OPTN Policy Oversight Committee
Meeting Summary
March 10, 2021
Conference Call

Alexandra Glazier, JD, Chair
Nicole Turgeon, MD, Vice Chair

Introduction

The Policy Oversight Committee (POC) met via Citrix GoTo teleconference on 03/10/2021 to discuss the following agenda items:

1. Refusal Codes Project Update
2. Biopsy Best Practices Workgroup Update
3. New Projects

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

1. Refusal Codes Project Update

UNOS staff shared an update on the refusal codes project. A request for community feedback is posted on the OPTN website.[1] All cross-committee presentations will be completed by 3/17 and the DAC aims to send the updated refusal codes to the Board for approval on 3/29. The Chair asked members to encourage participation in this effort across their committees.

2. Biopsy Best Practices Workgroup Update

The Chair of the Biopsy Best Practices Workgroup presented an update on the workgroup's progress.

Summary of discussion:

The purpose of the workgroup is to establish minimum criteria appropriate to initiate kidney biopsy, and to develop a standard pathology form to share information on kidney biopsies. The Workgroup has completed a review of current biopsy practices, including utilization of biopsy information in DonorNet®. The Workgroup established guiding principles to acknowledge that the clinical literature is not consistently supportive of using biopsies to evaluate organs, but there should still be standardization for the biopsies that are performed; and biopsies should be performed to determine which patient will receive the most benefit from an organ. The Workgroup Chair shared the minimum criteria appropriate for biopsy that were identified by the workgroup.

During upcoming meetings, the Workgroup will develop the standardized pathology report and finalize the recommendation as to whether these resources should be established in policy or as guidelines. The Workgroup plans to submit their recommendations to the Kidney Committee in April or May and seek project approval from the POC after that.

A member asked if there is any plan to incorporate telepathology. The member's transplant program has had issues with biopsies being read incorrectly, particularly for liver, so it is much preferred when

[1] "Project to Update Refusal Codes," OPTN, accessed March 29, 2021, https://optn.transplant.hrsa.gov/governance/key-initiatives/project-to-update-refusal-codes/.

transplant programs are able to view a picture of the slides directly, which could also reduce discard rates. The Workgroup Chair said that is probably a future effort and not in the scope of this project, but it would be great to centralize these processes and have specialists reading the biopsies. There is a group at UNOS that is working on biopsy imaging. Even though biopsies are controversial and the clinical literature does not necessarily support the use of biopsies to evaluate organs, they are occurring every day. Since at least half the organs – or at least kidneys – procured are biopsied, the Workgroup probably cannot end that practice, but at least the Workgroup can establish some minimum standards and create standardized reporting for biopsy results.

A member noticed that all of the proposed biopsy criteria assess "wear and tear" on the organ rather than glomerular disease. The member asked if the Workgroup considered criteria like significant proteinuria or active urine sediment. The Workgroup Chair said they discussed proteinuria but with acute kidney injury, it is difficult to differentiate between glomerular proteinuria versus tubular etiology, or if the donor was oliguric. It also depends who is reading the biopsy. The member recommended adding language to the guidelines that leaves it open since there may be good reason to ask for a biopsy, for example, if a brain-dead donor had significant proteinuria when admitted to the hospital and later suffered an acute kidney injury. The Workgroup Chair said the proposed criteria can be considered the very minimum to establish what transplant centers expect to learn from a biopsy conducted by the organ procurement organization (OPO), but other criteria could be requested in extenuating circumstances. OPOs are not routinely measuring protein-to-creatinine ratios on these patients so it usually comes up if a nephrologist sees something concerning on the initial urinalysis.

The Chair said she appreciates the progress the workgroup has made since this topic was identified a year ago as a priority. Standardization of the report itself is hugely important and addresses an identified inefficiency. The Workgroup Chair said the OPTN should not lose sight of the idea of centralized processing and reading of biopsies, since that could be extraordinarily important in the long run. The Chair said since biopsies may not be appropriate, this standardization will hopefully address inefficiencies in the process, and perhaps a determination can be made at a later date as to whether biopsies should be conducted.

Next steps:

This project will come back to the POC for project approval in a future meeting.

3. New Projects

The POC reviewed four new projects:

- Reassessing the Inclusion of Race in eGFR Equation (Minority Affairs & Kidney Committees)
- Data Collection Related to US Public Health Service Guideline 2020 (Disease Transmission Advisory Committee)
- Refine Lung Data Fields (Lung Committee)
- Ongoing Review of National Liver Review Board Diagnoses in Guidance and Policy (Liver and Intestine Committee)

Summary of discussion

Reassessing the Inclusion of Race in eGFR Equation

This project is co-sponsored by the Minority Affairs Committee (MAC) and the Kidney Committee in order to evaluate the use of the Black race coefficient in the estimated glomerular filtration rate (eGFR) calculation as it relates to listing wait time. The committees will explore if policy should be developed to exclude the Black race coefficient from the eGFR calculation, and if so, what that policy should be.

This project aligns with the strategic plan goal to increase equity in access to transplants. Key metrics would assess whether listing for transplant, eligibility for accruing wait time, and transplant rate increase for patients who identify as Black or African American as a result of this project. The POC reviewed alignment with the strategic policy priorities, estimated project resources, project sequencing, and collaborating committees. The MAC Vice Chair (VC) emphasized the importance of this project in terms of alignment with the Final Rule and its potential to promote social justice and equity.

The Chair asked how this project relates to continuous distribution of kidneys. The Kidney VC said this project would be carried out while the Kidney Committee is working on continuous distribution, but the project is not part of continuous distribution.

The MAC VC said that the ability to accrue waiting time is based on when a patient reaches a GFR threshold less than or equal to 20 mL/min, and the eGFR calculation overestimates the GFR of African American patients by 16%.[2] As a result, African American patients are underrepresented as patients who are accruing waiting time for kidney transplant relative to Caucasian patients, even though the majority of patients with chronic kidney disease are African American. Recently, the American Society of Nephrology and the National Kidney Foundation put together a taskforce that recommended removing the race coefficient from the eGFR equation,[3] and members of Congress have also demonstrated interest in this issue.

A member said this project also connects to an ongoing project exploring the limitation of the creatinine calculation in liver allocation due to differences between men and women. The Kidney VC explained that it is a bit different since race is categorized as either Black or non-Black, so large groups of people are roughly grouped together. The member said he fully supports the proposal and just meant to emphasize that the OPTN is thinking more about how creatinine is used and its limitations. The VC of the Lung Committee supported the proposal and said questions about creatinine and eGFR have also come up in the Lung Committee's discussions, as the Lung Committee was advised to use eGFR instead of creatinine for modeling the lung allocation score (LAS) and evaluating five-year post-transplant survival with Thoracic Simulation Allocation Modeling (TSAM). The Kidney VC explained there are different ways to estimate GFR, and some use creatinine and some do not. The formulas that use creatinine are the most widely used but have this penalty for patients whose race is listed as Black. The Kidney VC agreed that this is important work across organs, and for any situation in which degree of kidney function is a variable that plays into access to transplant.

The Data Advisory Committee (DAC) VC noted that OPTN policy does not specify the method used to determine renal function, and there are many ways to estimate or measure it. The DAC VC asked if this project could explore how transplant programs are measuring or estimating renal function when they report it so the OPTN has information on the methods being used, since it would be interesting to see if providers are using different methods in instances where the patients would be otherwise disadvantaged. The MAC VC said the OPTN cannot be too prescriptive and leaves it up to the transplant programs to report the information, but perhaps the OPTN can provide some guidance. The MAC VC and the Kidney VC explained that their transplant centers already eliminated the race coefficient from the equation so that eGFR is calculated the same way for all patients. The Kidney VC said that other transplant centers have contacted her with concerns that they cannot change how they calculate eGFR

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[2] Nwamaka Denise Eneanya, Wei Yang, and Peter Philip Reese, "Reconsidering the Consequences of Using Race to Estimate Kidney Function," *Journal of the American Medical Association* 322 no. 2 (2019): 113-114, doi:10.1001/jama.2019.5774.
[3] Letter from Paul M. Palevsky, National Kidney Foundation President, and Susan E. Quaggin, American Society of Nephrology President, March 9, 2021, accessed March 25, 2021, https://www.asn-online.org/g/blast/files/NKF-ASN-eGFR-March2021.pdf.

without raising concerns in UNOS site surveys, because the lab says that the GFR is 19 if the patient is white and 23 if the patient is Black, so it is important for the OPTN to be a leader on this issue.

A member said that the OPTN is very prescriptive in how it defines the safety net for liver for simultaneous liver-kidney allocation policy, so that could be a good point of reference for this project. The Kidney VC agreed.

Data Collection Related to US Public Health Service Guideline 2020

This project would collect more granular data of Public Health Service (PHS) risk criteria for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV). Collecting specific risk criteria could identify trends in donors on risk criteria that impact patient safety. The Disease Transmission Advisory Committee (DTAC) VC shared the risk criteria on which data would be collected. The project aligns with the strategic plan goal to promote living donor and transplant recipient safety. The key metric is stratification of donors with risk criteria by specific risk criterion present, which will allow the OPTN to identify trends in donors with risk criteria to limit disease transmission. These data will also support assessment of *Align OPTN Policy with U.S. Public Health Service Guideline, 2020*,[4] which was approved by the OPTN Board of Directors in December 2020. The POC reviewed alignment with the strategic policy priorities, estimated project resources, project sequencing, and collaborating committees. The DAC supported this project.

The Chair asked if DTAC considered collecting data related to increased time or cost as a result of the increased testing requirements for OPOs and for transplant hospitals as a method to monitor the impact of *Align OPTN Policies with U.S. Public Health Service Guideline, 2020*. The DTAC VC said that DTAC hopes to move forward with this data collection quickly, since DTAC had initially planned to include this data collection with those policy changes, but the DTAC VC offered to share that feedback with the committee to consider other ways to monitor the implementation. DTAC is monitoring pediatric volume and other considerations to assess the impact of *Align OPTN Policies with U.S. Public Health Service Guideline, 2020*.

The Lung VC noted that one of the refusal codes combines social risk and PHS risk in one code, and asked if they should be separated out. The Lung VC said there could be an opportunity to align this data collection with the refusal codes. The DTAC VC explained that this data collection will allow members to select one or more options, whereas generally only one refusal code is selected. The Lung VC explained that more refusal codes would clarify when various PHS risk factors impacted donation.

Refine Lung Data Fields

This project will create separate dates for height and weight on lung candidate registrations to allow application programming interface (API) integration, remedy alignment of LAS coefficients for certain diagnoses, and implement these changes in conjunction with LAS updates that have already been approved[5] and API integrations to maximize implementation efficiency. This project aligns with the strategic plan goal to increase equity in access to transplants, and the key metric is alignment between policy language and system implementation. The POC reviewed alignment with the strategic policy priorities, estimated project resources, project sequencing, and collaborating committees. The Lung VC

[4] "Align OPTN Policy with U.S. Public Health Service Guideline, 2020," Policy Notice, OPTN, accessed March 25, 2021, https://optn.transplant.hrsa.gov/media/4351/1004_align2020phsguideline_dec2020_policynotice.pdf.
[5] "Updated Cohort for Calculation of the Lung Allocation Score (LAS)," Policy Notice, OPTN, accessed March 25, 2021, https://optn.transplant.hrsa.gov/media/4244/updated-cohort-for-calculation-of-the-las.pdf.

noted that DAC is collaborating on this project and there are pediatric lung representatives on the Lung Committee participating on this project. There were no questions or comments from the POC.

Ongoing Review of National Liver Review Board Diagnoses in Guidance and Policy

This project will review National Liver Review Board (NLRB) guidance and policy to ensure clinical details remain up to date and aligned with current clinical practice. The Liver & Intestine Committee is seeking to begin a systematic and proactive approach to reviewing NLRB guidance and diagnoses. The committee plans to start with reviewing six diagnoses: hepatocellular carcinoma (HCC), ascites, gastrointestinal bleeding, hepatic encephalopathy, hepatic hydrothorax, and primary and secondary sclerosing cholangitis. The POC reviewed alignment with the strategic policy priorities, estimated project resources, and collaborating committees. In terms of project sequencing, the Liver & Intestine Committee is working on a number of projects but they felt it was important to move this project forward.

The VC of the Pediatrics Committee asked how they plan to incorporate changes to pediatric guidance. The Liver VC said they would welcome collaboration with the Pediatrics Committee where appropriate. UNOS staff explained this initial review does not include pediatric guidance, but the intent is to include the Pediatrics Committee in future efforts that do include pediatric guidance. The Pediatrics VC said if this will be a rolling schedule, it would be helpful for the Pediatrics Committee to have that information and plan accordingly.

Next steps:

Attendees did not express any concerns about the scope of these projects or the OPTN's authority to work on these projects. The POC voted to recommend approval for these four projects (19 – yes, 0 – no, 0 – abstain). The Executive Committee will consider these projects at their next meeting on 04/26/2021.

Upcoming Meetings

- April 14, 2021
- May 12, 2021

Attendance

- **Committee Members**
    - Alexandra Glazier, Chair
    - Nicole Turgeon, Vice Chair
    - Sandra Amaral
    - Marie Budev
    - Lara Danziger-Isakov
    - Alden Doyle
    - Garrett Erdle
    - Andrew Flescher
    - Heung Bae Kim
    - John Lunz
    - Paulo Martins
    - Stacy McKean
    - Sumit Mohan
    - Martha Pavlakis
    - Emily Perito
    - James Pomposelli
    - Kurt Shutterly
    - Titte Srinivas
    - Susan Zylicz
- **HRSA Representatives**
    - Vanessa Arriola
    - Jim Bowman
    - Marilyn Levi
    - Shannon Taitt
- **SRTR Staff**
    - Jon Snyder
- **UNOS Staff**
    - James Alcorn
    - Sally Aungier
    - Nicole Benjamin
    - Rebecca Brookman
    - Roger Brown
    - Matt Cafarella
    - Laura Cartwright
    - Julia Chipko
    - Abigail Fox
    - Betsy Gans
    - Chelsea Haynes
    - Courtney Jett
    - Sarah Konigsburg
    - Lindsay Larkin
    - Krissy Laurie
    - Lauren Mauk
    - Elizabeth Miller
    - Rebecca Murdock

- Kelley Poff
- Matthew Prentice
- Tina Rhoades
- Laura Schmitt
- Sharon Shepherd
- Leah Slife
- Peter Sokol
- Susie Sprinson
- Kaitlin Swanner
- Kaya Temple
- Susan Tlusty
- Kim Uccellini
- Ross Walton
- Sara Rose Wells
- Joann White

- **Other Attendees**
  - Natalie Blackwell
  - Alejandro Diez
  - PJ Geraghty
  - Jim Kim
  - Molly McCarthy
  - Oyedolamu Olaitan
  - Jennifer Prinz
  - Andrew Weiss