

**Interim Report of the
Policy Oversight Committee
October 16, 2007
Chicago, IL**

1. Review of Committee Charge/Goals. Janis Orłowski, MD, Committee Chair, reviewed the Committee's charge and its Annual Goals for 2007-2008. Mary Ellison, PhD, MSHA, Executive Assistant Director for Federal Affairs with UNOS, presented an overview of the OPTN policy development process.
2. Updates on Prior Committee Recommendations. Dr. Orłowski provided an update of the Board's actions regarding proposals the Committee had reviewed in prior meetings.

Incorporation of CPRA into Tennessee State Alternative System for Kidney Allocation

The Committee reviewed this request from the Tennessee OPOs and transplant programs to incorporate the CPRA into their statewide sharing system for kidneys in July 2007. The Committee supported this request, but asked that the Tennessee OPOs provide the protocol that would be used to determine unacceptable antigens. The Board approved the request in September 2007. Committee members reviewed the protocol and felt that it was acceptable.

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 in September 2007. 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. While reviewing the documents, 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-up¹. This ambiguity may lessen patients' willingness to be followed. Further, without specific language, the informed consent and follow-up process will not be consistent. Committee members stressed that consent for donation should be separate from the consent from data sharing.

Committee members felt that the OPTN must define what these documents (i.e., guidelines, recommendations, resource documents, white papers, position statements) are intended to accomplish. For example, is a resource document intended to provide educational or "aspirational" guidance, or something more prescriptive? Committee members suggested that the OPTN establish a timeframe for review of these documents that could be included within the document to ensure that they remain relevant over time,

The Committee will review the revised Medical Evaluation recommendations via conference call in December 2007.

¹ The consent document recommends that centers disclose: "that transplant centers are required to report living donor follow-up information for at least two years" and "The agreement of the potential donor to commit to postoperative follow-up testing coordinated by the recipient transplant center for a minimum of two years."

3. Proposed By-Law Modification Circulated for Public comment, September 2007. The Membership and Professional Standards Committee (MPSC) proposed changes to the OPTN Bylaws that would document the MPSC's current practice of holding informal discussions with members during its review of survival rates and activity at transplant programs. The Bylaw change is intended to delineate when "informal discussions" may be held with an institutional member. Committee members asked that UNOS counsel provide an opinion regarding what jurisdiction (e.g., Virginia or Illinois) applies for due process and peer review when these conversations are held, as the rules vary from state to state.
4. Policies 7.1.3 / 7.4 (Requirement for Length of Follow-up After Transplant/Graft Failure). In June 2006, the Committee recommended that Policy 7.1.3 be modified to eliminate requirement to follow patients after graft failure; this was subsequently approved by the Board. The Committee's 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 all patients would now be followed until death. SRTR analyses demonstrated that there are very few deaths after graft failure that are only known through OPTN data (i.e., cannot be found from another source). Further modifications to this policy were placed on hold due to the Operations Committee's proposed changes to Policy 7, which have been withdrawn. Therefore, the Committee unanimously approved the following modification, which will be submitted to the Board in February 2008:
 - 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.~~
5. Consideration of Policy Proposals in Development. The Committee reviewed several proposals that are being developed by other OPTN committees and have not been circulated for public comment.

National Kidney Allocation System/ Proposed Changes to the OABDR Mismatch Policy

Kenneth Andreoni, MD, Vice-chair of the Kidney Transplantation Committee provided an update on the development of a new national kidney allocation system. Some elements of the current system are anticipated to stay the same, such as pediatric priority for donors <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 to 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 typically excluded if they are difficult to measure, are not collected, or do not add to the LYFT calculation. Gender and age were included as they improved the predictive value of the equation. Age is also a measure for other comorbid conditions. Race was not included, as it is hard to define, with many possible reporting combinations, and is subjective. Other elements (e.g., peripheral vascular disease) were also excluded because the Committee felt they could not be defined accurately. It was noted that race has been shown to be a factor in

post-transplant outcomes, and may be a surrogate for socio-economic factors. A Committee member objected to the exclusion of race based on the inability to define it, as it is generally self-reported in social science research. Some members argued that self-identified racial identity could be manipulated to advantage savvy patients, while others felt this was unlikely. Other Committee members noted that this proposal is still in the development process, and that more analyses and modeling will be conducted prior to the final policy proposal and after 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 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.

Proposed Changes to the OABDR Mismatch Policy

Dr. Andreoni presented a proposed change to the kidney allocation system that would eliminate mandatory sharing for zero antigen mismatched (OABDR MM) kidneys except for pediatric and sensitized candidates. The Kidney Committee intends to circulate this for public comment in February, 2008. Dr. Andreoni pointed out that most paybacks currently go to recipients with a PRA of less than 20%. Alan Leichtman, MD, representing the SRTR, stated that the net loss in graft survival from payback kidneys almost offsets the gain from OABDR MM kidneys in non-sensitized patients. By a vote of 10 in favor, 0 opposed, and 1 abstention, the Committee supported the proposal concept.

Proposed Modification to Policy 3.8.8 (Waiting Time Reinstatement for Pancreas Recipients)

The Committee received a memorandum from Rainer Gruessner, MD, Chair of the Pancreas Transplantation Committee, regarding an issue with the current policy for waiting time reinstatement for pancreas recipients. Dixon Kaufman, MD, Vice-chair of the Pancreas 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. The process for waiting time reinstatement requires documentation of the operative report, presumably the pancreatectomy operative report, thus requiring two separate surgeries. The proposed solution is 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 Organ Transplantation performance 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 pancreas retransplants versus later retransplants. With these considerations noted, the Committee was generally in support of the proposal.

Proposed Modification to OPTN Policy 3.2.7 (Pancreas Waiting List Criteria)

The Committee received a second memorandum from Dr. Gruessner 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 waitlisted 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, in this situation the pancreas 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. Several Committee members felt that centers should not be charged for the pancreas if it would not have otherwise been used.

In initial discussions, the Committee members did not disagree with 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 as transplanted will increase the cost of the transplant unnecessarily. With these considerations noted, the Committee felt the costs and accounting issues should be resolved between CMS and HRSA before the Committee could offer its support.

6. Review of Existing Policies: Policy 3.7 (Allocation of Thoracic Organs). Maryl Johnson, MD, Cedric Sheffield, MD, Henry Randall, MD, and Jeff Orłowski were asked to review sections of the thoracic allocation policy. The lengthy policy was divided into those sections applying to heart versus lungs, with some overlap between the two. 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.

Dr. Johnson made two general comments: (1) the policy jumps back and forth between heart and lung policies; and (2) goals aren’t explicitly stated in the policy. Drs. Johnson and Sheffield provided extensive comments about the policy sections, including suggestions for making the policy clearer and more accurate. These will be considered during the re-write of the thoracic organ policy.

7. Review of Existing Policies: Policies related to Multi-organ Transplants. Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates) describes the process for allocating organs to candidates in need of a multiple organ transplant. However, many other OPTN policies address aspects of multiple organ allocation. Further, the policies as written are difficult to understand and include words such as “may,” “should,” and “recommended,” which are confusing to OPOs and centers when trying to allocate organs.

Several members cited cases when organs were wasted or allocated to less urgent patients due to varied interpretations of these policies. To remove any confusion, the policy should provide guidance regarding (1) what organ(s) should take precedence in multiorgan allocation and (2) how the list(s) should be run. Further, the policy should clarify whether multiorgan transplants always 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. 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 the OPTN establish a small working group with representation from the Liver-Intestine, Kidney, and Thoracic Committees to develop some consensus on these policies prior to rewriting them.

8. Working Group to Study Geographic Variations in Organ Allocation. During the Committee’s review of liver allocation policies in May 2007, members noted that MELD/PELD exceptions are handled differently by the Regional Review Boards, and that in some regions a patient may require several extensions (with increases in MELD/PELD scores) before getting transplanted while others may get transplanted earlier and at lower MELD/PELD scores. Committee members felt that differences based on geography should be addressed by the OPTN, as one of the allocation performance goals of the Final Rule is “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. Questions to ask might include: 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 factors 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. The Committee plans to discuss these issues further during its December 2007 conference call, and members are asked to identify patient groups where access may be limited due to geography.

9. Working Group on OPO Performance / Assessment of Program Goals. At the July 2007 meeting, organ procurement data by DSA related to the HRSA Program Goals were presented to the Committee. Members noted that, while the organ donation collaborative has been very successful in increasing the number of donors, a similar effort to increase yield has not been successful. 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 whether 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 addition, the Committee asked whether the SRTR analyses could account for organs that were never offered for transplant but could have been offered.

HRSA is preparing to submit a request to the Office of Management and Budget (OMB) to revise the program 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, and that these still need to be addressed.

10. 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 the specific needs for Living Donor data and to develop approaches appropriate for each need.