

OPTN Organ Procurement Organization (OPO) Committee

Meeting Summary

October 21, 2020

Conference Call

Diane Brockmeier, RN, BSN, MHA, Committee Chair

Kurt Shutterly, RN, CPTC, Vice-Chair

Introduction

The Organ Procurement Organization (OPO) Committee (the Committee) met via Citrix GoToMeeting teleconference on 10/21/2020 to discuss the following agenda items:

1. Clarify Multi-Organ Policies Project Update
2. Deceased Donor Registration (DDR) Review Project Update
3. Policy Oversight Committee (POC) Update
4. Additional Discussion Items

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

1. Clarify Multi-Organ Policies Project Update

The Committee was updated on the progress that the Multi-Organ Policy Review Workgroup has made on rewriting Policy 5.10.C. The following are the allocation criteria for heart-liver, lung-liver, heart-kidney, and lung-kidney candidates proposed by the workgroup:

Heart-Liver:

- Status 1, 2, or 3 heart candidates, OPO offers the liver if multi-organ transplant (MOT) candidate within 500 NM requires second organ
- No Status 1, 2, or 3 heart candidates within 500 NM, allocate liver alone to Status 1A, 1B, or MELD/PELD 35 or higher candidates prior to allocating to remaining heart statuses
- No Status 1, 2, or 3 heart candidates or liver Status 1A, 1B, MELD/PELD 35 or higher liver candidates - OPO determines next steps, allocates according to organ-specific policies

Lung-Liver:

- Lung candidates with a lung allocation score (LAS) of greater than 35, OPO offers liver if MOT candidate within 500 NM requires second organ
- Lung candidates with LAS of less than 35 within 500 NM, allocate liver alone to Status 1A, 1B, MELD/PELD 35 or higher candidate prior to allocating to other lung candidates
- No lung candidates with LAS greater than 35 and no liver Status 1A, 1B, MELD/PELD 35 or higher liver candidates – OPO determines next steps, allocates according to organ-specific policies

Heart-Kidney:

- Status 1, 2, or 3 heart candidate should also get kidney if MOT candidate is within 500 NM
- No Status 1, 2, or 3 heart candidate, allocate kidney alone following 1-7 classification
- No status 1, 2, or 3 heart candidates or Class 1-7 classification candidates - OPO determines next steps and allocates according to organ-specific policies

Lung-Kidney:

- Lung candidates with LAS greater than 35 should also receive kidney if MOT candidate within 500 NM
- Lung candidate with LAS less than 35, allocate kidney alone following 1-7 classification
- No lung candidates with LAS greater than 35 or 1-7 classification recipients - OPO determines next steps and allocated according to organ-specific policies

Summary of discussion:

Heart-Liver

A member inquired, out of the 45 heart-liver transplants in 2019, how many fit into the first or second category. A member stated that 37 of the heart-liver recipients were Status 1, 2, and 3. A member inquired whether these total numbers included pediatric patients. A member explained that pediatrics were included in this total and that pediatric candidates would be higher on the match list. A member inquired about the status of the remaining eight recipients and another member stated those recipients were Status 4.

A member inquired how many patients are currently waiting for a heart-liver and how many of these candidates were receiving transplants. UNOS Research staff agreed to see if this data is available.

Lung-Liver

A member noted that, of the 12 lung-liver transplants in 2019, all 12 recipients had an LAS of 35 or higher.

A member stated that this makes sense and is interested in seeing how the other multi-organs fit into this, such as a heart-lung-liver and a heart-liver candidate. A member stated that OPOs would still allocate that heart-lung with that patient being higher on the heart list. The member emphasized that this does not change the allocation list that OPOs have to follow.

Heart-Kidney

A member noted that, of the 219 heart-kidney transplants in 2019, 169 of those recipients were Status 1, 2, or 3. A member inquired about the kidney classifications 1-7. UNOS staff stated that classifications 1-7 were identified in order to capture medically urgent candidates.

A member inquired if there is specific criteria to list a heart patient to get a kidney, like there are now for liver patients. UNOS staff noted that there is currently no eligibility criteria for the kidney with the heart. Staff explained that this be part of the next phase of multi-organ discussion as well as the safety net.

Lung-Kidney

A member noted that, of the 13 lung-kidney transplants in 2019, all 13 recipients had an LAS greater than 35.

Additional Discussion

A member inquired what to do if an OPO has a heart-liver and a lung-liver to allocate. A member explained that the OPO will determine which list to use to allocate the organs, but they would still have to offer the multi-organ candidate before allocating to the liver alone candidate.

UNOS staff explained that the Committee did not want to mandate that OPOs have to use the heart match run or lung match run first. A member stated that, if the Committee does not mandate this, the

Committee should provide some level of guidance since there are going to be some OPOs struggling to operationalize this. A member suggested including a hyperlink on the match run, where OPOs can easily access the policy. Members agreed that the hyperlink idea is a good idea and that there needs to be clear guidance so OPOs are not making the allocation decisions. A member also pointed out that this is presuming that all the organs are of equal quality. If they are not, it will be a big factor in the OPO's decision about how to allocate.

Policy Language Discussion

UNOS staff presented two policy language options to the Committee. Both options include the criteria previously mentioned. The table in option 1 lists the combinations in separate rows, while option 2 combines the heart and lung combinations. A member noted that the biggest concern with the policy language is pulling livers away from sicker liver recipients and giving it to the heart or lung candidates, and this will probably come up during public comment. A member explained that, after discussion with the Liver Committee, they were supportive of this language and emphasized that there will be data collection to assess the impact of this policy change.

Members agreed that these options provide better guidance while also allowing flexibility for OPOs. A member stated that another concern was slowing the process down, but this could be addressed by having the first candidate on the liver list start coming in to the center before they know they are receiving a primary offer.

2. Deceased Donor Registration (DDR) Review Project Update

The Committee reviewed the progress that the Deceased Donor Registration (DDR) Review Workgroup has made regarding data modifications on the DDR form.

The following are the recommended modifications:

- Name – help documentation update
- Home city, state, and zip code – allow unknown and update help documentation
- Medical examiner/coroner – major change
- Did the patient have written documentation of their intent to be a donor – align with upcoming changes to the DNR
- Title of “Procurement and Authorization” section – remove “procurement”
- Serology – rename “infectious disease testing”
- NAT results – incorporate into “infectious disease testing”
- Inotropic medications at time of cross clamp – update to include “or at time of withdrawal of life-sustaining medical support” in order to capture DCD donors
- LV ejection fraction < 50% - update help documentation (use final echo)
- Coronary angiogram – better define “normal” and “not normal”
 - Normal – no evidence of coronary artery disease
 - Not normal – some evidence of coronary artery disease
- Was a pulmonary artery catheter placed?
 - Advanced invasive or minimally-invasive hemodynamically monitoring
 - 1 set of hemodynamic values (instead of initial and final)
 - Final set to be default
- Recovery date – replace with cross clamp information (move cross clamp information up)
- Recovery team # - use 4-digit code instead of provider number
- Flush/storage solution – remove requirement to report volume

The following are the recommended deletions:

- Was the authorization based solely on this documentation?
- Did the patient express to family or other the intent to be a donor?
- Tattoos
- Social Security number

The following are the recommended items to relocate in the DDR:

- Cardiac arrest since neurological event that led to declaration of brain death – update help documentation and move to organ recovery section
- Date/time of pronouncement of death – move to organ recovery section

The following are the recommended sections that need a complete overhaul:

- Donor Information section
 - Cause of death
 - Mechanism of death
 - Circumstance of death
- Organ Dispositions section
 - Reason code
 - Reason not transplanted

The DDR Review Workgroup asked for the Committee’s feedback on the following items:

- Citizenship – is this important to collect?
- If DCD, date/time organ recovered/removed from donor – potentially remove (or add DCD)
- Donor management – potential modification, donor records contain more detailed information
- Number of transfusions during terminal hospitalizations – collect volume, should there be a timeframe?

Summary of discussion:

A member questioned, in regards to the inotropes at the time of withdrawal of life support or life sustaining measures, whether there is some type of caveat around that because, historically, the number of hours that the patient was on inotropes used to be reported. For example, if this question is based on withdrawal of support and the DCD donor does not arrest for 90 minutes, is it relevant to capture information on inotropes given 90 minutes prior?

A member stated that it would not be as relevant, but noted that the focus is consistency between data collected on brain death donors and data collected on DCD donors. A member explained that this question is trying to capture if the patient was on inotropes at the time of cross clamp or withdrawal of support.

3. Policy Oversight Committee (POC) Update

The Committee reviewed the Strategic Policy Priorities and their involvement in ongoing work focused on these priorities.

The following are the Strategic Policy Priorities:

- Continuous distribution
- Multi-organ allocation
- Efficient donor/recipient matching to increase utilization

The following are the Strategic Policy Priorities projects the Committee is sponsoring or collaborating on:

- Multi-organ allocation: Sponsoring committee
- Efficient matching
 - OPO Committee identified as potential sponsor: Provision yes/conditional yes policy
 - OPO Committee identified as potential collaborator:
 - Provisional yes/dynamic match run system changes (Operations and Safety Committee)
 - Minimum set of donor kidney criteria appropriate for biopsy policy (Kidney Committee)

Summary of discussion:

A member inquired whether the OPO Committee had representatives on the POC workgroups. UNOS staff noted that there were representatives on each of these workgroups and the POC is still finalizing recommendations and working on a transition plan in order to shift the work to the various committees.

4. Additional Discussion Items

PHS Guidelines

A member expressed concern about the update to the Centers for Disease Control Public Health Services (PHS) guidelines and wanted to get feedback on the requirement that serology testing be completed within 96 hours of procurement. The member opined that it would be a burden on OPOs to ensure that requirement is in place all the time, when there are only certain situations when OPOs would want to retest donors.

A member stated that the Disease Transmission Advisory Committee (DTAC) had changed this requirement from 24 hours to 96 hours and suggested that the number of donors that would fall out of the 96-hour requirement was low, around 5%. Another member noted that New York State would not allow OPOs to do infectious disease testing until they have authorization for donation, which shortens the window for those OPOs.

A member mentioned that the liver allocation changes have increased case times and that has caused 15-20% of the OPO's donors to fall out of the 96-hour requirement. Members agreed that over the course of two years, case times have been continuing to increase.

A member highlighted that serology times are not reported in DonorNet so unless there was a manual data collection completed; there is not an electronic field that captures the date and time of collection. A member suggested the requirement be 96 hours from exposure instead of recovery, since that will be difficult. A member agreed and stated that if the patient was in the hospital for 3 or 4 days before the NAT testing, then they could receive inaccurate results.

A member pointed out that they thought, based on the 2013 release, the OPTN did not have to adopt the exact language as written in the PHS guidelines. A member stated that the language must be in alignment, but not the exact language. A member suggested adding a caveat that, if there are identified risk behaviors without already known positive serologies, allow for an additional day for the serology time requirement. A member stated that changing the language from "shall" to "should" would be helpful in solving this problem.

Pilot Programs

A member inquired about whether any of the committee members are participating in the image-sharing pilot and the pilot about communicating post-transplant testing results. Some members stated they were participating in these pilots and a member suggested an update during a future committee call. A member also stated there was a GPS pilot as well that they were participating in.

Upcoming Implementation of Kidney and Pancreas Policies

A member inquired about how many OPOs are offering a kidney-pancreas beyond 250 NM and whether they are separating the kidney-pancreas after 250 NM. A member stated that their OPO is going to offer kidney-pancreas beyond 250 NM, but to a certain point.

Another member questioned the criteria OPOs are using to determine what distance to stop offering kidney-pancreas. A member explained that they keep going until they are ready to set the OR time and hiring a full time surgeon to recover the kidney-pancreas creates more interest from centers to allocate beyond 250 NM.

Next Steps:

UNOS staff add the recommended items to the December 2020 conference call agenda.

Upcoming Meeting

- November 18, 2020 (teleconference)

Attendance

- **Committee Members**
 - Diane Brockmeier
 - Kurt Shutterly
 - Bruce Nicely
 - Catherine Kling
 - Chad Trahan
 - David Marshman
 - Debra Cooper
 - Jeffrey Trageser
 - Jillian Wojtowicz
 - John Stallbaum
 - Larry Suplee
 - Malay Shah
 - Meg Rogers
 - Sue McClung
 - Mary Zeker
 - Helen Irving
- **HRSA Representatives**
 - Adriana Martinez
- **SRTR Representatives**
 - Shannon Taitt
- **UNOS Staff**
 - Robert Hunter
 - Alice Toll
 - Ben Wolford
 - Darby Harris
 - Leah Slife
 - Matt Prentice
 - Peter Sokol
 - Rebecca Brookman
 - Rebecca Murdock
 - Tony Ponsiglione
 - Nicole Benjamin