

OPTN Operations & Safety Committee

Meeting Summary

February 24, 2022

Conference Call

Chris Curran, CPTC, CTBS, CTOP, Chair

Alden Doyle, MD, MPH, Vice Chair

Introduction

The Operations & Safety Committee (the Committee) met via Citrix GoTo Meeting teleconference 02/24/2022 to discuss the following agenda items:

1. Public Comment Presentation: Establish Minimum Kidney Donor Criteria to Require Biopsy
2. Public Comment Presentation: Standardize Kidney Biopsy Reporting and Data Collection
3. Update: Time Zone on Labels

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

1. Public Comment Presentation: Establish Minimum Kidney Donor Criteria to Require Biopsy

The Committee received a presentation on the OPTN Kidney Transplantation Committee's *Establish Minimum Kidney Donor Criteria to Require Biopsy* proposal.

Summary of discussion:

The Committee agreed with the proposed set of criteria. The Chair asked if the proposal includes language to address instances where an OPO encounters a donor hospital that refuses to perform a biopsy. The Vice Chair of the Kidney Transplantation Committee responded that the proposal intends to establish a reasonable foundation in which both organ procurement organizations (OPOs) and transplant programs will agree.

The Vice Chair mentioned that there is wide variation in interpretation of biopsy results based on who reads the results and their relevant experience. The Vice Chair recommended that there should be a progression towards whole slide scanning for biopsy review, as well as a centralized pathology service which is available 24-hours a day. The Vice Chair asked if there are proposed criteria for when a biopsy does not need to be performed. The Vice Chair of the Kidney Transplantation Committee responded that this proposal is a starting point, and it does not establish that type of criteria.

The Chair suggested that renal replacement therapy and fluid management should be distinguished. The Chair also suggested that a data field in DonorNet should be added to capture whether a donor is on renal replacement therapy. Another member agreed and suggested that adding "excluding fluid management" on the renal replacement therapy criteria is an important distinction. The Chair also suggested the proposal should consider whether to set guardrails for circumstances when two biopsies are performed and there are various biopsy result interpretations.

A member stated that biopsy slides should be available for transplant programs to use their own kidney pathologists, or biopsy slides should be digitalized and sent to a centralized pathology service. The member explained this would help eliminate contentious reports, and the need to re-biopsy. The member emphasized that transplant programs need as much information as available.

Another member asked why the criteria includes kidney donor profile index (KDPI) and expanded criteria donor (ECD). The Vice Chair of the Kidney Transplantation Committee stated that KDPI and ECD do not always equate, so that is why they are both included.

A member asked if pediatric en bloc kidneys are included within the minimum criteria for biopsy. The Vice Chair of the Kidney Transplantation Committee responded that pediatric kidneys are not included within the proposed minimum criteria.

Next Steps:

The Committee's feedback will be drafted into a formal public comment response and submitted.

2. Public Comment Presentation: Standardize Kidney Biopsy Reporting and Data Collection

The Committee received a presentation on behalf of the OPTN Kidney Transplantation Committee's *Standardize Kidney Biopsy Reporting and Data Collection* proposal.

Summary of discussion:

A member asked if the proposal includes a recommended number of glomeruli needed. The Vice Chair of the Kidney Transplantation Committee responded that there is not a recommended number of glomeruli in the proposal. The Chair suggested adding a recommendation at the top of the form to specify fifty glomeruli per kidney in order to receive an adequate sample size.

A member stated that operationalizing this may be difficult and expressed concern for it being a requirement due to remote transplant programs without centralized pathologists.

The Chair suggested that the form should be customizable in order to insert OPO specific contact information. Another member suggested that there should be a pathway for accepting transplant programs to be notified that biopsy information is available. Staff clarified that this proposal impacts UNet data collection in DonorNet and the Deceased Donor Registration (DDR) form. The Chair suggested adding renal replacement therapy into this data collection effort.

Next Steps:

The Committee's feedback will be drafted into a formal public comment response and submitted.

3. Update: Time Zone on Labels

The Committee was updated on recent time zone label enhancements.

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

Upcoming Meetings

- March 25, 2022 (Richmond, Virginia)
- April 28, 2022 (teleconference)

Attendance

- **Committee Members**
 - Alden Doyle
 - Andy Bonham
 - Audrey Kleet
 - Chris Curran
 - Dominic Adorno
 - Greg Abrahamian
 - Jami Gleason
 - Joanne Oxman
 - Kimberly Koontz
 - Melinda Locklear
 - Melissa Parente
 - Paige Oberle
 - Renee Morgan
 - Rich Rothweiler
 - Stephanie Little
 - Steven Johnson
 - Susan Stockemer
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Katie Audette
- **UNOS Staff**
 - Charles Fenderson
 - Joann White
 - Kayla Temple
 - Kerrie Masten
 - Lauren Mauk
 - Lauren Motley
 - Lindsay Larkin
 - Meghan McDermott
 - Susan Tlusty
- **Other Attendees**
 - Jim Kim