OPTN/UNOS Organ Procurement Organization Committee
Meeting Minutes
October 25, 2017
Chicago, Illinois

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Introduction

The OPO Committee met in Chicago, Illinois on 10/25/2017 to discuss the following agenda items:

1. System Optimizations Work Group
2. Expedited Organ Placement Work Group
3. HOPE Act
4. Virtual Crossmatching
5. Policy Oversight Committee
6. Zika Study Work Group
7. Data Discussion
8. DCD Discussion
9. UNOS IT Update
10. VCA Guidance Document

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

1. System Optimizations Work Group Update

Summary of discussion:

During public comment, five of the eleven regions supported the proposal in its entirety, four regions approved the proposal with amendments, and two regions did not approve the proposal. Three of the regions approving the proposal with amendments had the same recommendation to combine the proposed 30 minute/30 minute time limit for the initial two responses to electronic organ offers to a combined 60 minutes. One region approved the proposal for all organs except kidney. Several OPTN/UNOS committees reviewed the proposal: Liver and Intestine, MPSC, Transplant Coordinators, Transplant Administrators, Kidney and Thoracic. All were supportive of what the proposal is trying to do to improve organ placement and provided recommendations. The proposal also garnered feedback from several individuals and the following societies; their input is noted in subsequent sections below:

- American Society of Transplantation (AST)
- American Society of Transplant Surgeons (ASTS)
- Association of Organ Procurement Associations (AOPO)
- North American Transplant Coordinators Organization (NATCO)
- International Society of Heart and Lung Transplantation (ISHLT)

The Committee identified several similar themes identified during public comment and made policy language modifications to address the concerns. The themes, and the Committee's response, are detailed below.

Electronic Organ Offer Time Limits

Most of the public comments were in response to the reduction in time limits for acknowledging and evaluating electronic organ offers. The Committee was proposing that the current time limit of 1 hour for each response be reduced to 30 minutes for each.

The comments were predominately from the transplant hospital perspective. The common concerns included:

- Not providing enough time to review information to make an informed decision
- Not enough time to consult with other members of the team
- Busy programs can have multiple offers coming in for different candidates
- Shortened time might lead to more provisional yes responses

During the development of the proposal, the Committee's review of data showed that responses were received within 30 minutes of initial notification and evaluation across all organs in 90% of cases. The Committee agreed that in order to speed up the placement of organs, the total response times should be reduced from 2 hours to 1 hour.

The following commenters recommended that the two time limits be combined, allowing transplant hospitals a total response time of 60 minutes:

- Regions 4, 5, and 8
- Thoracic Organ Transplantation Committee
- Liver and Intestinal Organ Transplantation Committee
- Association of Organ Procurement Organizations

The Committee discussed the recommendation and agreed to modify the proposed policy language.

1 Hour Time Limit for Final Decision

This proposed change received the second highest number of responses. The Committee is proposing this new time limit because there is currently no policy language that allows an OPO to move on to the next candidate on the match run if a transplant hospital does not make a timely decision once their candidate becomes the primary offer. The responses received from the OPO and transplant hospital perspectives were antithetical. From a transplant hospital perspective, the comments focused on the time limit being too short to properly evaluate the donor information. Additionally, some comments noted that kidney programs need to contact their candidates and wait for final crossmatch results. From an OPO perspective, the comments suggested that one hour was too long and would be counter to the goals of the proposal. Additionally, several OPO commenters suggested the change was in conflict with *Policy 5.4.D: Backup Organ Offers* which requires transplant hospitals to "treat backup offers the same as actual organ offers and must respond within one hour of receiving the required deceased donor information for an organ" and recommended the policy remain silent on a time limit for a final decision.

Committee leadership discussed the comments and agreed that reducing the new one hour time limit to 30 minutes was a reasonable compromise. This language was presented to the System Optimizations Work Group during a conference call on October 19th and they agreed. While reviewing the revised policy language, the OPO Committee determined that the revisions did not meet the intent of what was presented during public comment. Additionally, the Committee agreed that the policy should differentiate between the initial primary offer and all other offers with a provisional yes response. The Committee agreed to specify that the primary transplant hospital will have one hour to make a decision once all required deceased donor information has been provided by the host OPO. All other transplant hospitals with a provisional

yes acceptance will have 30 minutes to make a decision once they are notified that they are now the primary offer and all required deceased donor information has been provided by the host OPO.

Another concern raised during public comment was the timing of the final crossmatch results for kidney donors. Kidney programs are hesitant to commit to an offer until they have final crossmatch results. The Committee discussed this comment and agreed that an exception should be made for final crossmatch results. Similar to the exception in the definition of organ offer acceptance that allows the organ offer acceptance to be "pending review of organ anatomy", the Committee added language stating that for "kidney offers, acceptance is also pending final crossmatch."

Organ Offer Acceptance Limit

This proposed change did not garner many comments. The Liver and Intestinal Organ Transplantation Committee supported the proposed limit as did the American Society of Transplantation. There were several recommendations to create transparency in the system so OPOs can view how many offers are being considered for a certain candidate.

There were several recommendations to create an exception for sicker candidates, such as fulminant liver and heart/lung failure candidates. The Committee ultimately decided that an exception was not necessary because transplant hospitals can still receive offers even if they already have two organ offer acceptances. They would just need to notify one of the host OPOs and release one of the previously accepted organs.

Deceased Donor Information

There was general support for the OPO Committee's effort to simplify and reorganize the list of required deceased donor information. However, the Thoracic Organ Transplantation Committee and the International Society for Heart and Lung Transplantation (ISHLT) both expressed concerns about the modifications to the list of required deceased donor information. They both recommended that OPOs be required to document why a bronchoscopy cannot be performed. The Committee discussed this recommendation and added that language back into policy. They also recommended that the list of required donor information be expanded, not reduced.

The Committee discussed this recommendation and ultimately decided to leave the policy language as proposed. The work group that developed the policy proposal spent a considerable amount of time making changes to the policy to update and simplify the policy language and eliminate redundant information. This included creating a list of general categories instead of specific lists of information. For example, the list of specific tests such as blood urea nitrogen (BUN), creatinine, and bilirubin are all captured as part of the donor medical history and donor management information and do not need to be listed separately. There is also some version of medical and social history information required across the different organs. Again, this is all captured under the general medical, behavioral, and social history categories and does not need to be listed under every organ.

The Committee noted that OPOs do everything possible to maximize donors and place organs. They provide all the information required for every organ and work with transplant hospitals to provide any additional information requested. The effort to update and simplify *Policy 2.11: Required Deceased Donor Information* does not impact the commitment that OPOs have to provide transplant hospitals with the necessary information to make decisions about organ offers.

<u>Next steps:</u>

Following discussions and final review of the policy language, the Committee unanimously voted to submit the policy language to the Board of Directors in December 2017.

2. Expedited Placement Work Group Update

The Committee chair provided a brief overview of this project. This project was approved in January 2017 with the goal of developing policy to add transparency and improve access to organs allocated using expedited placement. The work group is initially focusing on liver allocation in order to develop a framework that could be used for the other organ systems. The work group has reviewed data to help form a decision on a path forward.

Data Summary

- Between 1/1/2015 – 12/31/2016, there were 462 liver matches identified as expedited placement.
- The number of expedited placements as a percentage of the total number of transplants per year is small (most OPOs less than 2%)
- MPSC reviews all out of sequence allocations
- MPSC closed approximately 99% of the cases they reviewed
- 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

Summary of discussion:

The work group has discussed the components of expedited placement which includes the trigger, mechanism, and planned course. The work group has determined that two pathways need to be developed. 1) Pre-OR and 2) in the OR. The work group has also been discussing how transplant hospitals qualify for expedited placement lists.

Next steps:

The Committee will finalize a concept paper that will distributed for public comment in January 2018.

3. Other Significant Items

HIV Organ Policy Equity Act Update

UNOS staff provided an update on HOPE Act transplant activity which is summarized below:

- 37 programs across 21 transplant centers participating in HOPE Act research
- 34 transplants performed using organs from 14 deceased donors. (23 kidney, 11 liver)
- HIV positive transplants took place in 4 of the 11 regions
- Organs were recovered from 14 different OPOs

Due to the low number of transplants performed since the HOPE Act was implemented on Nov. 21, 2015, the OPO Committee developed a survey to find out if there are barriers preventing the utilization of organs from HIV positive donors. 42 of the 58 OPOs responded to the survey and some of the highlights included:

- 24 of the responding OPOs (57%) participate in the research
- Most common barrier is “low number of HIV positive individuals in the DSA”
- Lack of transplant center interest
- Most OPOs participating have a formal process to actively pursue organs from HIV positive donors

- Only one OPO stated that the NIH research criteria was a barrier
- No OPOs stated that state laws were a barrier

The goal of HOPE Act research is to study the feasibility and safety of performing transplants from HIV positive donors into HIV positive candidates who are willing to accept such organs. While the number of transplants has remained low, the Committee acknowledged the importance of this research. While the plan to "evaluate the results of the research" has not been determined, the OPO Committee agreed that the variance should be extended. The current expiration date is set for January 1, 2018. The OPO Committee unanimously voted to extend the expiration date to January 1, 2020. This request will be considered by the Board of Directors during its meeting on Dec. 4-5, 2017.

Virtual Crossmatching

The OPO Committee Chair provided the background information for this topic which originated from a memo from the Kidney Transplantation Committee. There was a member request to require OPOs to provide blood samples for the top 2 ranked highly sensitized (99-100% CPRA) candidates on the kidney match run. The Committee acknowledged that virtual crossmatching is a very predictive tool but not 100% accurate. However, the increased use of virtual crossmatching could potentially reduce the number of requests for blood samples prior to shipping kidneys. The Committee had previously deferred any action until it consulted with the Histocompatibility Committee ("Histo Committee").

The Histo Committee Chair noted that the key to this discussion is to better understand the center-specific practices. For example, what level of scrutiny are centers assigning unacceptable antigens for virtual crossmatch for candidates in order to predict a negative physical crossmatch? He also noted that results can depend on the type of material used for the crossmatch. For example, the level of HLA antigen expression for peripheral blood compared to other materials such as lymph nodes or spleen.

The Histo Committee is planning to review the percentage of kidneys that are shipped and eventually turned down for a positive crossmatch. They want to determine, at the transplant center level, if the same candidates are being offered kidneys and receiving positive crossmatch multiple times. In such cases, the transplant centers should use that information to update the list of unacceptable antigens which will allow the virtual crossmatch to become a better predictor of a negative physical crossmatch.

The OPO Committee will work with the Histo Committee to develop a survey to collect information on current practices. This information will help identify the next steps for developing additional educational materials.

Policy Oversight Committee Update

The OPO 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 and provide recommendations to the Executive Committee. Some of the most recent work of the POC included:

- May 2017 – Reviewed all 23 ongoing projects
- July 2017 – Reviewed 13 public comment proposals and 3 new committee projects
- September 2017 – Reviewed 1 new committee project
- October 2017 – Reviewed several goal 2 projects that could potentially be started depending on the Board's decision on the liver proposal in December

The Committee was provided with an update on the current alignment of projects and the anticipated availability of resources following the December 2017 Board of Directors meeting.

UNOS staff noted that as resources become available within certain Strategic goals, committees will have the opportunity to bring projects forward for review by the POC.

Zika Study Work Group

The Committee Chair provided an overview of the first work group meeting that was held on Oct. 20, 2017. The Health Resources and Services Administration (HRSA) requested the OPTN conduct a pilot project to collect data on zika testing results. The goal of this project is to assess the ability of the OPTN to quickly respond to a public health situation by creating an electronic infrastructure for data collection. The idea is to enlist OPOs willing to ship blood specimens to specific test sites to begin data collection. The concerns raised by the OPO Committee include:

- Logistics and cost
- Timing of tests
- Impact of false positives on organ and tissue donation
- What will OPOs be required to do with the information?
- Can the zika assay can be replicated at other sites?
- Impact on donor families
- Ability to respond to a public health situation will be dependent on the development of an appropriate screening test?

The OPO Committee agreed to provide additional representatives for this work group. The Committee will be provided with periodic updates as this work moves forward.

Data Discussion

Adding Toxoplasma to the Deceased Donor Registration (DDR)

UNOS Research staff noted that toxoplasma (IgG) was recently added to DonorNet®. The Committee was asked if this data point should be added to the deceased donor registration (DDR) form so that toxoplasma results can be used in risk adjustment models. The Committee unanimously supported this recommendation.

Member Question about the Death Notification Registration (DNR)

The Committee discussed a member concern about the authorization question on the death notification registration (DNR). For the question “Has authorization been obtained for organ donation?” only one of the following responses is required: “Yes”, “No”, “Authorization Not Requested”, and “Registry-Yes.” The member provided several scenarios that outlined the potential confusion when attempting to respond to the question. The Committee discussed whether this should actually be two separate questions as outlined below:

- Designated as a donor/signed up on a state registry?
  - Yes
  - No
- Has authorization been obtained for organ donation?
  - Yes, first person authorization
  - Yes, next of kin
  - No
  - Authorization not requested

One committee member noted that the registry question could also apply to a national registry. Another committee noted that the intent is to answer two questions. How many people are registered and has authorization been obtained for organ donation? The Committee also agreed it might be beneficial to see how many OPOs are pursuing first person authorizations for

donation after circulatory death (DCD) compared to brain death donors. The Committee agreed to form a small work group to address these questions.

Donor Hospital Project

UNOS Research staff noted that due to the ongoing broader sharing discussions, there is a project underway to identify a more precise location for donor hospitals. Currently, it is based on the zip code which varies greatly in size across the country. Initial discussions have focused on using the street address of the donor hospital. Committee members noted that most OPOs maintain the physical address of the hospital in their electronic medical records because they use it to deploy staff to the location. Committee members also noted the following scenarios should be included in the discussions:

- OPO recovery facilities
- DCD referral from a hospital that does not recover DCD donors
- Transferring to higher level of care
- Location of death declaration

The Committee agreed to assign several members to participate in these discussions.

DonorNet Attachments

UNOS staff provide an update on the proposed changes to how attachments are uploaded into DonorNet. The Committee agreed with the final list of categories and supported moving forward with the changes. UNOS Research staff noted that the changes will impact several other applications such as the user interface, organ center fax utility, and application programming interface.

DCD Policy Discussion

Committee leadership received a question from a member regarding *Policy 2.16: Requirements for Controlled Donation after Circulatory Death (DCD) Protocols*. The question focuses on the language that states “prior to the OPO initiating any discussion with the legal next-of-kin about organ donation for a potential DCD donor, the OPO must confirm that the legal next-of-kin has elected to withdraw life sustaining medical treatment.” The Committee discussed whether it was acceptable for OPO staff to accompany hospital personnel during the initial discussion about withdrawing life sustaining medical treat? The Committee also questioned whether OPOs need to have a separate discussion about DCD donation or can that be part of the “general” donation discussion. The Committee acknowledged that the practice varies across OPOs. The Committee members noted that the policy language should be revisited to ensure it is up to date with current palliative care practices. Several committee members noted that the current language was in response to several professional organizations who expressed concerns about the policy when it was distributed for public comment in 2013.

The Committee also discussed the timing of the healthcare team’s decision not to escalate care because the family is not ready to make a decision about donation. This could potentially lead to lost organs. Committee members shared examples of times where families have stated that they wish they had be made aware of donation earlier in the process. Committee members acknowledged that in the past a separate conversation was probably acceptable. However, with families being more educated about donation and the passage of first person authorization laws, the process becomes more dynamic and OPOs need to be able to adjust to meet the needs of the donor families.

There were several committee members that believed there should still be a separation between the end of life discussion and the donation discussion. However, the Committee

members noted that it might be acceptable if OPO personnel are supporting the healthcare team during the discussions.

The Committee agreed that *Policy 2.16: Requirements for Controlled Donation after Circulatory Death (DCD) Protocols* should be reviewed to determine if the policy needs to be updated. The Committee formed a work group to develop a project form.

UNOS IT Update

Offer Filters Project

The Committee was provided with an update on the offer filters project. Programming has begun and should be completed in the second quarter of 2018. The pilot program will initially focus on kidney candidates and donors. There are two parts to the pilot:

- Waitlist pilot will allow kidney transplant programs to create offer filters for their kidney candidates.
- The DonorNet Pilot will apply profiles prospectively on live kidney matches. Offers will not be screened but users will be able to see which offer filters apply to a particular organ offer.

Imaging Project

The Committee was provided with an update on this project that will allow OPOs to share imaging studies such as echocardiograms, CT scans, ultrasounds, and biopsies within DonorNet. OPOs would log into DonorNet to upload imaging studies and link the study to the donor record. Transplant Hospitals will be able to view the imaging study similar to how they view other attachments.

This pilot project is estimated to begin in the second quarter of 2018. This will require programming by both UNOS and the imaging sharing service in order to provide seamless integration with the DonorNet and to provide reliable uploads with the image sharing service. The project will require both OPO and transplant hospital participation.

Innovations Events

The Committee was provided with an update on the following projects that were developed as a result of discussions at several national conferences:

- Addition of transplant center contact information to match page in DonorNet *(November 2016)*
- Hide Refusals and Bypasses on Match Run *(December 2016)*
- Addition of O.R. times and “follow me” functionality *(May 2017)*
- *OPO – ABO Modal Window - Released*
    - Provide additional printable screen
        - 1st person who entered ABO (date/time stamp)
        - 2nd verifier (date/time stamp)
        - Same for subtype verification
- Transplant center – LI Waitlist Removal Labs - *Released*
    - Allow users to select the last set of labs to populate in removal labs section (editable)
- OPO/Transplant center – Notification of Primary/Backup – *December 2017*
    - Method to notify transplant center that their candidate is primary or back up
- Change highlight color for primary on match - *Released August 2017*
- Change to notification message – *December 2017*
- Add 5 DDR infectious disease test results missing in DonorNet - *December 2017*

- Add TXC name for primary on-call contact - *Released October 2017*
- Format phone numbers on OPO Console - *Released October 2017*
- Identifying information on Tiedi – *Coming soon*
- Post Recovery Test Results
    - Allow OPOs to electronically notify transplant centers when new information has been added to a donor record post recovery
- Donor XML Project
    - Eliminate errors when uploading data into DonorNet
    - Allowing data to flow seamlessly between the two systems
- Enhancements to the report of organ offers (ROO)
    - Increase the usability and available data in both the Tableau dashboards and Excel spreadsheets available on the Data Portal

<u>VCA Committee Guidance Document</u>

The Committee was provided with an update on the progress of the VCA Guidance Document for OPOs. This document will contain some background information on VCA transplantation, benefits of VCA transplantation, and recommendations and effective practices. The key considerations for the OPO Committee include identifying knowledge gaps on authorization and procurement. This guidance document is scheduled to be distributed for public comment in January 2018.

Upcoming Meeting

- Conference Call - TBD
- April 17, 2018 in Chicago, IL

Attendance

- **Committee Members**
  - Jennifer Prinz RN, BSN, MPH, CPTC
  - Diane Brockmeier RN, BSN, MHA
  - Jennifer Vazquez, MSN, RN, CPTC
  - Carolyn Welsh
  - Marty Sellers, MD
  - Chad Ezzell, CPTC, CTP
  - Jennifer Muriett, RN, BSN, CPTC
  - Candy Wells, RN
  - Julie Kemink, RN, MBA, BA
  - Daniel Disante
  - Kellie Hanner, RN, BSN, CPTC
  - Donna Croezen, MSN, RN, CPTC
  - Helen Nelson, RN, BSN, CCTC, CPTC
  - Lori Brigham, MBA
  - Lori Markham RN, MSN, CPTC, CCRN
  - Laura DiPiero
  - Kurt Shutterly, RN, CPTC
  - Tara Storch
- **HRSA Representatives**
  - Joyce Hager (on phone)
  - Jim Bowman (on phone)
  - Robert Walsh (on phone)
- **SRTR Staff**
  - Bert Kasiske, MD
  - Alyssa Herreid
  - Noelle Hadley (on phone)
- **OPTN/UNOS Staff**
  - Robert Hunter
  - John Rosendale
  - James Alcorn
  - Alison Wilhelm
  - Kerrie Masten
  - Ellie Willard
  - Chris Wholley
  - Darren Di Battista
  - Rob McTier
  - Leah Slife
- **Other Attendees (on phone)**
  - Chris Curran
  - Robert Bray