

**OPTN/UNOS Organ Procurement Organization Committee
Report to the Board of Directors
June 23-24, 2014
Richmond, Virginia**

**Richard E. Pietroski, MS, CPTC Chair
Sean F. Van Slyck, MPA, HSA, CPTC, Vice Chair**

Contents

Contents	1
Action Items	2
1. Allocation of Other Organs	2
Committee Projects	2
2. DDR Completion.....	2
3. Limit Paper Documentation	3
4. HIV Organ Policy Equity Act.....	4
Committee Projects Pending Implementation	5
5. Change Consent to Authorization.....	5
6. Imminent and Eligible Death Data Definitions	5
7. Donation After Circulatory Death	6
Implemented Committee Projects	6
8. Proposal to Document All Locally Assigned Unique Identifiers in the Donor Record	6
9. Alternate Label for Perfusion Machines.....	6
Review of Public Comment Proposals	6
10. Proposed ABO Blood Type Determination, Reporting, and Verification Policy Modification 6	
11. Proposal to Require the Collection of Serum Lipase for Pancreas Donors	7
12. Proposal to Align OPTN Policies with the 2013 PHS Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Solid Organ Transplantation	8
13. Proposal to Clarify Data Submission and Documentation Requirements	9
Meeting Summaries	9

**OPTN/UNOS OPO Committee
Report to the Board of Directors
June 22-23, 2014
Richmond, Virginia**

**Richard E. Pietroski, MS, CPTC, Chair
Sean F. Van Slyck, MPA, HSA, CPTC, Vice Chair**

This report reflects the work of the OPTN/UNOS OPO Committee during December 2013 to April 2014 period.

Action Items

1. Allocation of Other Organs

The Committee received a request to address this issue that came up at a recent Vascularized Composite Allograft (VCA) Committee meeting. Policy 5.9 addresses the allocation of “organs not specifically addressed in other policies.” Currently, all organs are addressed in policy but when the OPTN begins oversight of VCAs on July 3, 2014. The VCA Committee is developing policies for the allocation of VCAs; in the meantime, there is an opportunity for confusion if OPOs try to allocate organs using this outdated policy. VCA policies will be located in Policy 12. This policy is outdated and contains a point system for medical urgency and distance from the transplant center that has never been programmed. The Committee voted unanimously to strike this policy and submit the recommendation to the Board of Directors during its June 22-23, 2014 meeting.

RESOLVED, that Policy 5.9 (Allocation of Other Organs) be rescinded, as set forth in Exhibit A, is hereby approved, effective July 3, 2014, and shall expire on July 1, 2015.

Committee Projects

2. DDR Completion

*Public Comment: Fall 2014 (estimated)
Board Consideration: June 2015 (estimated)*

The DDR subcommittee has been working to address the information that OPOs need to submit on patients who are referred to the OPO as a potential donor and non-donors.

The current process for submitting donor information is outlined below:

- OPO adds a donor or potential donor into DonorNet®.
- If the OPO does not request or obtain authorization for organ donation, the OPO marks the record as “Referral Only” and has completed their data submission requirements.
- If authorization for organ donation is obtained, the OPO then fills out the Donor Organ Disposition (Feedback) for each organ (recovered or not).
- There is basic information on imminent and eligible deaths collected on the death notification report form.
- Once feedback is complete and reconciled with the transplant center, the DDR is generated. The OPO has 30 days to complete the DDR.

The DDR was never intended to be used for authorized but not recovered, or referral only donors. Prior to 2001, information on non-donors was collected on the Cadaver Donor Referral Form. When this form was eliminated, only the DDR remained. The subcommittee discussed the purpose of collecting data on authorized but not recovered donors or those for whom authorization was not obtained. Because OPOs do not have relevant information available on non-donors there is no need to collect it. The subcommittee also discussed the purpose of collecting information on decedents from whom organs are recovered for reasons other than transplant. The subcommittee agreed that the current process should remain in place where information is only collected on individuals from whom at least one organ was recovered for the purpose of transplantation.

The subcommittee agreed to the following recommendations:

- OPOs should only be required to complete the deceased donor registration (DDR) form on actual donors, defined as having at least one organ recovered for the purpose of transplantation.
- Make the following change to the deceased donor definition: An individual from whom at least one organ is recovered for the purpose of transplantation after declaration of death.
- Define a recovered organ as the “physical detachment and removal of an organ from the body.”
- Make the following label change to the deceased donor feedback form: Change “Referral Only” to “No organs were recovered for the purpose of transplantation.”

The subcommittee plans to finalize a proposal in time for the fall 2014 public comment period.

3. Limit Paper Documentation

Public Comment: *Spring 2015 (estimated)*
Board Consideration: *November 2015 (estimated)*

The Committee discussed this issue that was identified during the Electronic Tracking and Transport (ETT) Project while observing donor management and organ procurement practices in six OPOs and seven transplant hospitals. OPTN Policy 16.5.A requires that complete donor documentation be sent in the container with each transported organ. This often takes a coordinator a considerable amount of time to make copies of the large volume of documents that need to accompany each organ. These requirements originated prior to the availability of electronic medical records and functionality to upload information into DonorNet®. This project was transferred to the OPO Committee (from Operations and Safety Committee) in February 2014. This project was already approved by the POC and Executive Committee in November 2013.

The Committee briefly discussed the key information that should be included with the organs, such as ABO and serology results. The Committee acknowledged that this process should eventually be part of the ETT project because of the donor/recipient verification that is required with the barcode system. However, reducing the amount of paper documentation is an issue the Committee can begin to address now. The Committee agreed that the amount of paperwork that is sent with the organs can be greatly reduced.

The Committee will also develop guidance on what needs to be sent with the organ, what needs to be uploaded into DonorNet® at certain points in the process, and a standard way to package the information. The Committee will also need to collaborate with the Transplant Coordinators Committee and the Operations and Safety Committee.

4. HIV Organ Policy Equity Act

Public Comment: Fall 2014 (estimated)
Board Consideration: June 2015 (estimated)

The HIV Organ Policy Equity Act (HOPE Act) was enacted on November 21, 2013. The initial deadline for deliverables is November 21, 2015. The Secretary of HHS must develop and publish research criteria, and revise the OPTN Final Rule, while the OPTN must revise policies in accordance with the criteria developed by the Secretary. A joint work group was formed with representation from the OPO Committee, Operations and Safety Committee, Ad Hoc Disease Transmission Advisory Committee (DTAC), SRTR, and HRSA. The initial conference call was held on January 31, 2014, during which four subgroups were formed to address policy, patient safety, allocation, and labeling/transport. These subgroups were assigned policies to determine if changes were needed as well as identifying other issues that need to be addressed.

Policy Subgroup - The subgroup reviewed 5 policies with one recommended change to Table 14-2 (Requirements for Living Kidney Donor Medical Evaluations). The exclusion criteria section contains HIV so the language will need to be modified or removed. The subgroup also recommended that all policies that include exclusions should reference Policy 2.7. This will eliminate the need to revise multiple policies based on updates or results from the research study.

Patient Safety Subgroup - The subgroup reviewed 18 policies and made several recommendations, including several minor policy language changes. The subgroup also recommended the prohibition on storing HIV positive vessels be added to Policy 16.7.B (Vessel Storage). The subgroup also discussed infectious disease verification and supported the Operations and Safety Committee project to address this issue. Finally, the subgroup discussed indeterminate test results and several members noted that organs used as part of the research study should require definitive, final HIV test results.

Allocation Subgroup - The subgroup reviewed three policies and did not recommend any changes. The subgroup also discussed several issues including consent and authorization to participate in the research study, the impact of participation on the candidate's wait list status, and equity issues (access to organs for candidates). The subgroup also discussed the use of preservation machines and reusable coolers and agreed that the current practice of using universal precautions is acceptable for handling all potential infectious diseases.

Labeling and ETT Subgroup - The subgroup reviewed 7 policies and recommended changing the term "serology results" throughout the policies to align it with the PHS guideline. The subgroup did not recommend changes to the currently labeling system but noted that future integration into the electronic tracking system would be beneficial. The subgroup also discussed the management of HIV infected organs and whether the current process for HCV and HBV infected organs was appropriate. The subgroup agreed that label changes and infectious disease verification needs to be addressed with

electronic solutions. There needs to be further evaluation of programming and implementation issues as well as a backup plan in case of technology failure.

Next Steps – The work group will finalize policy language revisions to Policy 2.7 (HIV Screening of Potential Deceased Donors) which currently prohibits the recovery and transplantation of organs from deceased donors known to be infected with HIV. The work group will also determine the best approach to addressing the other policy recommendations. The plan is to distribute a public comment proposal in September 2014. The work group will continue to work on “non-policy” issues once more details about the research protocols become available.

Committee Projects Pending Implementation

5. Change Consent to Authorization

Public Comment: Fall 2011
Board Approval: June 2012
Projected Implementation: January 2015

Currently, UNOS policy uses the term “consent” to describe the act of making an anatomical gift. However, the public associates “consent” with the medico-legal concept of “informed consent” through which physicians must give patients all the information they need to understand the risks, benefits, and costs of a particular medical treatment. In the context of organ/tissue/eye donation after death, this blending of terms leads to misunderstandings about the act of donation that could hinder our national goal of increasing organ, tissue, and eye donation and transplantation. The OPO community has responded to this circumstance by changing the donation terminology from “consent” to “authorization.” This change focuses attention on the altruistic act of donation and reinforces the fact that donation after death does not involve medical treatment. This policy change was effective on September 1, 2012. Programming work is needed to update the terminology in UNetsm.

6. Imminent and Eligible Death Data Definitions

Public Comment: September 2012
Board Approval: Proposal - June 2013,
Revised effective date – November 2013
Projected Implementation: January 1, 2015

The proposed changes clarify the data collection definitions for determining whether a death can be classified as “imminent” or “eligible.” OPOs must classify a death as one of the following: Imminent Neurologic Death (“imminent”), Eligible Death (“eligible”), or neither “eligible” nor “imminent” (“neither”). The OPOs then report the “imminent” and “eligible” deaths to the OPTN. Because OPOs interpret reporting definitions differently and because brain death laws vary from state to state, OPOs are inconsistent in the way they report death data. The Committee asked the Board for a delayed implementation of January 1, 2015. The reason for the delayed implementation was to allow CMS time to implement the new definitions. At the time of this report there has not been any update from CMS. This proposal only requires a labeling update in DonorNet[®].

7. Donation After Circulatory Death

Public Comment: *Spring 2012*
Board Approval: *November 2013*
Projected Implementation: *TBD*

The proposed changes to the Donation after Circulatory Death (DCD) Model Elements will clarify and update language for the donation and transplantation community. These Model Elements identify specific requirements that OPOs and transplant centers must include in their DCD policies. This proposal only requires a labeling update in DonorNet®.

Implemented Committee Projects

8. Proposal to Document All Locally Assigned Unique Identifiers in the Donor Record

Public Comment: *Spring 2012*
Board Approval: *November 2012*
Implementation Date: *February 1, 2013*

This project developed a requirement that OPOs and living donor recovery transplant centers document all unique identifiers used to label any tissue typing specimen in the donor record. This will allow transplant centers to validate the unique identifier information. This proposal did not require IT programming.

9. Alternate Label for Perfusion Machines

Public Comment: *Fall 2011*
Board Approval: *June 2012*
Implementation Date: *September 1, 2012*

This project eliminated the use of alternate shipping labels on mechanical preservation machines and require OPOs to use a new standardized label that is part of the current color-coded labeling system distributed by the OPTN Contractor.

Review of Public Comment Proposals

The Committee reviewed 4 of the 17 proposals released for public comment from March – June, 2014.

10. Proposed ABO Blood Type Determination, Reporting, and Verification Policy Modification

The Committee discussed this proposal following a presentation by the Operations and Safety Committee (OSC) Vice-Chair. A Committee member asked if it was acceptable to use the same lab if the blood draw times were different. The OSC Vice-Chair noted that according to policy the practice is allowed as long as the draw times are different. The requirement to use separate labs applies when the two samples are from the same draw. Another requirement change is that blood type results must be known prior to the match run being executed where previously this needed to be done prior to the incision.

The Committee had concerns about how the host OPO can verify that the organ was transplanted into the intended candidate as required by Centers for Medicare and Medicaid Services (CMS) regulations. The proposed policy does not address this issue and in order to comply with CMS regulations, some OPOs use the match run to make this determination. However, some OPOs do not always know if the organ was transplanted into the original intended candidate. OSC staff noted that there were conditions in the draft policy language regarding the intended recipient being known or unknown, but the language was removed from the final proposal in favor of organ recovery verification being completed by the host OPO in conjunction with the onsite surgical recovery team. The OPO Committee suggested that the OSC consider adding “if the intended recipient is known” to the policy language.

The Committee briefly discussed the new requirements listed in Policy 5.6 (Organ Recovery, Check-In, and Pre-Transplant Verifications). The proposed policy language states that “OPOs and transplant centers must each develop and comply with their own written protocol to perform verifications as outlined in this policy.” There was concern from several OPO Committee members about the OPO’s ability to complete all of the verifications listed in the policy. The Committee recommended that the OSC consider clearly stating which member is responsible for the verifications listed.

The Committee discussed the issue of candidates not on the match run. The proposal states that most of these cases are due to directed donations or avoiding organ wastage. However, there was some concern that the new requirement to rerun the match run will not address the issue. The Committee asked if there was any discussion about requiring documentation when OPOs allocate to candidates not on the match run. OSC staff noted that the documentation requirements are listed in Policy 5.4.F (Allocation to Candidates Not on the Match Run).

The Committee supported the proposal and will provide feedback to the Operations and Safety Committee. Committee vote: 15 in favor, 0 opposed, and 0 abstentions.

11. Proposal to Require the Collection of Serum Lipase for Pancreas Donors

The Committee discussed this proposal following a presentation by a member of the Pancreas Transplantation Committee. The Committee noted that not all donor hospitals have the ability to perform serum lipase testing. Although the data presented by the Pancreas Committee shows that serum lipase is reported on the deceased donor registration form (DDR) 99% of the time for pancreas donors, it does not address the timeliness of the testing. The proposal makes serum lipase a required field in DonorNet® in order to make electronic pancreas offers. However, if serum lipase testing is not locally available or the test results are delayed for whatever reason, the ability to allocate the pancreas becomes difficult under the proposed policy.

The Committee discussed several other concerns:

- Is there scientific data to show how deceased donor serum lipase relates to pancreas graft survival? One member of the Committee volunteered to send recent literature on this topic to the Pancreas Committee.
- One of the purposes of the proposal is to promote a more efficient allocation system. However, Committee members argued that requiring serum lipase before making organ offers will make organ allocation less efficient.

- Because of the timing issues, it might be difficult for OPOs to comply with these new requirements.
- Does the data show that requiring serum lipase will lead to more pancreas transplants? If serum lipase is not available are the pancreata still being transplanted?
- Is it known why 1% of serum lipase results were not reported? Was it due to lab results being received later or unable to obtain at all?

Recommendations from the OPO Committee:

- Make serum lipase a desired test when available. One option is to require the tests be sent but organ offers can be made before test results are received.
- Support the creation of a new field in DonorNet® where OPOs will report the upper limit of normal (i.e. maximum normal value or highest reference value) of the laboratory's normal serum lipase reference range.
- Wait for information from the pancreas utilization subcommittee to determine impact on pancreas utilization.
- Make the Pancreas Committee aware that requiring serum lipase results before making pancreas offers will create logistical challenges for the OPOs.

12. Proposal to Align OPTN Policies with the 2013 PHS Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Solid Organ Transplantation

The Committee discussed this proposal following a presentation by the liaison for the Ad Hoc Disease Transmission Advisory Committee (DTAC).

Issues discussed:

- Were there special subgroups identified that require HCV NAT (nucleic acid testing)? DTAC staff noted that the current proposal requires HCV NAT for all donors, both deceased and living, whether they are increased risk or not. The DTAC did have discussions about the need to require testing for low risk pediatric donors and low risk elderly donors but interpretation of the Final Rule lead to the inclusion of all donors. Currently, most OPOs are using NAT for increased risk donors as well as an increasing number of overall donors.
- NAT results prior the match run - NAT is not required to generate a match run but is required to complete the DDR. OPOs are still required to have, at a minimum, screening test or combination antigen/antibody test results.
- False positives – with an overwhelming majority of OPOs using NAT, is there concern about the number of false positives that might result in lost donors? DTAC staff noted that the false positive rate is only 1%. There is a push for NAT from the public health service due to the growing epidemic of adult HCV and the risk/benefit assessment based on the 1% false positive rate favored NAT for all donors.

The OPO Committee was supportive of this proposal. The Committee also agreed to form a subcommittee to address the specific questions being requested in the proposal.

13. Proposal to Clarify Data Submission and Documentation Requirements

The Committee briefly discussed this proposal following a presentation by one of the liaisons for the Membership and Professional Standards Committee (MPSC). One Committee member asked if members were going to be retroactively reviewed for accurate data submission. MPSC staff noted that the practice has always been to monitor accurate data submission and this proposal will clarify that expectation. The OPO Committee fully supported this proposal due to the importance of accurate data submission.

Meeting Summaries

The committee held meetings on the following dates:

- April 24, 2014

Meetings summaries for this Committee are available on the OPTN website at: <http://optn.transplant.hrsa.gov/members/committeesDetail.asp?ID=95>.

Title: Elimination of Policy 5.9 – Allocation of Other Organs

Name of the Sponsoring Committee: Organ Procurement Organization Committee

Summary and Goals of the Proposal: To rescind an outdated policy that is not used by members and to facilitate the implementation of OPTN oversight of vascularized composite allografts (VCAs).

Background and Significance of the Proposal

The OPO Committee received a request to address this issue that came up at a recent Vascularized Composite Allograft (VCA) Committee meeting. Policy 5.9 addresses the allocation of “organs not specifically addressed in other policies.” Currently, all organs are addressed in policy but when the OPTN begins oversight of VCA transplants on July 3, 2014, there is an opportunity for confusion if OPOs try to allocate organs using this outdated policy. This policy is outdated and contains a point system for medical urgency and distance from the transplant center that has never been programmed. The Committee voted unanimously to rescind this policy and submit the recommendation to the Board of Directors during its June 22-23, 2014 meeting.

Additional Data Collection: N/A

Expected Implementation Plan

This policy will be expired earlier than our normal process. Due to the final rule modification timeline, these proposed modifications have not been distributed for public comment, but will be distributed during the next public comment cycle: fall 2014. Because of this, it is recommended that these policies be adopted with a sunset provision.

Communication and Education Plan

This policy change will be communicated as part of the comprehensive communication and education plan recommended by the VCA Committee.

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice	Transplant centers and OPOs	Electronic – Included in the monthly e-newsletter sent on the 3 rd Monday of each month	30 days after the Board of Directors approves the change.
Member E Newsletter	Transplant centers and OPOs	Email	Earliest issue after OPTN Board approves the policy change.

Monitoring and Evaluation: This policy is not currently being monitored by DEQ. The proposed deletion of the policy will have no impact on member compliance.

Policy Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

RESOLVED, that Policy 5.9 (Allocation of Other Organs) be rescinded, as set forth below, is hereby approved, effective July 3, 2014, and shall expire on July 1, 2015.

~~5.9 Allocation of Other Organs~~

~~5.9.A Statuses and Points~~

For the allocation of organs not specifically addressed in other policies, points are assigned for medical urgency according to *Table 5-1* below.

Table 5-1: Medical Urgency Points for Other Organs

If a candidate meets these criteria:	Then the candidate is this status:	And receives this many points:
At home, functioning normally, and transplant surgery would be an elective procedure.	4	4
Homebound and requiring continuous medical care which can be self-administered. Short hospitalizations for simultaneous or intervening conditions are not considered justification for a change in status.	2	8
Homebound and requiring continuous medical care which requires the assistance of an attendant. Short hospitalizations for simultaneous or intervening conditions are not considered justification for a change in status.	3	12
Requires continuous hospitalization because of the candidate's medical condition.	4	16
Requires continuous hospitalization as well as intravenous inotropic drug therapy.	5	20
Requires continuous hospitalization and a mechanical assist device for survival.	6	24

~~5.9.B Points for Distance~~

For the allocation of organs not specifically addressed in other policies, deceased donors and recipients receive points for the distance between the transplant hospital and the deceased donor or recipient. The point values are assigned according to *Table 5.2* below.

Table 5-2: Distance Points for Other Organs

If the distance to the transplant hospital is:	Then the deceased donor receives:	And the recipient receives:
0—50 miles	12 points	6 points
50—500 miles	10 points	5 points
500—1000 miles	8 points	4 points
1000—1500 miles	6 points	3 points
1500—2000 miles	4 points	2 points
2000—2500 miles	2 points	1 points
Greater than 2500 miles	0 points	0 points