OPTN/UNOS Organ Procurement Organization Committee
Meeting Minutes
April 19, 2017
Chicago, Illinois

Jennifer K. Prinz, RN, BSN, MPH, CPTC, Chair
Diane Brockmeier, RN, BSN, MHA, Vice Chair

Introduction

The OPO Committee met in Chicago, Illinois on 04/19/2017 to discuss the following agenda items:

1. System Optimizations Work Group Update
2. Expedited Organ Placement Work Group Update
3. HOPE Act
4. Changes to Organ Shipping Labels
5. Policy Oversight Committee Update
6. DonorNet® Attachments
7. DTAC Guidance Document
8. Data Reporting Presentation for OPOs
9. SRTR Report on Kidney Offer Acceptance
10. Imminent and Eligible Definitions

The following is a summary of the Committee's discussions.

1. System Optimizations Work Group Update

Summary of discussion:

The work group chair provided a project update. The work group is recommending the following policy changes to the OPO Committee:

- Reduce the current time limits for responding to electronic organ offers
- Add additional time limit of 1 hour to make a final decision once all required information has been provided
- Limit the number of offers that can be accepted for one candidate
- Require OPOs to manage match run acceptances in real time
- Revise or create definitions

The work group continues to work with UNOS IT on DonorNet enhancements that will help improve the organ allocation system. UNOS Customer Innovations staff performed a demonstration of some of the DonorNet Enhancements that were recommended by the work group. One of the recommendations was to provide an automated notification when a candidate at a particular transplant hospital becomes the primary offer. Additionally, Customer Innovations is testing a feature that allows a transplant center to "follow a donor." This will start with OR times and will eventually include other information.

The work group will also be addressing transplant hospital acceptance criteria. UNOS IT presented information on the Donor Profile Project that will allow transplant hospitals to use criteria in combination to screen offers more precisely.

Next steps:

Following work group review of policy language in May 2017, the OPO Committee will review and vote on final policy language that will be distributed for public comment in July 2017.

2. Expedited Placement Work Group Update

The Committee chair provided a brief overview of this project. The work group had an initial conference call in March 2017 with the plan to initially focus on expedited placement with liver allocation. The work group was provided with a preliminary review of allocation data intended to highlight some of the main issues associated with out of sequence allocation cases. UNOS Research staff noted that OPOs have different practices regarding expedited placement.

Data Summary

While this varies from year to year, generally:

- 70% of OPOs have at least one expedited placement reviewed by the MPSC each year
- Most OPOs have between 1 and 10 cases
- A small number of OPOs have had approximately 40 expedited placement cases reviewed per year
- The number of expedited placements as a percentage of the total number of transplants per year is small (most OPOs less than 2%)

In a one year period:

- 60% of liver expedited placements reviewed were associated with intra-operative turndowns
- 20% of expedited liver offers were associated with pre-cross clamp refusals for organ quality
- Four liver transplant programs received almost 50% of the expedited liver offers
- Approximately 30% of the expedited livers are reported to have >20% macro vesicular fat

Additional data include:

- Approximately 85% of expedited kidney placements were associated with refusals for organ quality after the donor OR.
- Four kidney transplant programs received more than 50% of the expedited kidney offers.
- In more than 25% of the expedited kidney placements, the kidneys were reported to have between 11-20 hours of CIT.
- Approximately 50% of the heart expedited placements were associated with pre-cross clamp refusals for organ quality (often ejection fraction and echo diagnosis/findings).
- Other less frequent (but not uncommon) reasons for expedited placements include donor family or hospital time constraints, crashing donors, and recipient issues.
- The MPSC closed approximately 99% of the allocations out of sequence cases they reviewed.

In most instances, the MPSC determined that OPOs were expediting placement of organs that would otherwise have gone to waste and that OPOs made a good faith effort to make as many offers as possible according to the match run before expediting placement.

Summary of discussion:

UNOS staff provided an overview of the Joint Societies Steering Committee (JSSC) meeting held on March 31, 2017. There is an agreement between the AST, ASTS, NATCO, HRSA, and UNOS that established a process for early involvement if policies being developed have the potential to direct or prescribe medical care. The JSSC recommended forming a Joint Societies Work Group (JSWG) for the expedited organ placement project and agreed that the Association of Organ Procurement Organizations should be involved as well. The expedited organ

placement project was temporarily placed on hold until UNOS leadership agreed to allow the work group to continue its work concurrently with the JSWG.

Next steps:

The work group will continue to work on developing expedited placement policy for liver allocation.

3. HOPE Act

HIV Organ Policy Equity (HOPE) Act Update

UNOS staff provided an update on HOPE Act transplant activity. There are currently 18 transplant hospitals participating in HOPE Act research. To date there have been 27 transplants performed using organs from 11 deceased donors. There are currently 133 HIV positive candidates on the waiting list who have indicated a willingness to accept an HIV positive organ (121 kidney, 12 liver).

According to the HOPE Act, by November 21, 2017, the Secretary in conjunction with the OPTN will review the results of scientific research to determine if policies need to change. The UNOS Research department has been providing HRSA with quarterly reports and UNOS will continue to work with HRSA to determine how to best meet this statutory requirement. Due to the low volume of transplants done so far, the OPO Committee will most likely submit a request to the Board of Directors in December 2017 to extend the variance which is due to expire on Jan. 1, 2018.

Part of the policy requirements include participating transplant hospitals submitting a schedule of their institutional review board (IRB) data safety monitoring reports and then submit those reports according to the schedule. Initial reports have been submitted to UNOS and they are being reviewed by the Chief Medical Officer. These reports will also be periodically reviewed by an ad hoc safety monitoring work group.

Due to the low number of donors and transplants, UNOS staff is developing a survey to send to OPOs with the intent to identify potential barriers to evaluating potential HIV positive donors and placing the organs as part of a research study.

4. Changes to Organ Shipping Labels

UNOS Research staff provided an overview of the new organ shipping labels. The labels were modified to make the placement of the TransNet^{sm} labels easier and more standardized. The Committee suggested minor changes to the kidney pump shipping label so it clearly states the label is for the kidney pump machine. The Committee also recommended minor changes to the numbering on the VCA label. The Committee unanimously supported the new labels.

5. Policy Oversight Committee Update

The Committee vice-chair provided a brief update on the work of the Policy Oversight Committee (POC). The POC continues to review committee projects and proposals to ensure alignment with the OPTN Strategic Plan. The POC approved nine new projects during its January 2017 review.

6. DonorNet Attachments

UNOS staff provided an update on the proposed changes to how attachments are uploaded into DonorNet. This issue was initially discussed as part of the limit paper documentation project and has also been mentioned during discussions of other projects, such as the system optimizations project. The goal of these changes will be to better facilitate the uploading of attachments by

OPOs, provide more consistency, and make it easier for transplant centers to find and use attachments.

The Committee provided the following suggestions:

- The Committee members acknowledged that the biopsy results category captures biopsies performed by the OPO. The Committee questioned whether the "Biopsy, other (specify)" should also capture previous pathology results. There was a suggestion to create a biopsy subcategory to delineate between current and previous test results.
- Medical and social history – One committee member noted that the new location for attaching medical and social information is on the donor summary/details page in DonorNet. UNOS staff noted that this scenario comes up within the other tabs, such as with CT reports, and the purpose for the proposed change is so all the attachments are on the same page.
- Liver and kidney biopsy images and reports – The Committee discussed whether to separate the images from the reports. It was determined that by clicking on the biopsy report dropdown you will see separate files for the image and the report. The Committee suggested identifying the kidney biopsy by laterality.
- The Committee discussed the ability to perform an audit report to see who has viewed the attachments. For example, if there are previous CT scan reports that are not necessarily being used to determine organ function, but the OPO wants the transplant centers to be aware of the results, it will be important to have the audit functionality.
- The Committee noted that it is important for tests to have an explanation in the comments field, but this would not be necessary for the attachments.

The Committee agreed it is important to develop an educational tool for OPOs and transplant centers once we finalize the changes.

7. DTAC Guidance Document

The DTAC chairman provided an overview of the Guidance on Explaining Risk Related to Use of Increased Risk Donor Organs When Considering Organ Offers. The Committee briefly discussed how some OPOs are changing their approach, largely as a result of the recent opioid epidemic, to infectious disease testing practices in order to best deal with the "window period" for infection. OPOs provided examples of practice changes including delaying testing by a couple of days, if allocation timing allows, or performing repeat testing. The involved OPOs believe this will allow for a better opportunity to confirm a positive exposure to certain infectious diseases. The Committee acknowledged the variability in practice based on the availability of testing. The Committee supports the guidance document.

8. Data Reporting Presentation for OPOs

UNOS Research staff provided an update on data reporting that is available to members. This included:

- OPTN Website
- UNOS Data Request System
- National DSA Dashboard
- UNet^{sm} Data Services Portal
    - ABO Validation
    - Deceased Donor Organ Outcomes
    - Wait List Registrations by Zip
    - Transplants by State
    - Transplants by Zip

    - National Residence Reports
    - OPO ROO Data File
    - OPO ROO Visualization – Demo using Tableau
- Organ Utilization Tool (OUT) – Demo using Tableau
- Recovery and Usage Maps (RUM) Report – Demo of report in development

9. SRTR Report on Kidney Offer Acceptance

The SRTR is developing a kidney offer acceptance report that will have three broad goals. These include providing general offer acceptance information in the public reports, giving detailed information to programs, and communicating relevant information to organ procurement organizations (OPOs). The plan is to provide general offer acceptance information for all offers and across important subgroups. Within the secure site OPOs will be able to access a report that categorizes the offer acceptance behavior of programs for subgroups of organs with hard-to-place characteristics. This includes high KDPI, PHS increased risk, DCD, and HCV. The "history of acceptance" uses a five-tier system of above average, somewhat above average, average, somewhat below average, and below average acceptances. The programs are listed from above average down the below average based on the offer acceptance ratio which is the likelihood the program will accept that organ relative to national average.

One of the reasons for creating the OPO report is that the level of variability in program-specific offer acceptance practices is quite large. For example, for high KDPI kidneys there is a 130-fold difference in offer acceptance between the most aggressive and most conservative program. The tiers allow OPOs to quickly identify programs more likely to accept marginal kidneys despite the large variability in offer acceptance practices.

One Committee member asked if the center identifying information is blinded. SRTR staff noted that an unblinded version is available to OPOs on the secure site. There was also a suggestion to also look at low weight (<15 kg) donor kidneys and centers more or less likely to transplant them. SRTR staff agreed to evaluate the suggestion.

10. Imminent and Eligible Definitions

The OPTN Contractor began collecting patient level data for all imminent and eligible deaths on January 1, 2008 in hopes that OPOs would have better performance modeling and identify missed donor opportunities. Periodic data review demonstrated large inconsistencies and variations in how OPOs reported data so the OPO Committee began work to revise the definitions in 2009. The Committee developed a list of organ specific exclusionary criteria and eliminated multi system organ failure (MSOF) as a criterion. The changes were approved by the Board in June 2013 and ultimately implemented on Jan. 1, 2017 following CMS regulatory changes.

Since implementation, several members of the community have expressed concern about "eligible casualties" which are cases previously defined as ineligible due to the inconsistent application of the MSOF category. The Committee noted that during the development of the proposal, the Committee conducted a comparative study based on 2 months data with 10 OPOs. The results showed a 4% increase in eligible deaths and a 30% decrease in imminent deaths. The Committee members agreed that if all OPOs are applying the new definitions as written, there is an expectation that imminent numbers will drop. One Committee member suggested that this message be distributed to OPOs in order to alleviate some of the concerns.

There have also been a number of questions raised by members regarding the application of the new definitions. Examples include how to assess sedation or no spontaneous breathing, how to handle the "one off" diseases or syndromes, and how to apply organs deemed not medically suitable after recovery. These questions are currently being handled by the liaison

and committee leadership. The Committee members were reminded to forward any questions they might receive to the committee liaison so that consistent answers can be provided to members.

Committee leadership noted that during a recent meeting there seems to be a general sense of ease in applying the definitions. There will also be a session at the upcoming AOPO annual meeting which is an opportunity to discuss the early observations and hear additional feedback. The definitions have only been in place for four months so it is too early to analyze the true impact of the changes. While the new definitions might drop conversion rates, there is also the potential to increase donation and transplantation by encouraging OPOs to pursue donors they haven't previously pursued. The Committee agreed to develop additional education materials such as frequently asked questions and a webinar based module.

Finally, the Committee recommended that site surveyors look at referral information and not focus solely on data that is reported on imminent and eligible deaths.

Upcoming Meeting

- June 13, 2017