 cases, graft failure is recorded but there is no record of a death or re-transplant. These anomalies were also seen for lung and heart recipients, and the SRTR will work with the OPTN to resolve these anomalies. The follow-up form is still needed to collect data for deaths on the day of graft failure. Modifications to this were on hold due to the Operations Committee's proposed changes to Policy 7, which have been withdrawn. In October 2007, the Committee approved the following resolution for consideration by the Board of Directors:

**** RESOLVED, that Policy 7.1.3 shall be modified as follows, effective pending notice and programming in UNetSM:**

- 7.1.3. ~~Each organ transplant must be followed until graft failure. The follow-up period for all transplant recipients will be until death or retransplantation. Following graft failure, every reasonable effort should be made to follow surviving recipients for a minimum of two years.~~

Committee Vote: 13 in favor, 0 opposed, 0 abstentions.

The Executive Summary for this proposal can be found in **Exhibit C**.

Other Significant Items

2. Review of Proposals and Bylaws Circulated for Public Comment. In October 2007, the Committee reviewed one Bylaw proposal that had been circulated for public comment. In December 2007, the Committee reviewed the Living Donor Committee's proposed Resource Document for the Medical Evaluation of Living Kidney Donors via conference call. In January 2008, the Committee reviewed seven policy proposals and two bylaw proposals scheduled for public comment in February 2008.

During the January 2008 meeting, Ann Harper, Committee Liaison, noted that the Committee would be using a slightly different process for policy review this time, as the proposals were still in the final writing phase (due January 16, 2008), and would be distributed for public comment in February 2008. This meant that the Committee would be taking an early look at these proposals, and that its comments would most likely not be incorporated into the proposal circulated for public comment. The Committee could assign reviewers to proposals that are too complex for an initial review. The sponsoring committees will meet in March, and will be able to review the POC's comments and provide input back to the Committee for its April 2008 meeting. In the interim, Committee members could assign the proposals a score using the policy scorecard. Committee members were reminded of the questions to keep in mind for policy review:

- Does the proposal have objective, measurable goals?
- Are the goals scientifically based?
- What aspects/elements of the proposal directly further the mission, strategic plan and long term goals of the OPTN and the HHS performance goals?
- What suggestions can the POC offer to the sponsoring committee to make this a stronger proposal?

The following summarizes the Committee's review of all 11 proposals:

- A. Proposed Bylaw Modification Circulated for Public Comment, September 2007. The Membership and Professional Standards Committee (MPSC) proposed changes to the OPTN Bylaws, Appendix B, Transplant Hospitals; Section B. Survival Rates; and Section C "Inactive Membership Status"; and Attachment I, Section II, "Inactive Program Status"; and to the UNOS Bylaws, Attachment I, Section II "Inactive Program Status" and Attachment II, Section XIII, C, (10) "Survival Rates." The change to the policy documents the MPSC's current practice of holding informal discussions with members during its review of survival rates and activity at transplant programs, and is intended to delineate when "informal discussions" may be held with an institutional member. Committee members asked that UNOS counsel review this in terms of the jurisdiction that applies for due process and peer review, which varies from state to state.
- B. Resource Document for the Medical Evaluation of Living Kidney Donors. During the December 2007 conference call, the Committee reviewed the history and intent of this proposal, including the Committee's previously stated concerns with the document. The proposal has undergone extensive revisions, and is now identified as a "resource document." Committee members listed items that are still problematic, such as the implied need for the donor to have disability insurance. Some Committee members still question the role of the OPTN in setting medical criteria. However, Committee members noted the importance of having such a resource document for living donors, and for those who advise them. Unfortunately, there are useful pieces of information (such as the risk of a donor losing medical insurance) that the community does not have at this time. The Committee approved the following motion:

Motion: The Committee accepts the proposed Resource Document for the Medical Evaluation of Living Kidney Donors in concept, with the following caveats:

- The language should more clearly outline the intent of the document;
- Some issues remain regarding the specific details of the proposal, such as:
 - The implied need for the donor to have disability insurance;
 - The list of viruses that the donor must be screened for (such as HTLV);
 - The blood pressure and metabolic evaluation seems excessive; and
 - The proposal still contains details (e.g., ABO blood typing X2) that make it appear to be prescriptive.

Committee vote: 9 in favor, 0 opposed, 0 abstentions.

- C. Proposal to Allocate Pediatric Donor Hearts More Broadly. The Committee reviewed proposed modifications to the allocation sequence of pediatric donor hearts. This is the first of a series of proposals related to the Pediatric Committee's charge to reduce deaths on the pediatric waiting list. The proposal was based OPTN descriptive analyses. The intent of the proposal is to share pediatric donor hearts more broadly to the sickest candidates first by combining local and Zone A offers for Status 1A pediatric candidates and for 1B pediatric candidates respectively. In addition, remaining pediatric candidates will receive offers for young pediatric donor hearts before adults within each status and allocation zone in an effort to direct these small organs to first to younger children.

Committee members asked whether this might adversely impact adult heart candidates. However, the relative position of adults on the list would not be changed. The proposal simply combines the local and Zone A pediatric categories for Status 1A and 1B, which are already above the respective adult categories. The diagram provided clarified the sequence. Committee members felt that the proposal language should be equally clear. The Committee suggested that the Pediatric Committee provide metrics that would demonstrate whether the proposal meets the goal of decreased pediatric waiting list deaths. Possible metrics include mortality rates in status for pediatric heart candidates by Zone, and waiting time by Status, both before and after the policy change.

- D. Proposal to Change Allocation of Pediatric Lungs and Allow Creation of a Stratified Allocation System for 0-11 Year-Old Candidates. The Committee reviewed proposed modifications to the allocation sequence for pediatric lung candidates (defined as age 0-11 yrs). The proposal was based on OPTN descriptive analyses. For young pediatric candidates, lungs are currently allocated based on waiting time alone. The proposal has two components: (1) a simple stratified system for pediatric candidates (based on objective medical characteristics) to direct donor lungs to the sickest of these candidates first; and (2) broader sharing for young pediatric donor lungs, allocating first to local, Zone A and Zone B young pediatric candidates, and then to local and Zone A adolescents before local offers are made to adults. The Committee suggested that the Pediatric Committee provide metrics that can demonstrate whether the proposal meets the goal of decreased pediatric waiting list deaths. The Committee asked whether the policy would include requirements for updating patient status. It was reported that the exact mechanics of the status recertification have not been determined. One Committee member cautioned that requirements for updating patient status that are at the discretion of the physician (as opposed to a specified time frame) may adversely impact patients of lower socioeconomic status who may not have as frequent access to their physicians.

- E. Proposed Changes to How 0-10 Year-Old Donor Livers and Combined Liver-Intestines Are Allocated. This proposal from the Pediatric Committee addresses allocation of young pediatric donor livers. The proposal was based on OPTN descriptive analyses. The intent of the proposal is to broaden sharing to the sickest pediatric candidates on a national level. All 0-11 year-old Status 1A pediatric liver and combined liver-intestine candidates would receive offers before local adult Status 1As, for donors age 0-11. Allocation for donors age 11-17 would remain as it is currently. The 0-10 age group was specifically chosen because, historically, only 1% of all livers from donors less than 12 years of age are transplanted into adults. The proposal is expected to reduce waiting list mortality for the children at highest risk of death without negatively impacting adult candidates. Committee members asked that the proposal clearly outline the allocation sequence for donors age 0-10, 11-17 and 17 and older. Committee members expressed confusion about how match run lists are generated for liver and liver-intestine candidates. Currently, both liver and liver-intestine candidates appear on the liver list if consent is obtained for both organ (and the consent is indicated on the match). There is a separate list for intestine-alone candidates, and the allocation for liver-intestine candidates is not made from the intestine list.
- F. Proposal to Change Organ Time Limits to Organ Offer Limits for Zero Antigen Mismatched (0ABDRmm) Kidneys, Pancreata, and Kidney/Pancreas Combinations. In September 2007, the Board approved changes to Policy 3.5.3.5 that allowed OPOs to make zero mismatch organ kidney offers, and required OPOs to make a certain number of 0ABDRmm kidney offers. The modifications were in response to the Executive Committee's May 2007 resolution to allow OPOs to make these offers. The number of offers was selected based on historical data from the Organ Center. The intent was to have a process that is applied consistently across OPOs, that is in line with DonorNet® advances, and can be monitored UNOS staff. However, although the policy for kidneys was approved in September 2007, the policy for offering 0ABDRmm pancreata and kidney-pancreas combinations was not changed at the same time. The current proposal would bring consistency to all policies related to 0ABDRmm offers.

The Committee asked about the programming implications of the proposal. The only programming needed would be to create an indicator to denote when the required number of 0ABDRmm offers has been reached. The OPO is not entitled to a payback for the kidney if the OPO continues to make zero mismatch kidney offers beyond what is required in policy. This can happen very quickly with DonorNet®. Currently, there is no way within DonorNet® to stop the offers at a certain number. Offers can be limited to a certain number of offers at a time, but until the organ is placed, offers will continue to be made. Committee members felt that OPOs should be informed that, if they choose to place these offers through DonorNet® rather than through the Organ Center, they risk losing a payback. This may be a short-term fix until a new kidney allocation system, without paybacks, is implemented. A member also asked that sections of the policy that still involve time (e.g., OPOs must offer kidneys within 8 hours of procurement) be clearly delineated from what must now happen based on the number of offers. The actual policy language will be assigned to committee reviewers.

- G. Proposal to Eliminate Mandatory Sharing of 0ABDR Kidneys for Unsensitized Adult Candidates. The Committee first reviewed this proposal in concept in October 2007. During that meeting, Ken Andreoni, MD, vice chair of the Kidney Transplantation Committee, presented a proposal to eliminate mandatory sharing for 0ABDRmm kidneys except for pediatric and sensitized candidates (**Exhibit D**). Dr. Andreoni pointed out that:
- Most paybacks are for 0ABDRmm recipients; and
 - Most 0ABDRmm recipients have a PRA <20%.

Alan Leichtman, MD, SRTR representative, noted that the net loss in graft survival from payback kidneys almost offsets the gain from OAMDRmm kidneys in non-sensitized patients. By a vote of 10 in favor, 0 opposed, and 1 abstention, the Committee supported the proposal concept. In January 2008, the Committee reiterated its support for this proposal.

- H. Proposed Modifications to Allow an Additional Method for Waiting Time Reinstatement for Pancreas Recipients. The Committee first reviewed this proposal in concept in October 2007. The issue was raised in a memorandum sent to the Committee from Rainer Gruessner, MD, Chair of the Pancreas Transplantation Committee, regarding the current policy for waiting time reinstatement for pancreas recipients. Dixon Kaufman, MD, vice chair of the Pancreas Transplantation Committee explained that, in 5-10% of pancreas transplants, there can be an immediate graft thrombosis resulting in non-function requiring retransplant. The patient may have waited years for the transplant. There is a process for waiting time reinstatement that requires documentation of the operative report, presumably the pancreatectomy operative report, thus requiring two separate surgeries. The proposed solution was to modify the policy so that waiting time can be reinstated if the pancreatectomy has not yet taken place, but to require a statement of intent from the transplant center to perform a pancreatectomy, and radiographic evidence indicating that the transplanted pancreas has failed. Committee members noted that it is very unlikely that a surgeon would remove a functioning pancreas, so the requirement for radiographic evidence seemed onerous. Further, most centers remove the failed pancreas and let the patient heal first before undergoing another transplant, so an immediate retransplant would be rare.

A Committee member asked how this proposal fits with the POC Policy scorecard and the Committee charge for policy review (i.e., the policy goals are objective, measurable and scientifically based and further the mission, strategic plan and long term goals of the OPTN and HHS Program Goals). The proposal would probably not score very highly, as it affects a very small number of patients per year, and does not directly impact the goals of the organization. The proposal relates to patient safety, and may fall into the Scorecard category of “serves a special or disenfranchised group.” Although it may take years, it would be important to look at the outcomes of immediate retransplants versus later retransplants. With these considerations noted, the Committee was generally in support of the proposal.

In January 2008, the Committee reviewed a slightly revised proposal from the Pancreas Committee, which will allow the Organ Center to reinstate waiting time if:

- A pancreas graft has failed within 2 weeks of transplant;
- The recipient needs a second pancreas transplant;
- The transplant center submits a completed waiting time reinstatement form;
- The transplant center submits a statement of intent to perform a pancreatectomy; and
- The transplant center maintains radiographic evidence of graft failure and will submit this documentation upon request.

The Committee reiterated its support of this proposal.

- I. Informed Consent for HIV Donors. In December 2007, the Executive Committee approved policy language to require that transplant centers inform potential organ recipients about any known high risk behavior (as defined by CDC Guidelines) by the donor. This policy was approved prior to public comment to address potential patient safety issues. The Executive Committee is seeking comment and will reconsider policy language during the June Board

Meeting. The intent of these changes is to clarify the criteria for high risk behavior that requires transplant professionals to notify potential organ recipients prior to implantation.

The Committee felt that this policy is appropriate with respect to the high risk donors, as defined by the CDC guidelines. However, members debated whether the recipient must be notified if the donor is considered “high risk” by the OPO but does not meet the CDC high risk criteria. One member commented that, while the information about CDC high risk behavior is provided at time of offer, information related to behavior considered by an OPO to be high risk may come much later. The OPO Committee has been tasked with working with AOPO to establish a standardized definition of “high risk” that can be applied throughout the U.S. The Committee asked that the Operations Committee and Disease Transmission Advisory Group provide some guidance regarding OPO and transplant center responsibility for disclosure to/consent from recipients for non-CDC “high risk” donors.

- J. Modification of Bylaws Appendix-B, Section II, G “Patient Notification. The Living Donor Committee is proposing a modification to Bylaws, Appendix B that would require recipient transplant hospitals to notify their living organ donors in writing within ten business days after the donation date. The notification must include the telephone number that is available for living donors and others to report concerns or grievances through the OPTN. It must also disclose that the recipient transplant center must submit follow-up forms on the living donor to the OPTN for a minimum of two years and outline the recipient transplant center’s plan for obtaining patient data for completion of those forms.

Committee members questioned why the responsibility is placed on the transplant center rather than the donor hospital. A Committee member explained that not all donor hospitals are OPTN members, so the OPTN must place the requirement for follow-up of living donors on the transplant centers. The Living Donor Committee is looking into the issue of non-OPTN donor hospitals. Other members asked whether the centers should provide this information to potential donors as part of the work-up and consent process, or just prior to surgery, rather than after the donation. One member noted that the policy should say “program” rather than “hospital.”

- K. Proposed Changes to the Bylaws to Restore Full Membership Privileges Following an Adverse Action. The MPSC is proposing a change to the bylaws that defines how a member may be considered for restoration for full membership privileges and also provides the expectations for a member to move from an adverse action to a lesser action or status. The Committee had no comments about this proposal.
3. Proposals in Development. The Committee reviewed several proposals that are being developed by other committees but are not yet ready for public comment.
 - A. Allocation of Organs from Non-Directed Living Donors. One of the Living Donor Committee’s annual goals is to “Review and consider if components of Ethics Committee white paper on altruistic non-directed living donation should become policy.” The Living Donor Committee reviewed the white paper and accepted the following recommendation: “Non-directed organ from living donors be allocated according to the existing algorithm governing the allocation of cadaveric organs within the appropriate sharing unit.” When the Committee reviewed the proposal in January 2008, it was in the collaboration and evidence-gathering phase.

Lee Bolton, MSN, ACNP, Living Donor Committee Liaison, clarified that the Living Donor Committee is planning to recommend that a test match should be run at the center where the individual appears for evaluation as a non-directed living donor. Thus, the sharing unit would be

the center rather than the OPO or region. The Living Donor Committee considered logistic and financial considerations when making this recommendation. Donors on the Living Donor Committee felt that these individuals would likely present at a center where they feel comfortable. However, the Committee is also planning to review data to better understand how these individuals choose where to donate. Committee members discussed the impact of this policy on live donor exchange chains. For example, a non-directed donor who presents at a center participating in a live donor exchange chain could initiate a series of transplants. Thus, preventing a non-directed donor from such exchanges (by requiring that the center run their list) could actually decrease the number of potential transplants. Once the National Kidney Paired Donation Kidney Exchange Program is in place, these situations could become more common. The Living Donor Committee's primary concern is that there are currently no rules for how these organs are placed, and no assurance that the organs are placed in the most appropriate candidate. One suggestion was to add language to allow non-directed donors to participate in exchange programs. Another suggestion was to limit the proposal to suggesting that the center run its list, without making it a requirement.

- B. New National Kidney Allocation System. During the October 2007 meeting, Dr. Andreoni provided an update on the development of a revised national kidney allocation system (**Exhibit E**). Some elements of the current system are anticipated to stay the same, such as pediatric priority for donors less than age 35 and priority for prior live donors. Other common themes heard during meetings and forums include: replacing the "SCD" and "ECD" designations with a continuous donor profile index (DPI); the desire for patients to 'move up' the list with time; the desire that the best kidneys go into recipients with long expected lifetime survival times (the appropriate organ for the appropriate recipient); opposition to paybacks; and some measure of predictability in the allocation system. The new allocation system will likely combine DPI, LYFT (Life Years From Transplant), and dialysis time.

The Committee discussed the data elements in the LYFT calculation. Variables were excluded if they are difficult to measure, are not collected, or do not add to the calculation. Gender improved the predictive value of the equation. Age was included as it was very strong and is a measure for other comorbid conditions. Race is hard to define as there are many possible reporting combinations and is subjective. A Committee member objected to the exclusion of race based on the inability to define it, as it is self-reported in social science research. The measurement of race is not like the measurement of a biological factor. It was noted that race has been shown to be a factor in post-transplant outcomes, but may be a surrogate for socio-economic factors. Other elements (e.g., peripheral vascular disease) were not included because the Committee could not define them accurately. Some members argued that self-identified racial identity could be manipulated to advantage savvy patients, while others felt this was unlikely. It was noted that these types of decisions must be based on evidence and not on assumptions. Other Committee members noted that this proposal is still in the development process, and there are more analyses, modeling and discussions that will be conducted prior to the final policy proposal and after its implementation to assess its impacts.

Dr. Andreoni reviewed the basic concepts of the LYFT score, the DPI, dialysis years, and age matching, and showed preliminary results of simulation runs being considered by the Kidney Transplantation Committee using these concepts. Simulation run "18-C", which utilizes a continuous DPI, appeared to allow better matching of donors and candidates. At this point, additional priority for sensitized patients has not been included but is being considered.

During the January 2008 meeting, Dr. Leichtman presented the most recent modeling runs being used for the development of the new kidney allocation system (**Exhibit F**). The Kidney

Committee has considered at over 30 potential policy configurations, with three remaining for serious consideration:

- Proposal 16A (LYFT for SCD): Standard criteria donors (SCD) would be allocated using LYFT, with expanded criteria donors (ECD) allocated using waiting time (dialysis time).
- Proposal 18f: This allocates the very best organs (lower donor profile index (DPI)) using LYFT but allocates organs with the highest DPI by dialysis time, and organs in between using a blend of dialysis time and LYFT. An organ that was in the 50th DPI percentile would be allocated by a score based half on dialysis time and half on DPI.
- Proposal 28: This proposal caps LYFT at 80%, so that the best organs are allocated with a score derived from 80%LYFT and 20% from dialysis years. The organs with the highest DPI would be allocated using a score derived 100% from dialysis years. The reason for this is that there was some concern that patients with high LYFT scores would not have an incentive to pursue living donation.

Dr. Leichtman presented data comparing the current system to these three alternatives. Metrics considered were life years gained, and the percentage of transplants by race, blood type, diagnosis, sensitization, and age. While 16A maximizes life years gained, the other proposals may result in more equitable distribution of organs by race, age, etc. Dr. Leichtman explained the rules for allocation used in the model (e.g., kidney pancreas allocation) and the components of the current model. These are shown in detail in **Exhibit F**.

Ciara Gould, MSPH, Kidney Transplantation Committee Liaison, informed the Committee that an initial proposal will be circulated in concept for public comment in February 2008. This will not include policy language. A public forum will be held during this phase. A second public comment proposal will include policy language, to be released in the summer of 2008. A list of 56 organizations that represent patients and professionals has been compiled, and these organizations will receive all notices related to the forum and public comment.

The concept paper will be posted in the Committee SharePoint[®] site, and the Committee will meet by conference call (tentatively a week prior to the February Board meeting) to discuss the proposal.

Proposal to prioritize highly sensitized (PRA>80) children over highly sensitized adults

During the January 2008 meeting, Dr. Andreoni quickly reviewed a proposal developed during the December 2007 meeting. This modification would prioritize highly sensitized (PRA>80) children over highly sensitized adults for all deceased donor kidneys, regardless of donor age and mismatch level, for local, regional, and national levels. This proposal is independent of the new system that is being developed. A small number of highly sensitized children on the list may not receive offers under the current policy, which would be corrected by this change. The Committee was in support of this concept.

- C. Proposed Modification to Policy 3.2.7 (Pancreas Waiting List Criteria). In October 2007, the Committee reviewed a memorandum from Rainer Gruessner, MD, chair of the Pancreas Transplantation Committee, regarding accounting for the pancreas in a multiple organ transplant when the pancreas is procured for technical reasons only. The issue was identified by the UNOS Department of Evaluation and Quality (DEQ) as being problematic when the candidate was not listed for a pancreas. Current policy states that “each candidate registered on the Pancreas

Waiting List must be diagnosed as a diabetic or have pancreatic deficiency.” However, in these cases, the patient does not need the pancreas except for technical reason related to the surgery. DEQ staff proposed to amend the policy to allow patients for whom “the procurement or transplantation of the pancreas for technical reasons as part of a multiple organ transplant” to be listed for a pancreas.

The current policy also impacts OPOs in two ways. First, the pancreas in this situation is not counted as a transplanted organ, and therefore is not included in the organs transplanted per donor (OTPD) metric. Second, this accounting issue causes problems with the OPO’s cost reporting with CMS if the OPO does not count it as a transplanted organ and CMS does not agree with that decision. One Committee member argued that centers should not be charged for the pancreas if it would not have otherwise been used.

In initial discussions, the Committee members were not opposed to adding “multiple organ transplant” as a reason to list for a pancreas, but felt that the OPO issues need to be taken into account. However, there was concern that putting the patient on the list and counting the organ will increase the cost of the transplant unnecessarily. The cost issue is really one that CMS must address. With these considerations noted, the Committee felt that it is important that the costs and accounting issues resolved between CMS and HRSA before offering its support.

4. Updates on Prior Committee Recommendations. During the October 2007 meeting, Dr. Orłowski provided an update on the Board’s actions in September 2007, regarding items the Committee had reviewed in prior meetings.
 - A. Incorporation of CPRA into Tennessee State Alternative System for Kidney Allocation. The Committee supported this request from the Tennessee OPOs and transplant programs to incorporate the CPRA into their statewide sharing system for kidneys, but asked that the Tennessee OPOs provide the protocol that would be used to determination unacceptable antigens. The Board approved the request in September 2007. The protocol was provided to the Committee, and the Committee felt that it was acceptable.
 - B. Living Donor Consent and Medical Evaluation Guidelines. The Board approved the “Resource Document for Informed Consent of Living Donors” developed by the Living Donor Committee. However, the Board asked that the recommendations for the Medical Evaluation of Living Kidney Donors be revised and resubmitted for public comment in November 2007, for consideration by the Board in February 2008. Some Committee members expressed ongoing concerns related to the consent document, stating that the language describing patient follow-up is too vague and does not state what will be done with the data collected during follow-up. This ambiguity may lessen patients’ willingness to be followed. Without specific language, the informed consent and follow-up process will not be consistent. Further, consent for donation should be separate from the consent from data sharing.

Committee members discussed the need for the OPTN to better define what these documents (i.e., guidelines, recommendations, resource documents, white papers, position statements) are intended to accomplish. For example, is the intent to provide educational or “aspirational” guidance or something more prescriptive? Committee members felt that the OPTN should establish a timeframe for review of these documents (and perhaps all OPTN policies) to ensure that they are still relevant over time, which could be included within the document.

5. Review of Existing Policies. During the October 2007 meeting, Maryl Johnson, MD, Cedric Sheffield, MD, Henry Randall, MD, and Jeff Orłowski reviewed sections of the thoracic allocation policy. During the January 2008 meeting, Henry Randall, MD, Ken Andreoni, MD, Ray Gabel, Jeff Orłowski, and Janis Orłowski, MD, reviewed Policies 3.3 (Organ Distribution: Acceptance Criteria), 3.4 (Organ Distribution: Organ Procurement, Distribution and Allocation) and 6 (Transplantation of Non-Resident Aliens). Each reviewer was asked to answer the following for each section:
1. Briefly summarize the function of policy.
 2. Does the policy present a clear statement of what is to be accomplished (e.g. maximize the person-years of life gained, reduce waitlist deaths, etc.)?
 3. Is the policy clearly worded and/or appropriately organized?
 4. Is the policy in keeping with current practice?
 5. Other Reviewer Comments/Concerns.

Allocation of Thoracic Organs

The thoracic organ allocation policy was divided into those applying to heart versus lungs, with some overlap between the two. Drs. Johnson and Sheffield made two general comments: (1) the policies jump back and forth between heart and lung policies and are therefore hard to follow; and (2) goals are not explicitly stated in the policy. Each provided extensive comments about the policy, including suggestions for making the policy clearer and more accurate. These will be considered during the rewrite of the thoracic organ policy. A summary of these comments is found in **Exhibits G and H**.

Dr. Sheffield asked for guidance regarding the mandate that policies should include a statement of purpose. There is an effort underway to rewrite the policies in plain language, with the intent to reorganize the policies so that they make sense in terms of their purpose, and to include the purpose and goals of each policy.

Policy 3.3 (Organ Distribution: Acceptance Criteria)

- **Briefly summarize the function of policy.** The policy as written applies to three areas of acceptance criteria: Donor Acceptance Criteria (OPO), Non-renal Acceptance Criteria (Transplant Center), and Renal Acceptance Criteria (Renal Transplant Center). The policy places the burden on the OPO/Transplant Center to develop acceptance criteria for donors or organs. In the case of Donor Acceptance Criteria, the OPO is further required by the policy to offer organs/donors that fall outside of its own criteria to transplant centers/OPOs with more liberal criteria. In the case of the Non-renal and Renal Acceptance Criteria, the transplant center is required to notify UNOS so that organs outside the center's criteria will not be offered.
- **Does the policy present a clear statement of what is to be accomplished (e.g. maximize the person-years of life gained, reduce waitlist deaths, etc.)?** This is not clearly stated; the implied purpose is to maximize organs being offered to centers most likely to accept them. Mr. Orłowski felt that this is not very effective (as has been discussed in many committees, including the POC) as (1) the system is not sensitive enough to allow for effective listing of all the subtle issues that go into organ acceptance and/or (2) centers respond to this lack of sensitivity by listing broad criteria to assure they are notified about every organ.
- **Is the policy clearly worded and/or appropriately organized?** As indicated above, the purpose is not clear. The policy is also relatively brief. Covering all the possible nuances in setting criteria and applying them would be somewhat difficult.

- **Is the policy in keeping with current practice?** Yes.
- **Other Reviewer Comments/Concerns.** Mr. Orłowski felt that, (1) with all the work that is being done on a new renal allocation system, (2) with the potential use of tiered acceptance to allow centers more sensitivity in entering acceptance criteria for patients, etc. and (3) given that this policy is generally/broadly accurate and not causing major issues operationally, he did not see a need to revise the policy at this time. Once some of the evolution of the allocation system that is pending has occurred, a slightly clearer and more specific document would be desirable.

Dr. Andreoni noted that the policy for back-up needs to be examined as it is being applied unevenly across the country. He also noted that Policy 3.3.6 mentions an organ being accepted “without conditions”, but in DonorNet[®] the user can indicate a preliminary yes or no, so this is not consistent.

Policy 3.4 (Organ Distribution: Organ Procurement, Distribution and Allocation)

- **Briefly summarize the function of the policy.** The policy outlines the time limits for organ acceptance via the electronic offering system (DonorNet[®]), and describes alternative allocation systems and emergency allocation procedures.
- **Does the policy present a clear statement of what is to be accomplished?** Yes, it describes rules for allocation of organs.
- **Is the policy clearly worded and/or appropriately organized?** No, as there are many terms that are not defined well (e.g., Alternative Allocation System, Alternative Local Unit, variance).
- **Is the policy clearly worded and/or appropriately organized?** No, as mentioned above, many terms and acronyms are not clearly defined. References to other policies are inaccurate.
- **Is the policy in keeping with current practice?** No. Examples of problems/issues with this policy include are included in **Exhibit I**.

Policy 6 (Transplantation of Non-Resident Aliens)

- **Briefly summarize the function of policy:** This describes the policies for transplantation of non-resident aliens and includes definitions of the terms used.
- **Does the policy present a clear statement of what is to be accomplished (e.g. maximize the person-years of life gained, reduce waitlist deaths, etc.)?** This describes how non-resident aliens can be listed and mandates certain actions.
- **Is the policy clearly worded and/or appropriately organized?** The policy has probably not been modified over the years, so it reads more clearly than other policies. However, the policy starts with the phrase “The following policies apply” but includes a section called “Guidelines.” It does not mention illegal aliens, thus, implying that transplanting these individuals is not prohibited. The policy requires a review of centers that transplant non-resident aliens, but the policy does not explain what actions might be taken if centers transplant more than the percentage stated.

- **Is the policy in keeping with current practice?** It is not clear that this is in keeping with what centers are doing, (e.g., the suggestion that centers have a mechanism for community participation and review).

Committee members noted that there is an issue of fairness in that, while there are limits to the number of non-resident aliens that can be transplanted, there are no restrictions to the procurement of organs from non-resident aliens.

6. Policies related to Multiorgan Transplants. In October 2007, the Committee reviewed a letter from a member who asked that the policies related to multiorgan transplants be reviewed (**Exhibit J**). Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates) describes the process for allocation organs to candidates in need of a multiple transplant. However, many other OPTN policies address aspects of multiple organ allocation. Further, the policies as written are difficult to understand and use words such as of “may,” “should,” and “recommended,” which are confusing to OPOs and centers.

Committee members cited cases when organs were wasted or allocated to less urgent patients due to varied interpretations of these policies. Members felt that the policy should provide guidance for what organ(s) should take precedence in multiorgan allocation and how the list(s) should be run. Further, the policy should clarify whether multiorgan transplants take precedence over other transplants.

Committee members also asked whether there should be minimum renal listing criteria when a candidate is listed for a kidney plus a heart and/or a liver, as currently there are no criteria. Dr. Andreoni presented data pertinent to liver-kidney transplants (**Exhibit K**). There has been an increase of kidney-liver transplants, with wide variations in the percentage of liver-kidney transplants by DSA.

The Committee recommended that a small working group be established, with representation from the Liver and Intestinal Organ, Kidney, and Thoracic Transplantation Committees, to develop consensus on these policies.

7. Study of Geographic Variations in Organ Allocation. During the Committee’s May 2007 review of the liver allocation policies, members noted that MELD/PELD exceptions are handled differently by Regional Review Boards, and that different scores may be assigned to patients in different regions. The policies seem to attempt to accommodate for geographic factors that may disadvantage patients. A member noted that the Final Rule mandates “distributing organs over as broad a geographic area as feasible.” At the time, the Committee submitted the following resolution to the Board, which was approved in June 2007:

*** RESOLVED, that the OPTN undertake a study to address geographic variations in organ allocation*

During the July 2007 meeting, the SRTR provided an overview of analyses relating to geography and organ allocation. During the October 2007 meeting, the Committee attempted to clarify the specific problem(s) to be addressed, and what information may be needed to move forward. What is it about the national system that is most concerning? What was the national system intended to do, and does it achieve those goals better in some parts of the country than others? The Committee recognized that the term “geography” may mean different things to different people. Committee members identified several possible issues/concepts for exploration:

- Equalizing access to organ transplantation;
- Minimizing the need for patients to “move around/multiple list” in order to gain access;

- Reducing geographic variations in waiting time to transplant; and
- The role of (kidney) “paybacks” in limiting access to kidney-pancreas candidates.

The Committee also noted that there are some things that the OPTN cannot influence, such as referral patterns, insurance plans, etc. Potential metrics to assess access would include transplant rates, waitlist mortality, and waiting time in urgency level.

In December 2007, the Committee reviewed a proposed approach to this study. First, the POC would review the goals and metrics identified by the organ-specific Committees (and approved by Board) in 2004. The OPTN and SRTR would begin to analyze the metrics identified by the Committees to determine whether the goals are being met by Region/DSA. This may reveal aspects of the allocation system with high geographic variability that can be addressed through policy changes. One benefit of this approach is that these metrics have been chosen by the Committees who are most familiar with the issues surrounding its organ allocation policies. The proposal is the review each organ system, starting with liver. The proposal for the study and the metrics established by the Liver and Intestinal Organ Transplantation Committee in 2004 are provided in **Exhibit L**. Another approach would be to look at the data by SMSA or “High penetration areas” (areas with a large concentration of transplant programs).

During the January 2008 meeting, James Burdick, MD, Director, Division of Transplantation, remarked that the underlying issue with geography is how much variability exists and its impact. The current administrative units are valuable for their purposes, but allocation should not be bound to the artificial geography of these administrative boundaries. There are data for hearts and livers that give an indication that freeing allocation from geography may improve survival. Dr. Orłowski cited an article by Dr. Burdick printed in Transplantation in 2001 that Committee members should review.

Committee members discussed the need to include the organ-specific committees more directly. The rationale for starting with liver was because the MELD/PELD system has been in place for several years and there is a great deal of data available. The Liver Committee has already formed a Broader Sharing Subcommittee that will be meeting soon to review data by region and DSA. However, committee members cautioned that the hypothesis should not default to broader sharing as the solution. Robert Wolfe, PhD, SRTR representative, noted that a commonly cited metric is the transplant rate. However, transplant rates are calculated based on the number of organs procured per candidate on the list, which represent two different biologic components: death rates within the population and incidence of organ failure. Thus, variation in both components will tell more than the variation in transplant rates alone.

Two potential pathways were discussed: (1) ask each committee how they would like to proceed and begin to partner with each committee or (2) begin work with the Liver Committee, as they have already formed a subcommittee, and their allocation system is relatively stable at this point. The Committee agreed to explore both pathways, beginning work with the Liver Committee while asking for the other organ-specific Committee’s input. The Committee discussed various aspects of geography, such as access to the waiting list, access to transplant once on the waiting list, and financial/insurance matters that might be rooted in geography, etc, some of which cannot be addressed by OPTN policy. The OPTN can assess its policies relative to the goals and metrics identified, determine whether those goals are being accomplished, describe the amount of variability, and determine whether the variability can be reduced by modifying OPTN policy. One approach would be for the SRTR to model each allocation system with and without geography and examine the outcomes. Once areas have been identified, these can be incorporated into a committee’s annual goals. To initiate this study, the POC will send a letter to each organ-specific committee describing this proposed process, and asking each committee to partner with the POC. The OPO Committee

should also be consulted about their insights on the impact of geography, and on the potential financial implications of broader sharing.

8. Living Donor Data Task Force (LDDTF). In June 2006, the Board approved the following resolution submitted by the Committee: “*Resolved, that a joint OPTN Committee be established to evaluate the use of living donor data.*” The LDDTF has been assembled, with the plan to identify specific needs for Living Donor data and (2) develop approach appropriate for each need. This Task for will begin meeting on January 29, 2008.
9. Working Group on OPO Performance / Assessment of Program Goals. At the July 2007 meeting, the Committee reviewed organ procurement data by DSA related to the HHS Program Goals. During the ensuing discussion, members of the Committee raised several points regarding the Program Goals and their applicability to current practice. The organ donation collaborative has been very successful in increasing the number of donors, but a similar effort to increase yield has not been successful thus far. It appears that these two program goals are in conflict. As the number of donors increases due to accelerated procurement from ECD donors, the number of organs transplanted per donor has decreased. In September 2007, the Board approved the following resolution submitted by the Committee:

*** RESOLVED, that the OPTN, after a task force study, requests that the HHS Secretary’s Advisory Committee on Transplantation (ACOT) review: (1) the current HHS Program Goals for the OPTN for organs transplanted per donor; (2) the data used to establish these goals; (3) how these goals might be impacted by the program performance and/or OPO performance standards set by CMS; and (4) to review these goals to determine if the goals have internal conflicts based on current practices.*

During the October 2007 meeting, the Committee reviewed the SRTR Analysis Plan for developing OPO performance metrics. The Committee asked that the analysis plan be clarified, asking if, for those organs intended to be transplanted, the “grade” of the organ (using some type of donor risk index, perhaps) could be considered so that the performance metrics could be applied fairly. In this way, an OPO would not be penalized for being “aggressive.” In addition, the Committee asked whether SRTR could account for organs that were never offered for transplant but perhaps should have been offered.

HRSA is putting together a request to the Office of Management and Budget (OMB) to revise the goals. The task force activity described in the Board resolution will be put on hold pending this request and further communication with OMB. Committee members noted that their original discussion was not only about the Program Goals, but also with CMS performance measures. It was reported in January 2008 that HRSA is in the process of requesting a revision of the program goals from the OMB.

OPO Performance Metrics

In January 2008, Dr. Wolfe presented the SRTR’s current work on OPO Performance Metrics (**Exhibit M**). Dr. Wolfe explained that there are two aspects of OPO metrics having to do with stages of procurement: (1) the donation rate, where eligible deaths are identified and converted to donors, and (2) the yield, or organs transplanted per donor. These involve different denominators. The OPTN began collecting imminent and eligible death data from OPOs on January 9, 2008. Data are now available for the age, race, gender and cause of death for eligible deaths. These data will allow the SRTR to calculate an expected donation rate, accounting for differences in OPO case mix. There is substantial variation in donation rates across OPOs. The new data and modeling will allow for a

better understanding of why some OPOs have donation rates that are below the expected rate. The SRTR is also developing models that will predict yield.

As the data collection of imminent and eligible deaths has just begun, there may be some learning curve for OPOs filling out the forms. UNOS has conducted several training sessions on how to submit the data, and members of the working group have been answering questions from members as well. Many of the data elements are pre-filled from the match run, so the learning curve should be short.

10. Ad Hoc Data Management Working Group (AHDMWG) Report. In January 2008, Robin Pierson, MD, co-chair of the AHDMWG, reported that the working group recently reviewed and approved three requests for patient-level data, although one was controversial with two of six members voting against the request. The concerns of those opposed could be addressed by the applicant. The three proposals have not received HRSA approval yet. Dr. Pierson reported that Felicia LeClere, PhD, co-chair of the AHDMWG, has some valuable feedback as to how patient-level data should be managed, and is working with HRSA to amend the relevant data use agreements. Summaries of the requests evaluated by the AHDMWG will be provided to the Committee in the future. The AHDMWG will continue to act on these requests and report back to the Committee.
11. Review of Public Comment Enhancements. During the January 2008 meeting, Ms. Harper described enhancements to the public comment process that are being introduced in February 2008. The Committee had indicated an interest in the public comment process in August and October 2006, and asked that it be kept up to date on efforts to improve the process. Based on the input from a member survey conducted in December 2006 and the “Consensus Conference on Increasing Public Input into OPTN Matters” in May 2007, UNOS staff developed a new format for the Policy Notice in 2007. This included a format that was easier to navigate, with a summary of policy modifications and board actions, a list of who might be affected by these changes and what actions must be taken. Rather than sending members multiple notices, this includes all policy modifications approved by the Board at its most recent meeting in one document, formatted so that readers can quickly link to policies of interest. UNOS received a great deal of positive feedback from this change. A similar format will now be applied to the public comment process. A template has been developed that will contain all necessary elements for a policy proposal (i.e., rationale, goals, evidence base, data burden, etc.), to be written in plain language. Each proposal will include a summary “At-a-Glance Box” and a list of targeted questions to help focus the public comment. An internal process has also been instituted that should promote better cross-committee collaboration prior to proposals being submitted for public comment. Committee members felt that the “at-a-glance box” should be fairly brief.

The website will also be enhanced so that proposals can be reached in one “click” rather than several. The public comment data entry page will be revised to include new fields providing for the collection of specific demographic information. The data entry page will be also modified to provide users with the ability to make corrections to comments before final submission and to upload attachments to their public comment record.

Christopher McLaughlin, OPTN Project Officer, asked whether the OPTN had developed a mechanism to provide feedback to commenters about the results of the policy decision. There has been discussion among UNOS staff members about how to accomplish this, perhaps with an “auto reply” message thanking commenters. The reply could also ask whether the commenter wants information about the outcome of the proposal.

Policy Oversight Committee		Meeting Date: 1/15/2008
NAME	POSITION	
Janis Orłowski, M.D.	Chair	X
Ray Gabel	At Large	By telephone
Simon Horslen, M.D.	At Large	X
Maryl Johnson, M.D.	At Large	X
Dixon Kaufman, M.D., Ph.D.	At Large	X
Mary Kelleher, B.S., M.S.	At Large	X
Felicia LeClere, Ph.D.	At Large	
Jeffrey Orłowski, M.S., C.P.T.C.	At Large	X
Richard Pierson, III, M.D.	At Large	X
Henry Randall, M.D.	At Large	X
Cedric Sheffield, M.D.	At Large	X
Judy Jones Tisdale, Ph.D.	At Large	
W. Kenneth Washburn, M.D.	At Large	
James Wynn, M.D.	At Large	
Monica Lin, Ph.D.	Ex Officio, non Voting	By telephone
Christopher McLaughlin	Ex Officio, non Voting	By telephone
Friedrich Port, M.D.	Ex Officio, non Voting	
Robert Wolfe, Ph.D.	Ex Officio, non Voting	X
Alan Leichtman, M.D.	SRTR Liaison	X
Guests		
Stuart Sweet, MD	Chair, Pediatric Transplantation Committee	X
UNOS Staff		
Ann Harper	Policy Analyst/Committee Liaison	X
Erick Edwards Ph.D.	Assistant Director, Research	X
Mary D. Ellison, Ph.D., M.S.H.A	Assistant Executive Director, Federal Affairs	X
Karl J. McCleary, Ph.D., MPH	Director, Policy, Membership, and Regional Administration, Committee Liaison	X
Shandie Covington	Liaison, Pediatric Transplantation Committee	By telephone
Ciara Gould, MSPH	Liaison, Kidney Transplantation Committee	By telephone
Elizabeth Sleeman, MHA	Liaison, Pancreas Transplantation Committee	By telephone
Lee Bolton, RN, ACNP	Liaison, Living Donor Committee	By telephone
Gloria Taylor, RN, MA, CPTC	Liaison, Operations Committee	By telephone
Joyce Hager, MPH	Liaison, Operations Committee	By telephone

Policy Oversight Committee		Meeting Date: 10/16/2007
NAME	POSITION	
Janis Orłowski, M.D.	Chair	X
Ray Gabel	At Large	X
Simon Horslen, M.D.	At Large	
Maryl Johnson, M.D.	At Large	X
Dixon Kaufman, M.D., Ph.D.	At Large	X
Mary Kelleher, B.S., M.S.	At Large	X
Felicia LeClere, Ph.D.	At Large	X
Jeffrey Orłowski, M.S., C.P.T.C.	At Large	X
Richard Pierson, III, M.D.	At Large	
Henry Randall, M.D.	At Large	
Cedric Sheffield, M.D.	At Large	X
Judy Jones Tisdale, Ph.D.	At Large	X
W. Kenneth Washburn, M.D.	At Large	X
James Wynn, M.D.	At Large	By telephone
Monica Lin, Ph.D.	Ex Officio, non Voting	By telephone
Christopher McLaughlin	Ex Officio, non Voting	X
Friedrich Port, M.D.	Ex Officio, non Voting	
Robert Wolfe, Ph.D.	Ex Officio, non Voting	X
Alan Leichtman, M.D.	SRTR Liaison	X
UNOS Staff		
Ann Harper	Policy Analyst/Committee Liaison	X
Erick Edwards Ph.D.	Assistant Director, Research	X
Mary D. Ellison, Ph.D., M.S.H.A	Assistant Executive Director, Federal Affairs	X
Karl J. McCleary, Ph.D., MPH	Director, Policy, Membership, and Regional Administration, Committee Liaison	X
Ciara Gould, MSPH	Liaison, Kidney Transplantation Committee	By telephone
Elizabeth Sleeman, MHA	Liaison, Pancreas Transplantation Committee	By telephone
Vipra Ghimire, MPH, CHES	Liaison, Thoracic Transplantation Committee	By telephone