

**OPTN Organ Procurement Organization (OPO) Committee
Meeting Summary
August 18, 2021
Conference Call**

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Introduction

The Organ Procurement Organization (OPO) Committee (the Committee) met via Citrix GoToMeeting teleconference on 08/18/2021 to discuss the following agenda items:

1. Data Collection to Evaluate the Logistical Impact of Broader Distribution
2. SARS-CoV-2 Testing for Lung Donors
3. Data Collection Related to US Public Health Service Guidelines

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

1. Data Collection to Evaluate the Logistical Impact of Broader Distribution

The Chair of the OPTN Operations and Safety Committee presented the Data Collection to Evaluate the Logistical Impact of Broader Distribution Proposal, and the Committee provided feedback.

Data summary:

This proposal aims to evaluate data elements to provide more insight into organ logistics and allocation with the goal to inform future policy development and to ensure efficiencies in data collection efforts are current and relevant.

The proposal provides several recommendations for modifications and removals of current data and proposes new data elements, specifically organ check out time, organ check in time, and time of first anastomosis.

The proposed new data elements will provide more information by serving as a surrogate for organ transport time, documenting chain of custody of organs, and capturing a more accurate account of timeline from recovery to transplant.

The proposed data element modifications and removals will improve quality of data by clarifying data fields and definitions and removing fields that do not provide sufficient information.

- Type of liver machine perfusion – remove non-specified response field “Other/Specify”
- Kidneys received on - remove non-specified response field “N/A”
- Kidney pump values: Time, flow, pressure, and resistance – collect initial, lowest, highest, and final values
- Organ reason codes
 - Remove “No recipient located (Code 208)”
 - Remove “Positive HTLV-1 (Code 211)”
 - Add “no candidate on the match run”

OPO staff would enter “organ check out date and time,” and transplant hospital staff would enter new data elements “time of first anastomosis” and “organ check-in date and time.” Transplant hospital staff would also need to evaluate current protocols and processes for organ check in per OPTN policy.

Summary of discussion:

One member expressed concern about removing refusal code 208 “no recipient located,” as this code is often used when the match run has been exhausted, and asked if there would be an alternative. The Chair of the Operations and Safety Committee explained that the match run is usually exhausted for a specific reason that remains unclarified by code 208. If the organ was declined throughout the match run due to small size, then size would be the reason the OPO did not recover the organ. The member commented that there are times when an OPO rules out an organ, and the decision not to recover is different than when a transplant center is declining due to other reasons. “No recipient located” still credits the OPO for trying to allocate the organ as opposed to ruling it out without making offers. The Chair of the Operations and Safety Committee noted that it is known when an OPO has made offers because a match run was executed as opposed to simply ruling out the organ and not making offers. The reason not recovered might be the same, such as an abnormal echocardiogram, but the indication as to whether the OPO made offers can be indicated on the match runs.

A member pointed out that the Data Advisory Committee is revising the transplant center refusal codes, which presents an opportunity for automation. The most commonly used decline codes could be automated to pop up as the discard code, instead of OPO quality staff making the determination about the reason the organ was not transplantable. The Chair of the Operations and Safety Committee agreed, but added that this could be the first step in getting more useable and intuitive data.

One member asked what the main goal of the proposal is, and asked if this data is intended to collect cold ischemic time (CIT). The Chair of the Operations and Safety Committee explained that the anastomosis component could help indicate CIT, but that transport times and CIT do not always correlate, especially for kidneys. The UNOS labs team did a project to track organ recovery, transport, and transplant timeframes, and found there is often substantial time between organ arrival and transplant. This proposal aims to identify key points along the transportation timeframe to draw out transportation times, CIT, and time from arrival to transplant. The member shared that once organs are recovered, the case is typically closed from an OPO perspective, and that what occurs prior to recovery and allocation is important to efficiency as well. The Chair of the Operations and Safety Committee agreed, adding that this goal of this project did not include issues of logistical impact and placement efficiency. The Chair of the Operations and Safety Committee continued that typically, the transportation organized by heart transplant and recovery teams is not accessible to OPOs. The variability of that kind of data is so broad, that the Workgroup developing this proposal decided it fell outside of the scope of the project.

A member asked how check-out time would be defined, sharing that some OPOs travel from the donor hospital back to the OPO before handing the organ over to a courier. The Chair of the Operations and Safety Committee noted that feedback on this definition is encouraged, and clarified that check-out time could be defined as the time that the OPO gives up custody of the organ to travel to the transplant center. The check out time element is intended to collect transportation to the transplant center.

One member asked if this proposal aimed to look at how long it takes for the organ to be packaged and sent to the transplant center, or just when it leaves the OPO. The Chair of the Operations and Safety Committee remarked that the packaging time and transport time are not even close most of the time. This data is intended to capture the time that organ is placed and is ready to be sent off to the transplant program, and will collect the time the organ leaves custody of the OPO and arrives at the

accepting center. The Chair of the Operations and Safety Committee provided an example – if there are 6 hours between arrival of the kidney and anastomosis, the data there will show that transportation may not have been the issue contributing to CIT, but potentially other resources in the system.

Another member recommended using date and time the organ is en route to the accepting center instead of when the organ leaves custody of the OPO. The Chair of the Operations and Safety Committee agreed that was the intended definition of “check-out time.” A member remarked that some OPOs have staff drivers that will transport the organ to the accepting center – so the organ is technically still in the custody of the OPO. Another member clarified that the check-out time denotes when the organ starts its journey to the accepting transplant center, whether that’s from the donor hospital, satellite storage, or OPO offices. The Chair of the Operations and Safety Committee agreed, noting that whether or not the OPO is driving does not make a difference, it is the transportation to the accepting center that matters.

One member asked if the data would be analyzed in terms of distance from the transplant recovery center or recovery facility to the accepting transplant center – not just the transport times. The Chair of the Operations and Safety Committee noted that one of the main goals in collecting this data is to find the average transport times from the OPOs to the transplant programs, and single out what factors are involved beyond just the transportation. The member added that geography in kidney allocation has a big impact on rural communities, and that transport time must take into consideration the traveled distance in order to be meaningful. The Chair of the Operations and Safety Committee agreed, adding that currently there is no good data surrounding this topic, which is the problem this proposal is trying to address.

A member pointed out that some accepting centers have the host OPO drop off a kidney at the transplant center’s OPO to put the organ on a pump. The member asked if the shipment from the transplant center’s OPO to the center itself would still be factored into that equation. The Chair of the Operations and Safety Committee commented that the arrival time would still be the arrival of the organ at the transplant center, not the accepting center’s OPO. That piece is still a component of the duration, even if it is not technically in transport.

One member asked how this data would indicate problems with transport. The Chair of the Operations and Safety Committee clarified that this data would not necessarily look at those variable circumstances, but instead the standard circumstances of direct transport.

2. SARS-CoV-2 Testing for Lung Donors

The Chair of the Disease Transmission Advisory Committee (DTAC) presented the SARS-CoV-2 Testing for Lung Donors policy, which is currently out for retrospective public comment. The Committee provided feedback.

Data summary:

The emergency policy required SARS-CoV-2 lower respiratory testing (e.g. Bronchoalveolar Lavage (BAL), tracheal aspirate) for all lung donors by nucleic acid test (NAT) with results available pre-transplantation of lungs.

The purpose of the emergency policy was to address the patient safety risk of donor derived COVID-19 to lung recipients. Before the emergency policy was approved in April 2021, 30-40% of lungs were not tested by lower respiratory sample, which supported the need for the requirement.

Before the implementation of the policy, there were three proven donor derived COVID-19 transmissions and one “near miss” in lung transplant recipients. The donor tested negative in the upper respiratory tract and later tested positive in a lower respiratory tract sample.

COVID-19 predominately affects lungs, thus lung transplant recipients are at a potentially higher risk of donor derived COVID-19. There is also a higher mortality risk for lung recipients with COVID-19 compared to other organs.

Summary of discussion:

One member remarked that most lung centers ask for this testing anyway, and expressed support for this policy. Several other members agreed.

One member asked if tracheal aspirate would qualify as a lower respiratory sample, and the Chair of the Disease Transmission Advisory Committee confirmed that the lower respiratory sample specified by policy includes a tracheal aspirate. The DTAC chose to use “lower respiratory tract sample” as opposed to BAL due to the potential for difficulties accessing BAL testing in certain areas and with donation after circulatory death (DCD) donors. Another member agreed that allowing both BAL and tracheal aspirate testing eased compliance with this policy.

The Vice-Chair asked the Committee if they were aware of any trouble accessing lower respiratory testing due to distance or logistics, or if this policy created any significant burden. No Committee members expressed difficulty in accessing testing. The DTAC Chair noted that as of the second month’s report post-implementation, 100 percent of lung donors have had SARS-CoV-2 testing.

The Chair noted that there was not necessarily a delineated timeframe for performing a BAL, and asked if there were recommendations for a timeframe. Staff clarified that the policy was written to be flexible for OPOs as far as timeframe, requiring that the results be available by the time of lung transplant in order to allow OPOs ample time to get testing done. Another member shared that transplant centers often ask for repeat tests closer to OR time, noting that the policy and the reality of trying to place and get the lungs transplanted may not be the same. One member expressed concern about adding a specific timeframe. The Vice Chair agreed, adding that if a timeframe was set, it should mirror the infectious disease timeframe of a maximum of 96 hours prior to crossclamp.

A member asked if any non-lung recipients have experienced COVID-19 transmissions. The DTAC Chair clarified that there has not been any proven or probable transmissions for non-lung transplants. The DTAC Chair explained that this review process is linked to the summary of evidence regarding donors with a history of or positive COVID-19 test, and that there is a recent effort to update the summary of evidence.

3. Data Collection Related to US Public Health Service Guidelines

The Chair of the Disease Transmission Advisory Committee presented the Data Collection Related to US Public Health Services Guidelines proposal, and the Committee provided feedback.

Proposal summary:

In June 2020, the US Public Health Service (PHS) guideline was published for assessing solid organ donors and monitoring transplant recipients for human immunodeficiency virus (HIV), hepatitis B (HBV), and hepatitis C (HCV) infection. The OPTN Board approved the updated policy to align with the 2020 PHS guidelines. During the development of the new policy, the lack of granular data regarding risk criteria for HIV, HBV and HCV was identified as a hurdle to understanding the repercussions of the new policy.

This proposal aims to collect more granular HIV, HBV, and HCV risk criteria data to better evaluate donor risk criteria trends that could affect patient safety and organ utilization. The proposal will also inform future iterations of the PHS guideline, assess the impact of OPTN policy changes, and support more efficient donor evaluation with discrete data fields.

The proposal will add individual PHS risk criteria as discrete fields to “overall risk” questions in DonorNet and the TIEDI Deceased Donor Registration (DRR) form. There will be “yes,” “no,” and “unknown” options for all risk criteria, and options for “not applicable” for two pediatric risk criteria.

Current data collection of PHS risk criteria in UNet is limited and difficult to analyze

- Information about specific criteria entered in text fields, not discrete fields
- Labor intense process to sample text fields, may require subjective interpretation – significant limitations to analyze data

Collecting better data on specific risk criteria will

- Help ensure better patient safety by evaluating the connection between risk criteria and rate of transmission
- Support effective review of OPTN policy implemented to align with 2020 PHS guidelines
- Inform future iterations of the PHS guideline

Summary of discussion:

One member remarked that the binary increased risk system fails to appropriately account for the scale of risks – some donors are significantly higher risk than others, and the increased risk data could be significantly more meaningful. Another member agreed, adding that this proposal provides significant benefit in adding context to increased risk. The member continued that the OPTN Pediatric Transplantation Committee has discussed this previously, noting that the risk for a donor on hemodialysis is different from a donor with a recent history of intravenous drug use. Once there is more data to correlate to actual outcomes to center declines, it can be analyzed and evaluated.

A member advocated that this data collection should be as simple as possible in order to allow OPOs to streamline data entry. Creating check boxes for certain increased factors would allow for simple and quick data entry that eases data burden and improves the donor management and information sharing process.

One member noted that most OPOs have the discrete increased risk data, but that DonorNet doesn't currently have the collection mechanism. The member continued that most donor risk assessment interview (DRAI) interview forms are entered into a system with discrete yes or no responses to donor risk questions. Another member agreed that OPOs have the discrete data and fields, but have no way to share the data other than uploading attachments. The Vice Chair expressed concern that this data now will require additional manual entry of data after already being collected somewhere else. The Vice Chair continued that there should be a way to upload the data directly from the UDRAI. Another member agreed. One member commented that not all electronic medical record (EMR) systems in use by OPOs and transplant hospitals interface with DonorNet, and any such capability would need to be consistent across all platforms.

A member added that the standard DRAI doesn't match the new PHS criteria, which creates inefficiencies. Another member agreed, noting that the addition of timeframes in particular has slowed down the process.

One member expressed support for this data collection, noting that there is significant value added. Several other members agreed. The Vice Chair agreed, adding that as this system is built into UNet,

there should be a plan to get this data seamlessly from the EMRs. The Committee expressed support for integration from EMRs and OPO data into DonorNet.

Upcoming Meetings

- September 8, 2021 (Teleconference)
- October 20, 2021 (Teleconference)

Attendance

- **Committee Members**
 - Kurt Shutterly
 - PJ Geraghty
 - Diane Brockmeier
 - Catherine Kling
 - Chad Ezzell
 - Chad Trahan
 - David Marshman
 - Erin Halpin
 - Jeffrey Trageser
 - Jennifer Muriett
 - Jill Grandas
 - John Stallbaum
 - Lawrence Suplee
 - Malay B Shah
 - Mary Zeker
 - Meg Rogers
 - Samantha Endicott
 - Susan McClung
 - Valerie Chipman
- **HRSA Representatives**
 - Jim Bowman
 - Adriana Martinez
 - Vanessa Arriola
- **SRTR Representatives**
 - Katie Audette
 - Matthew Tabaka
- **UNOS Staff**
 - Robert Hunter
 - Darby Harris
 - Katrina Gauntt
 - Kayla Temple
 - Abby Fox
 - Courtney Jett
 - Matthew Prentice
 - Meghan McDermott
 - Joann White
 - Nicole Benjamin
 - Leah Slife
 - Sara Moriarty
- **Other Attendees**
 - Merry Smith
 - Ricardo La Hoz
 - Christopher Curran
 - Lindsey Herlinger

