

Meeting Summary

OPTN Organ Procurement Organization Committee Technology Tools Workgroup Meeting Summary March 3, 2022 Conference Call

David Marshman, Workgroup Chair

Introduction

The OPTN Technology Tools Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 03/03/2022 to discuss the following agenda items:

- 1. Recap of Policy Oversight Committee (POC) and OPO Committee Discussion
- 2. Review of DonorNet Clinical Data Collection

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

1. Recap of OPTN POC and OPO Committee Discussion

The Workgroup reviewed discussions held by the POC and OPO Committee regarding resource constraints and estimates for each aspect of the project, which resulted in reprioritization to focus on information related to medications and fluids, echocardiogram, and donor after circulatory death (DCD) data.

Summary of discussion:

The Workgroup had no questions or comments

2. DonorNet Clinical Data Collection

The Workgroup discussed each of the proposed DCD data elements to identify the purpose of collecting each element, address data definitions, and determine how the information should be best collected and reported.

Summary of discussion:

Extubation, or withdrawal of support

One member remarked that "withdrawal of life sustaining measures" is the language used throughout OPTN policy, and should be used for data collection. Several members agreed. The Chair remarked that electronic medical records (EMRs) and electronic donor records (EDRs) likely truncate it to "withdrawal."

The Chair explained that withdrawal of support is "minute zero" in collecting DCD data, and is critical to capturing the larger picture of donor progression. Others agreed. The Chair noted that a simple date and time field would be sufficient to capture this element. Several members agreed.

Pulselessness, or asystole

The Chair commented that "cessation of circulation" would be a better term to use, and could reduce confusion regarding different uses of asystole.

One member explained that time of pulselessness is used to confirm donor death. The Chair noted that this element indicates the loss of circulation, and is the second milestone in capturing donor progression to death. The Chair continued that cessation of circulation is used to determine the agonal phase.

Staff asked if "cessation of circulation" would be different from "pronouncement of death," and the Chair explained that they can be separate, as physicians will assess for cessation of circulation and then wait a specific period of minutes before declaring death. Staff noted that the system currently defines pronouncement of death as "the irreversible cessation of circulatory and respiratory," and asked if the respiratory factor has a role in the separation between the two data elements. One member clarified that generally, respiratory systems cease before cardiac systems.

Staff asked the Workgroup if there was value in collecting asystole, particularly if it is capturing the same milestone as pronouncement of death. The Chair remarked that their EDR system has two fields to account for the observation period — one for time of cessation of circulation, and another for time of declaration. Pronouncement would equate to the latter field. Another member noted that their team will use the observation period to confirm cessation of circulation as time of donor death, and utilize cessation of circulation date and time in agonal phase calculations rather than pronouncement of death.

The member recommended adding cessation of circulation as a separate element, to improve consistency and data quality, as observation periods can vary between practitioners.

Pronouncement of death

The members agreed to leave the pronouncement of death date as it is currently collected.

Aortic flush time, or in situ flush

One member explained that aortic flush time marks the end of the agonal phase, essentially starting the clock on cold ischemic time and stopping the clock on warm ischemic time.

Staff noted that the deceased donor registration (DDR) currently collects flush time information for DCDs, but that this data collection will be changed in board-approved updates to the DDR. Staff clarified that the "if yes" selection will be removed in order to require collection of flush time for both DCD and brain dead donors. Staff asked the workgroup if in situ flush should include both abdominal and aortic flush. One member agreed that both abdominal and aortic should be included, to be thorough. The Chair remarked that it would make sense to collect abdominal aorta, thoracic aorta, pulmonary artery, and portal vein flush date/time, to keep the data collection aligned between DonorNet and the DDR. The Chair noted that the elements should be organized such that thoracic aorta and pulmonary vein flush times are together and the abdominal aorta and portal vein are together.

A member recommended including a caveat regarding time of initiation of extracorporeal membrane oxygenation (ECMO) for normothermic regional perfusion. The Chair agreed, but noted that this should be addressed in a later phase of this project.

DCD Hemodynamics

Staff asked the workgroup if the DCD hemodynamic data differs from the list of echocardiogram and heart-related hemodynamic parameters. The Chair explained that while the same fields and values are collected, the data is different for DCD. In talking about withdrawal of support, the elements being monitored – such as blood pressure and oxygenation – are significant for organ suitability.

Staff asked how the hemodynamic information should be collected for DCD. The Chair noted that the fields and data may be the same, but that the time delineations are different. The Chair pointed out that heart-related hemodynamic data is captured during the donor phase, but that DCD hemodynamics are a

very specific snap shot in time strategic to organ suitability, driven from time of withdrawal to cessation. One member agreed, adding that DCD hemodynamics are essentially vital signs. The Chair remarked that these hemodynamics are currently collected in different data fields, but are captured in the DDR for DCD hemodynamic data. Staff noted that DCD hemodynamic data collection will be removed with the implementation of updates to the DDR.

Staff asked the Workgroup if the DCD hemodynamics should be mapped separately, as separate data from donor phase hemodynamics, or simply displayed separately. The Chair clarified that the data are the same base values, such as blood pressure, but that they are linked differently. The Chair continued that the vitals from withdrawal should not be correlated in any way with vitals captured during the donor phase, such as during an echocardiogram. Another member agreed, and pointed out that heart and echocardiogram data are gathered while the patient has a heartbeat, while DCD hemodynamics explicitly capture vitals once all measures of support are removed.

Staff asked if the DCD hemodynamic fields need to be identified separately, and the Chair responded that heart rate and blood pressure are the most important fields. The Chair remarked that the hemodynamic data could be mapped together at the back end, but that the information should be displayed separately and as discreet fields related to DCD. Another member agreed and noted that DCD hemodynamics are very distinct. Staff suggested continued discussion on how to best store and display that data.

Echocardiogram/Hemodynamic Data Elements

Staff listed the specific elements for echocardiogram and heart hemodynamics, and provided an overview of where each element is collected in DonorNet:

- Donor management indicators
 - o Pulmonary artery (PA) pressure
 - Blood pressure
 - o Heart rate
 - Cardiac output
 - Cardiac index
 - o Wedge pressure
- Image studies
 - o Echocardiogram data
- Medications and fluids
 - Vasopressors
- Tests and diagnoses
 - o Rhythm electrocardiogram (EKG) serial option
- Organ data (heart)
 - Posterior wall thickness
 - Ejection fraction
 - Septal wall thickness
- Currently not collected in DonorNet
 - Left ventricular function
 - o Diastolic measures
 - End-systolic dimensions
 - End-diastolic dimensions

Staff noted that the OPTN Transplant Coordinators Committee (TCC) expressed support for the addition of the four data elements not currently collected in DonorNet. Staff added that the Heart Committee

leadership recommended consolidating display of hemodynamic drips, as many are inotropes, vasodilators, and/or vasopressors, and this will ease data entry and review. OPTN Heart Committee leadership shared that end systolic and end-diastolic dimension volumes are rarely reviewed, and that the left ventricular end-diastolic diameter (LVEDD) size and qualitative right ventricular (RV) size and function are more valuable data elements. For echocardiogram data, blood pressure and heart rate are critical for understanding right ventricular systolic pressure (RVSP) and magnitude of regurgitation. The Heart Committee leadership noted that there is a need for serial ejection fraction and echo elements, as well as uploaded reports. The TCC noted that DonorNet displays the date of uploaded for each Echocardiogram, but not the actual date and time of the test. Similarly, TCC recommended including information on the vasopressors the donor was on at the time of the test.

The Chair remarked that thoracic clinicians seemed more concerned about the echocardiogram report than the data collected in DonorNet. The Chair wondered if offer-evaluating clinicians would use Donornet data fields over a report uploaded to attachments. Staff noted that the purpose of the project is to enhance and improve data collection in order to facilitate communication and donor information review.

The Chair pointed out that a transplant center assessing a heart offer will need to scroll throughout the donor record in order to find the elements they need, and the current organization of elements significantly hinders assimilation and review of donor data. The Chair continued that serial echocardiograms could really reduce efficiency of donor information review, and asked whether this information could be reorganized to improve comprehensibility. Staff noted that transplant programs evaluating a heart offer may want to review donor information differently than a program evaluating a different organ offer from the same donor, and asked if this is the type of change the Chair was referring to. The Chair responded that there are clear inefficiencies in the current organization of heart-related data, and that these elements need to displayed and received in a comprehensible way. The Chair recommended collaborating with the Heart Committee to determine what elements are currently used, and if certain elements are not in use, why. The Chair pointed out that these fields may not be used currently in donor information review because they aren't organized logically, and that organization may be more beneficial than simple addition of serial echocardiogram data.

Next steps:

The Workgroup will continue discussions regarding echocardiogram and heart-related hemodynamic data during their next call on March 23, 2022. The POC will reconsider approval of the project based on the updated prioritization and resource estimate during its March 10, 2022 meeting.

Upcoming Meeting

March 23, 2022

Attendance

• Workgroup Members

- o David Marshman
- o Jeffrey Trageser
- o Bruce Nicely
- o Deb Cooper
- o Kenny Laferriere

• HRSA Representatives

- o Arjun Naik
- o Vanessa Arriola
- o Marilyn Levi
- o Jim Bowman

• SRTR Staff

- o Katie Audette
- o Matthew Tabaka

UNOS Staff

- o Robert Hunter
- o Kayla Temple
- o Katrina Gauntt
- o Lloyd Board
- o Leah Slife
- o Lauren Mauk
- o Kerrie Masten
- o Bonnie Felice