

**OPTN/UNOS Organ Procurement Organization Committee**  
**Meeting Summary**  
**September 23, 2014**  
**Chicago, Illinois**

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

*Discussions of the full committee on September 23, 2014 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*

The deceased donor registration (DDR) completion subcommittee has been working over the past year to address the information that OPOs are required to submit on patients who are referred to the OPO as a potential donor and non-donors. 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. Additionally, basic demographic information is collect on non-donors through the death notification registration form. The subcommittee provided the following recommendations to the OPO Committee:

- 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.
- Make the following label change to the deceased donor feedback form: Change "Referral Only" to "No organs were recovered for the purpose of transplantation."

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.

**2. Limit Paper Documentation**

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

The OPO Committee formed a subcommittee to address the paper documentation that is packaged and shipped with each organ. 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®.

The subcommittee held its initial conference call on August 25, 2014. The initial recommendation from the subcommittee 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 subcommittee also recommended 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. The subcommittee also discussed the development of standard naming conventions for these individual documents. Finally, the subcommittee agreed to draft recommendations to forward to the Transplant Coordinators Committee and Transplant Administrators Committee for feedback.

The subcommittee provided an update to the OPO Committee during its September 23, 2014, meeting.

### **3. HIV Organ Policy Equity Act**

*Public Comment:* Fall 2014 and January 2015  
*Board Consideration:* June 2015

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 work group met on several occasions to review policies and discuss potential operational issues. The work group developed an initial proposal to remove the prohibition on the recovery and transplant of HIV organs if participating in the research study. The initial proposal also prohibits the storage of HIV positive extra vessels.

The work group met by conference call on August 27, 2014 and approved the policy language. The OPO Committee reviewed the final policy language and unanimously supported the language moving forward to public comment on September 29, 2014.

### **4. Imminent and Eligible Death Data Definitions**

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. This proposal only requires a labeling update in DonorNet®. During the September 23, 2014 meeting, the OPO Committee agreed to the following:

- If CMS notifies the OPTN of their intention to make administrative changes to accept the new definitions, the effective date will remain January 1, 2015.
- If CMS cannot make the changes, the OPO Committee will request that the effective date be changed to January 1, 2016.

## **Review of Public Comment Proposals**

The Committee reviewed 7 of the 18 proposals released for public comment from September 29, 2014 – December 5, 2014.

### **5. Proposal to Establish a Quality Assurance and Performance Improvement Requirement for Transplant Hospitals and OPOs**

There was a question raised about what triggers the MPSC's review of a transplant center or OPO's QAPI plan. MPSC staff noted that CMS performs a more detailed review of QAPI plans so the MPSC would only review a plan if an OPO or transplant center was being reviewed by the MPSC due to compliance or performance issues.

### **6. VCA Committee - Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs)**

An OPO Committee member noted that one of the criteria listed under the definition of VCA addresses the use of devices. The member's OPO has plans to use a mechanical device to support VCA grafts and the recommendation was made to change "not combined with another article such as a device" to "not permanently combined with another article such as a device." The VCA Committee liaison noted that the intent was for any devices being permanently implanted at the time of transplant but agreed that the policy language should be clarified. It was also noted by UNOS staff that due to the evolving field of VCA transplants, if OPOs or transplant center are using technology to assist with VCA transplants they should notify the OPTN so there is an awareness and education about the technology. Additionally, this will assist when making the determination about what technology is monitored by the OPTN and by the FDA.

An OPO Committee member noted that currently a significant number of brain dead patients who get ruled out as organ donors could potentially qualify as a VCA donor. Moving forward, VCA alone donors could potentially have an impact on the OPOs observed versus expected data. It was noted by SRTR staff that VCA data is not currently being collected for that purpose.

There was a question raised about whether OPOs and transplant centers that are currently involved in VCA transplants will be required to submit a letter of intent to the OPTN. UNOS staff noted that a letter of intent will be required from all transplant centers wanting to perform VCA transplants and that letter will include the information about the OPOs they will be working with on VCA transplants.

The OPO Committee recommended that there be a central location for all the information about VCAs and that it includes specific information for OPOs. UNOS staff noted that once the guidance documents and other information is approved by the Board

of Directors, they will be posted on the OPTN website. Additionally, the OPO Committee recommends that for patient safety reasons future programming should be completed to facilitate VCA transplants.

## **7. Improving the OPTN Policy Development Process**

Upon review, the Committee had no comment regarding this issue.

## **8. Histocompatibility Committee - Proposed Changes to the OPTN Bylaws Governing Histocompatibility Laboratories (Phase II)**

An OPO Committee member noted that the proposal was not clear regarding the requirements within the PhD pathway for laboratory director. The proposal states within the PhD pathway that there be “at least two years full-time, post-doctoral experience or four years pre-doctoral experience in immunology, histocompatibility, or immunogenetics and two years post-doctoral training in directing or supervising clinical histocompatibility testing for solid organ transplantation.” It was not clear if the time period needed to be consecutive or concurrent events. The Histocompatibility Committee liaison agreed to bring the question back to the Histocompatibility Committee for clarification.

There was also a question raised about the reporting of HLA discrepant typing and the identification of labs that show a trend of discrepant typing. It was noted by UNOS staff that the computer system will flag discrepancies within Tiedi and through the donor and recipient histocompatibility forms. The Histocompatibility Committee has taken the additional step of reviewing the match runs to identify errors. Histocompatibility labs are provided with a report of all discrepancies that the system has identified so they can be resolved. The new policy requires that the discrepancies be resolved within 30 days.

## **9. Clarification of Multi-Organ Policies**

Upon review, the Committee had no comment regarding this issue.

## **10. Policy Rewrite Parking Lot “Quick Fixes”**

The Committee agreed to review the policy language to ensure that none of the proposed changes from “should” to “must” will create problems for OPOs. One committee member noted that the only change that might cause issues is the requirement to include the ABO on all the blood tubes. It could be a challenge for some blood banks to receive a red top tube with the ABO although that might be specific to living donors. The OPO Committee will review the policy language and provide feedback via email.

## **11. Proposal to Clarify Definition of Organ Transplant and Transplant Date**

Upon review, the Committee had no comment regarding this issue.

## **12. Serum Lipase Requirement**

The OPO Committee has reviewed this proposal during three committee meetings. The proposal makes serum lipase a required field in DonorNet® in order to make electronic

pancreas offers. The OPO Committee has previously noted that serum lipase testing is not always locally available and if the test results are delayed, the ability to allocate the pancreas becomes difficult under the proposed policy change. The OPO Committee also previously noted that not all donor hospitals have the ability to perform serum lipase testing. Below is an overview of the previous comments from the OPO Committee:

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.

Since the last discussion held during the April 24, 2014 OPO Committee meeting, the Pancreas Committee chair has reached out to several OPO Committee members. There were discussions about allowing for a “best practices” solution such as a letter from the lab director explaining the lab cannot provide the serum lipase value in time for the electronic pancreas offer. The OPO would then upload this letter to the donor record as a means to justify the non-compliance. It was noted that this would not be a policy compliance exemption.

The Pancreas Committee and OPO Committee leadership also had discussions via teleconference in an effort to find a solution that works for both parties. There was a suggestion made by the OPO Committee chair to monitor serum lipase similar to what was previously done for gamma-glutamyl transpeptidase (GGT) for liver donors, make serum lipase a “preferred field” (similar to some of the thoracic fields), or have some sort of guarantee that the OPO will not be in non-compliance if it cannot adhere to the serum lipase requirement. It was noted that DEQ does not monitor “preferred fields” so in order to make serum lipase a “preferred” field it would have to be written into policy. There are

some thoracic fields that are required upon request. Other suggestions included sending blood with HLA materials to the lab for serum lipase testing, using handheld chemical testing devices, or contracting with local labs when the main labs cannot provide timely results. The Committee noted that HLA labs do not perform serum lipase testing and the purchase and maintenance of handheld chemical testing devices would be expensive.

The OPO Committee has the following recommendations:

- The Committee remains in support of the new fields in DonorNet® to report the upper limit of normal (i.e. maximum normal value or highest reference value) of the laboratory's normal serum lipase reference range.
- The Committee does not support the requirement to report serum lipase prior to electronic pancreas offers because OPOs will be unable to comply with the new policy 100% of the time.
- While the option to obtain letters from the labs is an option, it could be burdensome for some OPOs.
- The OPO Committee did agree that OPOs should be able to justify the reasons why they were unable to get serum lipase results completed in time for the electronic pancreas offers in order to avoid a policy violation. It was recommended that the Pancreas Committee work with the OPTN contractor to address the potential compliance issues.
- The OPO Committee remains concerned that this requirement could impact pancreas allocation although OPOs are committed to placing as many organs as possible.
- The OPO Committee also recommends that the Pancreas Committee collect data to determine how many labs do not perform serum lipase testing and how many OPOs decline to test for serum lipase even though they had the capability to perform the test.

## **Other Significant Items**

### **13. Liver Redistricting Forum**

The Committee was provided with an overview of the Liver Redistricting Forum held on September 17, 2014 in Chicago, Illinois. Four ad hoc subcommittees were formed to address the metrics of disparity, finance, transportation and logistics, and increasing liver donation. These subcommittees will have OPO representatives.

### **14. Electronic Tracking and Transport Project**

The Committee was provided with an update on the ETT project. There was a recent "train the trainer" sessions held at the UNOS headquarters in Richmond, Virginia. The ETT team will begin additional testing at several transplant centers and the five OPOs prior to the Board of Directors meeting in November 2014.

## **Committee Project Updates**

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

- **Vessel Labels (with Operations and Safety Committee)** – The group continues to review data related to vessel packaging and labeling, disposition of extra vessels with attention to the percentage used in secondary recipients, and policy compliance data

with vessel labeling. The group has reviewed draft policy language and will continue to develop a policy proposal.

- **Sharing Updated Donor Information (with DTAC)** – This joint subcommittee utilized a failure mode and effects analysis (FMEA) to map out the process used by OPOs receiving post-transplant information and the pathway for communicating this information to transplant centers. The FMEA highlighted the potential failure points throughout the process and provide evidence for policy development meant to enhance patient safety. The next steps include identifying programming solutions, development of guidance documents, and policy changes.
- **Rerunning the Match Run (with DTAC and Operations/Safety)** – This project addresses the rerunning of match runs when there is a change in donor infectious disease testing that would impact a candidate's appearance on the match run (HBV, HCV, HTLV, CMV for intestines only). The subcommittee continues to review policy language changes that will address the scenarios that require that the match run be re-executed based on updated donor information.
- **Simultaneous Liver-Kidney (with Liver and Kidney Committees)** – The joint subcommittee was formed to address the issue of simultaneous liver-kidney allocation. The subcommittee agreed on the following problem statement:

*“There are minimal rules for SLK allocation. There is a need for more consistency for these transplants, especially when a liver is being shared (non-local). The lack of allocation rules is counter to Final Rule principles regarding the best use of organs and allocation policies being based on medical urgency.”*

The next steps include requesting data and reaching out to the Pediatric Transplantation Committee.

- **Imminent Death Donation (with Ethics Committee)** – This joint subcommittee was formed to address imminent death donation. The subcommittee consider the ethical issues surrounding surrogate consent for living kidney donation from the imminently dying, consider the circumstances of when imminent donation could be appropriate, review regulatory and legal implication of imminent death donation, and consider existing policy and how it would have to be modified to allow for imminent death donation.
- **Marking Kidney Laterality (with Kidney Committee)** – This project will address the inconsistent methods used to mark kidney laterality. The subcommittee is recommending the development of guidance instead of policy changes.
- **Heart-Lung Allocation** – The OPO Committee reviewed a draft guidance document developed in collaboration with the Thoracic Organ Transplantation Committee. The guidance document is intended to provide guidance to OPOs in order to provide greater consistency in allocating thoracic organs. The OPO Committee unanimously supported the guidance document which will be presented to the Board of Directors in November 2014. The guidance document will also be used to update policy language with plans to distribute a public comment proposal in early 2015. The OPO Committee continues to work with the Thoracic Committee to address ex-vivo lung perfusion issues.

## **New Business**

- **Recovery Center** – There was a brief discussion about the impact of organ recovery centers on organ allocation. Currently, the OPTN computer system contains donor hospitals and transplant centers, but not organ recovery centers. Thoracic organs are allocated according to concentric circles from the donor hospital. However, if the donor hospital is several hundred miles away, then shouldn't those concentric circles be based on the recovery center not the donor hospital? Additionally, some DCD donors are moved to hospitals that perform DCD recoveries and there could be significant distance traveled. The Committee leadership will determine if this becomes a project which will require a new project form being submitted and approved through the Policy Oversight Committee and the Executive Committee.

## **Upcoming Meeting**

- TBD