

**OPTN/UNOS OPERATIONS COMMITTEE REPORT  
SUMMARY**

**I. Organ Availability Issues**

**Action Items for Board Consideration:**

- None.

**Other Significant Items:**

- None.

**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 proposes modifications to Policy 3.2.4 (Match System Access), in response to the OPO Committee. (Item 4.a., Page 4)
- The Committee requests UNOS staff to examine all aspects of organ transportation and develop recommendations for Committee consideration. (Item 5.b., Page 6)
- The Committee supports the proposed/direct final rules entitled “Blood Vessels Recovered With Organs and Intended for Use in Organ Transplantation” as published in the Federal Register. (Item 6, Page 7)
- The Committee received demonstrations and considered several issues related to the new Patient Safety and Disease and Malignancy Transmission Reporting Systems and processes. (Various)

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**REPORT OF THE  
OPTN/UNOS OPERATIONS COMMITTEE  
TO THE  
BOARD OF DIRECTORS**

**Atlanta, Georgia  
June 29-30, 2006**

**Marlon Levy, MD, Chairman  
Richard Hasz, MFS, Vice-Chairman**

The Operations Committee met on May 11, 2006, in Chicago, Illinois. The meeting was convened by Dr. Marlon Levy, Chairman. Committee member and staff introductions were made. Dr. Levy reviewed the meeting agenda and the informational sections of the Committee packet.

**1. Policy and Quality Management Subcommittee Meetings**

Members of the Committee divided into separate sessions of the Policy Subcommittee and Quality Management Subcommittee. (The Technology Subcommittee did not meet during this round of committee meetings.) These groups met for approximately two hours to consider issues related to each Subcommittee's area of focus. Deliberations of the two subcommittees and their resulting recommendations are included in their reports to the full session of the Committee.

Following the Subcommittee meetings, the full Committee reconvened.

**2. New OPTN Policy Implementation Process**

Berkeley Keck, UNOS Assistant Executive Director, provided the Committee with a presentation on the new OPTN policy implementation process. He noted that the Board of Directors meeting schedule has changed from two meetings per year to four meetings per year to increase the efficiency and responsiveness of the OPTN. Committee meeting schedules and the policy public comment processes have also been modified to compliment this change. Associated with these improvements is a new policy development process which ensures that proposed policies are fully developed, including resource analysis, prior to consideration of the Board. Mr. Keck reviewed the steps of the new process, and highlighted the use of the OPTN Policy Development Checklist to ensure all requirements have been completed and the proposed policy change is ready for Board consideration. The composition and role of the new Policy Oversight Committee (POC) was discussed. Members expressed their desire that the work of the POC in combination with the new policy development process will result in fewer Board level policy changes and fewer referrals of proposals back to committee. It was noted that the new implementation process is being monitored and evaluated on an ongoing basis to judge its effectiveness.

**3. Electronic Organ Placement Working Group Report and DonorNet®2007 Demonstration**

Dr. Levy introduced this part of the agenda by discussing the composition and work of the Electronic Organ Placement Working Group. He noted that the Working Group is a diversely composed group that includes many members of the Operations Committee and the major transplant societies and organizations. Their work in advising UNOS technology staff in the development of the system has been productive and important. Dr. Levy noted that the Working Group will continue to meet and guide the project throughout the implementation of the new DonorNet®2007 system in January 2007.

Chris Williams, UNOS Director of Technology Services, provided a presentation on the DonorNet®2007 project. The presentation focused on the reasons for developing the system; the components and processes of the new system; and the communication and educational efforts that are underway toward implementing the system for national use. DonorNet®2007 Phase 1, which focuses on donor data collection and display, was implemented on April 29, 2006. The new screens and processes that are now available were demonstrated for the Committee.

The Committee discussed the new organ offer and acceptance processes associated with the DonorNet<sup>®</sup>2007 system. Discussion focused on the areas of electronic notification of organ offers and the ability of transplant center personnel to view the donor information in a timely manner over the Internet. It was noted that several issues, including the number of simultaneous organ offer notifications, are still being considered by the Working Group. The Committee expressed its satisfaction with the progress that has made in developing the system and with the implementation guidelines that have been established by the Working Group.

### ***Subcommittee Reports***

#### **4. Policy Subcommittee Report**

Richard Hasz, Vice-Chair and Policy Subcommittee Chairman, reported on the Subcommittee's deliberations from their earlier meeting.

- a. Consideration of a Request to Clarify Policy 3.2.4, Related to Maintaining ABO documentation - The Subcommittee considered a member request to clarify a requirement within Policy 3.2.4, that requires OPOs to maintain documentation that separate ABO verification has occurred and have this documentation available for audit. The member noted the UNet<sup>SM</sup> on-line verification process, which requires two separate users to enter the ABO of the donor, should satisfy this requirement since the system maintains a log of user actions that can be accessed if needed. The Subcommittee was advised that the OPO Committee considered the same request and, as a result, was proposing a change in policy to delete this requirement.

Members of the Subcommittee were concerned by the OPO Committee proposal since the original intent of this requirement was for OPOs to utilize a procedure of two-person verification of the two ABO source documents. They acknowledged that the current sentence placement of the requirement could lead to confusion. It was noted that policy modifications approved in 2004 separated this requirement from the requirement of "two separate determinations...of the donor's ABO type prior to incision." The Subcommittee stated that the process of two individuals reviewing the source documents of the donor's ABO testing and verifying correctness was a valuable part of patient safety that should not be eliminated. Also, the Subcommittee noted that the ABO source documents should be used to perform the on-line verification of the donor's ABO type. Since the OPO Committee's proposal to eliminate the requirement was in the process of publication, the Subcommittee was advised that the Operations Committee could provide their opinion and any recommendations for policy modification through the public comment process and through direct coordination with the OPO Committee. In response the Subcommittee proposed modifying Policy 3.2.4, to clarify the intent of the policy and to maintain the requirement of two-person verification of the ABO results. Hearing the report of the Subcommittee and the proposed policy modifications, the Operations Committee approved the following resolution:

**\*\*RESOLVED**, the Operations Committee supports the following proposed modifications to Policy 3.2.4 (Match System Access), in response to policy modifications submitted by the OPO Committee for public comment.

Committee Vote: 13 For; 0 Against; 0 Abstaining

**3.2.4 Match System Access.** OPOs are required to use the Match System (UNet<sup>SM</sup> for the allocation of all deceased donor organs. The Host OPO must enter required information about the donor (Policies 3.5.7, 3.6.9, 3.7.9 and 3.8.5) and execute the Match System to determine organ allocation priorities. Such information must be entered into the Match System for all deceased donors. The OPO shall be responsible for two separate determinations (e.g., 1) two samples sent to two labs, or 2) one sample sent to two labs, or 3) two samples from separate draws sent to the same lab) of the donor's ABO type prior to incision and for ensuring the accuracy of the donor's ABO data in UNet<sup>SM</sup>. The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit. Each OPO shall establish and implement a procedure utilizing the ABO source documents for ~~providing~~ on-line verification of donor ABO data by an individual other than the person initially entering the donor's ABO data in UNet<sup>SM</sup>. ~~The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit.~~ *(The remainder of Policy 3.2.4, is unchanged.)*

- b. Discussion of mandatory reporting of post-transplant adverse events - The Subcommittee considered a request by HRSA/DoT related to post-transplant reporting and surveillance of adverse events with the intent of strengthening the OPTN's disease transmission reporting policies. A key point of the request was to consider whether recipient death soon after transplant, or in certain other circumstances, should require immediate reporting to the OPTN to improve the surveillance of transmission events. This request was stimulated by a suspected disease transmission case that was reported to the OPTN. The background of this case was discussed related to current practices and reporting requirements. It was expressed that the current system for disease and malignancy reporting and follow-up is structured in a piece-meal approach and that a unified approach for handling these situations was needed. The Subcommittee also expressed concern that the results of the Data Reduction Task Force recommendations may further hinder these efforts by removing or limiting serology data. One member noted that the goal should be to work with the OPOs to provide better guidance on excluding suspicious deaths and to improve the OPTN tracking systems for disease and malignancies. This process would include revising the list of donor disease conditions in Policy 4.6 to designate conditions that may require donor exclusion, and developing a more simplified reporting process. A draft list of possible infectious disease exclusion criteria for organ donors was distributed. The Subcommittee was advised that this list may be used in revising Policy 4.6. The concept of a tiered approach to screening and reporting was discussed which would include a first tier of donor exclusions and a second tier of conditions requiring communication with potential recipient centers. It was also recommended that a policy be developed to require reporting to the OPTN all recipient deaths that occur within the first year post-transplant by the transplant center immediately at the time of their notification.

It was noted that the goal will be to have proposed revised policy language for Policies 4.6, 4.7 (disease screening and reporting) and Policy 7 (recipient death reporting) for the Policy Subcommittee to review at the next meeting. The process was explained that the policy proposals will be first developed and reviewed by the Disease Transmission Advisory Group, then the Policy Subcommittee, before it is distributed to the full Operations Committee and the OPO Committee for their review and approval. The Subcommittee agreed that changes to these processes will require a thorough educational effort targeting the OPO and transplant center communities. Ginny McBride, OPTN Project Officer, having participated in the Subcommittee and Operations Committee discussion of this issue noted that HRSA/DoT is satisfied with the discussions and the plan for action on this request.

- c. Review of proposed procedures and processes for urgent transfer of transplant candidates – The priorities that are used by the Organ Center in transferring or modifying candidate waiting time upon request were reviewed by the Subcommittee. The Subcommittee supported these priorities and offered minor wording changes.
- d. Status report on efforts to remove center-specific listing defaults from UNet<sup>sm</sup> – The Subcommittee was advised that to date the Liver and Intestinal Transplantation and Thoracic Organ Transplantation Committees have considered and supported the Operations Committee's request to remove center listing defaults from the waitlist entry process. The Kidney Transplantation and Pancreas Transplantation Committees have not met to consider this request. If approved, the removal of these default values is expected to improve the accuracy of the candidate match requirements and may also result in a more efficient organ placement process.
- e. Review of West Nile Virus (WNV) letter to OPOs - A recent draft version of a letter from the OPTN intended for all OPOs related to donor screening, testing, and reporting potential donors with suspected or confirmed West Nile Virus was reviewed. No actions were recommended by the Subcommittee.

## **5. Quality Management Subcommittee Report**

Dean Lichtenfeld, Quality Management Subcommittee Chairman, reported on the Subcommittee's deliberations from their earlier meeting.

- a. Patient Safety System - The Subcommittee reviewed the situations reported through the online Patient Safety System which was implemented for member use on March 8, 2006. A report of the two situations entered to date was provided. As a result of their discussions, the Subcommittee made the following suggestions:

- Handling of reported situations:
  - There is a moral obligation and responsibility to provide blinded reports to transplant centers and OPOs.
  - The intent is to allow for quality improvement efforts, corrective action plans, sharing of proposed best practices, and opportunities for monitoring trends.
  - The Patient Safety System is not a “whistle-blower” mechanism. If a “whistle-blower” system is desired, the OPTN (possibly through the Membership and Professional Standards Committee) may want to establish a mechanism such as a hot line which could be used by transplant centers, OPO staff, patients or family members.
- In response to a reported situation, an organ wastage survey should be developed:
  - The scope of the problem regarding organ wastage due to operating room changes needs to be evaluated.
  - A survey should be designed and circulated to OPOs to gather data on this issue.
  - The Operations Committee liaisons will work with Subcommittee members to design the survey.
  - A transplant center survey will be conducted at a later date.
- In response to a reported situation, a “time-out” process for verifying organ data will be recommended:
  - The “time-out” should include verifying the anatomy before the organ leaves the recovering operating room and a second verification at the recipient operating room to include anatomy and ABO.
  - These processes involve training for coordinators and surgeons, and perhaps presentations could be made at AOPO and NATCO.
  - The best practices which develop from the reported situations should be disseminated through an electronic E-Quality newsletter, reported at the regional meeting and shared with the AOPO Quality Council.

- b. Organ Transportation Report - The Subcommittee reviewed a report of transportation issues recorded by the Organ Center between May 1, 2005, and March 15, 2006. The report noted 11 transportation failures and 15 transportation “near-misses” that resulted in delays. Using the denominator of 3495 total transportations arranged by the Organ Center during this time period, the reported failure/near-miss rate equaled 0.74%. Subcommittee members agreed that additional data should be collected to develop a threshold of tolerance and to better characterize the magnitude of these transportation problems. The Subcommittee suggested discussing these problems with the transportation vendors. Radio Frequency Identification (RFID) was also discussed as an innovative idea to explore.

Upon reporting this issue to the Committee, it was requested that OPO and courier information be included in these reports. It was stated that acceptable failure/near-miss thresholds should be established. A request was made to share the Subcommittee and Committee concerns with the OPO Committee (who is also considering this information) to see if they would be interested in sponsoring a meeting of OPOs, Organ Center and courier companies to address these issues. A member asked if HRSA/DoT or the Transportation Safety Administration (TSA) could help the community with this problem. Ginny McBride, OPTN Project Officer, offered to bring this issue to the attention of DoT and TSA. It was recommended that new and innovative ideas for improving the current transportation system be considered. As a result of these discussions, the Committee approved the following resolution:

**\*\*RESOLVED**, the Operations Committee requests UNOS staff to examine all aspects of organ transportation, including the current transportation problems, and develop recommendations for Committee consideration.  
Committee Vote: 17 For; 0 Against; 0 Abstaining

- c. Living Donor Organ Packaging and Labeling - The Subcommittee examined communication between UNOS and a transplant surgeon regarding transporting live donor organs. The group examined multiple scenarios and made the following suggestions regarding possible live donor organ packaging and labeling:
- Any time an organ leaves the operating room suite it must be packaged and labeled according to OPTN/UNOS policy.
  - If there is a single donor-single candidate scenario within the same operating room suite, the organ(s) must be labeled, but can be transported in an appropriate sterile container. A verification “time out” before leaving the donor surgical room should take place, as well as a “time out” for a second verification of information upon arrival in the candidate surgical room.

- If there are multiple donors and candidates (i.e., expanded paired exchange) within the same operating room suite, the labeling and double verification “time outs” are recommended.
  - The Subcommittee will draft proposed language changes for Policy 5.0 and will submit these changes to the Policy Subcommittee at the next Operations Committee meeting.
- d. Match List Re-Running - During the previous Subcommittee meeting, reasons for re-running a match list were discussed and data were requested. Leah Edwards, Ph.D. from the UNOS Research Department provided counts of matches that were re-run in 2005 by organ and by time interval between subsequent re-runs. These data were shared with the Subcommittee and later with the full committee. It was noted that liver is the only organ for which there is specific policy language addressing re-running the match list. Additional data were requested to show differences by region and OPO. This information will be provided to the Subcommittee during the next meeting. The following suggestions were made to alleviate match list re-runs:
- The ‘run all matches’ button should not be checked for all organs.
  - A drop down list could be added to the program that will ask why the list is being re-run.
  - The weight range could be changed to a rolling range of +/- pounds rather than exact weights.

It was communicated that proposed policy modifications specific to situations of planned DCD donors that proceed to brain death is circulating for public comment and may have implications regarding this discussion. This issue will be revisited at the October 2006 meeting. It is anticipated that suggestions to reduce and/or capture reasons for re-run matches will be forwarded to the Electronic Organ Placement Working Group and UNOS IT staff. The Subcommittee liaisons were requested to consult with the UNOS Department of Evaluation and Quality regarding differences between OPOs in re-running matches when a sicker patient is identified after the initial match is run.

- e. Laparoscopic Nephrectomy Donor Clip Recall - The Subcommittee reviewed information that was widely distributed throughout the surgery and transplantation communities related to a surgical instrument recall. It was decided that OPTN/UNOS legal counsel be consulted before any such notifications or advisories to members are distributed.
- f. Organ Labels Update - The latest prototypes of organ packaging labels were presented to the Subcommittee for review. The new labels include an outside label, an internal Tyvek label and a carbon label. All labels will be color coded and have an appropriate organ graphic as well. Suggestions from the Subcommittee and Committee were incorporated into the new design. It was noted that the carbon label may work for the living donor packaging recommendations.

## **6. Consideration of Proposed Rules for Blood Vessels Recovered with Organs**

It was announced by Ginny McBride, OPTN Project Officer, that proposed/direct final rules for “Blood Vessels Recovered With Organs and Intended for Use in Organ Transplantation” were published on the day of the meeting in the Federal Register by the FDA. Copies of these documents were obtained and distributed to the Committee for review. Following ample time for consideration, Dr. Levy requested the Committee to discuss and/or provide their opinion of the published rule. Various members spoke in support of the rule stating that it appears to support the opinion of the transplant community that vessels recovered with organs for the purpose of transplantation should stay within the oversight and purview of the OPTN. It was noted that the UNet<sup>sm</sup> system currently tracks the recovery and disposition of donor vessels. Other processes relating to labeling, storing, and disposition are detailed on recently implemented OPTN policy. As a result of these discussions, the Committee approved the following resolution:

**\*\*RESOLVED**, the Operations Committee supports the proposed/direct final rules entitled “Blood Vessels Recovered With Organs and Intended for Use in Organ Transplantation” as published on May 12, 2006, in the Federal Register.

Committee Vote: 13 For; 0 Against; 0 Abstaining

## **7. Status report on ABO verification policies**

The Committee considered a data report (Exhibit A) generated from the candidate waitlist demonstrating the number and percent of candidates and donors who have had their ABO changed in UNet<sup>sm</sup> since system requirements for double verification of ABO by two separate system users were implemented on June 30, 2004. The Committee agreed that the incidence of ABO change is stable and within an acceptable level. They opined that the ABO verification policies and system requirements appear to be effective. This data will continue to be evaluated at each future meeting.

## **8. Report on the new Patient Safety System and Disease and Malignancy Transmission Processes**

Joyce Hager, MPH, Patient Safety Specialist, provided a demonstration of the new Patient Safety System that includes modules for members to report patient safety situations and disease or malignancy transmission situations. The presentation included demonstrations of how members access and enter information to make these reports, as well as the processes used by UNOS staff to follow-up with members and develop formal reports of these situations. The Committee requested Ms. Hager to repeat member training sessions on both systems to increase awareness of these reporting mechanisms.

Related specifically to disease and malignancy transmission reporting, Ms. Hager advised that a Disease Transmission Advisory Group has been established as a subgroup of the Operations Committee to consider these reports as they are received. The Advisory Group includes specialists in infectious disease and malignancy, and includes representatives from HRSA/DoT, CDC in addition to transplant physician/surgeons; transplant administrators; OPO and clinical transplant staff. She noted that UNOS staff are on-call around-the-clock to receive and follow-up on disease or malignancy reports. Ms. Hager reviewed a listing of disease or malignancy reports that have been received between December 2004 and April 2006. Of the 15 reports, eight were related to the transmission of malignancies and seven were related to a disease transmission between donor and recipients.

Chris Williams, UNOS Director of Technology Services, provided the Committee with an overview of the Transplant Transmission Sentinel Network (TTSN). UNOS, in conjunction with other major organ, tissue and eye transplantation organizations, was awarded the CDC cooperative agreement last fall to establish the TTSN. He noted that the TTSN is being established to function as an umbrella organization to coordinate and advise the organ, tissue, and eye transplantation communities toward a unified approach to reporting and tracking donor-related disease transmission. An Advisory Group has been established that includes representatives from the primary organ, tissue and eye transplantation organizations; the associated Federal agencies; and several recipient/end-user organizations. It was noted that Dr. Jay Fishman will chair the Advisory Group which will meet for the first time in June. Mr. Williams noted that the efforts and recommendations of the TTSN will be reported to this Committee.

## **9. Recognition of committee members**

Dr. Levy recognized those members whose terms of committee service are expiring this year. Each member was announced and presented with a certificate of appreciation.

## **10. Next Meeting**

The next Operations Committee meeting will be scheduled for Thursday, October 5, 2006, at the O'Hare Hilton Hotel in Chicago.

The meeting was adjourned at 2:30 p.m.

**OPTN/UNOS OPERATIONS COMMITTEE MEETING**  
**Chicago, Illinois**  
**May 11, 2006**

**Members Attending:**

Marlon Levy, MD	Chair (Region 4)
Richard Hasz, Jr., MFS	Vice Chair (Region 2)
Kevin O'Connor, MS, PA	Region 1
Shirley Schlessinger, MD	Region 3
Rebecca Menza, RN, CPTC	Region 5 (via teleconference)
Monica Johnson-Tomanka, RN	Region 6
Melissa Zimmerman, RN	Region 7
Martin Zamora, MD	Region 8
Tracy Evans-Walker, RN, BSN	Region 10
Kevin Myer, MSHA	Region 11
William Chapman, MD	At Large
Vicki Fioravanti, RN	At Large
Jay Fishman, MD	At Large
Dean Lichtenfeld, RN, MSN	At Large
Bruce Schmeiser, PhD	At Large
Dolly Tyan, PhD	At Large
Warren Rosenblum, MD	At Large
Laurel Williams, RN, MSN	At Large
Ginny McBride, RN, MPH, CPTC	<i>Ex Officio (HRSA/DoT)</i>

**Unable to attend:**

Helen M. Hauff, RN	Region 9
Daniel Hayes, MD	At Large

**UNOS staff attending:**

Chris Williams, RN, CPTC	Committee Liaison
Gloria Taylor, RN, MA, CPTC	Committee Liaison
Berkeley Keck, RN, MPH	Asst. Executive Director, Information Technology
Joyce Hager, MPH	Patient Safety Specialist
Leah Edwards, PhD	Acting Director, Research
Courtney Bland	IT Business Analyst

EXHIBIT A

**ABO Verification Report**  
**OPTN/UNOS Operations Committee**  
**May 11, 2006**

**Note: These ABO modifications do not include changes to subtypes, e.g. A1, A2, A1B, A2B.**

	1/1/04 - 6/29/04	7/1/04 - 12/31/04	%	1/1/05 - 6/30/05	%	7/1/05 - 12/31/05	%	1/1/06 - 3/31/06	%
Candidates added to the waitlist before 6/30/04, having their ABO value changed to another ABO type (re-listed). *		14	2.8	13	3.1	18	0.1	8	4.5
Candidates added to the waitlist on or after 6/30/04, having their ABO value changed to another ABO type (re-listed). *		5	2	7	2.5	9	3.1	3	2.1
Candidates having their ABO modified between the initial entry and the second entry (verification). #		29	1.2	27	1.1	27	1.1	9	0.7
Number of deceased donors with ABO modified between the initial entry and the second entry (verification)		4	0.7	5	0.8	9	1.5	8	2.7
<b>Prior to on-line verification:</b> The number of candidates having their ABO value changed to another ABO type.	53								

\* Percent based on total number of re-listed candidates during the time period with unique SSN.

# Of listing not unique by SSN