

OPTN Policy Oversight Committee

Meeting Summary

May 12, 2021

Conference Call

Alexandra Glazier, JD, MPH, Chair

Nicole Turgeon, MD, Vice Chair

Introduction

The Policy Oversight Committee met via Citrix GoToMeeting teleconference on 05/12/2021 to discuss the following agenda items:

1. Match Run Rules Workgroup Update
2. Technology Tools Workgroup Update
3. Portfolio Management Update
4. August Public Comment Preview
5. New Projects

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

1. Match Run Rules Workgroup Update

The workgroup chair presented on a phased approach with multiple projects starting with work on the increase offer filters project and the dynamic match run concept, with additional work on creating a "conditional yes" component being addressed at a future time.

- Phase I (develop framework/process standardization):
 - Define provisional yes, outline responsibilities of members
 - Mandate use of offer filters for kidney
 - Limit number of offers sent out dependent on organ quality factors / likelihood of offer acceptance
 - Time Limits on offers, to implement automated reminders within UNet based on times currently within policy, and expiration if transplant programs do not respond
- Phase II (dynamic match run):
 - Capability to filter off candidates from match run who no longer meet acceptance criteria when donor information is updated
 - Continuously evolving match run

Summary of discussion:

POC members suggested that the workgroup consider offer filters for organs other than kidney, but agreed that kidney was the logical starting point. One member recommended a patient representative on the workgroup, especially with the dynamic match run, to ensure that the patient perspective is considered as well.

2. Technology Tools Workgroup Update

The workgroup chair presented on multiple project ideas, and the workgroup is continuing to design and provide requirements for them:

- Single-nodal entry of key recovery dates and times in DonorNet mobile
- DonorNet clinical data collection
 - Update clinical data reported in DonorNet to better capture information utilized in donor and organ evaluation by transplant centers
- Automatic time zone conversion
- Image sharing of biopsies

The workgroup will be collaborating with Match Run Rules and the Biopsy Standards Workgroup to align DonorNet workflows and maximize efficiencies through coordinated timing of projects

Summary of discussion:

The POC agreed that this important work that supports that of the other policy priorities, and that the correct collaborators have been identified.

3. Portfolio Management Update

UNOS staff presented on the plan to provide further information on total available resources for POC consideration during project reviews, to more holistically consider resource costs of individual projects.

Summary of discussion:

Members agreed that it is necessary for them to understand the overall resources available at the project approval phase. Members wanted to know if this discussion was a result of any one project, and UNOS staff explained that this is an effort to provide a more holistic view of portfolio management and not in response to any committee or project. Members agree that overall this will be helpful, and would like to see more concrete examples of how this will be implemented.

Next steps:

UNOS staff will provide multiple graphics options for POC resource review on an upcoming call.

4. August Public Comment Preview

The POC heard presentations on the following proposals:

- Reporting Immediate Graft Dysfunction in Heart Transplant Recipients (Heart Committee)
- Review of Extension Requirements in Adult Heart Allocation Policy (Heart Committee)
- Membership Requirements for Uterus Transplant Programs (Vascular Composite Allograft Committee)
- Continuous Distribution of Lungs (Lung Committee)
- Data Collection to Evaluate the Logistical Impact of Broader Distribution (Operations and Safety Committee)
- Performance Monitoring Enhancement (Membership and Professional Standards Committee)
- Data Collection Related to the US Public Health Service Guideline 2020 (Ad Hoc Disease Transmission Advisory Committee)
- Citizenship Status Guidance Document (Ad Hoc International Relations Committee)
- Ethical Considerations of Continuous Distribution (Ethics Committee)
- Ongoing Review of NLRB Diagnoses in Guidance and Policy (Liver and Intestines Committee)
- Reassessing the Inclusion of Race in eGFR Equation (Minority Affairs and Kidney Committees)
- Continuous Distribution Concept Paper (Kidney and Pancreas Committees)
- Change CPRA Calculation (Histocompatibility Committee)
- HLA Equivalency Tables Update 2021 (Histocompatibility Committee)

Performance Monitoring Enhancement

The Liver Vice Chair recommended that the MPSC consider the impacts of the SRTR 5-tier system on transplant program behavior when considering a change on the OPTN side. He proposed that the 5-tier system has caused many programs to be risk-adverse when selecting organs or candidates due to the significant role played by post-transplant outcomes. The Data Advisory Vice Chair asked why transplant rates were not included as a potential metric, and the UNOS MPSC project manager explained that the MPSC wanted to focus on metrics completely in control of the transplant program for evaluation, and that transplant rates can be strongly influenced by the performance of local OPOs. The Liver Vice Chair also posed that transplant rates could also be manipulated by programs minimizing the size of their waiting list. The MPSC Vice Chair also posed the committee is looking to increase transplants by minimizing risk-adverse behavior caused by post-transplant outcomes being the only metric a program is judged upon, and working towards looking at programs more holistically. The Operations and Safety Vice Chair posed that the MPSC should consider the pressure from dialysis units for pre-emptive listings in new dialysis unit metrics.

Citizenship Status Guidance Document

The POC Chair commented that initial POC feedback was that the scope of this project may be too expansive, and that the feedback was incorporated.

Ethical Considerations of Continuous Distribution

The Kidney Vice Chair expressed concern at the timing of this document, due to multiple continuous distribution projects already being underway. The Ethics Vice Chair explained that the purpose of the document wasn't to discuss whether or not continuous distribution is ethical, because the committee agreed that it was, but on how to incorporate ethics within the framework when building this new system.

Reassessing the Inclusion of Race in eGFR Equation

Multiple members questioned why this proposal incorporated a request for feedback instead of immediately going into policy. The Operations and Safety Vice Chair brought up that policy does not specify what GFR calculation must be used, and that he was already able to change the GFR used at their program currently. The Kidney and Minority Affairs Vice Chairs explained that they had done the same, but one of their workgroup members faced strong resistance to this and was unable to do so at her program. They brought up that there was significant pushback to removal of race from eGFR at many programs, and there may need to be multiple phases to develop consensus. POC members recommended that the first phase of the proposal remind members that they are able to remove race-based eGFR calculations from their programs immediately, and provide literature and resources in support.

Change CPRA Calculation

The Operations and Safety Vice Chair recommended that the Histocompatibility Committee prioritize API upload of donor HLA typings as a measure to reduce discrepant typings. The Histocompatibility Vice Chair and UNOS staff liaison explained that the HLA Equivalency Tables Update 2021 includes the necessary precursor steps to allow for API upload of typings.

HLA Equivalency Tables Update 2021

The VCA Vice Chair asked if the addition of HLA-DPA1 unacceptable antigens could potentially create any disparities between the donor and recipient pools. The Histocompatibility Vice Chair explained that programs can choose whether or not to list unacceptable antigens, their use is voluntary and based on

clinical judgment to screen off incompatible donors. He explained that he did not believe that this would have any impact on racial-based disparities.

Next steps:

The POC did not have questions or comments on the remaining proposals. The POC will review all of the proposals again in July 2021 and recommend to the Executive Committee whether the proposals should be approved for public comment.

5. New Projects

The POC considered the following projects:

- Evaluate Living Donor Exclusion Criteria (Living Donor Committee)
- HLA Equivalency Tables Update 2021 (Histocompatibility Committee)
- Standardized Format for Pathology Report (Kidney Committee)
- Minimum Criteria for Biopsy (Kidney Committee)
- Modify Heart Policy for Pediatric Candidate and Intended Blood Group Incompatible (ABOi) Offers (Heart and Pediatric Committees)
- Transparency in Transplant Program Selection (Ethics Committee)

Transparency in Transplant Program Selection

The POC Chair explained that she had a discussion with the Ethics Committee Chair about this being a two-phase project. The first proposed phase would be the Ethics Committee providing the ethical framework on the data that needs to be provided to transplant candidates for program selection. The proposed second phase would be development of necessary data elements by the Minority Affairs, Data Advisory, and Patient Affairs Committees. She also explained that the Social Determinants of Health study being carried out by the OPTN would be critical in informing phase 2 of this work. The Ethics Vice Chair affirmed this, and that this would be an important collaboration in order to provide additional transparency in the process for transplant candidates.

The POC did not have questions or comments on the remaining proposals. No concerns about authority for any of the projects were expressed. The POC voted to approve all projects (16-yes, 0-no, 0-abstain).

Next steps:

The ExCom will consider these projects for approval during their meeting on 6/14/2021.

Upcoming Meeting

- June 9, 2021

Attendance

- **Committee Members**
 - Alden Doyle
 - Alex Glazier
 - Andrew Flescher
 - Emily Perito
 - Garrett Erdle
 - Heung Kim
 - John Lunz
 - Kurt Shutterly
 - Lara Danziger-Isakov
 - Marie Budev
 - Martha Pavlakis
 - Nicole Turgeon
 - Rachel Forbes
 - Rachel Patzer
 - Rocky Daly
 - Sandra Amaral
 - Stacy McKean
 - Susan Zylicz
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- **HRSA Representatives**
 - Adriana Martinez
 - Chris McLaughlin
 - Jim Bowman
 - Marilyn Levi
 - Vanessa Arriola
- **SRTR Staff**
 - Jon Snyder
 - Shannon Taitt
- **UNOS Staff**
 - Abby Fox
 - Amber Wilk
 - Ann-Marie Leary
 - Betsy Gans
 - Brian Shepard
 - Chelsea Haynes
 - Courtney Jett
 - Elizabeth Miller
 - James Alcorn
 - Joann White
 - Julia Chipko
 - Kaitlin Swanner
 - Kayla Temple
 - Kimberly Uccellini
 - Krissy Laurie
 - Kristine Althaus

- Laura Cartwright
- Laura Schmitt
- Lauren Mauk
- Leah Slife
- Lindsay Larkin
- Liz Robbins-Callahan
- Matt Cafarella
- Matthew Prentice
- Meghan McDermott
- Nicole Benjamin
- Rebecca Brookman
- Rebecca Murdock
- Robert Hunter
- Roger Brown
- Ross Walton
- Sally Aungier
- Sara Rose Wells
- Sarah Booker
- Sarah Konigsburg
- Sharon Shepherd
- Susan Tlusty
- Susie Sprinson
- Tina Rhoades
- **Other Attendees**
 - Alejandro Diez
 - Barry Friedman
 - Brian Feingold
 - James Pomposelli
 - Jennifer Prinz
 - Jim Kim
 - Molly McCarthy
 - Oyedolamu Olaitan
 - PJ Geraghty
 - Pooja Singh