

**OPTN Policy Oversight Committee
Biopsy Standards Workgroup
Meeting Summary
July 2, 2020
Conference Call**

Christopher Curran, CPTC, CTBS, CTOP, Chair

Introduction

The Biopsy Standards Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 07/02/2020 to discuss the following agenda items:

1. Review of Progress to Date
2. Biopsy Practices and Standards Discussion
3. Next Steps

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

1. Review of Progress to Date

The Workgroup reviewed takeaways from previous meeting.

Summary of discussion:

Key takeaways:

- Project will encompass all types of biopsies
- High variability in biopsy standards
- Challenges in accessing pathologists
- Discrepancies in biopsies results based on pathologists' level of experience and area expertise
- No consistency of getting results back to the offering organ procurement organizations (OPOs)
- Issues with availability and quality of biopsy images in DonorNet

2. Biopsy Practices and Standards Discussion

The Workgroup listened to presentations from UNOS research staff and SRTR staff, and continued discussion on biopsy standards.

Data summary:

UNOS research staff presented their new study, *Quantifying the Association between Kidney-Specific Prognostic Markers and Long Term, Post-Transplant Outcomes to Reduce Kidney Discard*, which aims to perform the first, U.S. national registry analysis of biopsy findings and long-term recipient outcomes.

- UNOS staff presented a graph that showed kidney discard rate is at nearly 20%, 3,755 kidneys were recovered for transplant but not utilized in 2018.
- A graph from *Diagnosing the Decades-Long Rise in the Deceased Donor Kidney Discard Rate in the United States* showed that biopsy findings may be a reason for unjustifiable discards of kidneys which might provide survival benefit. Another graph from this study showed, among kidneys recovered for transplant, the percent for which a procurement biopsy has doubled since 2000.

- A graph from *Variation in use of procurement biopsies and its implications for discard of deceased donor kidneys recovered for transplantation* showed that a biopsy is associated with a significantly higher odds of kidney discard.
- *Change in Acceptance Rates Associated with Experimental Manipulation of Biopsy Findings* graph showed a 40% acceptance rate on 'poor' biopsy findings, 71% acceptance rate on no biopsy, and 72% acceptance rate for 'good' biopsy findings.
- A graph, from a matched control study, showed that biopsy data appears to be predictive.

Summary of discussion:

A member asked if the biopsy data is from biopsies conducted by the host OPO. UNOS research staff responded that the majority of the data is from the OPO side.

SRTR staff presented *Procurement Biopsy Randomized Control Trial (RCT) Feasibility*. A member asked if SRTR was aware of any findings from a study in Europe which withheld biopsy results until after transplantation of the organ. SRTR staff was not aware of the study but mentioned a current, ongoing study from the UK in which they are piloting a centralized biopsy system.

A member asked if there is research on confocal microscopy for kidney or liver biopsies in regards to transplantability. SRTR staff responded they are not aware of any research but agreed there could be potential improvement in the optimization of biopsy technique and biopsy readings.

Another member asked if there are instances of further in depth pathology analysis on kidneys deemed non transplantable because of biopsies. SRTR staff responded that they are unaware of any related research but mentioned a small, observational study which they conducted. The study researched two biopsied kidneys, one transplanted and one discarded, and analyzed the long term outcomes of the transplanted kidney. A member asked if, in that study, the center that transplanted the kidney was the same center that refused the contralateral kidney. SRTR staff responded that the kidney was refused by multiple centers because of biopsy findings so it is hard to isolate one center as the reason for discard. The member also asked if the center which transplanted the kidney re-biopsied and found different results than the initial biopsy. SRTR staff believed the study did look at re-biopsies but would have to read the study for the details. The member stated that their center re-biopsies every kidney and often find themselves accepting kidneys that other centers refused based on initial biopsy findings, and wonders how the use of multiple biopsies can be used to drive decision making.

Another member stated the sampling error of biopsies creates a lot of the mentioned problems. A member asked if transplant centers in Europe review the same outcomes as the United States. SRTR staff responded that they think there are differences among the two countries. The Chair stated it is important to consider how to align the predictability of biopsy with transplant center outcomes, in comparison to Europe. The Chair mentioned the solution to this alignment and comparison is difficult because of the risk adverse culture that has been created because of the United States' payer system.

Members discussed the relationship between biopsies and biopsies reading with behavioral research. The Chair stated that studying behavior is important but changing behavior not may not be in the purview of the Workgroup's ability. The Chair suggested the Workgroup should focus on tangible recommendations that can be implemented in reasonable ways which enable centers to have the information they want to make decisions.

3. Next Steps

Members will receive a poll for their availability. Next Workgroup meeting will be scheduled to continue discussion.

Upcoming Meeting

- July 22, 2020 (teleconference)