OPTN Kidney Committee
Biopsy Best Practices Workgroup
Meeting Summary
December 17, 2020
Conference Call

Andrew Weiss, MD, Chair

Introduction

The Biopsy Best Practices Workgroup (the Workgroup) met via teleconference on 12/17/2020 to discuss the following agenda items:

1. Review Project History and Workgroup Goals
2. Review of Current Policy, UNet^{SM} Resources and System Behavior
3. Brainstorm: Minimum Criteria

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

1. Review Project History and Workgroup Goals

Staff reviewed the project history and workgroup goals, followed by discussion from the workgroup.

Data summary:

The OPTN Policy Oversight Committee (POC) established the Biopsy Standards and Practices Workgroup in April 2020. The workgroup was provided the following charter:

- Evaluate when in the offer acceptance process and how biopsy results are currently requested and used
- Assess the efficiency of the current system of requesting and providing biopsy results
- Recommend whether or not to pursue a project, and if so, whether policy, guidance, or education is most appropriate
- Report these findings to the Policy Oversight Committee

The Workgroup met four times from June-August 2020 and developed the following recommendations:

- Develop a minimum set of donor kidney criteria appropriate for biopsy
- Develop guidance to maximize the use of image sharing technology across the entire network
- Develop a form that pathologists would complete during biopsy readings to allow for consistent analysis across Organ Procurement Organizations (OPOs) and transplant programs
- Develop a minimum set of donor liver criteria appropriate for pre-recovery liver biopsy

The Biopsy Best Practices Workgroup will focus on two recommendations:

- Develop a minimum set of donor kidney criteria appropriate for biopsy
- Develop a form that pathologists would complete during biopsy readings to allow for consistent analysis across OPOs and transplant programs
- Determine if policy should be updated or guidance should be developed

Minimum Set of Donor Kidney Criteria Appropriate for Biopsy

- The POC's Workgroup identified the absence of an established minimum set of criteria that are appropriate to initiate a kidney biopsy
- The POC's Workgroup recommended establishing a standard set of criteria could prevent unnecessary biopsies and analysis, increase efficiency of offer acceptance, reduce cold ischemic time, and possibly reduce organ discards

Standardized Pathology Report

- The POC's Workgroup identified inconsistencies in the quality of biopsy analysis as a major hurdle to greater allocation efficiency including:
    - Discrepancies between the immediate biopsy report and final pathology report are common
    - Interpretation and analysis of biopsy results can vary
    - Some pathologists do not have organ-specific experience to address indicators that a transplant surgeon would look for in a pathology report
    - Transplant surgeons often request to do their own examination of the biopsy, slowing down efficiency
- The POC's Workgroup recommended developing a standard form to identify those characteristics and data points that are most useful to inform offer acceptance

Summary of discussion:

One member asked if the minutes from the previous workgroup were available to review. A staff member explained that the previous minutes can be found on the OPTN website under the Policy Oversight Committee's page. Another workgroup member asked if there will be a page for the workgroup to post their minutes and resources. The staff member replied that there would be.

The workgroup Chair remarked that almost half of all recovered kidneys are biopsied and a third of all rejected kidneys are due to biopsy results which emphasizes the significance of the Workgroup's objective. The Chair remarked that the lack of biopsy standards may be an obstacle to the transplantation process

A member of HRSA asked about an article from JASN comparing European to American biopsies which noted that higher KDPI kidneys are used in Europe without biopsies but lead to similar outcomes as American kidney transplants. The member noted that it is likely relevant to the work and they will distribute the article to the Workgroup. The Chair noted that while it may be challenging to change the current practices surrounding biopsies, that an establishment of standardized criteria could be very beneficial to the community. A HRSA representative noted that there are multiple variables to biopsies that impact how they are used.

2. Review of Current Policy, UNet Resources and System Behavior

Staff reviewed the current policy, UNet resources and system behavior in regards to biopsy results and minimum criteria, followed by workgroup discussion.

Data summary:

Staff shared OPTN Policy section *2.11: Required Deceased Donor Information* with the workgroup as well as current UNet functionality and examples of different pathology forms.

Summary of discussion:

The Chair recommended focusing on two questions: what factors would prompt a member to request a biopsy (age, manner of death, KDPI, etc). How is the biopsy information relayed to the transplant center, for example? Is it different for a wedge biopsy or needle biopsy? Who reviews the biopsy: a general pathologist or a nephro-pathologist? The Chair continued by noting that identifying who is responsible for interpreting the biopsies may also be useful information when thinking about which forms are helpful.

One member commented that they would like to review the literature. One thing of note is the different format and layouts of the forms and trying to identify which is most helpful. Another member noted that not all transplant programs have the same resources or specialists and that plays a role in how centers use the biopsy information and what organs are turned down.

A couple members noted that there is inherent subjectivity with analyzing a biopsy and factors such as the size of a wedge biopsy and the expertise of the reviewer less familiar with a needle biopsy impact how the results are interpreted. One member recommended reaching out to subject matter experts. Another member spoke in support of this idea. The first member pointed out that there are some professionals who had already done research on biopsies and the group could draw on their previous study and knowledge.

Another member noted that most of the time the transplant center tries to read the biopsy results but that most centers tend to re-biopsy the organ again which can introduce even more variability. The member also wondered if photos would help in a biopsy in the same way it does for a liver.

3. Brainstorm: Minimum Criteria

The Workgroup brainstormed potential minimum set of donor kidney criteria appropriate for biopsy.

Summary of discussion:

One member commented in support of establishing minimum criteria and best practices in the form of a guidance document rather than establishing new policies due to the variable nature of biopsies and how they are interpreted. One member specifically noted that while it may be too difficult to establish what biopsy results should result in a transplant versus a discard, that the workgroup could work to determine certain criteria that would automatically qualify for a biopsy.

One member asked if a member had ever run into an issue where the request for a biopsy had been turned down. Another member commented that in their experience, their OPO is very accommodating. Another member commented that their experience was opposite and that their OPO would deny a request for biopsy unless certain stringent criteria were met and therefore they would often choose to biopsy on their own. Another member noted that their OPO will automatically biopsy any kidney with a KDPI over 85. One member wondered who had determined the various OPO criteria and whether the workgroup should review those criteria as part of their efforts.

One member agreed with a previous statement to establish a set of best practices to recommend to the community. Another member wondered if there was any correlation to the amount of biopsies performed and the successful amount of transplants. Another member agreed that it would be interesting to know if there was any correlation between the amount of biopsies performed and the number of discards. At the same time, members noted that it is concerning to have a wide range of biopsy criteria from OPOs located near each other which result in different responses to similar biopsy requests. A member commented that it is unclear right now whether these biopsy criteria are based on specific local data or just individual standards.

One member commented that they had a specific experience with an organ that had a high creatinine clearance as well as a history of urological issues but the OPO refused the request for a biopsy in part because they had another center interested in the organ. The member felt this was not a good approach to biopsy and that some amount of standard practices would be helpful. One member commented that although many places in Europe have decided not to do any biopsies that since many in America prefer the option to review biopsy results that there should be some type of best practices to guide the biopsy process. The Chair noted that another concern for the Workgroup to consider is how the biopsy is performed and how the information is dispersed. Additionally, the literature does not show a correlation between the transplant and implant biopsies.

Another member remarked that it is still a question as to how accurate biopsies are particularly if literature does not show a correlation. It is important to determine which organs are best to biopsy.

Next steps:

The Workgroup will continue to meet to identify potential criteria for kidney biopsy standards and best practices.

Upcoming Meeting

- TBD

Attendance

- **Committee Members**
  - Andy Weiss
  - Arpita Basu
  - Catherine Klin
  - Colleen O'Donnell Flores
  - Dev Desai
  - Jim Kim
  - Malay B. Shah
  - Martha Pavlakis
  - Meg Rogers
  - Vincent Casingal
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Bryn Thompson
- **UNOS Staff**
  - Amanda Robinson
  - Kiana Stewart
  - Lauren Mauk
  - Lauren Motley
  - Lindsay Larkin
  - Matt Prentice
  - Tina Rhoades