

**OPTN/UNOS AD HOC 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:**

- The Board is requested to approve the establishment of a voluntary, confidential system for members to report situations that could affect patient safety, organ availability, and organ utilization so that the prevalence of these situations can be monitored and reported, and recurrence can be prevented, with the goal of enhancing quality outcomes and systems. (Item 1, Page 2)
- The Board is requested to grant final approval of Policy 3.1.4 (Patient Waiting List), to ensure the accuracy of a transplant candidate's ABO type on the waiting list by requiring transplant centers to enter and maintain transplant candidate data electronically using UNet<sup>sm</sup>; requiring transplant candidate ABO typing on two separate occasions prior to listing; and listing transplant candidates with their actual ABO type. (Item 2, Page 4)
- The Board is requested to grant final approval of Policy 3.2.3 (Match System Access), requiring that two separate determinations of the donor's ABO type be performed prior to initiating the organ recovery incision, and providing more specific policy language for the process of distributing organs using the match. (Item 2, Page 5)
- The Board is requested to approve of modifications to Policy 3.2.3 (Match System Access), requiring OPOs use the OPTN/UNOS match system for allocating all deceased organs. (Item 4, Page 6)

**Other Significant Items**

- The Committee will communicate with each organ-specific committee that inaccuracies in candidate listing ranges and criteria create major impediments in the organ allocation and placement process, and will request each organ-specific committee's assistance in addressing these issues and providing their recommendations to the Committee on how to define and correct these impediments. (Item 1, Page 3)
- The Committee will request the UNOS Information Technology Department to modify the UNet<sup>sm</sup> system to randomize the Donor ID number for improved patient safety. (Item 1, Page 3)
- The Committee will recommend to the Ad Hoc Living Donor Committee that a similar process for dual ABO verification that is proposed for deceased donors and candidates be also required for the living donor and candidate transplant process. (Item 2, Page 4)

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

**Minneapolis, Minnesota  
June 24 -25, 2004**

**Kevin Myer, MSHA, CPTC, Chairman  
Marlon Levy, MD, Vice-Chairman**

The Ad Hoc Operations Committee met on April 29, 2004, in Chicago, Illinois. The meeting was convened at 10:00 a.m. by Kevin Myer, Chairman. The agenda was reviewed, and Committee member introductions were made. Rebecca Menza, Region 5 Representative, and Bruce Schmeiser, At Large Member, were welcomed as new members. Minutes from the previous committee meeting on October 30, 2003, were reviewed with no comments recommended.

**1. Subgroup Working Sessions**

The morning portion of the meeting was dedicated to working sessions of the Committee's two established Subgroups. The Donor Management/Organ Allocation Subgroup was led by Kevin O'Connor and Dean Lichtenfeld. The Organ Recovery/Transplant/Waitlist Removal Subgroup was led by Laurie Williams. Prior to separating into groups the Chair tasked each Subgroup to develop process flow diagrams, including issues and potential points of failure for each of their Subgroup sections. To facilitate their deliberations, the Chair initiated a discussion of recent "near-miss" incidents. In a center and patient confidential manner, seven situations were volunteered by various Committee members: four situations involving ABO typing/listing errors; one organ packaging mix-up; and two situations in which there was confusion related to the organ to be recovered vis-à-vis the type of organ required by the intended candidate. At the end of this discussion, the Chair reiterated his charge for each group to focus on developing process flow diagrams for their areas of responsibility, then to identify the top issues or potential points of failure and begin working on solutions for these issues.

Following the Subgroup meetings, each group leader reported the results of its deliberations to the full Committee. The Organ Recovery/Transplant/Waitlist Removal Subgroup identified three issues for full Committee consideration:

- 1) Truth in listing – The Subgroup felt that the organ-specific committees should be requested to require specific ranges for organ acceptance variables such as weight and height ranges and distance to travel for an organ. By limiting candidates to strict ranges, the organ placement process could proceed more efficiently with offers being made only to those candidates who specifically meet the criteria, thereby reducing organ placement efforts to candidates listed with broad and sometimes unrealistic ranges. The Subgroup suggested that candidates who require broad ranges could be submitted, reviewed and decided upon by the regional review board. Additionally, the Subgroup suggested that the transplant community should work toward better waiting list management so that candidates who are not ready for transplant, for whatever reason, do not appear on match lists.
- 2) Using correct information – The Subgroup briefly discussed the importance of ensuring that candidate waiting list information is correct and that donor information provided during an organ offer is current and accurate.
- 3) Reporting near-miss situations – The Subgroup recommends that a mechanism be developed for transplant organizations to report issues/problems/near-miss situations. By having such a system, these situations could be better quantified, tracked and addressed.

The Donor Management/Organ Allocation Subgroup focused on the two following issues:

- 1) Developing a mechanism for reporting near-miss situations – The Subgroup felt it was imperative to develop a methodology for members to report near-miss situations. The recording of these events would not only assist in developing processes for preventing recurrence, but could help the transplant community learn valuable lessons from previous mistakes. The Subgroup hoped a resolution would result from the full Committee that would encourage development of a reporting system that is workable, and one in which the

transplant community is willing to participate. One Committee member commented that a near-miss reporting system utilized by their center is having a positive effect. The Chair expressed his opinion that the Committee needs this type of data and occurrence rates to more effectively perform its charge. It was stated that a reporting system should be confidential and include the option for anonymous reporting.

- 2) Correct labeling and packaging of organs – The Subgroup discussed several anecdotal incidents involving labeling and packaging problems. It was felt that these are important issues that will require more time and consideration.

John D. Persons III, UNOS Corporate Counsel, was requested to address utilization of a reporting mechanism for issues/problems/near-miss situations related to what a peer review process is and how it functions. He noted that peer review is required in the OPTN Contract and in the Final Rule. Mr. Person's related that the accepted definition for peer review is all information, interviews, reports, memorandum, and documents used in internal quality control for improving quality processes, quality care and reducing patient mortality. In order to maintain the peer review privilege, formal peer review proceedings are required. He noted that peer review is protected by state statute, but not by federal law. Peer review protection ensures the effectiveness of self evaluation. In concluding his remarks, Mr. Persons related that he feels the goals of OPTN/UNOS peer review are: 1) correction of a situation(s) to improve patient safety; and 2) to develop and impose sanctions, if necessary.

The Committee was provided the opportunity to pose questions and discuss the issues related by Mr. Persons. Through this discussion process, it was noted that:

- 1) A structure for peer review needs to be established before peer review begins;
- 2) Issues or circumstances considered during peer review can be used for the purpose of educating the broad community, as long as the confidentiality of the peer review process is maintained;
- 3) Anonymity is not a requirement of the peer review process, but having it may improve impartial consideration of the circumstances; and
- 4) The intent of the Committee is to review compiled statistics of the type and number of reported events, however it was recognized that certain specific situations would need to be considered, and where possible, these situations would be blinded.

In closing this topic of discussion, Mr. Persons advised the Committee to consider themselves a peer review body, and as such, each member should sign the OPTN/UNOS confidentiality agreement and conflict of interest statements.

The Chairman asked Joshua Czarda, JD, Assistant Director of Policy Compliance, to brief the Committee on processes that are being developed by the UNOS Policy Compliance Department that could impact/supplement the efforts of the Committee in reviewing issues of inefficiency and patient safety. Mr. Czarda reported that the Policy Compliance Department is currently involved in two projects that will provide improved monitoring and reporting of compliance issues. The Department is shifting to a more prospective review of compliance monitoring by developing routine computerized reports of specific metrics, such as tracking ABO listing changes or disparities; reviewing percent of urgent listings by center; and length of time waiting at an urgent status by center. He stated that the first group of these metrics will be presented at the next meeting of the Membership and Professional Standards Committee. Mr. Czarda informed the group that the second project his department was working on was the development a data repository to centralize various compliance data and information by institution. He offered to provide the Committee with a more formal presentation of these activities during their next meeting.

The Committee considered the information provided by these resources and following additional discussion developed the following recommendation for consideration by the Board of Directors:

**Resolved, that OPTN/UNOS establish a voluntary, confidential system for members to report situations that could affect patient safety, organ availability, and organ utilization so that the prevalence of these situations can be monitored and reported, and recurrence can be prevented, with the goal of enhancing quality outcomes and systems.**

Committee Vote: 15 for, 0 against, 0 abstained

Following the affirmative vote on this resolution, it was expressed that the Committee should be clear in communicating that this system of reporting and peer review will be different in purpose from the type of policy compliance peer reviews that are currently performed by the Membership and Professional Standards Committee.

The Committee considered other issues that were identified in the Subgroup meetings. The issue of “truth in listing” was discussed by the the full Committee. Points that were made include:

1. The match system should be programmed to screen candidates from the match list based on the distance entered for that candidate that the transplant program is currently willing to travel to recover an organ. Currently this information is shown on the match for informational purposes;
2. Request the Thoracic Organ Transplantation Committee to consider restricting the height range for lung candidates to 20 inches, and that exceptions to the range could be granted by the Regional Review Board. In addition, consider allowing inactive candidates to accrue waiting time to promote the practice of modifying temporary ineligible candidates to inactive status; and
3. Request all organ specific committees to determine what criteria are absolute disqualifiers from the match list and ask that they provide their guidance on implementing these factors.

As a result of their discussions, the Committee approved the following resolution:

RESOLVED, that the Committee will communicate with each organ-specific committee that inaccuracies in candidate listing ranges and criteria create major impediments in the organ allocation and placement process. The Committee will be reviewing data and investigating these impediments, and it requests each organ-specific committee’s assistance in addressing these issues and providing their recommendations to the Committee on how to define and correct these impediments.

Committee Vote: 15 for, 0 against, 0 abstained

An additional Subgroup issue was raised, briefly discussed, and approved as follows:

RESOLVED, that the UNet<sup>sm</sup> system be modified to randomize the Donor ID number for improved patient safety.

Committee Vote: 15 for, 0 against, 0 abstained

The Donor Management/Organ Allocation Subgroup raised for full Committee discussion the issue of moving toward having the ultimate decision-maker (transplant surgeon or physician) receive the organ offer directly from the donor OPO. The Committee discussed the benefits and potential barriers to this process. Due to the complexity of this topic, the Chair requested that this issue be further deliberated by the Subgroup.

## **2. Reconsideration of proposed policies circulated for public comment**

The Committee considered comments received from the general public and regional meetings related to proposed Policy 3.1.4 (Candidate Listing) (Exhibit A). The Chair noted that 89% of the public commenters who expressed an opinion on this policy proposal were in support, and 11% were opposed. The Committee approved allowing the Chair to write the Committee’s responses to each individual comment.

The Committee also considered the regional votes and comments made regarding this proposal through April 26, 2004. Seven of the eight regions considering this proposal supported its implementation. Specific comments related to time constraints and personnel availability to verify a listed candidate’s blood type. The Committee noted that there are no time constraints to be programmed in the system and expressed its opinion that every transplant program must have more than one person available (this may include physicians) who can verify the blood type of a candidate.

The Committee also considered the frequency of wait list modifications (additions, modifications, and removals) by group type (transplant center, OPO, lab and UNOS Organ Center) related to proposed Policy 3.1.4.1 (Exhibit B). Data from the OPTN/UNOS system demonstrated that in 2003, percentage of wait list modifications were as follows: Labs – 51%; Transplant Centers – 42%; OPOs – 2%; and UNOS Organ Center

– 5%. Data for the same time period demonstrated that only 0.6% of wait list additions were performed by the Organ Center at the request of members.

Following deliberation of this information, the Committee recommends the following resolution for consideration by the Board of Directors:

**RESOLVED, that the following modifications to Policy 3.1.4 (Patient Waiting List), having been distributed for public comment and subsequently reconsidered by the Ad Hoc Operations Committee, shall be approved and implemented on October 4, 2004:**

Committee Vote: 15 for, 0 against, 0 abstained

- 3.1.4 Patient Waiting List. The Patient Waiting List is the computerized list of patients who are waiting to be matched with specific donor organs in hopes of receiving transplants. Waiting List patients are registered on the Patient Waiting List by OPTN member transplant centers, ~~programs, or OPOs.~~ The candidate's transplant program shall be responsible for ensuring the accuracy of candidate ABO data on the waiting list. Each transplant program shall implement and operate an ~~internal~~ procedure for providing on-line verification of a candidate's ABO data on the waiting list against the source document by an individual other than the person initially entering the candidate's ABO data in UNet<sup>sm</sup>. The transplant program shall maintain records documenting that such separate verification of the source document against the entered ABO has taken place and make such documentation available for audit. Upon entry of the candidate's waitlist data, the candidate will be added to the waitlist but will not be listed as an active candidate until separate verification of the candidate's ABO data has taken place.
- 3.1.4.1 All transplant candidate interactions will be required to be completed through UNet<sup>sm</sup> by transplant programs. The Organ Center will facilitate patient listings and modifications in the event of computer and/or Internet failure. When the Organ Center facilitates a patient's listing or modification due to computer and/or Internet failure, the transplant center will be required to submit a statement explaining the event.
- 3.1.4.2 Each transplant candidate must be ABO typed on two separate occasions prior to listing.
- 3.1.4.3 Transplant candidates shall only be listed on the UNOS computer system with the candidate's actual blood type.

Associated with this proposed policy, the Committee reviewed public comments submitted related to whether proposed ABO verification processes should also apply to living donors and recipients. It was the Committee's opinion that these patient safety procedures apply to both deceased and living donor transplant processes. The Committee approved the following resolution for consideration by the Ad Hoc Living Donor Committee:

RESOLVED, that a similar process for dual ABO verification that is proposed for deceased donors and candidates be required for the living donor and candidate transplant process.

Committee Vote: 15 for, 0 against, 0 abstained

The Committee also considered comments received from the general public and regions related to proposed Policy 3.2.3 (Match System Access) (Exhibit C). The responses demonstrated that 86% of the public commenters who expressed an opinion on this policy proposal were in support, and 14% were opposed. Individual comments were reviewed by the Committee. Several commenters questioned the frequency of ABO errors and incompatible transplants. The Committee responded that there is known data from the blood bank community that demonstrates ABO testing and reporting errors do occur at a rate, anecdotally cited of 1 in 1,000 to 1 in 10,000 occurrences. It was also noted that within the Committee itself, four new ABO discrepancy situations were known to Committee members in the six months since the last committee meeting. It was mentioned that some regions had expressed confusion over what "two separate determinations" meant. The Committee agreed to modify the proposed language to include a parenthetical description of the three acceptable two determination processes. In concluding its discussion, the Committee gave its approval for the Chair to write the Committee's responses to each individual comment.

Following deliberation of public comments and regional feedback, the Committee recommends the following resolution for consideration by the Board of Directors:

**RESOLVED, that the following modifications to Policy 3.2.3 (Match System Access), having been distributed for public comment, modified and subsequently reconsidered by the Ad Hoc Operations Committee, shall be approved and implemented on October 4, 2004:**

**Committee Vote: 15 for, 0 against, 0 abstained**

3.2.3 Match System Access. The allocation of any and all organs from deceased donors must be made through the Match System. 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 computer programs, which determine organ allocation priorities. Such information must be entered into the Match System for all deceased donors. For all renal deceased donors, OPTN Members must enter all donor data into the Match System within 15 hours after organ recovery. 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 on UNet<sup>sm</sup>. Each OPO shall establish and implement an ~~internal~~ procedure for obtaining verification of donor ABO data by an individual other than the person initially entering the donor's ABO data. The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit. Organs shall be allocated only to patients who appear on a match run. In the event that an organ has not been placed after the organ has been offered for all potential recipients on the initial match run, the Host OPO may give transplant programs the opportunity to update their transplant candidates' data, and the Host OPO may re-run the match system. In any event, the organ shall be allocated only to a patient who appears on a match run. For all deceased donor organs, the organ must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. If an organ is accepted for a patient who ultimately unavailable to receive the transplant at his/her listing transplant center in the organ allocation unit to which the organ is being distributed, then the organ shall be released back to the Host OPO or to the Organ Center for allocation to other transplant candidates in accordance with the organ-specific allocation policies. The Host OPO may delegate this responsibility to the Local OPO. Further allocation at the local OPO level must be done according to the match run. The final decision whether to use the organ will remain the prerogative of the transplant surgeon and or physician responsible for the care of that patient. This will allow physicians and surgeons to exercise judgment about the suitability of the organ being offered for the specific patient. If an organ is declined for a patient, a notation of the reason for the decision refusing the organ for that patient must be made on the appropriate OPTN form and promptly submitted.

### **3. Comments from the DHHS Division of Transplantation**

The Chair recognized Virginia McBride, OPTN Project Officer, DHHS Division of Transplantation (DoT) and requested that she address the Committee on behalf of the DoT. Ms. McBride stated she was excited about this Committee's charge and the potential benefits its recommendations can have on the OPTN system over the next few years. She noted that she was glad to see that the Committee is focused not only on patient safety issues, but also on developing standards of practice. She reminded the group of the recent Secretary of Health and Human Services' transplantation initiative to increase the national average of organs recovered and transplanted per donor from the current rate of 3.2 to a goal of 3.75. DHHS will work toward this goal by identifying OPO best practices and through on-site audits. It is the Secretary's goal that every usable organ be recovered and transplanted. Ms. McBride stated that the DoT is dedicated to working with UNOS to implement technologies that will improve the organ placement process, and that the Division feels this Committee will play a role in achieving these goals. She concluded her remarks by stating that the DoT trusts and has much regard for this Committee's work.

The Committee discussed with Ms. McBride several questions related to how data will be handled, verified and reported with regard to the initiative to increase the donor yield.

#### 4. **Local matching and allocation issues**

The Committee was requested by the UNOS Policy Compliance Department to consider a situation in which an OPO generates a match run on its own computer system, separate and distinct from the UNet<sup>sm</sup> system used by the rest of the country. The OPO uses its own computer matching system for the allocation of local (within the OPO) kidneys after mandatory sharing requirements have been identified and addressed using the UNet<sup>sm</sup> match system. The Committee was advised that this OPO made an investment in its own technology at approximately the same time that UNet<sup>sm</sup> was implemented. The OPO assures UNOS that its match system is identical to UNet<sup>sm</sup> so that the outcomes are the same. To date, UNOS has been unable to verify this prospectively, only through allocation analysis post-organ offer, acceptance and transplant. This situation has raised many questions and difficulties for UNOS Policy Compliance staff. Therefore, UNOS Policy Compliance staff sought the Committee's guidance on whether such a system can co-exist parallel to the national system.

The Committee briefly discussed this situation and opined that every OPO should be using UNet<sup>sm</sup> for reasons of fairness, patient safety, quality assurance, and monitorability. The Committee unanimously approved the following resolution:

RESOLVED, that all OPOs are required to use the OPTN/UNOS Match System (UNet<sup>sm</sup>) for the allocation of all organs.

Committee Vote: 11 for, 0 against, 0 abstained

Several weeks after the Committee's meeting, the Committee was encouraged to consider recommending this resolution as a proposed policy as opposed to a statement of opinion. The rationale for this request is that if not incorporated into policy, these statements of opinion go into historical record but do not hold the force of policy and are not readily accessible to the membership. This request was discussed with the Kevin Myer, Chairman, who worked with UNOS staff to incorporate this recommendation into policy language for consideration by the Committee. This explanation and proposed policy language was distributed on May 25, 2004, to the full Committee for consideration and vote. The results of the Committee's vote as of June 2, 2004, was unanimously in favor of incorporating the approved language into the following proposed policy modification; which is hereby recommended for consideration by the Board of Directors:

**RESOLVED, that the following modifications (indicated in bold and double underlined text) to Policy 3.2.3 (Match System Access), as recommended by the Ad Hoc Operations Committee, shall be approved and implemented on October 4, 2004:**

**Committee Vote (e-mail): 12 for, 0 against, 0 abstained**

3.2.3 Match System Access. **OPOs are required to use the OPTN/UNOS Match System (UNet<sup>sm</sup>) for the allocation of all deceased donor organs. The allocation of any and all organs from deceased donors must be made through the Match System.** 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 computer programs, which determine organ allocation priorities. Such information must be entered into the Match System for all deceased donors. For all renal deceased donors, OPTN Members must enter all donor data into the Match System within 15 hours after organ recovery. 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 on UNet<sup>sm</sup>. Each OPO shall establish and implement an ~~internal~~ procedure for obtaining verification of donor ABO data by an individual other than the person initially entering the donor's ABO data. The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit. Organs shall be allocated only to patients who appear on a match run. In the event that an organ has not been placed after the organ has been offered for all potential recipients on the initial match run, the Host OPO may give transplant programs the opportunity to update their transplant candidates' data, and the Host OPO may re-run the match system. In any event, the organ shall be allocated only to a patient who appears on a match run. For all deceased donor organs, the organ must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. If an organ is accepted for a patient who ultimately unavailable to receive the transplant at his/her

listing transplant center in the organ allocation unit to which the organ is being distributed, then the organ shall be released back to the Host OPO or to the Organ Center for allocation to other transplant candidates in accordance with the organ-specific allocation policies. The Host OPO may delegate this responsibility to the Local OPO. Further allocation at the local OPO level must be done according to the match run. The final decision whether to use the organ will remain the prerogative of the transplant surgeon and or physician responsible for the care of that patient. This will allow physicians and surgeons to exercise judgment about the suitability of the organ being offered for the specific patient. If an organ is declined for a patient, a notation of the reason for the decision refusing the organ for that patient must be made on the appropriate OPTN form and promptly submitted.

**5. Consideration of other proposed policies circulated for public comment**

The Committee reviewed selected proposed policies circulated for public comment that were felt to be of interest and related to the charter of this Committee. Results of the Committee's deliberations were as follows:

RESOLVED, the Ad Hoc Operations Committee supports proposed Policy 3.6.2.1. (Allocation of Blood Type O Donors), with regard to allowing compatible blood type candidates to appear at the end of O and B candidate match run list as circulated for public comment. The Committee commented that this policy proposal is in line with an original recommendation of the ABO Subcommittee, and that it could promote increased organ utilization.

Committee Vote: 10 for, 0 against, 0 abstained

RESOLVED, in response to proposed Policy 6.4 (Exportation and Importation of Organs – Developmental Status), the Ad Hoc Operations Committee requests that this policy proposal include ABO verification requirements for imported organs similar to those required for deceased donors originating within the United States, such as required in proposed Policy 3.2.3 (Match System Access).

Committee Vote: 10 for, 0 against, 0 abstained

RESOLVED, the Ad Hoc Operations Committee supports proposed Policies 3.4.7 (Allocation of Organs During Regional/National Emergency Situations), 3.4.7.1 (Regional/National Transportation Disruption), and 3.4.7.2 (Regional/National Communications Disruption), as circulated for public comment.

Committee Vote: 11 for, 0 against, 0 abstained

The Committee discussed proposed modifications to Policy 3.6 (Adult Donor Liver Allocation Algorithm). It was noted that there are reference lab result differences from lab to lab, or machine to machine, for the lab values used in calculating MELD/PELD status which could result in status and listing variability. Dr. Marlon Levy, a member of the Liver/Intestine Transplantation Committee, volunteered to bring this concern to the Committee's attention.

**6. Review of Informational Items**

The Committee also considered the following informational items:

- It was noted that Kidney/Pancreas Transplantation Committee considers many requests for waiting time adjustment for listed candidates. There was concern expressed that there may be potential abuse of this system by centers that repeatedly make these requests for their candidates. The Committee requested that UNOS Policy Compliance staff look into this issue.

- Proposed policy modifications to Policy 5.0 (Packaging of Organs) are being developed by the OPO Committee.

- The OPO Committee responded to the request from the ABO Joint Subcommittee to develop protocols for situations when the match list is exhausted. The OPO Committee opined that recent modifications to Policy 3.2.3, provide a satisfactory additional mechanism for adding/modifying candidates then re-running a match list for additional allocation. These allowances should provide an additional step to promote organ utilization and to prevent organ discard.

- The OPO Committee responded to a request from the ABO Joint Subcommittee to define the role of a “coordinating OPO”. The OPO Committee opined that this definition is no longer necessary with the designation of responsibilities that are now included in Policy 3.2.3.
- The Chair encouraged the Committee’s Subgroups to utilize the Committee Management System found in UNet<sup>sm</sup> for posting subgroup deliberations and documents.

The meeting was adjourned at 4:00 p.m.

**OPTN/UNOS AD HOC OPERATIONS COMMITTEE MEETING**

**Chicago, Illinois  
April 29, 2004**

**Attending:**

Kevin Myer, MSHA	Chair (Region 11)
Marlon Levy, MD	Vice Chair (Region 4)
Kevin O'Connor, MS, PA	Region 1
Richard Hasz, Jr., MFS	Region 2
Shirley Schlessinger, MD	Region 3
Rebecca Menza, RN, CPTC	Region 5
Susan Gunderson, MHA	Region 7
Martin Zamora, MD	Region 8
Helen M. Hauff, RN	Region 9
Tracy Evans-Walker, RN, BSN	Region 10
Vicki Fioravanti, RN	At Large
Daniel Hayes, MD	At Large
Dean Lichtenfeld, RN, MSN	At Large
Laurel Williams, RN, MSN	At Large
Melissa Zimmerman, RN	At Large
Dolly Tyan, PhD	At Large
Bruce Schmeiser, PhD	At Large

**DOT staff attending:**

Virginia McBride, RN, MPH *Ex Officio*

**UNOS staff attending:**

Chris Williams, RN, CPTC	Committee Liaison
John Persons, JD	Corporate Council
Joshua Czarda, JD	Policy Compliance
Hilary Klein (via teleconference)	Policy Analyst

**Unable to attend:**

Glyn Morgan, MD	At Large
Monica Johnson-Tomanka	Region 6

## Summary of Public Comments

### Proposed Modifications to OPTN/UNOS Policy 3.1.4 (Patient Waiting List) (Ad Hoc Operations Committee)

As of 4/29/2004, 83 responses have been submitted to UNOS regarding this policy proposal. Of these, 43 (51.81%) supported the proposal, 5 (6.02%) opposed the proposal, and 35 (42.17%) had no opinion. Of the 48 who responded with an opinion, 43 (89.58%) supported the proposal and 5 (10.42%) opposed the proposal. Comments on the proposal received to date are as follows:

#### I: Individuals Comments:

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##### Comment 1:

*vote: Oppose*

I think that we have gone overboard with these policy revision. You MUST take into count the logistics of these proposed changes. I do know that what happened was a very unfortunate accident but most centers, as well as the revisions already in place, have made added safeguards against this ever happening again. I really think that the new revisions are knee jerk reaction and that we need to step back and be realistic. If this policy passes, are OPO's then going to be required to check donor blood types X2 prior to offering organs and are they going to have a similar system of checks when supplying information to UNOS prior to printing a list of potential recipients

##### Committee Response:

The Committee understands that implementation of the proposed policy will require additional time and effort from transplant center staff. However, the Committee believes that these requirements are realistic and necessary to assure patient safety. These changes will also be uniformly applied to ensure that all centers are applying these safeguards in a standard, verifiable manner. OPOs will be required to implement similar ABO verification processes for entry of donors and allocation of organs.

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##### Comment 2:

*vote: Oppose*

It is unclear what data form the basis for this proposal. How many inadvertent ABO-incompatible transplants occurred because of a mistyping vs. those that occurred because of an incorrect data entry or because of other reasons.

##### Committee Response:

The Committee recognizes that there is currently no measure of how often, or what types of situations occur. However, the Committee is aware of ABO error rates published by the blood banking associations, and has many anecdotal accounts of potential life-threatening situations related to ABO errors and near-miss incidents from within the transplant community. In order to have a more reliable means for obtaining this information in the future, the Committee is recommending that OPTN/UNOS establish of a voluntary, confidential system for members to report situations that could affect patient safety, organ availability, and organ utilization.

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**Comment 3:**

*vote: Oppose*

Makes the process more complicated and may hold up transplant for an urgent patient. Requires transplant centers to maintain staffing that may significantly increase costs.

**Committee Response:**

Reference the Committee's response to Comment 1.

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**Comment 4:**

*vote: Oppose*

The "pending" status is unfair to the candidate. There are too many issues bundled together in this proposal. 3.1.4.3 is beneficial, but a system for validating the ABO without penalizing the candidate needs to be found, i.e. UNOS assistance with it other than in the event of a computer or Internet failure.

**Committee Response:**

The Committee feels the pending status is fair since it allows the listed candidate to accrue time waiting in the interim of having their ABO verified by a second individual. It also safeguards that candidate from potentially being offered and/or receiving an organ of the incorrect blood type. With regard to requiring the transplant program to maintain their candidate lists on-line, the Committee has previously stated that in this day and time it is rare that transplant personnel would not have access to the internet (and UNet<sup>sm</sup>) to add, modify, remove candidates or verify a candidate's blood type. This recommendation further ensures that information is not verbally mis-communicated. Additionally, the Organ Center is available to assist transplant personnel in those rare circumstances when they cannot access UNet<sup>sm</sup> themselves. However, an explanation of this need will be required to track and prevent abuse of this safeguard.

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**Comment 5:**

*vote: Support*

1. It was presented at our regional meeting that UNOS organ center staff would be available during 'off hours' to receive a fax of the ABO type from the Tx center to perform the second verification. However, reading the policy, it suggests a very rigid and restrictive circumstance of the organ center being available. I would like to see policy language changes to reflect the availability of the organ center during of hours to receive a fax for the second verification. Secondly, it was also presented at our meeting that the proposed language was to reflect 'type on two occasions prior to 'transplant' and not listing. I would suggest we use 'prior to transplant' particularly to accommodate the circumstance of an urgent status 1 listing for liver transplant where time is essential.

**Committee Response:**

UNOS Organ Center assistance with verifying ABO from a fax copy of the ABO source document applies only for the addition of donors to the UNet<sup>sm</sup> system. This allowance was made because frequently there is only one OPO coordinator at the donor hospital who has access to the ABO source document, and the time constraints for adding a donor and offering organs can be very limited. The Committee did not feel these same constraints were applicable to the process of adding a candidate to the list, and noted that there should always be more than one person available at a transplant center (especially in urgent situations) to add a candidate and verify the ABO type.

The Committee feels that for candidates it is necessary to verify the ABO type before the candidate shows on a match list and is offered an organ rather than waiting until immediately before a transplant procedure. Waiting may increase the likelihood that this verification is overlooked. Additionally, verification of ABO typing prior to allocation safeguards that patient from potentially being offered and/or receiving an organ of the incorrect blood type, and prevents potential discard of an organ allocated to a candidate that is incompatible.

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**Comment 6:**

*vote: Support*

Although it would delay listing the patients, I can understand the safety precautions this provides. I do wonder about fulminants and how this will affect them. Also if there are going to be guidelines to the amount of time that must lapse between ABO typing.

**Committee Response:**

The Committee has offered that for fulminant (or any urgent) candidate there should always be more than one person available at a transplant center (especially in urgent situations) to add a candidate and verify the ABO type. This process should take no longer than any other preparatory process for transplantation. There have been no timelines established for on-line verification of a candidate's ABO type. The UNet<sup>sm</sup> system will, however, show the time that a candidate has been waiting for their ABO to be verified. This feature along with the transplant center's desire to have their candidates eligible for organ offers should limit the time a candidate is in a "pending" status. Furthermore, the Committee will monitor verification times to see if further intervention or recommendations are necessary.

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**Comment 7:**

*vote: Support*

Approve - no comments.

**Committee Response:**

The Committee appreciates the commenter's support.

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**Comment 8:**

*vote: Support*

ASHI supports the proposed new and modified policies for listing transplant candidates on the national waiting list. We feel the proposal is consistent with good laboratory practice.

**Committee Response:**

The Committee appreciates the commenter's support.

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**Comment 9:**

*vote: Support*

I strongly support the need for verification of ABO type by two entries. I also support that the transplant center would not be able to give the patient a "listed on date" until verification has been made. This would then also encourage the patient to follow up if they have not received a "listed on date" in a timely fashion. I'm a little unclear as to the listing of living donors. Are you saying that you would have to list at least 30 days prior to doing a living donor transplant? I thought that some were done more last minute. I know that Children's Hospital of Boston will only do living lung transplants if the alternative looks like it won't happen in time.

**Committee Response:**

The Committee appreciates the commenter's support. Regarding living donor events, the Committee feels the similar ABO safeguards are required for these transplant procedures. OPTN/UNOS Policy 7.5, requires that living donors be registered prior to surgery. A 30 day requirement is not listed.

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**Comment 10:**

*vote: Support*

The ABO verification process should be the same for living and deceased donor candidates.

**Committee Response:**

The Committee agrees with the commenter.

### UNOS Waiting List Maintenance Activity for 2003

Waiting List Changes By External User (No OC involvement)							
CtrTy	Type Description	# Adds	# Mods	# Removals	Totals		
IO1	Hospital Based OPO	0	17	35	52		
IT1	Hospital Based Lab	4794	84596	4841	94231		
OP1	Independent OPO	2971	3310	1783	8064		
PUP	General Public	195	388	115	698		
TT1	Independent Lab	3269	140614	5693	149576		
TX1	Transplant Center	31240	150104	20668	202012		
VA1	Veteran's Hospital	40	292	40	372		
		42509	379321	33175	<b>455005</b>		

Waiting List Changes By OC/UNOS Staff as requested by External User									
CtrTy	Type Description	# Adds	# Mods	# Removals	Totals	Removal Mods	Backdates	StatTim e Adj	Transfers
UNS	UNOS Staff	336	18160	6201	<b>24697</b>	139	866	46	2769

5%

## Summary of Public Comments

### Proposed Modifications to OPTN/UNOS Policy 3.2.3 (Match System Access) (Ad Hoc Operations Committee)

As of 4/29/2004, 83 responses have been submitted to UNOS regarding this policy proposal. Of these, 41 (49.40%) supported the proposal, 5 (6.02%) opposed the proposal, and 37 (44.58%) had no opinion. Of the 46 who responded with an opinion, 41 (89.13%) supported the proposal and 5 (10.87%) opposed the proposal. Comments on the proposal received to date are as follows:

#### I: Individuals Comments:

##### Comment 1:

*vote: Oppose*

I think it unnecessary to verify ABO twice PRIOR to initiating retrieval of the available organ(s). A second ABO typing specimen could be sent along with the organ(s) for verification of ABO type prior to Transplantation of each organ by it's Receiving Transplant Facility, could it not?

##### Committee Response:

The Committee disagrees, and feels it is a realistic and necessary safeguard to verify the ABO type before organs are recovered for a candidate. Preventing these errors earlier in the allocation/transplantation process will enhance the probability that the organ could be re-allocated to a suitable candidate and reduce the chance the organ is not transplanted as a result of cold ischemic injury secondary to transportation time to a potentially ABO incompatible intended candidate.

##### Comment 2:

*vote: Oppose*

The Board of UNOS considered this proposal previously and voted to oppose it. I am not sure why it is being brought up again. The committee admitted it did not know whether there had been any inadvertant ABO incompatable transplants (other than the one that generated this proposal). Even then the ABO typing was correct the first time. Thus this proposal would waste tremendous amounts of money to prevent a probelm that does not exist (or occurs less than an estimated 1 in 1,000,000) to prevent ABO incompatable transplants. It is not the wrong typing that leads to ABO incompatable transplants but human error in misreading them or not paying attention to them or the intentional ABO transplant. Thus repeat typing serves no purpose and prevents no unwanted outcome.

##### Committee Response:

The Committee strongly disagrees with the commenter. The Committee recognizes that there is currently no measure of how often or what type of ABO errors or near-miss situations occur in transplantation. However, the Committee is aware of ABO error rates published by the blood banking association (1 in 1,000 to 1 in 10,000), and these estimated error rates do not agree with the prevalence cited by the commenter. The Committee has been made aware of many anecdotal accounts of potential life-threatening situations related to ABO errors or near-miss situations from within the transplant community. In order to have a more reliable means for obtaining this information in the future, the Committee is recommending that OPTN/UNOS establish of a voluntary, confidential system for members to report situations that could affect patient safety, organ availability, and organ utilization. The Committee is of the opinion that a spectrum of possibilities including misreading, patient mix-up, data recording errors, lack of documentation, candidate not on the match list, and failure to compare ABO results, should be considered potential sources of error.

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**Comment 3:**

*vote: Oppose*

The process is too convoluted. The Duke case happened because a rule was broken, the recipient wasn't on the matchrun. What is the data regarding incorrectly documented donor ABO prior to a matchrun being generated?

**Committee Response:**

Reference the Committee's response to Comment 2.

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**Comment 4:**

*vote: Oppose*

Too confusing.

**Committee Response:**

The Committee appreciates the commenter's opinion.

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**Comment 5:**

*vote: Support*

Approve with comments: The policy should be modified to include reference to the possibility that Programs can have a Variance that allows transplant of ABO compatible kidneys for emergency situations (patients with "status 5"). These patients will not appear on the "match run".

**Committee Response:**

Current organ specific OPTN/UNOS Policy allows the transplantation of ABO compatible organs when appropriate. Local allocation areas may also apply for variances to the standard allocation system to include compatible transplants if the standard system does not currently include them. In both cases, compatible candidates will appear on the match list. The Committee, however, is firm in its belief that for patient safety and fairness, organs should only be allocated to candidates who appear on the match list for the donor organ that is being allocated.

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**Comment 6:**

*vote: Support*

I strongly support the need for verification of ABO type by two entries.

**Committee Response:**

The Committee appreciates the commenter's support.