

OPTN Organ Procurement Organization Committee Meeting Summary May 18, 2022 Conference Call

Kurt Shutterly, RN, CPTC, Committee Chair PJ Geraghty, MBA, CPTC, Vice Chair

Introduction

The OPTN Organ Procurement Organization (OPO) Committee (the Committee) met via Citrix GoToMeeting teleconference on 05/18/2022 to discuss the following agenda items:

- 1. Technology Tools Workgroup Update
- 2. Kidney-Pancreas Continuous Distribution Request for Feedback
- 3. Additional Updates

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

1. Technology Tools Workgroup Update

The Committee received an update on the OPTN Donor Data and Matching System Clinical Data Collection project in development by the Technology Tools Workgroup.

Presentation Summary:

The Technology Tools Workgroup recommends the addition and enhancement of several donation after circulatory death (DCD) clinical data fields to the OPTN Donor Data and Matching System.

- Withdrawal of life sustaining medical support, date/time
- Cessation of circulation, date/time
- Flush time (in situ), date/time
 - o Abdominal aorta
 - o Portal vein
 - o Thoracic aorta
 - o Pulmonary artery
- DCD hemodynamics
 - o Heart rate and blood pressure are already collected
 - Addition of oxygen saturation (SpO2)

The OPTN Data Advisory Committee supported the efforts of the Technology Tools Workgroup, and recommended the addition of a "type of DCD" element, to capture controlled and uncontrolled DCD cases, and a "low-high ejection fraction" data field. The DAC also felt it was unnecessary to incorporate new hemodynamic information into the OPTN Donor Data and Matching System, and recommended reconfiguring how the data is viewed once the DCD process begins

- The hemodynamic information is already there in various forms, and viewing is more critical for evaluating surgeons to see first hand
- Extra data entry effort could also increase potential for errors
- Variability in report interpretation

The OPTN Heart Transplantation Committee provided feedback on initially recommended additions of heart-related data elements. The Heart Committee did not support the addition of left ventricular function, diastolic measures, end-systolic dimensions, and end-diastolic dimensions, with the rationale that this information would not help screen donors. The members of the Heart Committee explained that, typically, clinicians want to review echocardiograms and other imaging, and take their own measurements. The Heart Committee provided the following additional feedback:

- Collect how cardiac output, cardiac input, and wedge pressure are measured with waveform from the catheter lab
- Vasopressors at time of echocardiogram
- Donor serial echocardiogram with reports and imaging
- Echocardiogram reports are not consistently posted in the same place
- Central venous pressures are important, as well as their mode of collection (central venous catheter, pulmonary artery catheter, etc.)
- Tracing and waveform are most helpful for swans and right heart catheters

Summary of discussion:

The Chair of the Technology Tools Workgroup remarked that the number of information technology implementation hours was significantly reduced after the heart-related data collection was dropped from the project, based on feedback from the OPTN Heart Transplantation Committee. Staff noted that the project focused on the addition of data useful to improving the efficiency of organ placements.

Staff added that blood pressure and heart rate are already collected, while oxygen saturation, SpO2, is not.

One member asked if data fields regarding normothermic regional perfusion (NRP) would be included, and requested clarification on how NRP information should be entered and captured in the OPTN Donor Data and Matching System. The Chair of the Technology Tools Workgroup shared that the Workgroup discussed the inclusion of NRP, and ultimately determined that there isn't yet an industry standard for NRP processes, and there is significant variability among OPOs and transplant programs in how it's charted. Staff added that there is currently an OPTN Ethics Committee project starting up to address the ethical and legal questions surrounding NRP practices, and that the Technology Tools Workgroup was hesitant to propose any NRP-related data collection until the Ethics Committee had made more progress.

<u>VOTE:</u> The Committee voted unanimously in support of sending the Enhancements to OPTN Donor Data and Matching System Clinical Data Collection Proposal to August 2022 Public Comment.

2. Kidney-Pancreas Continuous Distribution – Request for Feedback

The Kidney-Pancreas Continuous Distribution team discussed how facilitated pancreas allocation could be incorporated into the continuous distribution model.

Presentation summary:

The Kidney-Pancreas Workgroup is discussing the facilitated pancreas tool, and is seeking feedback on the following questions:

- When do OPOs decide to use the facilitated pancreas tool? What is the current practice?
- When thinking about the continuous distribution framework, when should OPOs initiate facilitated pancreas?

- Should there be a threshold or criteria for when OPOs are permitted to use the facilitated pancreas tool?
 - Should OPOs have the ability to switch to facilitated pancreas at any point on the match run, or exhaust a certain number or percentage of offers first?

The OPTN Pancreas Transplantation Committee discussed the facilitated pancreas tool at their May 2022 meeting, and agreed that the current facilitated pancreas policy should remain:

- Distance is a good mechanism to use, and should remain as currently written in policy
- For equity purposes, OPOs should continue to offer to all candidates within 250 nautical miles before they can initiate facilitated pancreas allocation

The Pancreas Committee expressed concerns about the language permitting OPOs to use the facilitated pancreas tool is no pancreas offers have been accepted 3 hours prior to scheduled organ recovery, and seeks feedback on the three hour requirement.

Summary of discussion:

One member remarked that the use of facilitated pancreas depends on who performs the pancreas recovery. The member explained that if there isn't a surgeon available to recover the pancreas, the OPO may need to allocate to someone that can recover the pancreas and get there within the timeframe, which may be more than three hours. The member noted that three hours is appropriate if there is a local surgeon available to recover the pancreas.

A member noted that the time threshold should be longer, as more pancreas programs want to recover their own pancreas with better outcomes for transplant team recovery of the pancreas. The member added that pancreata are tough to place, and recommended the time threshold be more like four or five hours. Another member agreed, adding that the allocation analysts should be understanding if facilitated pancreas is applied more than three hours from scheduled policy.

One member expressed that pancreas and kidney-pancreas allocation needs to be reimagined. The member shared that their OPO doesn't rely on facilitated pancreas, as the facilitated pancreas centers nearby are very conservative. The member recommended prioritizing centers who are willing to recover the pancreas themselves. The member wondered whether there is data available on utilization rates between local and center recovery of the pancreas, and if there is data on which pancreas programs are truly willing to accept a back-up pancreas or kidney-pancreas offer. The member emphasized that finding solutions to center recovery and identifying aggressive programs willing to accept back-up pancreata will benefit utilization. The member shared that the onset of the COVID-19 pandemic significantly reduced their OPO's pancreas utilization rates.

A member pointed out that there are several logistical challenges, particularly with relying on other transplant teams to procure the pancreas, to accepting pancreata. The member added that there are additional challenges to allocating and placing a pancreas in the circles-based distribution. The member remarked that it's likely more logistical, system-wide challenges. Another member wondered how the pancreas can get more priority in general allocation. Staff remarked that discussions regarding these issues and potential solutions are ongoing with the Pancreas Committee and Kidney and Pancreas Continuous Distribution Workgroup.

One member added that kidneys are often used in multi-organ combinations, and there is often no kidney available to be allocated with the pancreas. The member noted that placing an isolated pancreas is particularly difficult. Another member agreed, remarking that the kidneys are often allocated last, and by the time an OPO is able to allocate the kidney-pancreas or kidney-alone, the recovery is fast approaching.

Staff noted that this is the ongoing conversation for the Pancreas and Kidney Committees regarding operational components and incorporation into the continuous distribution framework. Staff thanked the OPO Committee for their feedback, and noted that this information will also be included as a concept paper during August public comment.

3. Additional Updates

Staff informed the Committee that the June 15, 2022 meeting will be rescheduled for June 9, 2022 due to a scheduling conflict with a national conference.

Staff also informed the Committee that the committee meeting platform will change from GoToMeeting to Cisco WebEx, effective on July 1, 2022.

Staff shared that there are supply chain issues with the Zebra Printers used to print organ transportation labels from the OPTN Organ Labeling, Packaging and Tracking System. Issues with information technology products are anticipated through the first quarter of 2023.

Summary of discussion:

One member explained that there is a vendor contact who would like to be the contact for OPOs seeking zebra printers, and that they can share that information with anyone interested. The member shared that there is an order out now for Zebra printers that is on back order due to supply chain issues.

Staff noted that there have been concerns regarding the shortage of computed tomography (CT) contrast fluid, and asked if this has had any impacts on OPO members. One member explained that there are impacts to obtaining scans and contrasts, as hospitals are rationing the supplies. The member continued that their coordinators are ensuring there is serious interest in the heart before going to the cardiac catheter lab, in order to avoid wasting a dose of contrast. The member added that the shortages could impact brain death testing and ancillary testing in some places, but that vendors expect to be back to full production in late June or July 2022. Another member noted that it hasn't impacted their OPO yet, and that their independent recovery centers haven't had difficulty obtaining contrast fluid. A member shared that hospitals in their areas are cancelling less urgent cardiac catheterization procedures due to the shortage. Another member remarked that donors are not a priority in terms of contrast fluid shortages, and that their state's Department of Health has made several recommendations for performing CT scans.

Upcoming Meeting

• June 9, 2022 – Teleconference

Attendance

• Committee Members

- o Kurt Shutterly
- o PJ Geraghty
- o Bruce Nicely
- o Catherine Kling
- o Chad Trahan
- o David Marshman
- o Deb Cooper
- o Diane Brockmeier
- o Erin Halpin
- o Jennifer Muriett
- o John Stallbaum
- o Kevin Koomalsingh
- o Larry Suplee
- o Mala Shah
- o Meg Rogers
- o Samantha Endicott
- Sue McClung

• HRSA Representatives

- o Adriana Martinez
- o Raelene Skerda

• SRTR Staff

- o Ajay Israni
- o Katie Audette
- UNOS Staff
 - o Robert Hunter
 - o Joann White
 - o Katrina Gauntt
 - o Ross Walton
 - o Taylor Livelli
 - o Susan Tlusty