

Meeting Summary

OPTN Organ Procurement Organization (OPO) Committee Meeting Summary November 18, 2020 Conference Call

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Introduction

The Organ Procurement Organization (OPO) Committee (the Committee) met via Citrix GoToMeeting teleconference on 11/18/2020 to discuss the following agenda items:

- 1. Clarify Multi-Organ Policies Project Update
- 2. Deceased Donor Registration (DDR) Review Project Update
- 3. Additional Discussion Items
- 4. Next Steps

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: Other Multi-Organ Combinations*. The following are the allocation criteria for heart-liver, lung-liver, heart-kidney, and lung-kidney candidates proposed by the workgroup:

Proposed thresholds for offering the second organ:

- Mandatory offers
 - Heart potential transplant recipient (PTR) Status 1, 2, 3, 1A, or 1B within 500 NM
 - Lung PTR LAS greater than 35 within 500 NM
- Permissive offers
 - o Multi-organ transplant (MOT) PTRs that do not meet the above criteria
 - Any single organ PTR that complies with all other OPTN policy
- · OPTN discretion on which match run to use

Offering the second organ to single organ PTRs

- Considered incorporating mandatory offers for sickest kidney or liver candidates
- Single organ offers are also impacted by other MOT policies
 - Example: "Before allocating the kidney to kidney alone candidates, the host OPO must offer the kidney with the liver to candidates who meet eligibility..." (Policy 9.9)
- Incorporating single organ offers into *Policy 5.10.C* may require developing priority between these policies to prevent conflict (next phase)

Summary of discussion:

UNOS staff explained that the table heading indicates which match run is being used, so if an OPO is allocating according to the heart match run then they are required to offer the liver or kidney according to the proposed policy language. UNOS staff stated that they didn't want this policy to mandate which match run to use since that discussion will occur during the next phase of this project. A member noted

that prioritization of the heart, lung, or liver would probably be one of the bigger discussions for the Workgroup to have.

UNOS staff explained that all of these combinations together make up about 300 transplants a year, but this new MOT policy will cover about 80% of MOTs. It was noted that phase 3 of this project will include eligibility criteria and safety nets.

A member inquired whether we need "at or within" instead of just "within." UNOS staff explained that "at or within" is required for IT programming purposes regarding distance. A member also suggested adding bullet points below the table instead of a paragraph and asked if permissible meant that the organ procurement organization (OPO) had discretion. UNOS staff explained that the Workgroup included permissible language because, in the event that all of these things are true, there would be conflict, so it allows for OPO flexibility.

A member inquired whether the language "a PTR appears on both match runs" means different PTRs show up on both match runs or the same PTR shows up on both match runs. A member explained that it means different PTRs appear on both match runs and the Workgroup was leaving it up to the OPO to decide which PTR to allocate the second organ to. The member suggested saying "a different PTR shows up on the heart/lung match run".

A member questioned whether the Committee will review any changes to this policy after public comment. UNOS staff explained that the Workgroup will try to anticipate changes that will come about during public comment, so the Committee will see these revisions during the public comment period.

Members approved sending the MOT Policy language out for public comment – 16 support, 0 abstain, 0 oppose

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 Death Notification Records (DNR)
- Height
- Weight
- Terminal lab data
- 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 donation after cardiac death (DCD) donors
- Does the donor have risk factors for blood-borne transmissions
- Was the donor removed under DCD protocols
- Date/time agonal phase begins
- If yes, measurements between withdrawal of support and (circulatory standstill or circulatory death)

- Core cooling
- History of MI
- LV ejection fraction % and method
- 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?
 - o Advanced invasive or minimally-invasive hemodynamically monitoring
 - o 1 set of hemodynamic values (instead of initial and final)
 - Final set to be default
- % macro vesicular fat
- Lung bronchoscopy
- Lung machine perfusion
- 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
- Cancer free interval
- Recovery date
- If DCD, total urine output during OR recovery phase
- Biopsy (heart donors only)

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
- NAT results move to the serology section ("Infectious Disease Results" section)
- Clamp date/time/time zone replace with recovery date

The following are the sections that will be proposed as a separate project:

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

Summary of discussion:

The DDR Review Workgroup requested feedback from the Committee on the following items:

• Donor Management

- The list of medications do not provide much useful information. These are collected as yes, no, or unknown responses and do not provide dosages or identify how long these medications were given to the donor
- Issue of reliability because of the varying interpretation of what should be entered.
 Examples include: Type of diuretics (loop vs. osmotic). Heparin is this a heparin drip during donor management or heparin in the OR?
- Members agreed that any clarification would be helpful for anyone entering or using this data

• DCD Protocols – Serial Data

- If yes, measurements between withdrawal of support and (circulatory standstill or circulatory death)
- Question change how often these need to be recorded?

Core Cooling

- Suggestion to rename to align with more commonly used terminology such as perfusion or flush
- o "Gray out" the fields if the initial response is "no" or somehow indicate that the remaining responses are not necessary
- Remove "if yes", so the core cooling information is collected on both donation after brain death (DBD) and DCD donors

Lung Machine Perfusion

- Lung machine perfusion intended or performed yes or no
- Operations and Safety Committee workgroup discussion remove the "or". The
 question should record whether or not it was performed, not just intended. If intention
 to perfuse is important, collect as a separate question.

Organ Dispositions

- Why is this only collected for DCD
- o Should we recommend removal of "If DCD" so this information will be captured for both DCD and DBD donors?

Donor Management

A member stated that there was broad agreement that yes or no responses do not provide reliable data. UNOS staff also explained that the DDR Workgroup had mentioned removing these fields from the DDR and relying on DonorNet; however, not all fields are required in DonorNet, so this information may not be captured.

Members agreed with warranting feedback on this section during public comment and then making revisions or removing the data fields.

DCD Protocols - Serial Data

A member explained that the data that should be collected is the start of agonal phase and time of flush or clamp, whichever would be more important.

A member stated that these aren't required data and inquired whether the DDR Workgroup would make it required. A member noted that while it may not be required, centers can still get audited on it. Another member mentioned that one can navigate out of an audit by saying that this isn't required.

A member stated that their OPO would continue to collect data every minute, since different teams have different processes. A member stated that there wasn't much benefit for the DDR purpose to have someone updating this every minute.

A member noted that they just do an automatic DDR upload. UNOS staff questioned whether this is collected in their EMRs every minute. A member stated that yes it's updated every minute as well in the EMR. Member questioned why this would need to be collected again in the DDR and if there was any impact on SRTR modeling? UNOS staff explained that there is no effect on SRTR modeling. Members suggested collecting the values at extubation time, agonal phase, and cross-clamp.

Core Cooling

A member inquired what the intent of this data collection is and agreed that the name should be changed. A member explained that there should be a clear definition of core cooling and it shouldn't just be for DCD donors. A member inquired if there's a distinction between two types of cooling.

A member stated that there are different interpretations for what this question is trying to capture.

A member inquired whether this field adds value to the DDR and suggested reviewing feedback from public comment and, then, deciding whether to keep the field and clean it up.

Lung Machine Perfusion

A member noted that there are times when an OPO is referring to a third party perfusion lab, with the hopes of placing the lung after perfusion contingent on performance on the pump, and doesn't have this information readily available. A member questioned value of knowing if the lung was intended for pump. There is a situation where the lungs are recovered because we think they will be pumped and then they're not.

Members agreed that the intent to perfuse is less important than reporting whether perfusion was actually performed. A member stated that there may be interest in why the lungs were recovered, maybe because there was intent to perfuse the lungs. Another member pointed out that the OPO only knows what they are being told and questioned the validity of this data as well.

A member explained that this field would be marked as "yes" if there's documentation that the perfusion was performed and the field wouldn't be reviewed if it was just "intended." A member explained that this was meant to capture if the lungs were pumped, but the patient didn't receive the transplant.

Members agreed to go with the Operations and Safety Workgroup recommendation.

Organ Dispositions

Members agreed to remove "If DCD" to capture this information for DCD and DBD donors.

Members approved sending the DDR recommendations to public comment – 16 support, 0 abstain, 0 oppose

3. Additional Discussion

A member inquired whether other members are going to have issues with the new kidney allocation policy, where some of the OPOs first level of allocation will be national since there are no centers within 250 NM.

Members stated that there could be some issues in North Dakoda, South Dakoda and New Mexico.

4. Next Steps

Committee members should volunteer for the new POC workgroups:

- Match Run Workgroup
- Donation Process Workgroup

Upcoming Meeting

• December 16, 2020 (teleconference)

Attendance

Committee Members

- o Diane Brockmeier
- o Kurt Shutterly
- o Bruce Nicely
- Catherine Kling
- o Chad Trahan
- o David Marshman
- o Debra Cooper
- o Jeffrey Trageser
- o Jennifer Muriett
- o Jill Grandas
- o Jillian Wojtowicz
- o John Stallbaum
- Larry Suplee
- o Meg Rogers
- o Sue McClung
- o Mary Zeker
- o Helen Irving

• HRSA Representatives

o Robert Walsh

SRTR Representatives

o Katie Audette

UNOS Staff

- o Robert Hunter
- o Alice Toll
- o Darby Harris
- o Peter Sokol
- o Rebecca Brookman
- Shannon Edwards
- o Nicole Benjamin