

OPTN/UNOS OPERATIONS COMMITTEE REPORT

Report to the Board of Directors

March 2-3, 2009

Houston, TX

SUMMARY

I. Action Items for Board Consideration

- None

II. Other Significant Items

- The Committee reviewed a request from the Living Donor Committee regarding the allocation of living altruistic donor organs and suggested issues for exploration. The Committee supports the donor's right of choice regarding the locations they would prefer to have surgery. (Item 2, Page 3)
- The Committee reviewed a request from the Living Donor Committee regarding two separate ABO confirmatory tests for living donors and supports this policy proposal. (Item 3, Page 3)
- The Committee discussed the need to establish a Patient Safety Situation Review Group and unanimously supports this endeavor. The Committee deems this action of paramount importance and brings it to the Board of Directors attention. (Item 6, Page 4)

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**REPORT OF THE OPTN/UNOS OPERATIONS COMMITTEE MEETING
TO THE BOARD OF DIRECTORS
March 2-3, 2009
Houston, TX**

**Richard Hasz, MFS, Chairman
Marwan Abouljoud, MD, Vice-Chairman**

The Operations Committee met on September 4, 2008, and the meeting was led by Richard Hasz, MFS, Chairman. The meeting began with Committee member introductions and an agenda overview.

1. **Orientation Sessions** – New and returning committee members were provided presentations by UNOS Information Technology, Federal Affairs, and Research staff. Paula Bryant, MBA, Information Management Systems Director and Aaron Powell, PMP, Project Management Office Manager, provided a presentation on policy implementation and technology considerations. Mary Ellison, PhD, Federal Affairs Assistant Executive Director, presented “OPTN/UNOS Committee Orientation” and Leah Edwards, PhD, Research Assistant Director presented “OPTN Committees: Research Support.” Following the presentations Committee members had the opportunity to ask questions and address issues. The Committee discussed the potential impact the current IT backlog will have on future Committee work.
2. **Allocation of Altruistic Donor Organs** – The Committee reviewed a request from the Living Donor Committee to consider the operational issues regarding the allocation of living altruistic donor organs. The Living Donor Evaluation Subcommittee is recommending that organs from altruistic living donors be allocated according to the match run, based on the Ethics Committee proposal contained in a white paper titled “Allocation of Organs from Non-directed Living Donors” that “non-directed organs from living donors be allocated according to the existing algorithm governing the allocation of cadaveric organs within the appropriate sharing unit.”

In its discussion, the Operations Committee highlighted several topics for exploration by the Living Donor Committee including: geographic distribution of kidneys within paired exchanges and donation chains; similarities and differences of established altruistic donor programs; match run scenarios where payback concepts might apply; cost indications for acquisition charges; procedural issues where the recipient center may not perform live donor recoveries or be qualified to do so; and live donor self referral to a particular center that the donor desires to have perform the surgery. The Committee supported the donor’s right of choice regarding the center where they would prefer to have surgery. The Committee also recommended that feedback should be sought from the Ethics and Patient Affairs Committees.

3. **Two Separate ABO Tests for Living Donors** – The Committee reviewed a request from the Living Donor Committee to consider the operational issues regarding two separate ABO tests for living donors. Requiring two separate ABO tests was a recommendation proposed in the Living Donor Committee’s original “Guidance for the Medical Evaluation for Living Kidney Donors” document. However, the recommendation was removed from the original document and deemed too prescriptive. Subsequently, there was an adverse event reported that would have been prevented by the stricken recommendation to require two separate ABO tests.

The Operations Committee questioned why there would be less stringent requirements for living donors than deceased donors, which in turn creates a double standard for living donors. The

Committee supports a policy proposal that promotes patient safety for living donors regarding two separate ABO determinations and indicated that such a proposal should mirror the existing deceased donors requirements. The Committee also noted that if a candidate is not on the waitlist, there is no requirement for two separate ABO determinations and recommended that a proposal to protect both donors and candidates be considered. Additionally, a complete separate set of Living Donor policies is supported by the Committee as long as the basic tenets of patient safety are upheld by such policies.

4. **Policy 5 Update** – The Committee was informed that the OPO Committee has undertaken a complete revision of Policy 5.
5. **Consideration of Public Comment Proposals** – The Committee considered current proposed policies, which were included in the Public Comment document dated June 30, 2008. The Operations Committee opinion is shown below for the selected proposals the Committee considered within its purview:
 - **Proposal to verify that foreign agencies importing organs to the United States are legitimate and test organs for transplant safety – Policies affected: 6.4.2 (Developmental Protocols in Organ Exchange) and 6.4.3 (Ad Hoc Organ Exchange)**. The Committee supported this proposal in concept, but voiced concern regarding the burden this proposal places on the U.S. OPOs and transplant centers. The Committee determined that this burden was misplaced, and the responsibility should rest with the foreign entities to prove they meet U.S. organ recovery and transplantation standards. For each U.S. transplant program to develop a relationship and agreement with each foreign entity is an overwhelming proposition. The Committee proposed that instead of allowing these events to be handled on an ad hoc basis, that more proactive measures should be taken ahead of time by a higher level institution (perhaps OPTN/UNOS) to create a credentialing process for foreign programs that would set forth expectations for exporting recovery agencies as well as importing transplant programs. This type of mechanism would provide for patient safety on both imported and exported organs. The Committee stressed that patient and OPTN member protection is paramount. Additionally, the Committee raised concerns regarding laws in other countries governing exportation of organs. The Committee was unclear as to what the term “certify” implied in this proposal.
 - **Proposal to improve the safety of living donor organs by restricting the acceptance and transplant of living donor organs to OPTN Member Institutions – Policy affected: Add Policy 3.3.7 (Center Acceptance of Organs from Living Donors)**. The Committee viewed this proposal as a patient safety and quality issue. However, they were not clear on the mechanism that would be used to track this type of activity. The Committee suggests that the Living Donor Committee consider creating a new membership category for Living Donor Recovery Institutions.

Committee Vote: 16 For; 0 Against; 0 Abstaining

6. **Establishment of a Patient Safety Situation Review Group** – The Committee discussed the need to establish a Patient Safety Situation Review Group (PSSRG) at length and unanimously supported this endeavor. The Committee proposes this to be a peer review group that will serve as a resource/advisory group to the UNOS Patient Safety Staff. The PSSRG will review de-identified patient safety situations in a peer review setting and provide guidance regarding potential policy implications and donation and transplantation community guidance, education, and process improvement. Additionally, this peer review group would have the ability to secure more details proximal to the situation, be privy to internal analysis and the member’s corrective actions, and develop policy modification proposals based on the community’s experiences. The Committee would

like this group modeled after the former Disease Transmission Advisory Group (DTAG) with an externally facing, password protected SharePoint® site.

The Committee discussed the Air Force model for self-reporting of safety situations. The Air Force employs a protected investigation where any means can be taken to fix the problem, and everyone learns from the individual's mistake. The offender is rewarded for reporting and fixing the problem as long as it does not pass a certain Air Force designated threshold. This practice results in complete buy-in by the members, and they help themselves by deliberately identifying problems while protecting themselves from site visits, audits, or other punitive actions. People are more inclined to identify a problem and correct it in this environment.

The Committee thought that there should not be automatic immunity for simply reporting a problem/situation into the Patient Safety System. However, they did think that the idea of a threshold was important. Their discussion suggested that policy violations short of critical or category 1 could be a possible threshold. The potential for patient harm or organ wastage were not the only negative outcomes considered. The Committee considered the difference between a mistake and a deliberate action in violation of a policy. When there are clear policies/rules set for particular reasons and individuals deliberately decide to do otherwise, this is unacceptable behavior and should be considered a violation of another type of threshold. The Committee concluded that there needs to be an investigation of the reported patient safety situations to establish what the individuals were thinking when the situation occurred. The Committee acknowledged that fear of retribution keeps members from reporting patient safety situations and the ability to provide a protected investigation is essential. Additionally, the manner in which these situations are currently handled via the Department of Evaluation and Quality and the Membership and Professional Standards Committee is of concern to the Operations Committee. The Committee deems this of paramount importance and would like this communicated to the Board of Directors.

7. **Patient Safety Situations Report** – UNOS staff provided reports of all cases since the Committee's last meeting (April 2008) for consideration. The Committee commented about the number of patient safety situation reports and believes these situations are underreported. The patient safety situation reports are voluntary and are not required to be reported by policy. All the patient safety situation data needs to be analyzed, categorized, and prioritized to evaluate process improvement opportunities and possible proposed policy modifications.
8. **Ad Hoc Disease Transmission Advisory Committee (DTAC) Update** – Michael Ison, MD, DTAC Chair, provided an update regarding the Committee's current charges, the elevation of Disease Transmission Advisory Group (DTAG) to an Ad Hoc Committee, and the planned path forward. Questions were entertained.
9. **Organ Center Transportation Report** – The Committee reviewed the Organ Center transportation report and indicated that these data have implications for potential policy changes as six kidneys were discarded. The Committee indicated a desire for more information regarding these discards in order to propose policy changes. This report needs to be ongoing, and the data need to be analyzed, categorized, and prioritized to evaluate opportunities for process improvement as well as policy modifications.
10. **Finalize Establishment of Operations Committee Implementation Subcommittee with Education Subgroup** – The Committee decided to move forward with the establishment of an Implementation Subcommittee. This group's primary purpose will be to review all technology-related proposals and solutions on behalf of the Operations Committee. This group's work will

include review and approval of specifications documents as well as providing direction for educational initiatives regarding technology-related projects.

11. **DonorNet® UNOS IT Update** – Bonnie Felice, IT Business Analyst, provided a status report for the Committee regarding DonorNet®. The report included DonorNet® metrics, information regarding the most recent enhancements, and future enhancement updates. Staff sought feedback from Committee members regarding various facets of DonorNet®. Members shared their experience with the system thus far and identified areas for educational opportunities. Questions were entertained.
12. **UNOS Research DonorNet® Data Reports** – Leah Edwards, PhD, Research Assistant Director, provided the Committee with requested DonorNet® data reports. These reports were: *Use of Provisional Yes and Characteristics of Organs Offered but Not Accepted* and *Characteristics of Organs Offered but Not Accepted*. Questions were entertained. These data were considered valuable by the Committee and will be used in educational efforts for the donation and transplantation community and in efforts of Committee work groups.
13. **Research Organization Access to DonorNet® Update** – UNOS Staff provided the Committee the Policy Notice for Policy 3.2.1.2 regarding access to DonorNet®. There was no discussion.
14. **Canadian and Mexican Transplant Center Access to DonorNet® Update** – UNOS Staff provided an update for the Committee regarding the security, legal/statutory, policy and resources concerns regarding this subject.
15. **UDHQ-OPE Project: A Uniform Donor Risk Assessment Presentation** – Scott Brubaker, Chief Policy Officer of the American Association of Tissue Banks (AATB), provided a presentation on the Uniform Donor History Questionnaire project. This is an effort to reduce the complexity of the current medical and social histories and provide uniformity throughout the organ, tissue, and eye community regarding donor history. The Committee responded favorably to the presentation and Rick Hasz, Committee Chair, will represent the Operations Committee on the AATB's project task force.
16. **Finalize Tiered Acceptance Working Group Plan** – The Committee confirmed creation a subgroup to address Tiered Acceptance Criteria. Operations Committee members will work with an OPO Committee representative, Organ Availability Committee representative and former members of the DSA Task Force to outline possible paths forward for this initiative.
17. **Status report on ABO verification policies** – A status report from UNOS Research regarding ABO modifications made for candidate and donor listings was provided to the Committee. It was noted that there was little change in the data since the last Committee meeting. The Committee will continue to receive status reports.
18. **Committee Meeting Dates for 2009** – The Committee will meet on May 7, 2009, and September 10, 2009, at O'Hare Hilton Hotel, Chicago.

OPTN/UNOS OPERATIONS COMMITTEE MEETING ATTENDANCE

Name	Position	Chicago, Illinois September 4, 2009
Richard Hasz, Jr., MFS	Chair (Region 2)	x
Marwan Abouljoud, MD	Vice Chair (Region 10)	x
Philip Camp, Jr., MD	Region 1	x
Kevin Carney, RN, CCTC	Region 2	x
Erin Wray, CTBS	Region 3	By phone
James Cutler, CPTC	Region 4	x
Shanna Perales	Region 5	x
Wayne Dunlap, RN, BSN, CPTC	Region 6	x
Barry Friedman, RN, BSN, MBA, CPTC	Region 7	x
Douglas Bremers, BA, CPTC, CTBS	Region 8	x
Lisa Johnson-Berger, RN, NP, CCTC	Region 9	x
Steven Rudich, MD, PhD	Region 10	x
Patrick Northup, MD, MHS	Region 11	x
William Cotts, MD	At Large	
Karen Cox, PhD, RN	At Large	x
Oscar Grandas, MD	At Large	
Julie Heimbach, MD	At Large	x
Michael Ison, MD	At Large	x
Gwen McNatt, MS, RN	At Large	x
J. Elizabeth Tuttle-Newhall, MD	At Large	
Lewis Teperman, MD	At Large	
Marlon Levy, MD	Ex Officio	By phone
Michael Hagan, DO, MHSA, CMQ	BOD Liaison	x
Richard Durbin, MBA	Ex Officio	By phone
Robert Walsh	Ex Officio	x
Craig Lake, MS	SRTR	By phone

UNOS staff attending:

Gloria Taylor, RN, MA, CPTC	Committee Liaison
Janet Smith, BS, MBA, PMP	Assistant Executive Director, Chief Information Officer
Mary D. Ellison, PhD	Assistant Executive Director, Federal Affairs
Leah Edwards, PhD	Assistant Director, Research
Bonnie Felice	IT Business Analyst

UNOS staff attending via conference call:

Paula Bryant, MBA	Director, Information Management Systems
Aaron Powell, PMP	Manager, Project Management Office

Guest attending:

Scott Brubaker, CTBS

American Association of Tissue Banks (AATB) Chief Policy Officer