

**OPTN Policy Oversight Committee
Biopsy Standards Workgroup
Meeting Summary
June 3, 2020
Conference Call**

Christopher Curran, Chair

Introduction

The Biopsy Standards Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 06/03/2020 to discuss the following agenda items:

1. Review of Purpose
2. Discussion

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

1. Review of Purpose

The Workgroup the purpose of their incorporation by the OPTN Policy Oversight Committee (POC) reviewed the purpose of their creation, the focus of the project, and the process of OPTN policy development.

Summary of discussion:

The Workgroup will evaluate the need for rules or guidance regarding biopsy practices in order to increase efficient donor and recipient matching and will report their findings and recommendations to the OPTN POC. The Workgroup is charged with:

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

The Workgroup is in the problem analysis phase in which they will identify areas for improvement and best practices.

2. Discussion

The Workgroup discussed current biopsy practices and standards.

Summary of discussion:

The Workgroup Chair asked members to share their experience regarding how biopsies are conducted. The Chair stated that they are aware of certain centers using needle biopsies on kidneys, while others use wedge biopsies for kidneys. A member asked if the Workgroup project includes intraoperative or bedside biopsies. The Workgroup Chair responded that they should create a framework that encompasses all types of biopsies.

A member shared their experience with discrepancies between the immediate biopsy and the final pathology report. The ability to make a precise diagnosis with an immediate biopsy may be limited because it uses a frozen section and the quality of the slide is not as good as a fixed, paraffin imbedded, cut, and stained section. Additionally, a member added that the pathologists are not necessarily trained in organ specific pathology, which could cause misinterpretations because they do not have the experience in that given area. Members agreed that they have also found discrepancies based on where (geographically) the biopsies were read and who read them.

The Workgroup discussed the types of biopsies that occur in deceased donors. A member asked if there are uniform criteria in bedside liver biopsy, and if not, would there be a benefit of setting minimum criteria when a bedside liver biopsy would be acceptable. A member responded that their organ procurement organization (OPO) has a centralized process for liver biopsies. The member further elaborated that biopsy criteria poses a complex situation in which geography, pathologists' expertise, and OPOs' philosophies have to be considered. Another member responded that there is high variability in criteria and agrees that there are several reasons to explain to this variability. A member suggested that the workgroup come up with a minimum set of criteria of when to do a biopsy while leaving more unique circumstances up to individual regions or programs.

A member explained that their OPO recently worked on developing guidelines for kidney biopsy. From their experience, some issues to consider are the reliability of biopsy readings and what specific biopsy results are used to drive decisions. The member suggested that on a national scale, it might make sense to have a repository where you have nephropathologists on call to look remotely at samples. Members agreed that remote pathologists could be helpful. A member suggested that the Workgroup could make recommendations on tools that would allow biopsy images to be available for experienced pathologists. A member asked how the Workgroup could encourage community partnerships so that transplant centers can look at the slides themselves and decide what is best for their patients. Members agree that technology should be utilized but need to assess the current state of technology and what type of technology is needed to create a reasonable biopsy image for a pathologist.

A member shared that typically they perform needle and wedge liver biopsies in the operating room and wedge kidney biopsies in the operating room. Due to geography, they do not always have access to a pathologist to read the biopsy so the slide arrives with the organ. The member suggested that there needs to be consideration paid to personnel and logistic factors. Members agreed with the challenges in finding a pathologist to read the biopsy, especially those in rural areas. A member stated that they have an internal policy in which slides must be read at a transplant center. This specific policy has inherent problems with time delays caused by getting kidneys and biopsies back to transplant centers. The member agreed in the benefit of biopsy standardization but recognizes the added layer of complexity that comes with creating standards.

The Workgroup Chair discussed how biopsy results are currently used for decision making and post-transplant treatment of recipients. A member asked if there are any OPOs that use biopsies to rule in and rule out donors. A member responded that for their OPO they only use biopsies in circumstances where they provide the information to transplant centers to let them decide. A member stated that the Disease Transmission Advisory Committee (DTAC) occasionally sees cases where a kidney biopsy of a lesion is interpreted as a carcinoma, resulting in that organ not being transplanted. The member explained that, in some of these cases, a good kidney is discarded because they could have conducted a segmental section of the tumor and the incidence of bilaterality may be low. In response to this, a member remembered a guidance document that DTAC produced about renal cell carcinoma and the size of lesions that should be considered for transplantation or consideration of contralateral kidney

transplantation. A member responded that this issue is still being discussed and researched. The Workgroup Chair asked if members think that determining the medical suitability of donors falls under the scope of this project. Members agreed that they should keep the scope narrow and focus on kidney and liver biopsies. A member suggested to continue this conversation with DTAC.

The Workgroup Chair facilitated conversation regarding how biopsy results are provided. A member explained their experience is many OPOs do not put biopsy results in DonorNet. If they do, it is only as a scanned report and the data is not pulled into the designated fields within DonorNet. The member explained this causes issues with real time review as well as poor quality of scanned biopsy results. A member agreed that the quality of images is variable and asked if the Workgroup could receive data about the frequency of available biopsy images.

A member stated that when a kidney is placed with another transplant center outside the OPO and that center chooses to do a biopsy, there is no consistency or guidelines of getting results back to the offering OPO. The Workgroup Chair stated it would be helpful to set up a system that supports performing needed biopsies so that kidneys do not leave an area without getting biopsied. A member asked if initiation of biopsies come from OPOs or transplant centers and suggested that guidance could be helpful on this topic. The Workgroup Chair stated that a lot of OPOs have standard criteria under which they biopsy and entertain requests otherwise. The Workgroup Chair suggested having further discussion around situations when the backup center requests a biopsy but both primary programs have no interest in a biopsy.

Next steps:

A summary of discussion will be provided to the Board of Directors. A next meeting will be scheduled to continue discussion and begin developing a recommendation for the POC.

Upcoming Meeting

- July 2, 2020 (teleconference)