

**OPTN Operations and Safety Committee
Meeting Summary
September 23, 2021
Conference Call**

**Christopher Curran, CPTC, CTBS, CTOP, Chair
Alden Doyle, MD, MPH, Vice Chair**

Introduction

The Operations and Safety Committee (the Committee) met via Citrix GoTo Meeting teleconference on 09/23/2021 to discuss the following agenda items:

1. Public Comment Presentation: Report Primary Graft Dysfunction in Heart Transplant Recipients
2. Vice Chair Nomination Process
3. Update: Redefining Provisional Yes (Match Run Rules) project

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

1. Public Comment Presentation: Report Primary Graft Dysfunction in Heart Transplant Recipients

The Committee received a presentation on the OPTN Heart Transplantation Committee's *Report Primary Graft Dysfunction in Heart Transplant Recipients* proposal.

Summary of discussion:

The Chair asked what information, besides assessing heart transplant outcomes, will primary graft dysfunction data offer. The Chair of the Heart Committee responded that primary graft dysfunction data will help the heart community identify a standard definition for primary graft dysfunction, which will also help develop a better understanding of the implications. The Chair of the Heart Committee clarified that primary graft dysfunction data will not be utilized to assess transplant programs.

The Chair asked once a primary graft dysfunction definition is determined, if correlations would be made to draw conclusion regarding primary graft dysfunction and donor management. The Chair of the Heart Committee responded that reviewing whether the transplant recipient developed primary graft dysfunction based on a determined definition and donor data will lend to better understanding.

A member asked if the four-hour window for time points for primary graft dysfunction data collection result in an eight-hour window total. The Chair of the Heart Committee responded that it is a four-hour window on either side of the time frame, so it is correct that there would be an eight-hour window total.

Another member asked if the intention is to collect primary graft dysfunction data on all donors because that could be a significant data burden. The Chair of the Heart Committee clarified that the proposed data collection is for all transplant recipients.

A member stated appreciation for the Heart Committee's work and noted that the collection of this data is an important step forward.

There were no additional questions or comments.

2. Vice Chair Nomination Process

The Committee reviewed the process for Vice Chair nominations.

Summary of discussion:

There were no comments or questions.

Next steps:

The Committee will receive a call for Vice Chair nominations beginning October 2021.

3. Update: Redefining Provisional Yes (Match Run Rules) project

The Committee reviewed the work to date accomplished by the Match Run Rules Workgroup (the Workgroup) regarding the redefining provisional yes project.

Summary of discussion:

The Chair stated the Workgroup discussed potential policy modifications, which would outline formal expectations for transplant programs when entering a provisional yes. The Chair explained that these formal expectations would be set up in a tiered approach depending on the transplant program's place on the match run. The Chair stated that there are additional projects to addressing system enhancements, which aim to reduce the volume of organ offers transplant programs receive, and policy modifications will further enhance the authentic review of organ offers. A member responded that it may be difficult to add expectations and regulations into policy when the community does not know the impact the other enhancement projects will have on their organ offer and acceptance practices. The member stated that if the other impending projects do not have the expected impact, then regulatory measures could be considered.

Another member asked if organ offers have been evaluated for the type of information that is regularly missing. The Chair responded that the Workgroup received a presentation, but the Committee could review it to ensure that the current required information is complete. The Chair added that policy outlines several requirements for organ procurement organizations (OPOs) to be able to send organ offers, however there are no guidelines for transplant centers to review and accept organ offers.

A member suggested limiting the number of provisional yes entries on any given match run in order to pressure transplant programs to realistically evaluate organ offers. The member stated that due to the wide variety of donation scenarios, this would not be a practical solution.

Another member stated that not being able to view the number of transplant programs on any given match run is an issue in assessing organ offers. The Chair responded that the Workgroup has discussed this issue.

Potential policy modification: Transplant programs must not turn down organ offers based on information that was previously available

The Chair stated that the intent of this potential policy modification is to ensure that transplant programs are authentically reviewing organ offer information. The Chair explained a scenario in which the primary transplant program requests the OPO to perform a catheterization test, the results of the test come back clean, and then the primary transplant program declines due to size. The Chair stated that this scenario wastes time and that this potential policy modification would try to eliminate those types of scenarios. The Chair emphasized that this type of behavior negatively impacts every other transplant program on the match run and disadvantages transplant candidates waiting for the next offer.

Members agreed that this potential policy modification would be difficult to enforce. A member added that the potential policy modifications should not be punitive to programs. The Chair stated that the Workgroup discussed how to enforce these potential policy modifications. The Chair explained that

these potential policy modifications do not need to be a part of the program evaluation plan. The Chair explained that due to these expectations being placed in policy, it would allow members to submit complaints if a transplant program neglects one of the formal expectations and that results in an organ being lost or not giving the due opportunity to the next transplant candidate. The Chair stated the policy would provide guardrails and a way to hold transplant programs accountable.

Another member stated that it would be difficult for transplant programs to determine how to meet a requirement such as this, especially when there are other projects to be implemented that will affect their organ offer and acceptance practices. The member suggested creating a pathway for OPOs to report incidents, rather than creating policy modifications. The Chair stated that the problem is many of the scenarios in which a transplant program delays the efficiency of the organ offer and acceptance system, there has been no policy violation.

A member suggested that retooling the way organ offers are done may be more effective. The member suggested a system in which the first transplant program that says they will accept the organ, receives it.

Potential policy modification: Transplant programs must confirm candidate availability for transplant

A member asked if the definition of provisional yes could be updated to address this specific policy modification. The member suggested that the definition of provisional yes include that the transplant candidate has been notified and is accepting of the organ.

Potential policy modification: Transplant programs must document a patient's consent to receiving increased risk organs before receiving organ offers

The Chair stated that this suggestion should be removed due to the recent OPTN policy alignment to Public Health Service (PHS) guidelines. The Vice Chair suggested this potential policy modification could be clarified to state that transplant programs must document that a patient will accept a positive hepatitis C virus (HCV) organ before listing a patient for a HCV positive organ.

Potential policy modification: Transplant programs must assess histocompatibility

The Chair stated that OPOs frequently receive requests from transplant programs to send blood samples before they have performed a virtual cross match. The Chair explained that this potential policy modification intends to have transplant programs before some type of histocompatibility assessment before requesting the OPO to carry out additional measures.

There were no additional comments or questions.

Next steps:

The Committee will continue to review and discuss the redefining provisional yes project.

Upcoming Meetings

- October 15, 2021 ("in-person", virtual)

Attendance

- **Committee Members**
 - Andy Bonham
 - Alden Doyle
 - Audrey Kleet
 - Charles Strom
 - Christopher Curran
 - Dominic Adorno
 - Jami Gleason
 - Joanne Oxman
 - Kimberly Koontz
 - Melinda Locklear
 - Paige Oberle
 - Rich Rothweiler
 - Stephanie Little
 - Susan Stockemer
- **HRSA Representatives**
 - Jim Bowman
- **SRTR Staff**
 - Katie Audette
- **UNOS Staff**
 - Eric Messick
 - Joann White
 - Keighly Bradbook
 - Kristine Althaus
 - Laura Schmitt
 - Leah Slife
 - Meghan McDermott
 - Nicole Benjamin
 - Randall Fenderson
- **Other Attendees**
 - Richard Daly