

Meeting Summary

OPTN Operations and Safety Committee Meeting Summary May 27, 2021 Conference Call

Christopher Curran, CPTC, CTBS, CTOP, Chair Alden Doyle, MD, MPH, Vice Chair

Introduction

The Operations and Safety Committee (the Committee) met via Citrix GoTo Meeting teleconference on 05/27/2021 to discuss the following agenda items:

1. Review and Discussion: Data Collection to Evaluate Ischemic Time

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

1. Review and Discussion: Data Collection to Evaluate Ischemic Time

The Committee reviewed the Broader Distribution Data Collection Workgroup's (the Workgroup) proposed data set.

Summary of discussion:

A member suggested including data on time between organ procurement and start of pump as well as total time on pump. The Chair agreed this is important data but is outside the scope of this project. The Chair added that there is a lot of variability in collecting the suggested data, and it would be difficult to determine the essential data elements that would accurately capture it.

Another member suggested collecting normothermic regional perfusion data. The Chair agreed that is data that needs to be collected in the future, and that the public comment proposal could include a feedback question related to normothermic regional perfusion data collection.

A member expressed concern regarding collecting data while allocation processes are not stable due to recent and ongoing changes. The member stated that the data might not be useful since the new processes have not yet stabilized.

Proposed data element: Organ Check-in

The Chair of the Workgroup stated that collecting organ check-in time will allow for delineation between time of transport and time of implant. The Chair of the Workgroup explained that this will aid in understanding time relative to travel versus scheduling logistics. The Chair of the Workgroup added that the collection of this data point will increase public trust that the community can efficiently and safely move organs. The Committee agreed and stated that collecting organ check-in time would not be burdensome.

The Chair of the Workgroup stated that capturing an accurate transport time allows for expected time of transport to be calculated. The Chair explained that these baseline expectations can be utilized to assess outliers as well as programs performing efficiently.

Staff asked if the proposal should include an organ check-out time. The Vice Chair stated that organ check-in time is an important data element because it is the point where the custody of the organ

changes from the organ procurement organization (OPO) to the transplant program. Another member stated that organ check-out time could be captured when the organ is scanned into TransNet. The Chair of the Workgroup stated that organ check-out time could be included in the proposal as a new data element. The Chair of the Workgroup added that the OPO has custody from cross-clamp to organ-check-in, and that time period can be used to measure efficiency of the OPO moving organs.

A member asked whether a transplant program will have to enter an organ check-in time if a transplant program receives an organ but decides not to transplant the organ. The Chair of the Workgroup responded that organ check-in will need to be defined. The Chair suggested organ check-in to be defined as the check-in time documented at the organ's final disposition (where the organ was transplanted).

Proposed data element: Time of first anastomosis

Staff asked if transplant programs will be expected to submit a total cold ischemic time or will the discrete fields be utilized as a way to calculate cold ischemic time. A member stated that time of first anastomosis does not reflect the end of cold ischemic time. The Chair stated that regardless of what the duration of time is titled, it is an important data element to collect and removes the burden of members manually calculating a number. The Chair stated that the definition of transplant in policy is first anastomosis which is the reason members use it as a surrogate of end of cold ischemic time. A member added that first anastomosis is how transplant programs prove compliance with ABO verification policy. The Vice Chair suggested that reperfusion as a time point could be considered.

Another member stated that due to various philosophies of transplant programs, there will be huge discrepancies in cold ischemic time which do not necessarily reflect the ultimate outcome of the organ. The Chair agreed and stated that that is the reason that discrete data points should be collected.

The Chair of the Workgroup stated that data points have been grouped into defining cold ischemic time, and suggested asking the community what is beneficial for transplant programs to make organ acceptance decisions. The Chair of the Workgroup stated that the purpose of trying to capture these data elements is for individuals to make decisions to safely transport organs, and if cold ischemic time is not a helpful surrogate for the quality of an organ why should it be collected. The Chair of the Workgroup added that cold ischemic time is important from a research standpoint to understand the impacts of time outside the body, but this information seems variable based on how the organ is handled once it is procured. The Vice Chair responded that while cold ischemic time does not capture the whole story, it still helps with decision making. The Vice Chair added that it is a discrete, understandable field that helps with partial understanding of moving into continuous distribution frameworks.

There were no additional questions or comments. The meeting was adjourned.

Next steps:

The Committee will review a revised data collection proposal and vote to send it to Summer 2021 Public Comment during their June 10, 2021 meeting.

Upcoming Meetings

- June 10, 2021 (teleconference)
- July 22, 2021 (teleconference)

Attendance

• Committee Members

- Alden Doyle
- Audrey Kleet
- Christopher Curran
- Dominic Adorno
- o Greg Abrahamian
- o Joanne Oxman
- Kimberly Koontz
- o Luis Mayen
- o Melinda Locklear
- o Rich Rothweiler
- Susan Stockemer
- Susan Weese

• HRSA Representatives

- o Jim Bowman
- o Vanessa Arriola

SRTR Staff

Katie Audette

UNOS Staff

- Carly Engelberger
- Dawn Beasley
- o Emily Womble
- o Joann White
- Kristine Althaus
- Leah Slife
- Matt Prentice
- Meghan McDermott
- Nicole Benjamin
- o Randall Fenderson
- Supraja Malladi