

OPTN/UNOS Organ Procurement Organization Committee
Meeting Summary
March 31, 2015
Chicago, Illinois

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Discussions of the full committee on March 31, 2015 are summarized below and will be reflected in the committee's next report to the OPTN/UNOS Board of Directors. Meeting summaries and reports to the Board are available at <http://optn.transplant.hrsa.gov>.

Committee Projects

1. Deceased Donor Registration Completion

Public Comment: Fall 2014

Board Consideration: June 2015

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. However, 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 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).

2. HIV Organ Policy Equity Act

Public Comment: Fall 2014 and January 2015

Board Consideration: June 2015

The HIV Organ Policy Equity Act¹ (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

¹ <http://www.gpo.gov/fdsys/pkg/PLAW-113publ51/pdf/PLAW-113publ51.pdf>

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 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 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 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. 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).

3. Limit Paper Documentation

Public Comment: *Fall 2015 (estimated)*

Board Consideration: *November 2015 (estimated)*

OPTN Policy 16.5.A (Organ Documentation) requires that complete donordocumentation 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 the OPO Committee 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.

4. Imminent and Eligible Death Data Definitions

Public Comment: September 2012

Board Approval: Proposal - June 2013,

Board Approval: Revised effective date – January 2016

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 is currently set for January 1, 2016, with hopes that CMS (Centers for Medicare and Medicaid Services) will take action to accept the new OPTN definitions prior to the implementation date. The Committee is currently developing education and communication plans to assist OPOs in preparation for the effective date.

Review of Public Comment Proposals

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

5. 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.

6. 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 center 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.

7. 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. Is the intent to verify the specific organs the recovery surgeon intends to recover or is 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? A representative from the Operations and Safety Committee noted that 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 member 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 that the policy language aligns with the CMS interpretive guidelines by stating “two different collection times.”

8. 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.

9. 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, the OPO Committee recommends collecting information on the location of the transplant and EVLP.

Other Significant Items

10. Liver Redistricting Forum

The Committee was provided with an update on the work of the four ad hoc subcommittees that were formed to address the metrics of disparity, finance, transportation and logistics, and increasing liver donation. The subcommittees will

continue their work leading up to the next liver redistricting forum scheduled for June 22, 2015, in Chicago, Illinois.

11. Data Advisory Committee

The Committee was provided with an update on the charge and functions of the Data Advisory Committee (DAC). One of the DAC projects will review the OPO Metrics and the OPO Committee expressed interest in being involved in that effort.

12. Committee Terms

The Committee discussed a request from the Policy Oversight Committee (POC) to provide feedback on the issue of increasing term limits for committee members. The POC is requesting feedback from all committees to determine the level of support for a potential bylaw change to increase the terms from two to three years. The OPO Committee supported this by a vote of 13 in favor, 0 opposed, and 0 abstentions.

13. Strategic Planning

The Committee was provided with an update on the changes to the OPTN Strategic Plan. The upcoming changes, which will be approved by the Board of Directors in June 2015, will have an impact on committee work.

Committee Project Updates

The Committee was provided with an update on the following projects:

14. Vessel Labels (with Operations and Safety Committee)

The group continues to review changes to the internal vessel label. The current label contains a list of infectious diseases which makes it difficult to complete and can lead to mistakes. The subcommittee is reviewing several options for a new label and plan to submit a recommendation to the Board of Directors in June 2015.

15. Infectious Disease Verification (with Operations and Safety Committee)

This joint subcommittee has been addressing improvements to reporting infectious disease testing results. The subcommittee is discussing a process similar to that of ABO verification and plan to develop a proposal in time for the August 2015 public comment period.

16. Imminent Death Donation (with Ethics Committee)

This subcommittee continues its discussions regarding kidney donation from the imminently dying and whether there are circumstances when imminent donation could be appropriate. The subcommittee is also discussing regulatory and legal implication of imminent death donation, and reviewing existing policy to determine how it could be modified to allow for imminent death donation.

17. TransNetsm Project

The Committee was provided with an update on the TransNetsm project. The team has recently started "train the trainer" sessions which are held at the UNOS headquarters in Richmond, Virginia. The team is developing an iOS application for iPads and will continue to gather transplant center requirements.

18. Living Donor Organ Transport (with Living Donor and Operations/Safety Committee)

The Committees were asked to consider if new policies for the transport of living donor organs are needed. Specifically, if standardization for how living donor organs are shipped throughout the county may be required. The number of transported living donor organs is rapidly increasing related to the increase in kidney paired donation. The subcommittee is utilizing the Healthcare Failure Modes and Effects Analysis methodology to identify key failure points. The subcommittee is currently working to identify those failure points with plans to develop a public comment proposal or guidance document.

19. Simultaneous Liver-Kidney Allocation (with Liver and Kidney Committees)

The joint subcommittee was formed to address the issue of simultaneous liver-kidney allocation. The subcommittee has been seeking input from various stakeholders as they work to develop criteria for medical eligibility as well as a safety net for prioritization on the kidney alone waiting list for liver recipients with post-operative dialysis dependency or significant renal dysfunction. Once these have been finalized, the plan is to incorporate the SLK recommendations into the larger multi-organ proposal.

20. Update on Kidney Allocation System

The Committee was provided with an update on the new kidney allocation system. There continues to be inconsistencies in practice with regards to the logistics of shipping kidneys, shipping blood for crossmatch in advance of the kidney, and performing virtual and physical crossmatches prior to acceptance. The OPO Committee will continue to work with the Kidney Committee to address these issues.

New Business

21. Data Questions

There was a brief discussion about proposing changes to DonorNet® to allow for multiple entries of infectious disease results. There was also an issue raised about entering pulmonary artery catheter information in the deceased donor registration (DDR) form. Finally, the Committee received a letter from Donate Life America with a number of request to change data collection and update help documentation in the DRR. A data subcommittee was formed to address these questions and develop recommendations for review by the full committee.

Upcoming Meeting

- September 23, 2015 in Chicago, Illinois