

**OPTN Kidney Committee
Biopsy Best Practices Workgroup
Meeting Summary
May 24, 2021
Conference Call**

Andrew Weiss, MD, Chair

Introduction

The Biopsy Best Practices Workgroup (the Workgroup) met via teleconference on 05/24/2021 to discuss the following agenda items:

1. Welcome and Updates
2. Review Project Timeline
3. Discussion: Data Request Development

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

1. Welcome and Updates

The Workgroup was informed of OPTN Policy Oversight Committee approval of both Workgroup projects, as well as upcoming OPTN Data Advisory and Executive Committees review of projects for endorsement and approval.

Summary of Discussion:

The Workgroup had no questions or comments.

2. Review Project Timeline

The Workgroup reviewed the project scope, goals, and timeline leading up to public comment.

Summary of discussion:

The Workgroup had no questions or comments.

3. Discussion: Data Request Development

The Workgroup discussed and developed a data request to inform the minimum criteria appropriate to initiate biopsy project, including incorporating feedback provided by the OPTN Kidney Transplantation Committee.

Summary of discussion:

The Chair remarked that the data request should include a retrospective of what kinds of donors have been biopsied, and how many would have met the proposed criteria. This kind of data would help indicate if such a policy would result in a general increase or decrease in the number of biopsies performed. The Chair continued that data on retrospective biopsy performance could also be stratified by Kidney Donor Profile Index score (KDPI). The Chair also pointed out that the focus of the project is to standardize biopsy practice, and will be critical to framing both the data and the proposal.

One member suggested including utilization and discard rates along with the volume of biopsy. If discard rates are associated with increases in biopsy, it may warrant further discussion and updates to the

criteria. Staff clarified that this data will be retrospective, and won't be predictive of future biopsy, utilization, and discard rates.

A Scientific Registry of Transplant Recipients (SRTR) representative recommended expanding the criteria to include evidence of left ventricular hypertrophy via an echocardiogram, as this indicates that the donor kidneys may be impacted by unknown or undiagnosed hypertension. The Chair iterated that the minimum criteria represents the minimum of donors that should default to being biopsied, and that other kidneys may still be biopsied as necessary or requested. The SRTR representative pointed out that some organ procurement organizations (OPOs) may be reluctant to biopsy any kidneys not meeting the minimum criteria. The Chair agreed that was a good point, and that would be an unintended consequence to consider in the development of the proposal. Another member remarked that the literature points to biopsy leading to discard, and that more restrictive minimum criteria for mandatory biopsy would be preferable. The member continued that the Workgroup will need to thoroughly review the literature to develop and support the reasoning for the minimum criteria.

One member asked the group whether nephrotic range proteinuria should be included in the criteria. An SRTR representative responded that the vast majority of donors have proteinuria at some point, and that proteinuria is not typically quantified for all donors.

The Workgroup Chair shared an article¹ finding that about half of all deceased donor kidneys are biopsied, including 85 percent of all extended criteria donors (ECDs), and that biopsy findings were reported as the main reason for discard for 37 percent of all discarded kidneys. The Chair continued that this is why the Workgroup focus centers biopsy utilization for appropriate placement, instead of discard. A Workgroup member remarked that it can be difficult to point to discards as a result of biopsy, particularly as many donors for whom biopsy is requested have a number of issues that could lead to decline. In situations where a biopsy is requested and not performed, a decision must be made without potentially critical information. In situations where a biopsy is requested, performed, and produces poor results, then the decline is very often appropriate for that candidate. The Chair agreed, and pointed to literature comparing similar kidneys from the European Union (EU) and the United States that found the outcomes do not differ significantly, but that the EU discards and biopsies at lower rates.

Staff prompted the Workgroup to explain the motivation for performing a biopsy and the details of how biopsy information can inform organ offer evaluation. An SRTR representative explained that the reason for biopsy request matters – for younger donors with high creatinine due to trauma, a biopsy can confirm there is no lesion or other irreversible damage to the kidney. In a situation where the donor is anuric, the biopsy would confirm presence of cortical necrosis. If the donor is older, interstitial fibrosis and glomerular sclerosis can indicate if a marginal kidney is appropriate for a given candidate. The SRTR representative continued that a 10 to 20 percent glomerular sclerosed kidney wouldn't perform as well in a larger patient, but could be beneficial for an older petite patient. The SRTR representative added that extreme biopsies with severe fibrosis and sclerosis could indicate a non-transplantable organ, but that otherwise, biopsies inform the candidate-organ matching. The Workgroup Chair agreed, and presented an example of two patients – the first a 65 year-old diabetic patient on dialysis, with a life expectancy of maybe 3 years; the second is a 35 year-old polycystic kidney disease patient on dialysis, with decades of life expectancy. In a situation where a kidney has a fair amount of scarring that could last 6 to 8 years, the kidney could be an opportunity to remove a patient from dialysis and the waiting

¹ Carpenter, Dustin et al: Procurement Biopsies in Evaluation of Deceased Donor Kidneys. *Clinical Journal of the American Society of Nephrology* 13: 1876-1885, 2018

list, such as the former. However, it would be a poorly matched kidney for the latter patient, as that patient will likely return to the waiting list in 6 to 8 years.

Staff remarked that there could be a fair amount of selection bias influencing outcomes data and the results of a descriptive analysis. The Chair agreed, noting that the literature does discuss the relationship between biopsy results and outcomes, and the criteria on the screen and outcomes. An SRTR representative noted that so many factors influence kidney acceptance and decline, including kidney morphology. The SRTR representative agreed that the decision is multi-faceted, and a decline decision is rarely based on biopsy alone.

The Workgroup achieved consensus that the data request as discussed so far, including retrospective biopsy performance volume, volume of donors meeting proposed minimum criteria that were and were not biopsied, whether the implementation of minimum criteria would indicate a change in the number of biopsied kidneys, and utilization and discard rates were a solid starting place.

The Workgroup chair asked the group whether they would return to the criteria if the data results showed that set of minimum criteria for mandatory biopsy could result in *more* biopsies being performed. Staff clarified the data request is retrospective only, and not prospective or revealing projected effects. An SRTR representative responded that the data would inform the project, but not drastically alter the goal or the criteria of standardization, and that such data results would not invalidate a rationale of standardization. Another member agreed.

Upcoming Meeting

June 28, 2021 – Teleconference

Attendance

- **Committee Members**
 - Andrew Weiss
 - Arpita Basu
 - Catherine Kling
 - Dominick Santoriello
 - Jim Kim
 - Julianne Kemink
 - Meg Rogers
- **HRSA Representatives**
 - Jim Bowman
 - Marilyn Levi
 - Raelene Skerda
- **SRTR Staff**
 - Bryn Thompson
 - Jon Miller
 - Nick Salkowski
 - Peter Stock
- **UNOS Staff**
 - Lindsay Larkin
 - Amanda Robinson
 - Kayla Temple
 - Tina Rhoades
 - Ross Walton
 - Benjamin Welford
 - Lauren Motley
 - Leah Slife
 - Nicole Benjamin