

**OPTN/UNOS Organ Procurement Organization Committee
Meeting Minutes
April 17, 2018
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 04/17/2018 to discuss the following agenda items:

1. Expedited Organ Placement Work Group
2. System Optimizations Work Group Update
3. Deceased Donor Information Guidance Document
4. DCD Policy Review Project
5. Death Notification Registration Form
6. Donor Hospital Location Project
7. Ad Hoc Geography Committee Update
8. HIV Organ Policy Equity (HOPE) Act Update
9. Policy Oversight Committee Update
10. Recovery Date Discussion
11. Imminent and Eligible Death Definitions Data Report
12. UNOS IT Update
13. UNOS Research Update

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

1. Expedited Organ Placement Work Group

UNOS staff provided an overview of the comments received on the concept paper that was distributed during the January 22 – March 23, 2018 public comment period. UNOS staff noted that the concept paper was part of a pilot study to test new methods for collecting public comments. The goal of the study was to enhance the public comment process in order to increase public comment participation and gain more information to enable committees to perform public opinion and qualitative analysis on the substance of the comments submitted during public comment. UNOS staff provided an overview of the responder's relationship to transplant, how the responses were received, and overall opinion of the proposal:

- Responder's relationship to transplant
 - Transplant hospital - 78
 - OPO – 25
 - Family – 9
 - Other - 2
- How responses were received
 - Regional meetings – 107
 - Committee member - 25
 - OPTN website – 8
- Opinion of the proposal – 84% strongly supported or supported
 - Strongly support - 31
 - Support - 85

- Neutral - 16
- Oppose - 6
- Strongly oppose - 0

The Committee requested feedback on the following questions in the concept paper:

1. Should an allocation system include an expedited placement trigger based on defined donor characteristics that would allow an OPO to expedite the placement of an organ? 87% of the responders strongly or somewhat agreed.
 - Strongly Agree - 64
 - Somewhat Agree - 55
 - Neutral - 7
 - Somewhat Disagree - 8
 - Strongly Disagree – 3
2. Should an allocation system include an expedited placement trigger based on an event like an organ declined in the OR that would allow an OPO to expedite the placement of an organ? 89% of the responders strongly agreed or somewhat agreed.
 - Strongly Agree - 81
 - Somewhat Agree - 42
 - Neutral - 8
 - Somewhat Disagree - 3
 - Strongly Disagree – 4
3. Should the allocation system allow an OPO to move to an expedited list after a well-defined point in the allocation process (e.g., after offers to x candidates, after offers to x hospitals, within x hours of the scheduled OR time)? 88% of the responders strongly agreed or somewhat agreed.
 - Strongly Agree - 73
 - Somewhat Agree - 48
 - Neutral - 11
 - Somewhat Disagree - 3
 - Strongly Disagree – 3
4. Once an expedited placement trigger has been met, should the OPO use their own discretion to get the organ placed for transplantation?
 - Strongly Agree - 24
 - Somewhat Agree - 60
 - Neutral - 11
 - Somewhat Disagree - 27
 - Strongly Disagree – 17
5. Once the expedited placement trigger has been met, should the list of potential candidates be limited to those at transplant hospitals with a recent history of transplanting organs from similar donors?
 - Strongly Agree - 30
 - Somewhat Agree - 33
 - Neutral - 21
 - Somewhat Disagree - 30
 - Strongly Disagree – 25

6. Should transplant hospitals be allowed to choose whether or not they want to have their candidates on an expedited list?
 - Strongly Agree - 60
 - Somewhat Agree - 54
 - Neutral - 12
 - Somewhat Disagree - 8
 - Strongly Disagree – 5
7. Should the allocation system give higher priority to candidates more likely to accept an organ that has a higher likelihood of discard based on statistical models?
 - Strongly Agree - 20
 - Somewhat Agree - 51
 - Neutral - 31
 - Somewhat Disagree - 20
 - Strongly Disagree – 16
8. Should DonorNet[®] set a transplant hospital's acceptance criteria based on the hospitals past acceptance practices?
 - Strongly Agree - 18
 - Somewhat Agree - 30
 - Neutral - 14
 - Somewhat Disagree - 36
 - Strongly Disagree - 40

The goals of this project include providing more transparency, increasing access to organs, providing guidance for OPOs and transplant hospitals, and providing consistent expedited placement practices across the country. While there was a lot of support for creating an expedited placement system, there was limited support for OPOs using their discretion to place organs or using transplant hospital acceptance history. Committee members agreed that it would be difficult for a system to work without using acceptance history to identify transplant hospitals that actually accept organs based on a set of criteria.

The Committee members agreed to continue moving forward with this project by establishing criteria for the expedited placement triggers and using acceptance history as a starting point to identify transplant hospitals. The Committee did acknowledge that there needs to be a way for transplant hospitals to identify certain patients on their list that are in urgent need of an organ and would be willing to accept an expedited offer. The Committee agreed that while the previous work of other committees is important, they also recognized that the practices have changed over the years and there is an opportunity to explore new options.

The Committee also discussed having an “opt-in” or “opt-out” system as well as a system that does not exclude candidates but instead “changes the order” of the match run based on transplant hospital acceptance history. One committee member noted that some transplant hospitals might be willing to accept an expedited offer, just not for a candidate higher on their list.

UNOS Information Technology staff provided an update on the offer filters project. Offer filters will allow transplant hospitals to use criteria in combination to screen offers more precisely.

Waitlist currently allows transplant hospitals to enter donor acceptance criteria for candidates; however, these criteria can be broad. For example, transplant hospitals can set a maximum acceptable donor age rather high in order to avoid missing offers from healthy older donors. UNOS IT staff provided a demonstration of how the tool works and the additional screening

criteria available. The Committee fully supports this project and agreed that this tool would be useful in conjunction with expedited placement.

UNOS Research staff provided an overview of additional concepts that the Committee could consider as they move forward with this project. These include using various factors such as donor characteristics, probability of discard model, likelihood of acceptance, and candidate specific screening criteria. Most of the work has been done using kidney but the models could be applied to other organs. The Committee members were extremely interested in this concept but acknowledged that more details need to be worked out.

The Committee agreed that all of these concepts and tools should be considered by the expedited placement work group as they move forward with a proposal.

2. System Optimizations Work Group Update

UNOS staff provided an update on the implementation of the policies that were approved by the Board of Directors in December 2017.

- Changes to Policies 2.2 (OPO Responsibilities) and 2.11 (Required Deceased Donor Information) as well as the elimination of Policy 2.12 (Requested Deceased Donor Information) went into effect on March 1, 2018 since no programming was required.
- Changes to Policies 1.2 (Definitions) and 5.6.B (Time Limit for Review and Acceptance of Organ Offers) will go into effect on May 2, 2018.
- Changes to 5.6.C (Organ Offer Acceptance Limit) will go into effect on June 13, 2018.

UNOS staff noted that educational and system notices were distributed in early April with additional communications planned leading up to the implementation dates for the policies.

The Committee briefly discussed next steps for this project. Several committee members noted that the “provisional yes” is an issue that still needs to be addressed.

3. Deceased Donor Information Guidance Document

The Committee reviewed the public comments received on the guidance document that was distributed during the January 22 – March 23, 2018 public comment period. The guidance document was supported by all eleven regions and four professional organizations. Three of the organizations commented that the guidance document could be strengthened by inclusion of kidney biopsy reports and the use of telepathology. The Committee reviewed the recommendations and agreed to make the change. There were a couple of recommendations to include a reference to the guidance document in policy. The Committee did not accept this recommendation because OPTN policy does not include references to documents outside of policy. The Committee noted that these are guidelines and do not supersede the need for communication between transplant centers and OPOs.

The Committee reviewed the final language and recommended one minor change to also include telepathology under the liver biopsy section.

The Committee voted unanimously to submit the guidance document to the Board of Directors in June 2018.

4. DCD Policy Review Project

UNOS staff provided an update of this proposed project. The work group met in January 2018 to discuss the necessary information to include in the project form prior to submitting it to the Policy Oversight Committee (POC). Internal review of the project form led to the decision to allow the committee to review the entire policy in order to determine exactly what changes might need to be made to the policy. The work group members reviewed *Policy 2.15: Requirements*

for *Controlled Donation after Circulatory Death (DCD) Protocols* and determined that the policy should be modified to allow more flexibility around the timing of the DCD donation discussion. The Committee plans to submit a revised project form to the POC in June 2018.

5. Death Notification Registration (DNR) Form

The Committee discussed proposed changes to the death notification registration form. This change originated from a member concern about the following question and how to accurately answer the question:

- Has authorization been obtained for organ donation? There are four responses to choose from including yes, no, authorization not requested, or registry-yes. This is a required field and only one response is permitted.

During a previous meeting, the Committee agreed that this question should actually be two separate questions. The rationale was that the community is really interested in analyzing two things: How many people are registered and has authorization been obtained for organ donation?

The Committee reviewed the following proposed questions and the corresponding help documentation:

1. Did the patient legally document their decision to be a donor?
 - Yes
 - No
 - Unknown

Help Documentation:

Did the patient legally document their decision to be a donor? If the patient had a donor designation such as donor registration (online registration, driver's license, etc.), donor card, or other written legal documentation – select "Yes." If not, select "No." If unable to check the registry, select "Unknown."

2. Has authorization been obtained for organ donation?
 - Yes, first person authorization
 - Yes, hierarchy utilized
 - No, declined
 - No, not requested

Help Documentation:

Has authorization been obtained for organ donation? If authorization was obtained through first person authorization (registry, donor card, etc.) – select "Yes, first person authorization." If authorization was obtained through the hierarchy– select "Yes, hierarchy utilized." If authorization was pursued but not obtained through first person authorization or the hierarchy – select, "No, declined." If authorization was not requested – select "No, not requested."

The Committee recommended a minor change to the help documentation for question 1. Instead of "if it is unknown whether or not the registry was searched, select unknown" the Committee recommended the following language: "If unable to check the registry, select unknown." The Committee supported the work group's proposed definition of hierarchy which is "the list of the persons, who are reasonably available, in order of priority stated by the relevant state's uniform anatomical gift act, who are legally entitled to make an anatomical gift."

Finally, the Committee supported the proposed deletion of the following questions:

- Did this referral meet your DSA definition of a timely referral? Yes or No
- Did authorization process meet your DSA definition of effective requesting? Yes or No

The rationale for deleting these questions was that they do not capture a standard across all donation service areas.

The Committee unanimously supported the proposed changes by a vote of 14 in favor, 0 oppose, and 0 abstentions.

The Committee agreed that the next step is to submit the proposed changes to the Data Advisory Committee and UNOS Data Governance department. They also agreed that the revisions and deletions should be considered separately in case there are concerns raised about one of the recommendations, the other one can move forward.

6. Donor Hospital Location Project

UNOS IT staff provided an update on the donor hospital location project. One of the goals of this project is to improve the data on donor hospital locations. UNOS staff noted that they are currently working to compile a list of addresses for each active donor hospital. Committee leadership recommended that each OPO could run a report from the electronic records and submit it. If UNOS IT staff could provide a template or format for the information, it would help OPOs provide the information. UNOS IT staff noted they will be sending an email to OPOs in May 2018. The Committee members made a recommendation to send the email to all OPO Executive Directors/Chief Executive Officers and include each of the OPO's UNet administrators.

7. Ad Hoc Geography Committee Update

The Committee was provided with an update on the work of the Ad Hoc Geography Committee. This Committee was formed at the December 2017 Board of Directors meeting because of several recent projects addressing organ distribution policies. The purpose of this Committee is not to change existing policy, but to recommend organ distribution principles and models that are aligned with the Final Rule and can be used when analyzing and reviewing our policies. The Committee will provide recommendations to the Executive Committee and the Board of Directors in June 2018.

One Committee member asked what principles are being discussed. UNOS staff noted that the principles are still being discussed with no final decision at this point. More information will be provided to the community following discussions at the Board of Directors meeting in June 2018.

8. HIV Organ Policy Equity (HOPE) Act Update

UNOS staff reminded the Committee that in December 2017, the Board of Directors approved an extension of *Policy 15.7 (Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors)* which was scheduled to expire on January 1, 2018. The new expiration date is January 1, 2020.

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

- 40 programs across 23 transplant centers are participating in HOPE Act research
- 50 transplants have been performed using organs from 24 deceased donors. (31 kidney, 18 liver, and 1 en-bloc kidney)
- HIV positive transplants took place in 9 of the 11 regions
- Organs were recovered from 19 different OPOs

9. Policy Oversight Committee Update

The Committee was provided with an update on the activities of the Policy Oversight Committee. The POC has reviewed seven projects since the last update in October 2017. The POC also reviewed twelve public comment proposals prior to public comment in January 2018. Finally, the POC will review the entire committee project portfolio as its upcoming in-person meeting on May 7-8, 2018 in Richmond, Virginia.

10. Recovery Date Discussion

The Committee was provided with an update on this issue that came up during public comment. The Operations and Safety Committee distributed a proposal during the January 22 – March 23, 2018 public comment period to address changes to the extra vessel policies. The Operations and Safety Committee received feedback requesting that they address how the extra vessels recovery date is determined and recorded. Currently, the recovery date is determined based on the date the donor enters the operating room. This date is used by the extra vessel reporting system to calculate both the 14 day limit on extra vessel storage and the 7 days to report final disposition.

Another consideration is the use of TransNet. Because the extra vessels labels are printed in real time, this could potentially lead to confusion or errors when determining the correct date for the expiration of vessel storage as well as mandatory reporting by transplant hospitals. Therefore, the Operations and Safety Committee is working to align these dates by proposing policy changes that will define the donor recovery date as the cross-clamp date.

The OPO Committee fully supports this change and expressed interest in being involved in the policy development.

11. Imminent and Eligible Death Definitions Data Report

UNOS Research staff presented a report to review the first year of data since the eligible and imminent neurological death data definitions changed on January 1, 2017.

Highlights of the data report comparing 2016 to 2017:

- Eligible deaths reported: There was an 8.7% increase from 10,719 to 11,653.
- Imminent deaths reported: There was a 16.8% decrease from 12,725 to 10,587.
- All DNRs reported: 5.1% decrease from 23,444 to 22,240.
- The percentage of increase in eligible deaths by Region ranged from 3.0% for Region 5 to 19.2% for Region 10.
- The percentage change in imminent deaths ranged from a 66.4% decrease in Region 6 to a 17.8% increase for Region 2.
- Eligible deaths reported by OPO ranged from 45 to 576. 14 OPOs had a decrease while 44 OPOs had an increase in reported eligible deaths.
- Imminent death reported, 39 OPOs had a decrease and 19 had an increase. The largest decrease was 88.5% and the largest increase was 616.7%.
- Eligible deaths for donors greater than or equal to 71 years of age, 11 OPOs did not report any eligible deaths.

There was some concern about the 11 OPOs that did not report any eligible deaths for donors 71-75 years of age. There was a comment made by committee leadership about the possibility of reaching out to those OPOs to figure out what might be happening.

One Committee member asked if there was some way to capture the hepatitis C (HCV) positive donors, whether it is nucleic acid testing (NAT) or antibody testing, because they had a lot of donors fall into the higher age group that were HCV positive. UNOS staff noted that there is

limited clinical information provided on the DNR for those eligible donors that do not proceed to donation.

12. UNOS IT Update

UNOS staff provided an update on the DonorNet® attachments project. This project was initiated following the proposal several years ago to limit the amount of documentation required to be packaged and shipped with organs. The Committee made a commitment to improve how attachments are uploaded by OPOs so that transplant hospitals can easily access them. This included creating categories and subcategories for the attachments. UNOS staff noted that on the attachments page in DonorNet, the list of categories includes a number next to the name showing how many attachments are currently uploaded into that particular category. This project is scheduled to be implemented in early 2019.

UNOS staff provided a schedule of upcoming innovation events. The next event is scheduled for August 2018 at the NATCO Annual Meeting. One of the ideas being developed for that meeting is to provide the ability for transplant hospital users to search by Donor ID on the organ offer report instead of requiring the Match ID. Another idea is to create a tool in custom report generator that would allow members to assign permissions to other individuals at their centers, not just the site administrators. One of the committee members asked about the ability to share the reports. UNOS staff noted that members can save the reports on their desktop to share them that way. Another question was raised about giving members the ability to see what other reports have been requested by other members.

There is also an idea being presented that could add a link to comment fields (such as medical/social history, donor highlights, etc.) that will display the contents of the audit table such as change user, change date and change requester information. Several Committee members expressed concern about showing every change made in DonorNet prior to a match run being generated. Once a match run is generated, the Committee members agreed that is reasonable to provide that information.

Finally, UNOS staff noted there are discussions to improve the medication/fluids page in DonorNet. One Committee member noted that during the System Optimizations Work Group discussions, there were discussions about the need to improve some of the pages in DonorNet to better display donor information for transplant hospitals. For example, there is currently no place to enter information about continuous renal replacement therapy and other types of dialysis which provides important information for kidney programs.

13. UNOS Research Update

UNOS staff briefly discussed the need to address several issues with the deceased donor registration (DDR) form. The Committee agreed to form a small work group to address these issues.

Upcoming Meeting

- Conference Call - TBD