OPTN Organ Procurement Organization Committee
Meeting Summary
January 19, 2022
Conference Call

Kurt Shutterly, RN, CPTC, Committee Chair
PJ Geraghty, MBA, CPTC, Vice Chair

Introduction

The OPTN Organ Procurement Organization (OPO) Committee (the Committee) met via Citrix GoToMeeting teleconference on 01/19/2022 to discuss the following agenda items:

1. Feedback on Warm Ischemic Time Data Definition
2. Public Comment Preview
3. Additional Updates

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

1. Feedback on Warm Ischemic Time Data Definition

The Committee reviewed and discussed the current definition of warm ischemic time utilized in UNet℠, and developed a draft updated definition.

Data summary:

The Data Advisory Committee (DAC) has a quarterly data definition review process, to review definitions for OPTN collected data. The DAC is looking to clarify the current definition for warm ischemic time, and is seeking input from the Committee.

The OPTN Liver and Intestine and Kidney Committee Leadership have provided some feedback, including:

- Objective measures, such as key time-related data points or a flow sheet, are better measures
- Pressure can be more reliable than oxygen saturation – it is not always clear if the clock should start if the saturation drops below threshold and rises again
- "time to core cooling" should be when flushing begins

The Committee discussed several questions:

- How would "start of agonal phase" be defined? If the blood pressure drops below threshold at 12:05, and remains below threshold through to 12:10, does the agonal phase start at 12:05 or 12:10?
- If a donor's blood pressure drops below threshold for 5 minutes, and later rises above the threshold before eventually dropping back down – how should the warm ischemic time then be calculated?
- Can 1(c) be simplified?

Current UNet℠ definition:

Warm ischemic time: Enter the warm ischemic time in minutes. Warm ischemic time must be between 0 and 180 minutes.

If the donor is a DCD donor, the warm ischemic time is the time from:

1. the time of Agonal Phase onset (from the time of cardiac arrest when the systolic pressure meets the following conditions for greater than five (5) minutes):

a. Newborn up to 28 days, with a systolic blood pressure less than 60 mm Hg, **OR**

b. 29 days up to 12 months, with a systolic blood pressure less than 70 mm Hg, **OR**

c. 1 year up to 10 years, with a systolic blood pressure less than 70 mm Hg, plus 2 times the age of the patient in years, not to exceed 79 mm Hg, **OR**

d. 11 years or older, with a systolic blood pressure less than 80 mm Hg, OR when the oxygen saturation is less than 80% at any age, to the time when core cooling is initiated.

2. The calculated time using the serial data to be collected beginning with the agonal phase and ending with the initiation of core cooling.

Summary of discussion:

One member addressed the potential situation where a donor's blood pressure drops below the threshold hold and later rises above it again, and remarked that this requires a clinical judgement. The member added that their OPO typically considers the true agonal phase to begin once a blood pressure drops below threshold and remains below the threshold. The member also noted that 5 minutes seems like an appropriate time period.

Another member agreed that clinical judgement is often necessary in situations where the blood pressure varies around the threshold, noting that the degree to which the blood pressure drops is also meaningful, particularly in context with donor factors. The member added that the procuring liver team often has influence over how to evaluate situations where the blood pressure varies above and below the threshold.

One member remarked that trends in blood pressure and oxygen saturation are often more meaningful.

The Vice Chair pointed out that OPO practices and the warm ischemic time reported to the OPTN are often different, sharing that his OPO typically reports the overall vital signs every minute to let the transplant programs make the decision. The Vice Chair continued that the warm ischemic time is reported to the OPTN as required in the Deceased Donor Registration form (DDR), but that transplant programs typically make judgements based on donor history, recipient needs, and other factors.

The Vice Chair oriented the discussion, asking the group how to standardize the definition for OPTN reporting purposes. The Vice Chair pointed out that the calculation required in 1.C in the current definition was unnecessary and confusing, and recommended eliminating the calculation. A member agreed that the definition should be simplified for consistency. Others agreed. The Chair remarked that it would be important for the Committee to come to consensus on a definition

One member asked whether this discussion would result in new fields in DonorNet®, or where the change would be seen. Staff responded that this would be updating the data definition utilized in UNet. It was clarified that both the DDR and DonorNet have a data field for warm ischemic time. Another member recommended linking the definition near the data field to encourage consistency in data reporting.

A member expressed concern about the oxygen saturation criterion, pointing out that oxygen saturation can be very positional and inconsistent.

The Vice Chair remarked that the oxygen saturation condition should be separated out, so it is clear that oxygen saturation is considered a trigger for agonal phase onset. Others agreed. The Vice Chair

recommended reorganizing the definition to make it clear, agonal phase onset is qualified by either systolic blood pressure or oxygen saturation criteria. The age-specific blood pressure requirements can be broken out as 2(a), 2(b), etc.

A member suggested clarifying that the blood pressure must meet criteria for a continuous five minutes, not five minutes in total. Others agree.

One member recommended reorganizing the age-related blood pressure criteria, so that the adult criteria were at the top, and clarifying the language of "11 years or older" to make clear that criterion included adult donors.

The Vice Chair asked the Committee if it made sense to maintain 4 different age bands for the blood pressure criteria, and recommended removing the calculation for the "1 year up to 10 years old" criterion and establishing a set blood pressure threshold. One member agreed the calculation should be removed, but noted that data or research would be needed to determine what the set threshold should be. The Vice Chair pointed out that the calculation has ages 1 to 10 in a 10 mm Hg range, such that any donor between 5 to 10 years old would have an 80 mm Hg threshold. This means the "11 years and older" age band with an 80 mm Hg threshold could essentially be expanded to "5 years and older."

The Vice Chair continued that donors 1 year up to 5 years could have a set number, so a calculation isn't necessary. The Chair agreed that it would be better to choose a set threshold, such as 75 mm Hg. Another member agreed, pointing to the brevity of the range. The Vice Chair suggested eliminating that line, and expanding the "29 days to 1 year" age band to "29 days up to five years" with a systolic of 70 mm Hg or less. The group agreed and expressed general approval. A member remarked that the set number threshold is much clearer.

One member asked if the OPTN Pediatric Committee had originally provided the recommendations for the age-related blood pressure criteria. Another member remarked that they didn't believe the Pediatric Committee discussed it recently. Staff added that this data definition is being reviewed as a result of a member question, and will be circulated with other OPTN Committee leadership for consensus.

A member asked about the "cardiac arrest," noting that the definition is defining agonal phase as when one of those conditions are met for 5 minutes. The Vice Chair remarked that cardiac arrest shouldn't be included at all, and that the definition should reference agonal phase as after extubation, once one of the following conditions are met and sustained for five minutes. Warm ischemic time would be defined as agonal phase onset to core cooling.

One member recommended recalibrating the first few lines of the definition, so that it is clearer exactly how warm ischemic time should be calculated. Another member suggested the language "warm ischemic time is the time from agonal phase to core cooling." The member pointed out that the majority of the definition is defining the onset of agonal phase.

The Committee discussed the removal of the "calculated time using the serial data" language, noting that policy already requires OPOs to capture serial data once the agonal phase is reached.

One member recommended updating the language of the "Five years or older" to "age greater than five years," so it is clear that adults are included.

A member suggested utilizing the language of "withdrawal of life sustaining measures" to replace extubation. Others agreed.

The Committee achieved consensus on the below definition.

<u>Draft updated definition:</u>

Warm ischemic time: Enter the warm ischemic time in minutes. Warm ischemic time must be between 0 and 180 minutes.

If the donor is a DCD, the warm ischemic time is the time from Agonal phase onset to initiation of core cooling.

Agonal Phase onset is defined as: after withdrawal of life-sustaining measures once either of the following conditions are met and sustained for greater than five (5) minutes

a. oxygen saturation is less than 80% at any age, **OR**

b. Blood pressure criteria by age:

1. Age greater than 5 years, with a systolic blood pressure less than 80 mm Hg **OR**

2. 29 days up to 5 years, with a systolic blood pressure less than 70 mm Hg, **OR**

3. Newborn up to 28 days, with a systolic blood pressure less than 60 mm Hg

2. Public Comment Preview

The Committee received a brief preview of upcoming public comment items for the January 2022 Public Comment cycle.

Data summary:

Pediatric Candidate Pre-Transplant Human Immunodeficiency Virus (HIV), Hepatitis B (HBV), and Hepatitis C (HCV) Testing

- Sponsoring Committee: Ad Hoc Disease Transmission Advisory, Pediatric Transplantation
- Adjusts the timing requirements for pre-transplant HIV, HBV, and HCV testing

Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation

- Sponsoring Committee: Ad Hoc Multi-Organ Transplantation
- Creates medical eligibility criteria for when a kidney should be allocated with a heart or lung
- Establishes safety net policy for those organs, and provides clarity for multi-organ transplants

Redesign Map of OPTN Regions

- Sponsoring Committee: Executive
- Request for feedback surrounding the restructuring of OPTN geographical regions
- Potential to inform a future policy proposal

Proposal to Revise the OPTN Charter

- Sponsoring Committee: Executive
- Proposal surrounding areas of interest identified in the OPTN charter

Change Calculated Panel Reactive Antibody (CPRA) Calculation

- Sponsoring Committee: Histocompatibility
- Identifies inequity in the current CPRA calculation and will better reflect candidate sensitization
- Most impactful to African-American candidates and women, who are currently disadvantaged

Modify Living Donor Exclusion Criteria

- Sponsoring Committee: Living Donor

- Evaluates current living donor exclusion criteria to create opportunities for increased living donation while maintaining donor safety

Improving Liver Allocation: Model for End-Stage Liver Disease (MELD), Pediatric End-Stage Liver Disease (PELD), Status 1A and Status 1B

- Sponsoring Committee: Liver and Intestinal Organ Transplantation
- Adds a sex variable to MELD calculation that gives additional points to women
- Updates the PELD score

Ongoing Review of National Liver Review Board Diagnoses (NLRB)

- Sponsoring Committee: Liver and Intestinal Organ Transplantation
- Updates guidance documents for the NLRB
- Focusing on Hepatocellular Carcinoma (HCC) policy, ischemic cholangiopathy guidance, and polycystic liver diease

Modify Graft Failure Definition for Vascularized Composite Allograft (VCA)

- Sponsoring Committee: VCA
- Updates the definition of graft failure and associated data collection surrounding graft failure to include VCA graft removal

Establish Minimum Kidney Donor Criteria to Require Biopsy

- Sponsoring Committee: Kidney Transplantation
- Identifies a minimum standard for when a procurement biopsy must be performed
- Does not set a limit on biopsy performance

Standardize Kidney Biopsy Reporting and Data Collection

- Sponsoring Committee: Kidney Transplantation
- Alongside previous proposal, will create a standardized set of information to be reported from procurement biopsies
- Designed to be useful at all levels of pathology

Establish OPTN Requirements for Race-Neutral Estimated Glomerular Filtration Rate (GFR) Calculations

- Sponsoring Committee: Minority Affairs and Kidney Transplantation
- Requires programs to calculate eGFR using a formula that does not include a race-based variable for kidney candidates
- Is not designating a specific formula to use

Several items were identified as of interest to the OPO Committee:

- Request for Feedback: Continuous Distribution of Kidneys and Pancreata
- Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation
- Redesign Map of OPTN Regions
- Improving Liver Allocation: MELD, PELD, Status 1A and Status 1B
- Establish Minimum Kidney Donor Criteria to Require Biopsy
- Standardize Kidney Biopsy Reporting and Data Collection

<u>Summary of discussion:</u>

One member remarked that OPO Committee had previously given feedback that the Minimum Kidney Donor Criteria proposal should not require biopsy, as some OPOs do not have consistent access to

biopsy services. Staff responded that the feedback was shared with the OPTN Kidney Committee sponsoring the proposal, and that the Kidney Committee decided to gather more feedback on accessibility of pathology services during public comment.

3. Additional Updates

The Committee discussed upcoming dates, including the winter 2022 Public Comment cycle and the implementation of the Clarify Multi-Organ Allocation policy.

Data summary:

Winter 2022 Public Comment will be open from January 27 through March 23, 2022. All regional meetings will be virtual this cycle.

The Clarify Multi-Organ Allocation Policy approved by the Board of Directors in June 2021 is scheduled to be implemented on February 10, 2022.

- Pre-implementation notice sent out January 13, 2022
- Educational offering on updated multi-organ policy will be available on UNOS Connect on January 20, 2022
- External user acceptance testing will be performed January 24 through January 26, 2022

Summary of discussion:

The Chair asked about potential work with OPTN data requirements regarding imminent and eligible death definitions. Staff responded that they are currently coordinating with the Scientific Registry of Transplant Recipients (SRTR) to schedule further discussion.

Upcoming Meeting

- February 16, 2022 – Teleconference
- March 15, 2022 – In-person Meeting or Teleconference

Attendance

- **Committee Members**
  - Kurt Shutterly
  - PJ Geraghty
  - Diane Brockmeier
  - Bruce Nicely
  - Chad Trahan
  - Debra Cooper
  - Erin Halpin
  - Jeffrey Trageser
  - Jennifer Muriett
  - John Stallbaum
  - Lawrence Suplee
  - Malay Shah
  - Mary Zeker
  - Meg Rogers
  - Merry Smith
  - Samantha Endicott
  - Sue McClung
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
  - Raelene Skerda
  - Vanessa Arriola
- **SRTR Staff**
  - Ajay Israni
  - Katie Audette
- **UNOS Staff**
  - Robert Hunter
  - Kayla Temple
  - Katrina Gauntt
  - Leah Slife