

**OPTN Policy Oversight Committee
Biopsy Standards Workgroup
Meeting Summary
August 13, 2020
Conference Call**

Christopher Curran, CPTC, CTBS, CTOP, Chair

Introduction

The Biopsy Standards Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 08/13/2020 to discuss the following agenda items:

1. Review of Progress to Date
2. Biopsy Practices and Standards Discussion
3. Next Steps

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

1. Review of Progress to Date

The Workgroup reviewed takeaways from previous meetings.

Summary of discussion:

Potential recommendations to date:

- Minimum set of donor kidney criteria for biopsy
- Minimum set of criteria for pre-recovery liver biopsy
- Project aimed to maximize the use of image sharing

Potential recommendations under consideration:

- Recommendations on type of pathological readings which can performed with each tissue
- Recommendations on samples for pathology in clinical assessments of the donor suitability as well as other non-organ pathological assessments

2. Biopsy Practices and Standards Discussion

The Workgroup continued discussion on biopsy standards and potential recommendations.

Summary of discussion:

A member stated that the recommendations made to the Policy Oversight Committee (POC) need to take into consideration the resources available to local community hospitals compared to a major universities and transplant centers. The member expressed interest in a pathway that develops guidance for pathologists in terms of what to look for in biopsies as well as how to report findings. Additionally, the member mentioned that if image sharing becomes a pathway, there needs to be compatibility with DonorNet.

The Chief Medical Officer of UNOS suggested the Workgroup could recommend a minimum set of test criteria which should be completed during each biopsy. A member agreed with this idea and responded that the Workgroup could recommend the development of a form which pathologists complete during

biopsy readings to allow for consistency across organ procurement organizations (OPOs) and transplant programs. Other members agreed.

A member stated that the ability to capture images and share them with recipient centers or a third party would be a great advance in standardizing. The member stated that the quality of the image depends on what a pathologist is looking for. The member explained that scanning an entire biopsy slide takes more time and bandwidth. The Chief Medical Officer of UNOS stated that if the Workgroup is recommending pathways towards standardizing the use of biopsies, then the use image sharing needs to occur so that programs have the ability to read slides themselves to guide decisions.

A member stated that some OPOs have microscopes which can digitize slides. Another member agreed that an OPO which has the ability to create frozen sections would also have access to a microscope, a camera, and internet access. A member responded that this is not a fair assumption. The member explained their experience in which they have worked with a lot of small, rural hospitals that only can create slides that they send out for readings. Additionally, the member mentioned there has been instances where the pathologist was not familiar with transplant biopsies and would print out a picture of the slide. The pathologists would then take a picture of the print out to send. The member emphasized that these small communities do not have the resources nor the technology available to image share. A member responded that the recommendation could include a best practice and then a backup plan if programs are not able to conform to the best practice due to lack of resources.

Another member stated that these recommendations are standardizing approaches and expanding capabilities, so these potential projects should be able to be completed in the short-term. The member stated these pathways could utilize existing technology, which is why it could be completed in the short-term. A member asked how standardized are the histological assessment of donor organ biopsies. Members agreed that most programs are looking for similar characteristics within biopsies. The member also asked how uniform are the acceptances and declines of specific organs. Members agreed that organ acceptances and turndowns, based on pathology readings, vary among programs.

IT staff responded that DonorNet collects three primary parameters in regards to kidney biopsies, glomerulosclerosis, vascular sclerosis, and interstitial fibrosis. IT staff continued that, during allocation, there is high variability among what is entered into DonorNet as well as uploaded attachments which describe biopsies findings. There may be opportunities to standardize what information is shared.

Members agreed that having a standardized form with a standardized review process would be helpful. UNOS staff responded that the OPTN has the authority to require certain trainings or certifications for pathologists.

Health Resources and Services Administration (HRSA) staff asked whether there can be a system where images can be shared with specific programs so there are no delays in receiving valuable readings, and if the OPTN or individual OPOs would manage this. A member responded that individuals OPOs would be better to manage a system such as this because they are in a position to access local resources and relationships. Another member agreed and stated the idea of having groups of pathologists that could read biopsies, centrally, for their geographic areas or act as consultants through OPOs.

A member asked if it could be the responsibility of those programs receiving the organ to capture and share the biopsy image. Another member responded that does happen when there is not access to a pathologist prior to acceptance. The member explained that accepting an organ, transporting the organ to the accepted transplant program, and then conducting the biopsy adds cold time. This means that having biopsy results prior to acceptance is the ideal process to expedite a transplant. The member stated that the challenge is creating a system that can be replicated through every donor hospital in the country.

3. Next Steps

The Workgroup will solidify and prioritize recommendations.

Upcoming Meeting

- TBD

Attendance

- **Workgroup Members**
 - Andrew Weiss
 - Catherine Kling
 - Charles Marboe
 - Julianne Kemink
- **HRSA Representatives**
 - Marilyn Levi
 - Robert Walsh
 - Shannon Taitt
- **SRTR Representatives**
 - Bertram Kasiske
 - Katie Audette
- **UNOS Staff**
 - Craig Connors
 - Darren Stewart
 - David Klassen
 - Elizabeth Miller
 - James Alcorn
 - Kaitlin Swanner
 - Matt Prentice
 - Meghan McDermott
 - Randall Fenderson
 - Robert McTier
 - Scott Castro
 - Tina Rhoades
- **Other Attendees**
 - Nicole Turgeon