

Meeting Summary

OPTN Organ Procurement Organization Committee Technology Tools Workgroup Meeting Summary January 24, 2022 Conference Call

David Marshman, Workgroup Chair

Introduction

The OPTN Technology Tools Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 01/24/2022 to discuss the following agenda items:

- 1. Data Collection Proposal Things to Do
- 2. DonorNet® Clinical Data Collection
- 3. Prioritization

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

1. Data Collection Proposal - Things to Do

The Workgroup reviewed the policy process related to data collection projects, including the Data Advisory Committee's (DAC) guidance process and Standards of Review Checklist, Policy Oversight Committee request for approval, public comment release and board approval, submission to the Office of Budget and Management, and programming.

Summary of discussion:

The Workgroup had no questions or comments

2. DonorNet Clinical Data Collection

The Workgroup discussed the purpose and benefit of the proposed data elements.

Data summary:

Echocardiograms

- Date/time
- Vasopressors types, dosages, and date/time
- Interpretation data fields
 - Ability to report multiple interpretations
- Posterior wall thickness
- Ejection fraction (EF)
 - Ability to report multiple EF results
- Pulmonary artery pressure

- Blood pressure
- Heart Rate
- Rhythm
- Cardiac output
- Cardiac index
- Wedge pressure
- Left ventricular function
- Diastolic measures
- End-systolic dimensions
- End-diastolic dimensions
- Septal Wall thickness



Meeting Summary

Medications and Fluids

- DonorNet lacks specificity and flexibility
- Better shared and reported in OPO flowsheet format:
 - Medication type, dose, administration time over the course of donor management
 - o Text field and "other option" will always be necessary for meds/fluids

Infectious Disease Testing

- Improve ways to collect infectious disease results
- Allow reporting of multiple results for each test type
- "Other infectious disease testing" option only provided for COVID-19 testing, and should allow for additional testing
- Recommend collaborating with the OPTN Disease Transmission Advisory Committee

Donor after Cardiac Death (DCD) Information

- Flush time
- Extubation or withdrawal of mechanical support
- Cessation of circulation (i.e. pulselessness, asystole)
- · Declaration of death
- Organ Specific Flush time
- Heparin time
- Reintubation (for lung donors)

Summary of discussion:

One member remarked that these data elements are basic information that should be there for organ allocation. The member continued that there are added benefits of collecting this data, including analyzing correlations donor data and recipient outcomes.

The Chair noted that these data fields could cascade to the Deceased Donor Registration form (DDR), and reduce data burn post-recovery.

A member commented that any changes to make DonorNet more user friendly are important, particularly the ability to filter. The member added that increased, readable information makes those split, in the moment decisions easier and more efficient.

One member noted that these fields can streamline communication, such that transplant programs can access the information when they receive the offer. The member continued that more robust information in DonorNet allows transplant hospitals to make the best decisions for their patients. Another member agreed, adding that this can increase efficiency and reduce risk for human error in communication.

A member remarked that multiple echocardiogram interpretations is a "nice to have" element, and could easily be cut to meet resource constraints. Transplant programs typically want to see the images themselves and having at least one report is helpful.

One member commented that the way infectious disease testing operates in DonorNet currently is not sensible, with one result per pathogen and a box to indicate if the specimen was diluted. Hospitals typically look at test results by samples, including whether or not samples were hemodiluted or taken pre- or post-transfusion and data columns of results if there are multiple samples and results for each

test type. The member continued that it would also be helpful to show historic results and testing if available, instead of having to figure out which test should be used. Another member agreed. The member added that this data collection could pair nicely with the post-recovery test results reporting project. Other members agreed.

The Chair asked if a yes/no data element should be included for normothermic regional perfusion (NRP), noting that it could be value added as the practice becomes more common. The Chair noted that there was uncertainty previously about what data needs to be collected regarding NRP. Staff shared that previous discussions indicated uncertainty due to the practice being relatively new and still experimental. Another member agreed, noting that including NRP data elements could open the door to include more data fields than is feasible to program, given the resource constraints. The member continued that a simple yes/no NRP field could trigger transplant programs to ask for more information as necessary.

3. Prioritization of Clinical Data Collection

The Workgroup discussed and prioritized each section of the proposed data elements.

Data summary:

- The addition of proposed DCD elements is estimated to be a very large programming effort.
- The addition of the proposed echocardiogram elements is estimated to be a large programming effort.
- The addition of the proposed medications/fluids elements is estimated to be a large programming effort.
- The addition of the infectious disease testing elements and updates is estimated to be a small programming effort.

Summary of discussion:

The Chair remarked that each set of proposed elements are value-added projects, and that the size of the project is important when considering project approval relative to research constraints. The Chair continued that the infectious disease testing is a smaller scale project, and could be an appropriate place to start as far as prioritization. The Chair added that the DCD data elements, although a large project, could be broken up into separate projects and still provide significant values.

One member shared that they would prioritize DCD over infectious disease testing, then the medications/fluids data, and end with echocardiogram data. The member noted that around 30 percent of donors are DCD, and there aren't many data points related to it. The four key data points – extubation time, time of pulselessness, declaration time, and flush time – are the most essential, and should be prioritized first. The member added that infectious disease testing elements should be prioritized since the programming effort is relatively small, and that the medications and fluids data are currently available in other ways, though not ideally. Another member agreed, remarking that infectious disease testing should be prioritized, since the project is a small effort and infectious disease testing is highly regulated by the OPTN.

A member recommended including oxygen saturation during the first two hours for DCDs as an element. Another member agreed that could be an important metric, but that it would be secondary compared to the four key elements. The member continued that the initial ask to include hemodynamics and oxygen saturation through withdrawal, agonal, and flush, but if that's too large of an effort, it could be carried over and developed in a later project or second phase.

Staff remarked that Workgroup seems to have decided the DCD and infectious disease elements are higher priority compared to medications/fluids and echocardiogram data. A member agreed.

Staff shared that the Ad Hoc Disease Transmission Advisory Committee may be addressing infectious disease results in one of their own projects. Staff asked if the Workgroup had a preference between DCD and infectious disease data. The Chair commented that the projects should be broken up as much as necessary to mitigate concern about resource constraints, adding that it would be better to get started towards updating DonorNet data collection, even if it's a reduced effort. The Chair noted that the project could also be completed in phases. Another member commented that it might be inefficient to break it up, and that it would be ideal to complete the project at the same time. Staff remarked that it could make more sense to complete the project at once, instead of in phases, and that Staff will find out the best approach for programming.

Upcoming Meeting

• March 3, 2022

Attendance

• Workgroup Members

- o David Marshman
- o Jeffrey Trageser
- o Christopher Curran
- o Kenny Laferriere
- o Erica Simonich
- o Debra Cooper

HRSA Representatives

o Vanessa Arriola

• SRTR Staff

- o Katie Audette
- Matthew Tabaka

UNOS Staff

- o Robert Hunter
- o Kayla Temple
- o Katrina Gauntt
- o Leah Slife
- o Susan Tlusty
- o Ben Wolford
- o Kerrie Masten
- o Lauren Mauk
- Sara Moriarty