OPTN Kidney Transplantation Committee
Biopsy Best Practices Workgroup
Meeting Summary
September 27, 2021
Conference Call

Andrew Weiss, MD, Chair

Introduction

The Biopsy Best Practices Workgroup (the Workgroup) met via teleconference on 09/27/2021 to discuss the following agenda items:

1. Welcome and Project Timeline Review
2. Data Results – Minimum Donor Criteria Appropriate to Initiate Biopsy
3. Finalize Project Discussion

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

1. Welcome and Project Timeline Review

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

Summary of discussion:

The Workgroup had no questions or comments.

2. Data Results Report – Minimum Donor Criteria Appropriate to Initiate Biopsy

Staff presented the Minimum Donor Criteria data report requested by the Workgroup in May.

Data report:

Data included all deceased kidney donors recovered in 2019, and was evaluated utilizing the proposed criteria. Anuria and donor renal replacement therapy were unable to be identified within the data, and were not considered. This report also looks at characteristics of past kidney donors who were biopsied and utilization and discard rates.

There were 11,151 kidney donors recovered in 2019. Of those donors, 3,171 met the proposed criteria and 7,980 did not. From those donors that met criteria, 1,202 had a history of diabetes, 1,654 had a Kidney Donor Profile Index score (KDPI) of 85 percent or greater, and 2,337 met the expanded donor criteria (ECD). These counts do not sum to total as some donors met multiple criteria.

50 percent of all kidney donors had at least one kidney biopsied in 2019. 90 percent (n = 2868) of donors meeting the proposed criteria were biopsied in 2019, compared to 46 percent (n = 3648) of donors not meeting criteria that were biopsied in 2019. Looking at biopsied donors by KDPI, higher KDPI donors were more likely to be biopsied. About 18 percent of KDPI 0-20 percent donors were biopsied, compared to 93 percent of KDPI 86 to 100 percent donors. Donors with a history of hypertension were more likely to be biopsied; 86 percent of donors with a hypertension were biopsied, compared to 45 percent of donors with no history of hypertension being biopsied. This is similar for diabetes as well, with 91 percent of diabetic donors having at least one kidney biopsied compared to 54 percent of donors with no history of diabetes.

95 percent of donors over the age of 64 were biopsied, while only 34 percent of donors age 18 to 34 were biopsied. Biopsied donors tended to have higher body mass indices (BMI), with a median BMI of 28 compared to 25 for donors without a biopsy. Donors meeting ECD criteria were more likely to be biopsied as well, with 93 percent of ECD donors biopsied in 2019 compared to 49 percent of non-ECD donors.

Donors meeting the proposed criteria had a discard rate of 45 percent compared to around 10 percent for donors not meeting the criteria. Biopsied donors have a discard rate of about 30 percent compared to about 5 percent for donors who are not biopsied.

Summary of discussion:

The Chair pointed out that the criteria requires biopsies for significantly fewer donors than were biopsied, and so the criteria itself will not likely result in increased biopsy rates. Staff noted that the number of donors meeting the criteria is about half the total number of donors that had renal biopsies. The Chair remarked that a graph or slide showing that the number of proposed criteria biopsies is well below the total number of biopsies that are done would be helpful to ease the concern that requiring renal biopsy for donors meeting minimum criteria would result in increased biopsy rates. The Chair continued that biopsies could be performed outside of the minimum criteria, on a case by case basis. Staff noted that, rather than having a discussion about whether or not to biopsy for half of all kidney donors, about a quarter of deceased kidney donors will meet that criteria and require biopsy without need for discussion.

One member pointed out that the goal of the minimum criteria is to create a minimum standard for biopsy performance. The member continued, noting that the 3,000 or so donors that don't meet criteria can be biopsied, but the donors that do meet the criteria must be biopsied, meaning that those 303 donors that met criteria and weren't biopsied should have been. The member expressed the need to clarify that this project doesn't discourage biopsy for other donors not meeting criteria and that the project won't force significantly more biopsies to be performed. Another member agreed, and asked what the discard rate was for the kidneys from the 303 donors that met criteria and weren't biopsied. Staff offered to follow up with that data, noting that it was not included in the original report. The Chair agreed that discard rates would be interesting to look at. The member added that, if the discard rate of the 303 donors meeting criteria that weren't biopsied was higher than that of the 2,868 donors meeting criteria that were biopsied, this data could further support establishing the minimum criteria. Another member commented that the discard rates will be important to look at, for those donors not meeting criteria as well.

The Chair remarked that part of the rationale for the proposal should include efficiency, as standardizing a minimum set of donor criteria to require biopsy saves organ procurement organizations (OPOs) from having a discussion or debate with each organ.

3. Finalize Project Discussion:

The Workgroup reviewed the minimum donor criteria appropriate to initiate kidney biopsy, and discussed several options for both the minimum criteria and standardized pathology report projects.

Drafted Minimum Donor Criteria Appropriate to Initiate Biopsy

- Anuria
- Renal replacement therapy
- Diabetes
    - Any history of diabetes, including diagnosis during donor evaluation
- KDPI ≥ 85 percent, excluding pediatric donors

- Donor age 60 or older
- Donor age 50-59, and at least two of the below risk factors:
    - Hypertension
    - Manner of death: Cerebrovascular Accident (CVA)
    - Terminal creatinine ≥ 1.5

Summary of discussion:

One member noted that the data report utilized KDPI greater than 85 percent, not KDPI equal to or greater than 85 percent. Staff clarified that "sequence D" donors are strictly KDPI greater than 85 percent, and that this cut off is in line with policy, particularly for required patient consent to receive high KDPI donor kidney offers. The Chair commented that the criteria should be consistent with policy, and asked if there was any issue with utilizing KDPI greater than 85 percent. Another Workgroup member agreed.

The Workgroup Chair confirmed for a member that the last two criteria are from the old expanded donor criteria (ECD) definition, for which there is consensus.

A Workgroup member recommended including hypertension as a standalone criterion. The Chair noted that hypertension was included in the ECD criteria, and added that including hypertension alone could significantly and unnecessarily expand the donor pool meeting the minimum donor criteria appropriate for biopsy. The Chair continued that hypertension could often be more of a case by case basis, providing examples: a 40 year old donor with controlled hypertension may not need a biopsy, while another 40 year old donor with hypertension requiring several medications and proteinuria may need a biopsy. Staff pointed out that the criteria is intended to set a minimum of donors to receive kidney biopsy, and that a donor that does not meet the minimum criteria may still be biopsied.

The Workgroup member asked if the Workgroup planned to propose the minimum criteria as a policy change requiring kidneys to be biopsied, and the Chair responded that while the Workgroup still had to finalize the decision, that was the current plan. The member pointed out two situations that a proposed policy will need to account for. The first is if a donor meets criteria, but the accepting surgeon doesn't want a biopsy for a given reason, such as associated delays. The second is what an OPO should do if they cannot perform a biopsy. The member explained that the donor hospitals in rural Alaska can make slides, but don't have the staff to read or process the biopsy samples, and those samples can't be read until they arrive with the kidneys in Seattle, Washington. The Chair agreed, remarking that it makes sense to have contingencies for these situations. The member added that documentation of why a biopsy can't be performed could be sufficient for the latter scenario. The Chair agreed.

Project Options:

Minimum Donor Criteria Appropriate to Initiate Kidney Biopsy

- Policy proposal – finalize requirements for when an OPO must perform a biopsy on deceased donor kidneys
- Request for information – broaden the conversation and collect community feedback for standardizing biopsy performance
    - Workgroup and OPTN Kidney Committee could reconvene to review feedback and decide on next steps, including potential for policy proposal

Standardized Pathology Report

- Policy proposal – propose standardizing biopsy data reporting and collection in DonorNet℠
    - Require data entry if biopsy performed

- Previously, the Workgroup preferred DonorNet℠ data collection vs. a form

Summary of discussion:

One member remarked that it could be helpful to request information from the community, particularly the OPO Committee and OPO community about the minimum donor criteria.

Staff clarified that a policy proposal process still includes a feedback piece with public comment, where the project will be presented to different committees to gather feedback. Once public comment closes, the proposal can be modified based on the feedback received before it is sent on to the Board of Directors. A request for feedback would allow the project to collect feedback over two public comment cycles, if the Workgroup or Kidney Committee ultimately decided to propose the minimum criteria.

The Chair advocated that the Workgroup opt for a policy proposal for the minimum donor criteria, pointing that in broader sharing, the centers initially offered these kidneys are not always the ones accepting these organs. In some cases, the initial centers receiving organ offers choosing not to request a biopsy could prevent the next round of evaluating centers from having access to biopsy information that could be influential. The Chair added that standardizing minimum biopsy performance around the country improves efficiency and allows for quicker, more informed allocation. Another member agreed, noting that as kidney allocation moves towards continuous distribution, it will be harder to place kidneys from donors meeting this criteria. The member added that certain OPOs on the east coast deal with more than 60 transplant centers for each donor, and standardizing biopsy performance and reporting can improve efficiency and ease of their work.

A member shared that initially they were hesitant to require biopsy due to availability of pathologist services and other nuances, but that looking over the data report, requiring biopsy for these donors seems very reasonable. The member continued that, as with other requirements, there will be instances where it doesn't happen for whatever reason, and OPOs can document the deviation from policy and reason for it. These deviations can be monitored. The member expressed support for proposing the minimum donor criteria as policy.

Another Workgroup member agreed, pointing out that the intent of the projects was to standardize biopsy performance and reporting. The member remarked that the Workgroup should pursue a policy option for both projects, noting that the Workgroup spent considerable time and effort ensuring the report and its data elements were well designed and relevant.

One member asked the Workgroup where the most pushback would be for a standardized biopsy report. Staff shared that some data collection proposals can face pushback out of concern for data burden. The member remarked that they haven't heard similar complaints from OPOs. Another member added that a standardized form for OPOs to use would be preferable.

The Workgroup achieved consensus to release policy proposals for both the *Minimum Donor Criteria Appropriate for Biopsy* and the *Standardized Pathology Report* projects.

Upcoming Meeting

- October 25, 2021

Attendance

- **Workgroup Members**
  - Andy Weiss
  - Arpita Basu
  - Catherine Kling
  - Colleen O'Donnell Flores
  - Dominick Santoriello
  - Jim Kim
  - Julie Kemink
  - Mark Orloff
  - Meg Rogers
- **HRSA Representatives**
  - Adriana Martinez
  - Jim Bowman
- **SRTR Staff**
  - Christian Folken
  - Jon Miller
- **UNOS Staff**
  - Amanda Robinson
  - Lauren Motley
  - Leah Slife
  - Lindsay Larkin
  - Kayla Temple
  - Ross Walton
  - Nicole Benjamin
  - Ben Wolford