OPTN Organ Procurement Organization Committee
Deceased Donor Registration (DDR) Review Workgroup
Meeting Summary
November 5, 2020
Conference Call

Jeffrey Trageser, Workgroup Chair

Introduction

The OPTN DDR Review Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 11/05/2020 to discuss the following agenda items:

1. Complete Reviews – Review List of Recommendations
2. Next Steps

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

1. Complete Reviews – Review List of Recommendations

The Workgroup reviewed the following outstanding items:

- Terminal lab data
- Clinical infection confirmed by culture
- Was the donor recovered under DCD protocol
    - Date/time of withdrawal, date/time agonal phase begins, core cooling
- History of MI (myocardial infarction)
- Lung bronchoscopy

Summary of discussion:

The following is the summary of the Workgroup's discussion:

Terminal Lab Data

A member explained that there was concern about having "N/A", "not done", "missing", and "unknown" as response options because the Scientific Registry of Transplant Recipients (SRTR) would treat these as missing data. A member stated that the Workgroup's initial recommendation was to align with the fields in DonorNet.

United Network for Organ Sharing (UNOS) staff stated that there could be a timing issue when determining what final value to use. It was suggested to use the last value entered into DonorNet, but then create a time window between the value being input and the cross-clamp date. A member questioned whether it mattered if the lab values were input 24-36 hours before the donor was transported to the operating room (OR) or cross-clamp. A member explained that there are some policy requirements that certain labs be performed within a certain timeframe. A member mentioned that the UNOS work instructions said that the final lab value should be the lab closest to recovery.

Members stated that it could be clarified that the last value obtained prior to recovery will pertain to all labs. A member suggested using the last value obtained before moving to OR because it can cause problems if values are entered from labs done in the OR. Members agreed with using "before transporting donor to OR".

A member expressed concern about setting a timeframe for the lab values because the OPO may not have obtained the values by then. A member explained that there are currently mechanisms in place to follow-up when centers are outside of policy with those lab results, therefore the validity of the DDR data would still stand.

UNOS staff explained that there is no linkage between the lab values entered in DonorNet and those on the DDR. The only way to ensure that lab values cascade would be to have some sort of requirement in DonorNet because there's always potential that no other values are added after the allocation is finished and prior to recovery.

A member suggested using the language "last value documented in DonorNet prior to transfer to the OR". A member stated that might remind centers to do another upload in DonorNet. A member noted that if it's the last value entered in DonorNet then that could be right before recovery or it could be hours before recovery and that might not be consistent from OPO to OPO. A member explained that this is prior to recovery not during recovery, so any values obtained during recovery should not be entered because the recovery procedure might affect lab values. Members noted that the "last value prior to entry to the OR" should be used for both DCD donors and brain death donors.

A member stated the restrictions on the ranges for some lab values are too short and those inputting the values often have to change the value to get it to upload into DonorNet and then go back into iTransplant and change it again, like for lipase. UNOS staff mentioned that this was inhibiting UNOS from collecting accurate values and asked the member to send the example in order to follow-up on this problem.

A member inquired about the best response option for a patient that never had an amylase lab done. A member suggested having "not done, never done" or "no lab values on this submission" as response options and mentioned that it is not necessary to have both a "no" and "not done" option. A member suggested using options that work best for SRTR purposes since the Workgroup doesn't want those situations to show up as missing data. SRTR staff mentioned that generally "not done" responses are treated as missing data.

A member expressed concern that there is not an option for serologies to be equivocal and indeterminate. A member suggested that an option should say "indeterminate/equivocal" to cover both scenarios.

A member inquired about the purpose of "cannot disclose." UNOS staff stated that the same lookup table is used on the transplant recipient forms because certain tests, such as HIV results, cannot be disclosed due to state laws. A member inquired about how many OPOs are using genotyping for Hepatitis C patients. A member explained that genotyping is not used very frequently and this may not need to be included in the DDR.

UNOS staff asked about terminology differences between DonorNet and DDR regarding NA vs. serum sodium. A member stated that "NA" is just the acronym for sodium. Members agreed that the terminology should be the same in DonorNet and the DDR and recommended using serum sodium.

Clinical infection confirmed by culture

A member stated that the Workgroup could ask the Disease Transmission Advisory Committee what would be the best way to define infections confirmed by culture.

A member mentioned that, from the transplant center perspective, if a donor had any positive culture during their admission the center would want to know about them even if they were treated; however, if the donor has a lot of cultures it becomes more complicated. It was explained that transplant centers

request as many cultures as possible especially when a recipient comes up with something that was not initially reported in the final donor cultures.

A member noted that there are mechanisms in place that compel the OPO to report all of the cultures and follow-up on them. A member inquired about the turnaround time for completing the DDR and whether all culture results would be completed in time. UNOS staff stated that the DDR is due 30 days after submitting the donor organ disposition and will change to 60 days following implementation of recent policy changes.

A member questioned whether the source (blood, lung, urine, or other) of infection confirmed by culture cascades into the DDR from DonorNet. UNOS staff stated that it does not cascade into the DDR and members agreed that it would be ideal if it did. A member questioned whether the final result is entered into DonorNet or is it captured in the DDR. A member pointed out that, if there were two sets of blood cultures done a week apart, the more recent culture is going to be more important than the first one. A member stated that centers report everything so all the results from the cultures would be available.

Was this donor recovered under DCD protocols?

A member stated there's an option "unknown" which is unnecessary because the OPO will know whether the donor was DCD or not. Members agreed with the recommendation to have this field auto-generated from DonorNet (donor summary screen).

Date/time of withdrawal and agonal phase begins, core cooling

Members stated that this information was collected in DonorNet. They agreed that it is important to collect withdrawal of life sustaining measures and time of cross-clamp since these fields are not currently captured.

A member stated that there should be a consistent definition for agonal phase – warm ischemic time will end with the flushing of the organs. A member asked if OPOs are still entering vital signs into the DDR every minute. A member mentioned that this field is a lot of data entry and another mentioned that every five minutes would be more appropriate. Another member suggested having a conversation with the OPO Committee regarding how frequently this data is entered. A member inquired whether this data is used in SRTR modeling. SRTR staff explained that they have not seen any donation after circulatory death (DCD) blood pressure in SRTR models; however, warm ischemic time is used in the SRTR models.

A member questioned the importance of including vital signs in this field. The vital signs would be important before withdrawal of support, but that will be captured in DonorNet. UNOS staff explained these data were added by the Organ Availability Committee, which no longer exists, because they were interested in the impact on outcomes of DCD organs. UNOS staff were not aware if the data had been utilized for that purpose and mentioned that this question could be included as part of the public comment proposal.

A member highlighted another issue, which is when a donor hits agonal phase and then comes out of agonal phase, and questioned whether this would cause confusion when entering the values. A member suggested changing this field to "date/time sustained agonal phase begins." Members also agreed with removing the "If DCD, total urine output during OR recovery phase" field.

A member mentioned that there have been questions regarding the definition of core cooling. A member stated that the consensus had been that core cooling is used on all donors. A member mentioned the assumption that core cooling is referring to when the organs are being flushed at the

time of cross-clamp. A member inquired about whether this data has produced any meaningful results. A member noted that core cooling is also used on brain dead donors, so why collect this only on DCD donors.

Members agreed to modify this field by asking "time/date of flush of the aorta, portal vein and the pulmonary artery" without all the extra confusing language and move it out of the DCD section and have it for all organs.

History of MI

A member inquired whether this data needed to be collected. A member expressed concern that the people entering the data into DonorNet are the clinical people managing the donor and, often, the people entering the data into the DDR are data entry personnel that have to interpret the information being entered into the DDR.

A member inquired if this data captured for anything related to the heart outcomes or other SRTR analyses. SRTR staff mentioned that this field is used in some of the risk adjustment models.

Another member inquired whether this field is asking if the patient had MI at admission or if the patient has ever had it. Members agreed that this field should be in DonorNet and cascade into the DDR, instead of having different people entering the values at different times.

UNOS staff questioned whether history of coronary artery disease (CAD) is a better field to collect and if so, the data that is currently collected in DonorNet could cascade over. A member mentioned that if a donor has severe CAD but never had MI, then that could have an impact on prediction models. A member inquired if the "History of MI" field could be added into DonorNet and if SRTR staff would still be able to access that data. UNOS staff explained SRTR staff would have access to the data, but the problem is that not all fields in DonorNet are required.

Members agreed that both fields should be captured, and the best way to accomplish this is to collect both history of CAD and MI in DonorNet and cascade to the DDR.

Lung bronchoscopy

A member suggested treating these like the terminal lab data – use the last bronchoscopy performed before transporting the donor to the operating room. Members also agreed adding a drop down option for "bronchoscopy results, abnormal – other" and removing "unknown if bronchoscopy performed."

2. **Next Steps**

- UNOS staff will distribute the final recommendations to the Workgroup members prior to sending it to the OPO Committee for review prior to the November 18, 2020 conference call.

Upcoming Meetings

- TBD

Attendance

- **Workgroup Members**
  - Jeffrey Trageser
  - Debra Cooper
  - Kristine Browning
  - Meg Rogers
- **HRSA Representatives**
  - Adriana Martinez
- **SRTR Staff**
  - Andrew Wey
  - Bertram Kasiske
- **UNOS Staff**
  - Robert Hunter
  - Carly Engelberger
  - Darby Harris
  - Leah Slife
  - Meghan McDermott
  - Pete Sokol
  - Rebecca Brookman
  - Sarah Taranto
  - Kerrie Masten
  - Nicole Benjamin