

Meeting Summary

OPTN Operations and Safety Committee Meeting Summary May 25, 2023 Conference Call

Alden Doyle, MD, MPH, Chair Kim Koontz, MPH, Vice Chair

Introduction

The OPTN Operations and Safety Committee (the Committee) met via Citrix GoToMeeting teleconference on 05/25/2023 to discuss the following agenda items:

- 1. Review and Discussion: Collect Donor CRRT, Dialysis, and ECMO Interventions Data proposal
- 2. Discussion: Offer Filters in Continuous Distribution

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

1. Review and Discussion: Collect Donor CRRT, Dialysis, and ECMO Interventions Data proposal

The Committee reviewed and voted on the final language for the Committee's *Collect Donor CRRT, Dialysis, and ECMO Interventions Data* proposal.

The purpose of the proposal is to develop a standard format for tracking the use of donor support interventions with the OPTN Donor Data and Matching System and Data System for the OPTN. Currently, this data is not collected in a standardized/uniform format. The intent of the data collection is to help inform decisions for offer filters (ex. creatinine values (true values or reflective due to support intervention) as well as assess outcomes.

The Committee is proposing two data fields:

- Parent field that indicates the initiation of a donor support therapy: This field will ask if any
 donor support therapies have been initiated from the time of terminal event and would require
 a "yes" or "no" response. If the response is "no", no futher action is needed. If the response is
 "yes", a subsequent field will appear to document specifications of the donor support therapies.
- Support Interventions Specifications (subsequent field): If the response is "yes" from the previously outlined data field, this field will appear and ask for the type of donor support therapy used and the date/time the therapy began and ended.

The Donor Support Interventions Workgroup ("the Workgroup") met on May 3, 2023 to review and provide additional input for the Committee to consider in finalizing the proposal. The Workgroup were in support of the project and suggested generalizing the list of donor support therapies as follows:

- VV ECMO
- VA ECMO
- Impella
- CRRT
- RVAD

- LVAD
- Hemodialysis
- Balloon pump
- Inhale Therapies

Summary of discussion:

The Committee Chair commented that the correct term should be "inhaled therapy" (versus "inhale therapy"). Additionally, the Committee Chair suggested in keeping the terms gernalized, rather than using hemodialysis, the term should be generalized to intermittent kidney replacement therapy (KRT) and continuous kidney replacement therapy (CKRT).

A member recommended to include a definition detailing KRT and CKRT to ensure uniformity about what they entail, since medical personnel may not be the only ones filling out the Support Intervention Specification data fields. Another member suggested to group the terms together broadly, since there are many versions of technologies and KRT's now.

The Committee Chair asked the Committee, specifically those with thoracic experience, what category Impella devices would fall into. A member responded that it would be under 'Temporary Mechanical Circulatory Support', or Temporary MCS'. It was recommended by a member to include a descriptor of dialysis to enforce uniform understanding.

There were no further questions or comments. The Committee was called to a vote on the policy language and revisions that would be included in the proposal that would be going out for the July 2023 public comment cycle.

Vote:

- Support 13
- Oppose − 0
- Abstain 0

Next steps:

The final language will be included in the *Deceased Donor Support Interventions Data Collection* proposal that will be submitted for the July 2023 public comment cycle.

2. Discussion: Offer Filters in Continuous Distribution

The Committee was updated on operational discussions related to the Kidney-Pancreas (KP) Continuous Distribution (CD) project and provided feedback on the functionality of the offer filters tool within the framework once implemented in the future.

<u>Summary of discussion:</u>

The Committee began discussions surrounding the question, "should region and donation service areas (DSAs) be available as a factor for transplant programs to create filters?". A member suggested that DSA should be converted to distance. The Committee Chair suggested that DSA should be eliminated in organ allocation entirely because this is the direction everything else is going in organ allocation. A member emphasized the importance of consistency in terminology and recommended that if current terminology is not correct, it should be removed. A member suggested that if DSA is removed, region should also be removed, as they did not believe it was appropriate for allocation purposes and are considered to be arbitrary. The Vice Chair emphasized that there is no reason to keep regions since it should be focused on distance. A consensus was reached with the Committee recommending that DSA be removed as an option from filters and convert DSA and region into distance. The Chair recommended this remediation take place, followed by education about the removal of DSA and regions and transforming these filters into distance.

The next discussion question was "does there need to be a pause on automatic enabling of model-recommended filters when CD is implemented?". A member inquired about the timelines for

implementation for both CD and for offer filters. Staff let the member know that the anticipated date is June 2024 for BoD approval and implementation typically takes a year, depending on any delays that may arise, however there is no formal implementation date at this time. The Chair added that following BoD approval, there would be a period of time during which transplant programs are adjusting to the new system regarding offer filters, and then there would be a period of time to allow programs to adjust to kidney CD. A non-Committee member suggested that transplant centers use a separate browser window, which could be helpful when they open a match run by giving further detail about the offer and how to use the sequence.

The next discussion question was: "is it still appropriate to provide the option to exclude candidates with O-ABDR mistmatch from filters or should this be modified to O-DR?". A member said that her institution would want to keep it as ABDR, as clinical staff will make a different clinical decision on a different kidney for that type of patient. The Chair acknowledged that the Committee wants to leave flexibility going forward, depending on what the transplant community wants to do, but does not want to lose the specific category of O-ABDR.

The Committee then discussed the question: "are there concerns with having different screening rules between the 2 tools or is this appropriate as they are applied differently?". A member voiced support for the two tools, agreeing that they will operate differently and screen biopsy results in different ways, which will be beneficial. The Chair and Vice Chair affirmed this.

UNOS staff asked OPO staff if their organization enter data via the Offer Filters Data Collection window. It was requested that OPO staff who are also Committee members bring this information to the next meeting.

Next steps:

The Committee's feedback will be taken back to the OPTN Kidney Transplantation Committee for further review. The Committee may be consulted with again as the Kidney Committee continues work to finalize recommendations the Continuous Distribution of Kidneys proposal.

Upcoming Meeting

• June 22, 2023 (Teleconference)

Attendance

Committee Members

- o Alden Doyle
- o Kim Koontz
- o Andy Bonham
- o Dominic Adorno
- o Jami Gleason
- o Jennifer Smith
- o Jill Campbell
- o Jillian Wojtowicz
- o Julie Bergin
- o Mony Fraer
- o Renee Morgan
- Norihisa Shigemura
- o Paige Oberle
- o Melissa Parente
- Sarah Koohmaraie
- o Snehal Patel
- o Stephanie Little
- o Susan Stockemer

HRSA Staff

o Jim Bowman

• SRTR Staff

Katherine Audette

UNOS Staff

- o Betsy Gans
- o Kim Woodard
- o Kerrie Masten
- o Carlos Martinez
- o Joann White
- o Isaac Hager
- o Kerrie Masten
- o Laura Schmitt
- o Lauren Motley
- o Lauren Mauk
- o Rob McTier

Other

- o Anja DiCesaro
- o Nicole Toran