

**OPTN Operations & Safety Committee  
Broader Distribution Data Collection Workgroup  
Meeting Summary  
April 20, 2021  
Conference Call**

**Dominic Adorno, Chair**

## **Introduction**

The Broader Distribution Data Collection Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 04/20/2021 to discuss the following agenda items:

1. Recap of 3/16 Meeting & Project Update
2. Review and Discussion: Review of Feedback Proposed New Data Elements, Data Definitions
3. Next Steps

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

### **1. Recap of 3/16 Meeting & Project Update**

The Workgroup reviewed discussions from the previous meeting.

#### Summary of discussion:

The Workgroup completed a comprehensive review of current data elements related to cold ischemic time and perfusion data as well as recovery team and organ disposition. The Workgroup discussed proposing new data elements related to transportation mode and coordination time/allocation.

#### Next steps:

The proposal will continue to be circulated to stakeholder committees for feedback in the development of the data collection proposal.

### **2. Review and Discussion of Current Data Elements**

The Workgroup continued reviewing and discussing current data elements related to broader distribution.

#### Summary of discussion:

##### *Review of Feedback*

The project summary was shared with stakeholder Committees in which they reviewed the Workgroup's recommendations for data elements:

- Include in data collection proposal
- Remove
- Data definition clarification
- Refer to respective Committee for further input

There has been overall support for the data collection efforts. Additionally, there has been overall caution expressed regarding the data burden of introducing new data elements. Initial feedback about the proposed transportation mode data element is as follows:

- May not be applicable for all organs
- Use of Deceased Donor Registration (DDR) form may be a challenge; For thoracic, transportation is usually dictated by transplant programs
- Reasonable to collect, not too burdensome
- Other fields to consider: 'date/time', 'charter company', 'other' with free text, collect only primary or various modes of transport modes

Initial feedback about the proposed transport time data element is as follows:

- Difficult to define; Organ may go to various locations before truly transporting to recovery hospital
- Transportation time is not what drives cold time – the issue is scheduling
- Use a mathematical equation to estimate actual travel time
- Organ Tracking Pilot – would this provide a sufficient amount of data without asking all programs to start tracking transport time?

Specific feedback from the Policy Oversight Committee:

- Reframe focus of project: Project has morphed from assessment of broader distribution to developing a data set to inform future policy
- Remain in collaboration with other projects that complement these data efforts

*Proposed New Data Elements: Transportation Mode & Transport Time*

The Workgroup discussed whether proposing transportation mode as a new data collection element would be too complex.

The Chair explained that due to the complex nature of organ travel, some situations are difficult to report. The Chair also asked if there is validity in transportation mode as a data element because organ procurement organizations (OPOs) and transplant programs might not track the same way.

A member stated that cold ischemic time is more value than transport time due to its complexity. The member suggested there may be value in collecting transportation mode as "Air travel (Y/N)". The member stated that capturing cold ischemic time by collecting cross clamp and transplant time, and creating clear data definitions would be helpful. The member added that Global Positioning System (GPS) tracker data could be used to fill in the gaps in the future.

The Chair stated that accurately capturing cold ischemic time would allow for data analyses for standard deviation times for each organ based on acuity circles, as a way to find outliers. The Chair explained a future project could address those outside one standard deviation to analyze the differences.

The Workgroup previously discussed adding the following as options for the transportation mode data element: 'Air; commercial', 'Air; charter', 'Ground; courier', 'Ground; staff'. The Chair suggesting adding more options, such as a free text field. Members agreed to collect helicopter and drone as options, citing that it is better to have less free text field entries.

The Chair stated that primary mode should be defined as how the OPO gets the organ to the transplant program, not how OPOs transport it around donation service areas. A member agreed and suggested that the data element could allow for multiple modes to be selected. The member explained that these selections would be based on once the organ is shipped from the OPO, which excludes any travel related to OPO logistics.

The Workgroup discussed capturing the most complex mode of transportation but cited it is not always clear what mode is more complex (e.g. helicopter versus five hour airplane travel).

The Workgroup discussed the data burden related to entering transportation mode.

The Chair asked if the staff member that arranged the travel logistics would be entering the data or a different staff member, therefore requiring case notes documenting each mode of transportation. A member responded that their electronic medical record system allows them to document this information. The staff member entering the travel information into the electronic medical record system is different than the staff member entering Deceased Donor Registration (DDR) form data. The member explained that this is a new system to their OPO, so OPOs without this could have a more difficult process to enter travel mode data.

Another member stated that when multiple teams come in from out of town, the OPO does not have all the information of travel logistics.

The Chair asked whether these discussions were centered around kidneys or non-renal organs. The Chair stated that the impact of broader distribution may be less on kidneys, and because of that the Workgroup might suggest to collect transportation mode related to non-renal organs as it is unnecessary to collect too many data points. The Chair explained that transportation mode may be more impactful for livers than kidneys. A member agreed but expressed concern regarding the validity of the data. The Chair agreed that there is concern over validity and quality of the data captured. The Chair stated it would be difficult to gather information from data when there is an option to select multiple modes of transportation. Another member agreed that the burden of this data collection is too high and the validity of the data is too questionable.

The Chair stated support for collecting transplant time. The Chair explained that time of transplant (first anastomosis) minus cross clamp would capture cold ischemic time; theoretically, there would be an increase in cold ischemic time observed through broader distribution.

The Workgroup reviewed the data that would be collected through the UNOS organ tracker pilot, which will collect data through GPS trackers.

The Chair stated that the data collected with GPS trackers is much better than placing the burden on OPOs to collect for all seven organs from a donor. The Chair stated that GPS trackers should be mandated for each organ because it is precious cargo and it would supplement the manual work that this Workgroup is discussing to propose. A member agreed that the data from GPS trackers would result in a more robust data set to analyze. The Workgroup agreed that relying on the GPS tracker for data is better than relying on OPOs to fill out transportation mode for each organ on the DDR.

#### *Data Definitions*

Data element: Total Cold Ischemia Time Left Kidney/Right Kidney EnBloc

- The Workgroup agreed that the data definition should delineate between transport time and cold ischemic time. Additionally, the Workgroup agreed that there should be a delineation between transport time from origin to destination and cold ischemic time from cross clamp to transplant time.

Data element: Lung(s) perfused prior to transplant

- The Workgroup agreed to modify the data definition to reflect “machine perfusion” prior to transplant.

Data element: Left/Right Kidney final resistance at transplant

- The Operations and Safety Committee suggested that data entered should be the final parameters on the OPO side, to have it be reflective of the organ when the OPO sends it out.

- A member asked where OPOs send out kidneys on a pump with a courier. The Chair responded that some OPOs do but they will know the pump parameters before it leaves.

Data element: Kidney Pump Parameters: Time/Flow/Pressure/Resistance

- The Operations and Safety Committee suggested that the final data point is the most relevant. The Operations and Safety Committee recognized there is calibration time, so if initial data point is collected, then it should be collected two hours after the organ is on the pump. A member agreed and stated that most programs make decisions based on the final pump parameters. The Workgroup agreed to collect on the final pump parameters.
- The Workgroup discussed whether it should be mandated to upload pump parameters at a certain frequency. A member stated that their pumps generate PDF reports that could be uploaded. Another member stated that uploaded a final pump report is acceptable, but would not recommend periodic uploading of pump reports. The Workgroup agreed.

Data element: Total organ preservation time from cross clamp to in situ reperfusion

- The Workgroup agreed to define total organ preservation time as cross clamp to transplant time rather than defining warm ischemia and cold ischemia time.

#### Next Steps:

The Workgroup will continue review and discuss data to identify gaps and recommend data element changes. The Workgroup will continue to seek feedback as a data collection proposal is developed. A data collection proposal is expected to go out for Summer 2021 Public Comment.

#### **Upcoming Meeting**

- May 18, 2021 (teleconference)

## Attendance

- **Workgroup Members**
  - Daniel Stanton
  - Dominic Adorno
  - Jillian Wojtowicz
  - Kim Koontz
  - Rich Rothweiler
  - Steve Johnson
- **HRSA Representatives**
  - Arjun Naik
  - Marilyn Levi
- **UNOS Staff**
  - Ben Wolford
  - Casey Humphries
  - Dawn Beasley
  - Joann White
  - Katrina Gauntt
  - Kimberly Uccellini
  - Kristine Althaus
  - Lauren Motley
  - Matt Prentice
  - Meghan McDermott
  - Melissa Lane
  - Nicole Benjamin
  - Randall Fenderson