OPTN/UNOS Organ Procurement Organization Committee
Report to the Board of Directors
June 1-2 2015
Atlanta, Georgia

Sean F. Van Slyck, MPA/HSA, CPTC, Chair
Jennifer K. Prinz, RN, BSN, MPH, CPTC, Vice Chair

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This report reflects the work of the OPTN/UNOS OPO Committee during the November 2014 to April 2015 period.

Action Items

1. Deceased Donor Registration Completion

   Public Comment: September – December, 2014

   Policy 18.1 (Data Submission Requirements) requires all OPOs to complete the deceased donor registration (DDR) for all deceased donors and authorized but not recovered potential deceased 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 OPO Committee has observed inconsistent data reporting on potential donors that do not proceed to donation. The Committee discussed the purpose of collecting data on authorized but not recovered donors or those for whom authorization was not obtained. Because there is limited information available on non-donors, the Committee agreed that it was appropriate to eliminate the requirement. During the discussions, the Committee also agreed to propose a minor modification to the definition of a deceased donor.

   During a conference call on September 5, 2014, the Committee reviewed the final policy language and unanimously supported the proposal moving forward to public comment on September 29, 2014. The proposal received unanimous support from all the regions, committees, and organizations. The OPO Committee reviewed the final policy language during its March 31, 2015, meeting and unanimously approved the language for consideration by the Board of Directors (12 support; 0 oppose; 0 abstentions).

   RESOLVED, that additions and modifications to Policy 1.2 (Definitions) and Policy 18.1 (Data Submission Requirements), as set forth in Exhibit A, are hereby approved, effective pending programming and notice to the OPTN membership.

2. HIV Organ Policy Equity Act

   Public Comment: September – December, 2014

   Public Comment: January – March, 2015

   The HIV Organ Policy Equity Act[1] (HOPE Act) was enacted on November 21, 2013. The Hope Act states that the Secretary of Health and Human Services (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 by November 21, 2015. 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 work group developed an initial proposal which was distributed for public

[1] http://www.gpo.gov/fdsys/pkg/PLAW-113publ51/pdf/PLAW-113publ51.pdf

comment from September 29 – December 5, 2014. The intent of the proposal was to provide notice to the transplant community about the upcoming changes to OPTN/UNOS policies and the Final Rule related to the research study. The proposal was unanimously supported by all the regions, committees, as well as the American Society of Transplant Surgeons (ASTS), the American Society of Transplantation (AST), the HIV Positive Women's Network, and the HIV Medicine Association.

The work group completed a comprehensive review of all OPTN/UNOS policies and bylaws to determine if additional changes were required to meet the requirements of the Hope Act. This review led to additional policy changes that became the focus of a second proposal distributed for public comment from January 27 – March 27, 2015. One significant change was the creation of an "open variance" to address the requirements for members participating in a Hope Act institutional review board (IRB) approved research study. The initial proposal created a new section of policy (15.3) to address the recovery and transplantation of HIV positive organs. However, subsequent discussions and input from the Board of Directors led to the decision to classify these transplants as an open variance, meaning any member can participate by declaring their intention to do so. The transplants performed according to the criteria being developed by the National Institutes of Health (NIH) will be part of a time-limited study that will be re-evaluated, as outlined in the Hope Act, to determine if it will become permanent policy. Classification as a variance also allows the Board of Directors the flexibility to extend, amend, or terminate the variance at any time, as outlined in the variance policies. Because of this change, the originally proposed change to Policy 15.3 was withdrawn and replaced by a new section in Policy 15.6. The remaining policy modifications, including post public comment changes, can be found in **Exhibit B**. On March 31, 2015, the OPO Committee voted to recommend modifications to the policy language for consideration by the Board of Directors (13 support; 0 oppose; 0 abstentions).

RESOLVED, that additions and modifications to Policies 2.7.A (Exceptions to HIV Screening Requirement), 5.3.C (Liver Acceptance Criteria), 5.4.B (Order of Allocation), 5.4.F (Allocation to Candidates Not on the Match Run), 13.6.B (Requirements for Match Run Eligibility for Potential KPD Donors), 14.4.E (Living Donor Exclusion Criteria), 15.3 (Informed Consent of Transmissible Disease Risk), 15.4.A (Transplant Program Requirements), 15.6 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors), 16.7.B (Vessel Recovery, Transplant, and Storage), 16.7.C (Blood Type Verification Prior to Transplant of Deceased Donor Vessels), and 16.7.E (Blood Type Verification Prior to Transplant of Living Donor Vessels), as set forth in Exhibit B, are hereby approved, effective pending programming and notice to OPTN membership.

Committee Projects

3. Limit Paper Documentation

Public Comment: August 2015 (estimated)

Board Consideration: November 2015 (estimated)

OPTN/UNOS Policy 16.5.A (Organ Documentation) requires that complete donor documentation be sent in the container with each transported organ. The OPO Committee has been collaborating with the Transplant Coordinators Committee (TCC) and Transplant Administrators Committee (TAC) in an effort to reduce the amount of paper documentation that is shipped with each organ. The initial recommendation from was to require the ABO verification and infectious disease testing documentation to be included with the organs.

Additional information such as anatomy information and authorization forms can be uploaded into DonorNet®. The Committee will also consider the development of a guidance document to address when to upload the information as well as document management strategies to allow transplant centers to easily locate the documents. This includes creating separate documents instead of one large PDF file that contains numerous documents and developing standard naming conventions for these individual documents. The Committee plans to develop a proposal in time for the August 2015 public comment period.

Committee Projects Pending Implementation

4. Imminent and Eligible Death Data Definitions

   Public Comment: *September 2012*

   Board Approval: June 2013 (Proposal)

   Board Approval: November, 2013 (Revised effective date)

   Board Approval: November 2014 (Revised effective date)

   Projected Implementation: January 1, 2016

   This proposal was developed over several years in an effort to improve the inconsistent reporting of imminent and eligible deaths by OPOs. This proposal was approved by the Board of Directors in 2013 and the effective date has been delayed until January 1, 2016, with hopes that CMS (Centers for Medicare and Medicaid Services) will take action to accept the new OPTN/UNOS definitions prior to the implementation date. The Committee is currently developing education and communication plans to assist OPOs in preparation for the effective date.

5. Change Consent to Authorization

   Public Comment: *September 2011*

   Board Approval: June 2012

   Projected Implementation: Second quarter, 2015

   Currently, OPTN/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 UNet℠.

6. Donation After Circulatory Death

   Public Comment: *March 2012*

   Board Approval: November 2013

   Projected Implementation: Second quarter, 2015

   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®.

Review of Public Comment Proposals

The Committee reviewed 5 of the 10 proposals released for public comment from January 27, 2015 – March 27, 2015.

7. Membership Requirements for Vascularized Composite Allograft Transplant Programs (Vascularized Composite Allograft (VCA) Committee)

   The OPO Committee supports this proposal. The OPO Committee briefly discussed the variability among OPOs regarding the creation of standards to qualify recovery surgeons. The VCA Committee member noted that the proposal adds specific requirements for primary VCA surgeons and physicians and OPOs can use these to develop their own requirements.

8. Proposal to Require Re-Execution of the Match Run when a Deceased Donor's Infectious Disease Results Impact Potential Recipients based upon Screening Preferences (Ad Hoc Disease Transmission Advisory Committee (DTAC))

   The OPO Committee supports this proposal to better define in policy the processes that should be followed when new results are learned after the execution of the initial match run. The OPO Committee suggests that the language is clearly stated and addresses the issues occurring when the organ is allocated, new results are obtained and the accepting hospital continues to want the organ for the accepting recipient. It is the OPO Committee's understanding that in this scenario, the OPO is not required to re-run the match run but might opt to do so for backup offers.

   The OPO Committee briefly discussed the issue of notifying the accepting transplant hospital within one hour of receipt of new test results. The policy language does not specify the method of notification but the OPO Committee acknowledged that a phone call to the transplant hospitals is the standard method along with documentation in the donor highlights field and updating serology results.

9. Proposed ABO Blood Type Determination, Reporting, and Verification Policy Modifications (Operations and Safety Committee)

   The OPO Committee supports the proposal to the ABO policy yet seeks clarification on the pre-recovery surgeon verification requirements. Table 2.1 outlines the verification requirements for the donor ID, organ, and blood type using the donor record or OPTN computer system. The Committee asked whether the intent was to verify the specific organs the recovery surgeon intends to recover or if this meant to be a review of general donor-specific information similar to "report" that is given to recovery surgeons as part of standard OPO practice. The Operations and Safety Committee member noted the intent of the language is to verify that it is the correct donor and correct organ, not to verify that an organ is being recovered for a particular recipient. There are additional verification requirements for the OPO to perform if the intended recipient is known which aligns with CMS requirements. Additionally, in the case of an expedited recovery where there is no match run

(e.g. “OPTN computer system”) the OPO would meet the verification requirements by reviewing the donor medical record with the recovery surgeon along with the organs they intend to recover.

The proposed changes will require donor-specific and organ recovery verification by the recovery surgeons, which will be a new requirement for the OPO community. The OPO Committee recommends the creation of a template verification form, or modification to the existing verification template, and would be willing to work with the Operations and Safety Committee to create a form to assist the community with compliance.

The Committee also discussed the issue of separate blood draws. One question raised was if the hospital ABO result that is done prior to the patient becoming a donor counts as one of the two separate draws? The Operations and Safety Committee noted that it would count as one of the draws. There was also a question raised about the timing of the blood samples and the definition of “drawn on two separate occasions.” The Operations and Safety Committee member noted the policy language aligns with the CMS interpretive guidelines by stating “two different collection times.”

10. Proposal to Modify the Sterile Internal Vessels Label (Operations and Safety Committee)

    The OPO Committee supports the proposal to modify the sterile container vessel label. The proposed changes will improve the current OPO vessel labeling process, will mitigate potential labeling failure points and will continue to ensure appropriate patient safety safeguards. One OPO Committee member requested feedback on whether the positive indication for HBV should be for any positive HBV testing result or solely for HBsAg positive results as storage of these vessels is prohibited by policy. The Operations and Safety Committee member will seek clarification on this point from the vessel label subcommittee.

11. Proposal to Collect Ex Vivo Lung Perfusion (EVLP) Data for Transplant Recipients (Thoracic Organ Transplantation Committee)

    The OPO Committee supports this proposal to collect additional data specific to EVLP use which will provide the community with a better understanding of this emerging technology.

    The OPO Committee recommends that the Thoracic Committee consider expanding the data collection beyond only those lungs transplanted to all lungs placed on an EVLP device, which will also capture aborted or discarded lung data. Additionally, collect information on the location of the transplant and EVLP.

Meeting Summaries

The committee held conference calls on the following dates:

- December 19, 2014
- March 3, 2015

Meetings summaries for this Committee are available on the OPTN website at: http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=18.