

**OPTN Kidney Committee
Biopsy Best Practices Workgroup
Meeting Summary
April 20, 2021
Conference Call**

Andrew Weiss, MD, Chair

Introduction

The Biopsy Best Practices Workgroup (the Workgroup) met via teleconference on 04/20/2021 to discuss the following agenda items:

1. Review Project Goals, Timeline, and Summarize Discussions
2. Review Kidney Committee Feedback
3. Finalize Recommendations

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

1. Review Project Goals, Timeline, and Summarize Discussion

The Workgroup reviewed the project purpose and goals, the project timelines leading up to Public Comment, and the recommendations developed by the group so far, including a set of minimum criteria appropriate for kidney biopsy and a standardized pathology report.

Data summary: Minimum criteria appropriate for biopsy:

Absolute criteria:

- Anuria
- Renal replacement therapy
- Diabetes, including diagnosis during donor evaluation
- KDPI \geq 85 percent
- Donor age 60 or older
- Donor age 50-59, and at least two risk factors: hypertension, cerebrovascular accident as manner of death, and/or a terminal creatinine \geq 1.5

Summary of Discussion:

A Scientific Registry of Transplant Recipients (SRTR) representative noted that many younger donors with significant hypertension history are not often biopsied, but have significant disease that would have been found in a biopsy. These are particularly tricky because they have a low Kidney Donor Profile Index score (KDPI), and are allocated to pediatric and low Estimated Post-Transplant Survival patients. The Chair agreed, pointing out that the proposed criteria is only the minimum criteria, and that biopsies may be performed on donors that do not meet those criteria. The SRTR representative expressed concern that minimum criteria could result in organ procurement organizations (OPOs) entertaining fewer requests for biopsies. The language could potentially reflect this opportunity for surgeons and nephrologists to request a biopsy on a donor not meeting that minimum criteria, but for whom it would still be appropriate.

The Chair proposed altering the language from “minimum criteria” to “recommended criteria.” A member disagreed, as “recommended” removes a sense of mandatory performance, but agreed that some kind of language should be included so surgeons can request biopsies as they are needed. Another member agreed. A HRSA representative recommended removing the age requirement from the 50-59 and two risk factors criterion. Members disagreed, as this could lead to kidneys being biopsied inappropriately and ultimately result in more unnecessary biopsies.

Several members agreed that the “criteria for consideration of biopsy performance” should be excluded, as such general wording adds little value and could cause confusion.

One member expressed concern about “diabetes, including diagnosis during donor evaluation,” remarking that many donors have high sugars due to the steroids used in donor management. Another member responded that this diagnosis on evaluation would be more reflective of an elevated hemoglobin A1C.

The Chair recommended the Workgroup review the previous years’ donor data to see how many donors would meet the criteria, as well as potential differences in the size of the biopsied donor pool and the size of donor pool that met minimum criteria. This data will be helpful in developing appropriate policy and in providing a strong rationale for standardization.

The Workgroup achieved consensus that these criteria were reasonable and sufficient.

Data summary: Standardized Pathology Report

Standardized Pathology Report:

- Biopsy type: Wedge, Core Needle
- Tissue preparation technique: frozen section, formalin-fixed paraffin-embedded section
- Number of glomeruli: ____
- Number of glomeruli sclerosed: _____
- Percent globally sclerotic glomeruli: less than 5 percent, 5-10 percent, 11-25 percent, and greater than 25 percent
- Nodular sclerosis: present, absent
- Interstitial fibrosis / tubular atrophy: less than 5 percent, 5-10 percent, 11-25 percent, 26-50 percent, and greater than 50 percent
- Vascular disease (percent luminal narrowing): none (1-10 percent), mild (11-25 percent), moderate (26-50 percent), severe (greater than 50 percent)
- Cortical necrosis: focal (less than 10 percent), diffuse (greater than 50 percent)
- Fibrin thrombi: focal (less than 10 percent), diffuse (greater than 50 percent)

Summary of discussion:

One member noted that the breakdowns between diffuse and focal were not clear, and that classic renal pathology defines focal as less than 50 percent and diffuse as greater than 50 percent for fibrin thrombi and cortical necrosis characteristics. The member continued that typically, a pathologist would give the percentage for both characteristics in the diagnosis, and suggested altering those response options to “absent” or “present”, and have “present” prompt an estimated percentage. Leaving the categories as “focal” and “diffuse” results in a loss of information. The Chair recommended providing the definitions for “focal” and “diffuse” beneath the appropriate characteristics as well, in order to ensure those evaluating the report have greater context and comprehension.

One member remarked that the operationalization of the standardized form will likely impact the best response formatting for each characteristic and element.

2. Review Kidney Committee Feedback

The Workgroup reviewed feedback given by the OPTN Kidney Transplantation Committee after project presentation on April 14, 2021.

Data summary:

The Kidney Committee provided the following comments:

- A standardized minimum process to establish when a biopsy should be performed will help decrease the discard rate
- The Workgroup could utilize minimum donor criteria to compare previous donor and biopsy data to see how many biopsies would have been performed with new criteria versus the number performed
- Future projects could link biopsy results to allocation, which could help ensure kidneys with less optimal results can be efficiently and appropriately placed
- Keeping absolute values for number of glomeruli and number of glomeruli sclerosed is critical, but the percentage categories for globally sclerotic should be more granular at the upper levels

Summary of discussion:

The Workgroup Chair remarked that the Kidney Committee was sensitive to the possibility that a set of minimum criteria could result in more biopsies being performed, as opposed to uniformity in occurrence and performance. The Chair continued that education will be critical if a policy is put forth, particularly about utilizing biopsies to optimize recipient-organ matching instead of determining overall organ usability.

3. Finalize Recommendations

The Workgroup finalized their project recommendations to send to the Data Advisory Committee (DAC) for endorsement and the Policy Oversight Committee for approval, including decisions to pursue policy or guidance and operationalization of the biopsy report form in UNetSM.

Summary of discussion:

A member remarked that the wording of the policy language will be critical, particularly to avoid any misunderstanding regarding biopsy performance for kidneys not meeting the minimum criteria. Another member agreed.

Several members noted that updating policy to require kidney biopsy for donors meeting the minimum set of criteria would be preferable to develop a similar guidance document. The Chair agreed, and pointed out that standardization of biopsy performance does not necessarily need to result in more biopsies overall. The Chair continued that developing guidance regarding biopsies may not be as impactful as a policy in standardizing practices. Another member disagreed, and noted that guidance documents can be critically useful for both transplant programs and OPOs. The member added that guidance is a strong option if there is potential for a proposal to fare poorly in public comment.

The Workgroup achieved consensus that policy should be updated to require kidney biopsy performance for donors meeting a set of minimum criteria.

A member pointed out that expanding mandatory data entry could receive pushback from the community, although recent data efforts for COVID-19 and updated increased risk guidelines has moved forward with little controversy. Another member added that the data entry element could also receive negative feedback from the OPTN Policy Oversight Committee upon project review and approval. Staff

shared that all policy proposals summarize and highlight the potential impacts of the proposed policy on transplant programs, OPOs, and other kinds of members.

The Workgroup Chair recommended maintaining distinction and separation between the minimum criteria appropriate for biopsy and standardized pathology report projects, so they are not dependent on each other.

Staff remarked that integrating the biopsy report fields into UNet could increase implementation time for the standardized pathology report.

One member suggested operationalizing the report as a paper form first, with the intention to integrate that data into UNet later on. One member noted that UNet currently collects biopsy data, just not to a granular extent. The member continued that many OPOs do not currently input the data into these fields. The Chair remarked that OPOs collect and share the information anyway, and that centralizing data entry to UNet would improve efficiency. Another member agreed, adding that incorporating the data into UNet would provide the greatest benefit, as it will ultimately be simpler and more efficient for both OPO and transplant program users. One member noted that incorporating the data to UNet would also allow biopsy data to be tracked and potentially utilized later on.

The Workgroup achieved consensus that the standardized biopsy report should be operationalized as data entry fields in UNet.

Upcoming Meeting

TBD

Attendance

- **Committee Members**
 - Andy Weiss
 - Colleen O'Donnell Flores
 - Dominick Santoriello
 - Jim Kim
 - Julianne Kemink
 - Malay B. Shah
 - Martha Pavlakis
 - Meg Rogers
- **HRSA Representatives**
 - Marilyn Levi
- **SRTR Staff**
 - Bryn Thompson
 - Nick Salkowski
 - Peter Stock
- **UNOS Staff**
 - Lindsay Larkin
 - Kayla Temple
 - Amanda Robinson
 - Ben Wolford
 - Lauren Motley
 - Nicole Benjamin