

**OPTN Operations and Safety Committee
Meeting Summary
September 24, 2020
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 GoToMeeting teleconference on 09/24/2020 to discuss the following agenda items:

1. Public Comment Presentation: Align OPTN Policy with US Public Health Service Guideline
2. Workgroup Updates
3. Discussion: New Project Ideas

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

1. Public Comment Presentation: Align OPTN Policy with US Public Health Service Guideline

The Chair of the Disease Transmission Advisory Committee (DTAC) presented the Public Health Service (PHS) Guidelines Proposal. The purpose of this proposal is to align OPTN policies with updated PHS Guidelines for assessing solid organ donors and monitoring transplant recipients for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) infection.

Summary of discussion:

The Committee Chair suggested refining the definition of procurement further as either entry to the operating room (OR) or time of cross-clamp. Additionally, the Committee Chair expressed concern about expectations of the results of repeat testing being available before transplantation of an organ. The DTAC Chair appreciated the comments. Staff responded that the policy does not state when repeat testing results need to be available but will continue to research this topic.

A member asked for information regarding the reason to ask "high risk" questions of the donor if the term "high risk" is not used. The member also asked how organ procurement organizations or transplant programs expected to handle these donors differently, especially since recipients are tested after transplant. The DTAC Chair responded that the approach to informed consent is different. The DTAC Chair explained the approach shifts from utilizing a potentially dissuasive term to patient-centric conversations about weighing specific risks of disease transmissions and waitlist mortality.

The Committee Vice Chair asked the expected change in percentage of previously categorized "increased risk" donors based on the new compressed time frame and other changes. The DTAC Chair did not have exact data but has been analyzing different populations to see the effect of new revisions. Additionally, the Committee Vice Chair requested further information about the conversations regarding vaccinations. The DTAC Chair responded that it is not in the purview of the OPTN to require vaccinations but will suggested it as a best practice. The DTAC Chair added that while vaccination will not be required, DTAC would still like for the data to be collected to understand the context. The DTAC Chair

explained that possible data collection would add elements for HBV surface antibody levels as well as a vaccinated yes/no element.

Another member asked for clarification on extra vessel labels with regard to recovery date data. The Committee Chair responded that there are ongoing discussions whether recovery data is defined as date of entry to OR for recovery or data of cross clamp.

A member asked for more information regarding the rationale behind universal post-testing of all recipients. Is there some fear that the change in these guidelines will increase disease transmission? The DTAC Chair responded that the safety of this system currently relies on the information provided by next-of-kin which can potentially be unreliable depending on who provides the information. Dropping the time frame from 1 year to 1 month, the DTAC Chair had a number of discussion of the optimal timeframe. Although the data suggested that the safety of one month is acceptable, there was still some concern from the DTAC to provide a system that allows for catching transmissions even after removing risk factors and shortening the timeframe.

Public Comment Sentiment Vote:

Strongly Support- 36% (4), Support – 64% (7), Neutral/Abstain – 0% (0), Oppose – 0% (0), Strongly Oppose 0% (0)

There were no additional comments or questions.

Next Steps:

The comments received by the Committee will be synthesized into a formal statement that will be submitted for public comment.

2. Workgroup Updates

The Committee received updates on the Broader Distribution Data Collection and Organ Packaging projects.

Summary of discussion:

Broader Distribution Data Collection Workgroup

The Workgroup Chair reported that data elements out of the scope of the project include TransNet data, late turndown data, and cost. The next steps include the Workgroup evaluating data, providing input, and providing recommendations.

Organ Packaging Workgroup

During the last Workgroup meeting, a subject matter expert (SME) reviewed thermodynamics and cryobiology as potential contributing factors to organ freezing. The SME suggested that saline, specifically the concentration of saline in a solution, likely contributes to frozen organs. The Workgroup discussed organ procurement organizations' (OPO) packaging protocols and project scope. The Workgroup decided the analyzing policy and possible policy modifications to address variations in organ packaging as well as guidance. Representatives from the OPO Committee have been added to the Workgroup and will join the next meeting to continue packaging protocols and techniques. The project will be presented to the Policy Oversight Committee (POC) on October 14 for feedback.

3. Discussion: New Project Ideas

The Committee reviewed new project ideas that were previously discussed.

Summary of discussion:

Potential Project Ideas

- Defining data fields specific to donation after cardiac death (DCD)
- Identifying and addressing safety measures that have or may arise during COVID-19
- Analyzing recent policy changes to review their effect on liver discards
- Putting directed deceased donors on the match run to resolve issues such as ABO verification
- Effects of heparin dosage on DCDs
- Kidney discards due to kidney pump issues (cassette failures)

Defining data fields specific to DCD

The Chair stated that more than 20% of donors in the United States are DCD but currently there are no DCD specific data fields in DonorNet.

Identifying and addressing safety measures that have or may arise during COVID-19

The Chair mentioned that there are currently several proposals surrounding donor data collection related to COVID-19 as well data collection for patients in need of transplant due to COVID-19 infection.

Analyzing recent policy changes to review their effect on liver discards

The Chair stated that the project idea regarding liver discards arose from a policy change that enabled transplant programs to accept multiple organs for the same candidate. The Chair added there was data that suggested it led to an increase discard rate of livers. The Chair mentioned that it could be difficult to parse out what is due to broader sharing of liver and what is due to multiple organs being accepted for the same patient. That Chair asked whether other OPTN Committees have had these discussions. Staff responded they will follow up to find if there are any other projects working in relation to this. The Chair suggested reaching out to the Liver Committee to see if there are additional data related to this. A member stated that this issue is not unique to livers, they have also experienced it with kidneys. The member suggested also talking to the Kidney Committee regarding this and any available data. Another member suggested data could be analyzed by looking at the how close to the time of operating room (OR) are organs being declined. The Chair asked if the Broader Distribution Data Collection Workgroup has had conversations with the OPTN Data Advisory Committee (DAC) about their project regarding late turndowns. Staff responded that DAC is sponsoring a Refusal Codes & Late Turndowns Workgroup and will follow up with them for more information.

Putting directed deceased donors on the match run to resolve issues such as ABO verification

The Chair asked if there was data on the number of directed donations where the patient was not on the deceased donor matchrun. Staff will follow up. The Chair thought this would be great for transplant programs to print out the pre-transplant verifications since they do not appear on match runs often. The Chair thinks this is worthy of discussion and further research to understand how big the issue is.

Effects of heparin dosage on DCDs

A member stated that while working with different OPOs, they have experienced variations in when heparin is given as well as dosage variation. The member added that with a continual increase in the amount of DCDs, it would be helpful to understand the effects and potentially create standardization. The Chair asked if this project could be included in the other DCD project idea. The member agreed.

Kidney discards due to kidney pump issues (cassette failures)

A member stated that they have experience several kidney discards related to kidney pump cassette failures. The Chair asked if the member has seen the rate of discards related to kidney pump failures decrease since the cassettes have changed. The member believed they have decreased but that assumption is not based on any data. The Vice Chair suggested the Committee could sponsor an educational and guidance project. The OPTN Kidney Transplantation Committee will be contacted to see if they have any efforts related to kidney pump issues.

Next steps:

The Committee will prioritize the project ideas.

Upcoming Meetings

- October 20, 2020 (teleconference)
- November 19, 2020 (teleconference)
- December 17, 2020 (teleconference)

Attendance

- **Committee Members**
 - Alden Doyle
 - Angela Bullard
 - Alan Koffron
 - Audrey Kleet
 - Christopher Curran
 - Dominic Adorno
 - Gregory Abrahamian
 - Joanne Oxman
 - Kim Koontz
 - Luis Mayen
 - Melinda Locklear
 - Melissa Parente
 - Michael Marvin
 - Rich Rothweiler
 - Susan Stockemer
 - Susan Weese
 - Vandana Khungar
- **HRSA Representatives**
 - Marilyn Levi
 - Vanessa Arriola
- **SRTR Staff**
 - Katie Audette
- **UNOS Staff**
 - Alice Toll
 - Chelsea Haynes
 - James Alcorn
 - Joann White
 - Kaitlin Swanner
 - Katrina Gauntt
 - Kristine Althaus
 - Lauren Motley
 - Leah Slife
 - Meghan McDermott
 - Nicole Benjamin
 - Peter Sokol
 - Sara Rose Wells
- **Other Attendees**
 - Erika Lease
 - Karl Schillinger