OPTN/UNOS ORGAN AVAILABILITY COMMITTEE REPORT

SUMMARY

I. Organ Availability Issues

Action Items for Board Consideration

- None

Other Significant Items

- The Committee resolved to work with other Committees to develop recommendations to explore how to modify the reimbursement criteria for DCD recovery teams. (Item 2, Page 3)

- The Committee authorized the expenditure of OPTN funds available to the OAC for a preliminary study including focus groups to develop the living donor kidney survey instrument to determine why living donors decide to donate. (Item 12, Page 5)

- The Committee resolved that the long-term donation plan be a living kidney donor exchange program with the potential of expanding the local programs to regional and national programs if possible. Components of the plan will include education and removing disincentives for living donors. (Item 13, Page 5)

II. Patient Access Issues

Action Items for Board Consideration

- None

Other Significant Items

- None

III. Other Issues

Action Items for Board Consideration

- None

Other Significant Items

- The Committee will request the OPO Committee to consider developing recommendations for OPOs to disseminate hospital-specific information obtained by the OPO and data from the Scientific Registry of Transplant Recipients (SRTR) to keep their hospitals apprised of their performance based on the requirements of CMS and JCAHO. (Item 15, Page 6)

REPORT OF THE
OPTN / UNOS ORGAN AVAILABILITY COMMITTEE
TO THE BOARD OF DIRECTORS

Minneapolis, MN
June 24-25, 2004

Stuart M. Greenstein, M.D., Chairman
Dale A. Distant, M.D., Vice Chairman

The following report represents the OPTN/UNOS Organ Availability Committee's (OAC) deliberations and recommendations on matters considered by the Committee during its May 3, 2004 meeting.

I. Organ Availability Issues

1. Financial Analysis of Potential Donor Management at a Medicare Approved Transplant Hospital. One member presented an analysis on the de-escalation of care in his hospital of known brain injured patients.

   It was noted that trauma and neurosurgery services inform families of their loved-one's futile condition prior to the organ procurement organization (OPO) being contacted making consent for organ donation difficult to obtain. The analysis illustrated that the average cost of care for the brain injured patient was much higher than the average reimbursement to the hospital for the same patient and the average reimbursement to a hospital for a donor was much higher than the average reimbursement to the hospital if the same patient was not a donor.

   It was noted that when hospital administrators are approached with the possibility of a patient on life support being a potential donor they sometimes argue that they cannot involve themselves or their staff for ethical reasons. It was also noted that administrators don't have to involve themselves but just talk to their staff about the process. A Committee member commented that transplant hospitals do not have this particular financial information available to them.

   It was suggested that the analysis presented to the Committee be submitted for consideration at the next OPTN/UNOS Transplant Management Forum meeting.

2. Expedited Placement of Donation After Cardiac Death (DCD) Donors. The Committee was asked by President-elect, Robert Metzger, MD, to address expedited placement of DCD donors and suggest innovative ways of getting more OPOs to recover DCD donors.

   The following points were made:

   - The Committee has been collecting data on graft survival of DCD donors that suggest that the graft survival of DCD kidney donors and standard kidney donors are similar. It was also noted that these data have not been disseminated to the transplant community.
   - The goal is to educate the hospital's ethics committee and others (e.g. transplant physicians and surgeons) directly involved with donation regarding the establishment of a DCD protocol.
   - OPOs that are currently successful at DCD donor recoveries utilize machine preservation. This preservation method is not currently utilized by OPOs as it had been in the past.

- It has been argued that surgeons are reluctant to procure organs from a DCD donor due to the amount of time involved waiting for the patient to expire; most surgeons would not wait more than one hour and a half for a DCD donor to expire.
- Study the top five DCD programs in the country and learn what their best practices are and how they overcome problems.

Discussion ensued regarding the reimbursement of kidney teams procuring DCD donors with the following points made:

- The government could provide an additional reimbursement to kidney teams that procure DCD donor organs.
- Offering additional monies will not be enough for a kidney team and surgeon to wait in the middle of the night with a full schedule the next day. An additional reimbursement won't solve the problem.
- It would be worthwhile to investigate a monetary incentive for DCD recovery.
- A DCD donor is more demanding and allows more room for error.

The SRTR data representative presented an analysis of the effect of pumping on DCD kidney graft outcomes, the impact of the resistance of pumped kidneys on outcomes and whether pumping and resistance measurements affect the odds of discard of kidneys. The following points were noted:

- Pumping data are currently only collected from the OPO and not from the transplant center.
- The updated transplant recipient and deceased donor registration forms will include more complete pumping information. Items that will be collected include: if the kidney arrived on the pump, was it placed on the pump when it arrived, and final resistance.
- Pumped standard kidneys have a lower but not significantly lower rate of graft failure and pumped DCD donor kidneys have a higher but not significantly higher, rate of graft failure over those DCDs not pumped.
- For all kidneys, the donor characteristics that were linked to a higher odds of discard are: DCD donors, ECD, donors with diabetes, kidneys that were biopsied, and kidneys from African American donors.
- Of the pumped standard kidneys the only factors that were statistically significant for the odds of discard were ECD, biopsy, and resistance values in the upper two quartiles. (>.26).
- When reviewing discard rates of procured ECD donor kidneys only, they were more likely to be discarded from male donors, diabetic donors, DCD donors, and pumped donors.
- For pumped ECD kidneys only, the resistance measures were significant: the resistance > .26 were more likely they would be discarded.

The Committee then discussed kidney biopsies with the following noted:

- The great majority of kidneys are turned down because of the biopsy;
- The method for obtaining a biopsy needs to be standardized;
- Biopsy data are collected by OPOs; and
- The transplant community needs a better understanding of biopsy outcomes because what one surgeon turns down the next one may accept.

A motion was unanimously passed that the OAC will work with other committees to develop recommendations to explore how to modify the reimbursement criteria for DCD recovery teams. 11 For: 0 Against: 2 abstentions

A subcommittee was formed to discuss further DCD donor issues that will include the OPO, Kidney Pancreas and Liver Intestine Committees.

3. Proposed Modifications to Local Voluntary Alternative System for Assigning Priority in Kidney Allocation to Original Intended Candidates for Living Donor Kidneys. These proposed modifications would create a generic alternative system that would provide priority in the kidney allocation system for original intended candidates (ICs) for living donor kidneys who are incompatible with their living donors due to crossmatch results or ABO blood type, when the living donors donate to candidates on the list of patients waiting for deceased donor kidneys.

   After thorough discussion, the Committee unanimously voted to support these modifications.

4. Proposed Modifications to OPTN/UNOS Policies 3.5.3.3 (Mandatory Sharing) and 3.5.5 (Payback Requirements) ("Exemption of Kidneys Recovered from Donation after Cardiac Death (DCD) Donors from Sharing Requirements for Zero Antigen Mismatched Kidneys or Payback). These proposed modifications would exempt Donation after Cardiac Death (DCD) donor kidneys from the requirements of the zero antigen mismatch kidney sharing policy, except at the local level of organ distribution, as well as, the kidney payback policy.

   After thorough discussion, the Committee unanimously voted to support these modifications.

5. Proposed Modifications to OPTN/UNOS Policy 3.5.5 (Payback Requirements) ("ECD Kidney Exemption from Payback Sharing Requirements"). These proposed modifications would exempt expanded criteria donor (ECD) kidneys from the requirements of the kidney payback policy. OPOs would retain the option to offer expanded criteria donor kidneys for payback, but would not be required to do so under the policy.

   After thorough discussion, the Committee unanimously voted to support these modifications.

6. Proposed Modifications to OPTN/UNOS Policies 3.5.5.1 (Kidney/Non-Renal Organ Sharing) and 3.5.5.2 (Deferment of Voluntary Arrangements). These proposed modifications would increase the ABO blood group payback debt threshold from four to six in terms of an OPO's ability to retain local kidneys or receive shared kidneys to be used in a simultaneous kidney-pancreas transplant.

   After thorough discussion, the Committee unanimously voted to support these modifications.

7. Proposed Modifications to OPTN/UNOS Policy 3.6.2.1 (Allocation of Blood Type O Donors). These proposed modifications would allow any remaining blood type compatible candidates to 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 local, regional and national level.

   After thorough discussion, the Committee unanimously voted to support these modifications.

8. Proposed Guidelines for Living Liver Donor Evaluation (Item 1 of 2). These proposed guidelines would establish specific guidelines for potential living liver transplant recipient and donor evaluation, including provisions for an independent donor team, psychiatric and social screening, and appropriate medical, radiological, and anesthesia evaluation.

The Committee agrees with the concept of the proposed guidelines in that everything should be done to protect the donor; however, the Committee perceives multiple difficulties with the language and requirements as stated. In addition, the Committee agrees that the criteria are too difficult to implement. The Committee voted not to support this policy as written. For: 12 Against: 0 Abstentions: 2

- The Committee would like clarification of terms such as "no connection."
- One Committee member commented that rather than the OPTN/UNOS setting guidelines for living donors, the OPTN/UNOS should consult others on guidelines for living donors.
- It was clarified that NOTA only deals with deceased donors but HRSA has asked UNOS to collect follow up data on living donors under the OPTN contract.

9. Proposed Guidelines for Living Kidney Donor Evaluation (Item 2 of 2). These proposed guidelines would establish specific guidelines for potential living kidney transplant recipient and donor evaluation, including provisions for an independent donor team, psychiatric and social screening, and appropriate medical, radiological, and anesthesia evaluation.

- The Committee would like clarification of terms such as "no connection."
- One Committee member commented that rather than the OPTN/UNOS setting guidelines for living donors, the OPTN/UNOS should consult others on guidelines for living donors.
- It was clarified that NOTA only deals with deceased donors but HRSA has asked UNOS to collect follow up data on living donors under the OPTN contract.

The Committee agrees with the concept of the proposed guidelines in that everything should be done to protect the donor; however, the Committee perceives multiple difficulties with the language and requirements as stated. In addition, the Committee agrees that the criteria are too difficult to implement. The Committee voted not to support this policy as written. For: 12 Against: 0 Abstentions: 2

10. Proposed Modifications to OPTN/UNOS Policy 3.1.4 (Patient Waiting List). These proposed modifications address new and modified policies for listing transplant candidates on the national waiting list.

After thorough discussion, the Committee voted to support these modifications. 11 For: Against: 0 Abstentions: 1

11. Proposed Modifications to OPTN/UNOS Policy 3.2.3 (Match System Access). These proposed modifications would require two separate determinations of the donor's ABO type prior to initiating the organ recovery incision, and more specific policy language for the process of distributing organs using the match run.

After thorough discussion, the Committee voted to support these modifications. For: 11 Against: 0 Abstentions: 1

12. Living Donation Questionnaire. UNOS staff updated the Committee on the progress of the living donor questionnaire. It was noted that funds would be available through the OPTN contract to cover related expenses. UNOS staff has spoken with a consultant who suggested focus groups to obtain information for the development of a questionnaire to determine why living donors donate.

Discussion ensued with the following points made:

- The current questionnaire is at a point that needs professional work done to it.
- The focus groups will allow a consultant to design the questionnaire so that it produces measurable results.
- It was suggested to do focus groups via conference call.

A motion was unanimously passed to authorize the expenditure of OPTN funds available to the OAC for a preliminary study including focus groups to develop the living donor kidney survey instrument to determine why living donors decide to donate.

13. Long-Term Donation Plan. It was noted that living donation efforts are under the purview of the OPTN and therefore the Committee suggests the long-term donation plan focus on providing more options for those wanting to be a living donor.

Discussion ensued with the following points made:

- The Ohio kidney exchange program was reviewed. There is a benefit in this program where two recipients will receive "living" donor kidneys, unlike an intended recipient exchange where a living donor donates to the general pool of candidates in order to have their loved-one receive an allocation priority on their local waiting list to receive a "deceased" donor kidney.
- There are a few OPOs with a kidney exchange program offering more options for living donors.
- UNOS should facilitate this living donor exchange program locally, regionally, and then nationally.
- The problem with nationalizing an exchange system is the traveling to and from transplant centers.
- This would be a voluntary system and that not all transplant programs will opt in to this system. Of the centers that would participate, would they have UNOS be the repository?
- More education and support are needed in the transplant centers.
- The paired exchange program will give a small increase in the number of donors, but one is better than none.
- There is an assumption that every medical review board would agree that living unrelated donation is a good thing. Paired exchanges can be viewed as similar to anonymous donation.
- One reason why the paired exchange is unsuccessful is because the majority of patients are blood type O who cannot find an A or B donor.
- There is a consideration that this will not be ethical to implement when there are people waiting that do not have access to a living donor.

A motion was unanimously passed that the long-term donation plan be a living kidney donor exchange program with the potential of expanding the local programs to regional and national programs if possible. Components of the plan will include education and removing disincentives for living donors.

14. Hepatic Anomalies. A motion from the last meeting was reviewed: *that in the event of hepatic vascular arterial variations such as replaced right-hepatic artery; the procurement of the liver and pancreas will occur if recipients are identified for each.* It was noted that both the Kidney Pancreas and Liver Intestine Committees
supported the motion and the OAC plans to collaborate with the Kidney Pancreas and Liver Intestine Committees to draft language for policy.

The OPTN data representative presented data related to the discarding of pancreata due to the procurement of the liver under certain anatomical conditions:

- All deceased donors recovered between 2000 and 2003 from whom a liver was recovered and transplanted were examined.

- There were 21 cases between the ages of 15 and 50 where the pancreas was reported discarded due to the needs of liver and/or intestine recovery.
- An additional 14% of pancreata were not procured due to anatomical abnormalities; however the type of abnormality was not documented.
- 11 cases indicated inadequate or no vessels were sent with the pancreas.
- It was noted that if a pancreas is recovered for transplant and then used for islet cell transplantation, there is no place where the reason must be documented as to why the whole pancreas was not transplanted.

Discussion ensued with the following points made:

- There needs to be acceptance from the transplant programs.
- There needs to be a standard for discarded pancreata and those not following the standard will be in violation.
- National data indicate that this is not a significant problem.
- There needs to be an educational component supporting the policy such as a white paper.
- UNOS plans to include the fellowship committee of ASTS.

II. Patient Access Issues

- None

III. Other Issues

15. Hospital Ownership. A letter sent to hospital CEOs from their OPO addressing the requirements of the Hospital Conditions of Participation (CoP) to increase organ donation was reviewed. The purpose of discussing this letter was to determine ways hospitals could have more of a role in the donation process.

It was noted that OPOs are responsible for the recovery of organs and there has never been a component in the OPO's performance standards dealing with how hospitals are performing in the organ procurement process.

It was also noted that in the recent past, the Centers for Medicare and Medicaid Services (CMS) and the Joint Commission on Accreditation of Healthcare Organization (JCAHO) surveyors have had more of a role reviewing hospital accountability in organ donation. Both CMS and JCAHO are currently working to revise their standards for their hospital survey protocol. One member suggested that JCAHO be provided with a checklist of items that must be followed regarding the organ donation process.

The following additional comments were made:

- JCAHO surveyors select a particular patient population. Those patients' charts are reviewed and if a patient happens to be a potential organ donor, the surveyors will extend their screening to include the donation process.
- Most OPOs would like to be proactive and get the word out to their hospitals about the changes JCAHO is making.
- It was noted that it is not routine for an OPO to provide its hospitals with referral and death rates.

The Committee unanimously resolved to request the OPO Committee to consider developing recommendations for OPOs to disseminate hospital-specific information obtained by the OPO and data

from the Scientific Registry of Transplant Recipients (SRTR) to keep their hospitals apprised of their performance based on the requirements of CMS and JCAHO.

16. Breakthrough Collaborative. Mary Ganikos, PhD, Chief of Public Education, Division of Transplantation presented HRSA's Breakthrough Collaborative at the request of the Committee from the last meeting. One member from an OPO applauded HRSA's efforts and described the collaborative as being encouraging, providing a positive experience with a high level of energy. The same member noted that his OPO has already seen higher rates and is changing their culture.

17. Implications for Organ Donation of Clinical Practice Patterns Regarding Life Support and an Empirical Methodology for Estimating Potential for Donation after Cardiac Death. The Association of Organ Procurement Organizations (AOPO) asked the Committee to review its proposed study and offer support. The goals of the study are to 1) investigate how practices regarding mechanical ventilation and physiological support of severely neurologically injured patients facing death affect potential for organ donation –both brain dead or DCD, and 2) to assess potential for donation after cardiac death at the hospital level in order to estimate a national potential for DCD.

    One member mentioned that there is a HRSA funded study to validate a set of proposed clinical criteria that have been designed to identify patients who will expire rapidly following removal of life-sustaining treatments.

    MOTION: The OAC unanimously voted to support AOPO's proposal.

18. HIV, HTLV, HbsAg positive donors. One member commented that donors with positive serologies are an additional source of the donor pool not fully utilized.

    Discussion ensued with the following points made:

- HTLV occurs fairly frequently. In one OPO alone, there were 40 infected donors in 4 years and of those 50-60% were negative on the confirmatory tests. A rapid confirmatory test is available that is used by some OPOs.
- The true transmission rate of HTLV is not known and is probably a slow virus. There has only been a 3-4% transmission rate in the last 10 years.
- For life-saving organs, the policies be modified to remove the confirmatory test requirement and leave the donation to the discretion of the transplant program.
- HIV positive donors are used for HIV positive recipients.
- Using HIV positive donors is an absolute rule-out according to the National Organ Transplantation Act of 1984.
- The Committee should contact the CDC.

Attendance at the Organ Availability Committee Meeting

September 16, 2003

Committee Members in Attendance

Stuart Greenstein, M.D.	Chairman
Deborah Savaria, RN, CPTC	Region 1
Sharon Kiely, M.D., MPM	Region 2
Sameh Abul-Ezz, M.D.	Region 3
Lisa Florence, M.D.	Region 6
Martin Mozes, M.D.	Region 7
Laurel Williams, RN, MSN	Region 8
Steven Rudich, M.D., Ph.D.	Region 10
Dinesh Ranjan, M.D.	Region 11
Joseph Roth	OPO Committee Representative
Michael Hagan, DO	At Large Representative
Alice Thurston, Esq	At Large Representative
Stephen Oelrich	BOD Liaison
Margaret Schaeffer, RN, CPTC	BOD Liaison
Judy Jones Tisdale, PhD	BOD Liaison
Mary Ganikos, Ph.D.	DoT Representative

UNOS Staff in Attendance

Kim Johnson, MS
Sarah Taranto

URREA Staff in Attendance

Laura Christensen, MS
Akinlolu Ojo, M.D.

Committee Members Unable to Attend

Dale Distant, M.D.	Vice Chairman
Anthony Sebastian, M.D.	Region 4
Sean Cao, M.D.	Region 5
John Davis	BOD Liaison