

**OPTN Policy Oversight Committee
Biopsy Standards Workgroup
Meeting Summary
July 22, 2020
Conference Call**

Christopher Curran, CPTC, CTBS, CTOP, Chair

Introduction

The Biopsy Standards Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 07/22/2020 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. Additionally, the workgroup reviewed the *OPTN Guidance on Deceased Donor Information* document as well as policy changes made to *OPTN Policy 2.11 Required Deceased Donor Information*.

Summary of discussion:

Key takeaways:

- Recommendations will encompass all types of biopsies
- High variability in biopsy standards currently exist
- Challenges in accessing pathologists
- Discrepancies in biopsies results based on pathologists' level of experience and area of expertise
- No consistency of getting results back to the offering organ procurement organizations (OPOs)
- Issues with availability and quality of biopsy images in DonorNet

Staff presented a proposal overview, which aimed to improve the efficiency of organ placement, developed by the Organ Procurement Organization Committee and passed by the Board of Directors in 2017. The policy changes added language to require OPOs to provide results "if performed" for kidney (*OPTN Policy 2.11.A*) and liver (*OPTN Policy 2.11.B*). Additional policy changes removed *OPTN Policy 2.12 Requested Deceased Donor Information*, which subsequently informed the content of the *OPTN Guidance on Deceased Donor Information* document. The guidance document outlines kidney and liver biopsy information, with modified language which states "biopsy" instead of the previously used terminology of "wedge biopsy" of a specified size.

A member asked how can the Workgroup create compliance among issues such as OPOs expressing resistance to obtain pre-recovery liver biopsies. The Chair agreed that there is a lot of variability among OPOs performing pre-recovery liver biopsies, and stated that the Workgroup could recommend the creation of minimum criteria for performing a pre-recovery bedside liver biopsy.

A member stated that it is important to consider the varying resources among programs when creating guidelines or guidance. The Chair responded that the recommendations should create a pathway.

2. Biopsy Practices and Standards Discussion

The Workgroup continued discussion on biopsy standards and potential recommendations.

Summary of discussion:

A member asked about the plausibility of creating a centralized pathology review with pathologists who have subspecialties in reading kidney or liver biopsies. The Chair responded that this could not be mandated by policy but it could be recommended that OPOs contract with experienced transplant pathologists groups. Another member stated that some areas have centralized pathology but it occurs in high population density areas which have readily available resources. The Chair responded that if the Workgroup recommends guidance for utilizing experienced pathologists, then the sponsoring Committee could create a process that allows varying best practices based on an OPO's available resources.

The Chair suggested the Workgroup could recommend the creation of a minimum set of donor criteria which OPOs are required to biopsy. This potential recommendation to the Policy Oversight Committee (POC) would aid in achieving consistency among biopsy standards.

A member stated that there instances of universal testing among organ donors and biopsies should not be considered too differently. The Chair asked if the member's recommendation would be that the POC create a project which would address the criteria under which OPOs should perform pre-recovery bedside liver biopsies. The member agreed, and added that the efficiency in organ placement increases when there is more data available in real time.

Another member asked if the Workgroup has data to support these recommendations. The Chair responded that the Workgroup provides recommendations, while the sponsoring committees of these potential recommendations will be charged with analyzing the data to inform the development of pathways.

A member suggested discussing optimization of the technical capabilities of OPOs in order to provide quality biopsy slides images. The Chair agreed that maximizing the use of telepathology image sharing in organ donation could be a recommendation the Workgroup makes to the POC. The Chair stated that some of these ideas could overlap so the Workgroup should consider where combined recommendations could be made.

Another member mentioned these discussions align with radiological image sharing practices and wondered if standardizing the capability for appropriate image sharing could be an IT project. The Chair agreed and stated that UNOS has an image sharing pilot program.

IT staff asked the Workgroup for clarification on if technology for image sharing would be utilized to share images with pathologists, surgeons, or both. A member responded that it is both. IT staff asked the Workgroup if the imaging needs of surgeons and pathologists are the same. Another member responded that the needs are the same. Additionally, a member stated that the quality of the transmitted image is the priority because transplant programs generally have the ability to read biopsies. The Chair agreed that the best practice should be to have a high quality image that is accessible to both transplant programs and pathologists.

IT staff asked if a pathway is needed to send information back to an OPO after a transplant program has read a biopsy. The Chair responded that the pathway would be helpful if there was a disagreement

among readings, but more frequently a transplant program will rebiopsy an organ and have a different interpretation of the rebiopsy compared to the initial biopsy performed by the OPO.

The Chair stated that a platform to share images with programs that are considering organs should be created. The Chair suggested that a recommendation to the POC could be maximizing the use of image sharing. The Chair stated that the term 'image sharing' would allow the solution to be more encompassing rather than limiting the focus to biopsies. Members agree with this recommendation.

IT staff asked if the purpose of image sharing is to enable transplant programs the ability to perform their own interpretations. Chair confirmed and stated that in addition to that IT solution, a sponsoring committee of this potential project would have to develop recommendations surrounding identifying expertise that can make quality readings.

The Chair asked the Workgroup if they should consider recommendations about the type of pathological readings that can be performed with each tissue. Recommendations would come from analyzing different types of pathology readings as well as new and emerging technology, such as confocal microscopy.

The Chair asked the Workgroup if they should consider recommendations on samples for pathology in the clinical assessment of the donor suitability as well as other non-organ pathological assessments.

Potential Recommendations

1. Minimum set of donor kidney criteria for biopsy
2. Minimum set of criteria for pre-recovery liver biopsy
3. Project aimed to maximize the use of image sharing
4. Recommendations on type of pathological readings which can performed with each tissue
5. Recommendations on samples for pathology in clinical assessments of the donor suitability as well as other non-organ pathological assessments

Next steps:

The Chief Medical Officer of UNOS will be invited to join the Workgroup meeting to further discussion. The Workgroup will continue discussion about obstacles regarding the logistical implications of requesting and providing biopsy results. The Workgroup will continue to develop recommendations for the POC.

3. Next Steps

Members will receive a poll for their availability. Next Workgroup meeting will be scheduled to continue discussion.

Upcoming Meeting

- TBD