OPTN Data Advisory Committee Refusal Codes & Late Turndowns Workgroup Meeting Summary April 15, 2021 Conference Call

Introduction

The Refusal Codes & Late Turndowns Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 4/15/2021 to discuss the following agenda items:

1. Review committee and community feedback received

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

1. Review committee and community feedback received

The Workgroup members reviewed and discussed feedback from the various OPTN committees and feedback submitted by community members through the OPTN website.

Summary of discussion:

UNOS staff shared a document of the compiled committee and community feedback included in the meeting materials.

Candidate requires different laterality

The Workgroup members considered a recommendation to change this code to "incompatible anatomy." A member commented that incompatible anatomy may include more scenarios for refusal than what is intended by this code as is. The Workgroup decided leave this code as "candidate requires different laterality."

Candidate requires multiple organ transplant

The Workgroup members readdressed the decision to include "unavailable vessels" in the "candidate requires multiple organ transplant" refusal code description. The members determined that these two reasons should not be combined. The members considered if the lack of vessels is a refusal reason that is common enough to merit a standalone code. Members commented that these instances are rare and that vessels are typically stored by transplant programs. The members decided that there does not need to be a separate code that describes refusal due to unavailable vessels.

Refusal due to candidate financial or insurance reason

The Workgroup members readdressed the decision to combine a refusal reason relating to both medical unsuitability and insurance or financial constraints. Based on the feedback received, the members determined that there should be a separate code to describe reasons for refusal relating to lack of insurance or financial considerations. The members decided to modify this code's title to return to "candidate temporarily medically unsuitable" and add a second code "candidate temporarily ineligible due to insurance or financial issue" so that these two refusal reasons are exclusive.

A member asked if a candidate should be listed as inactive if they are currently not able to accept an organ for insurance or financial reasons. A member provided an example of a kidney candidate who may have less touchpoints with their transplant program and has a lapse in insurance after they are

activated. UNOS staff commented that this recommendation came from the Transplant Administrator Committee (TAC) as well as several survey respondents. Members agreed that this reason is common enough to merit an additional code and that the data collected may provide valuable insights.

Epidemic/Pandemic – Candidate

The members reviewed the description for the "Epidemic/Pandemic – Candidate." The members did not have additional comments on the description presented.

Donor cells (or specimen) unavailable for crossmatching

The members considered feedback to add a second code that would allow for a distinction between if the reason for refusal was due to hemodilution or due to the organ procurement organization (OPO) being unwilling or unable to send the specimen ahead of the organ. The members did not express interest in splitting this code to describe these two reasons.

Donor size

The members considered feedback from OPTN Committees and survey participants to combine the two proposed codes for "donor size-height" and "donor size-weight." A member suggested combining the code as "donor size mismatch." UNOS staff suggested "predicted organ size too large or small" as recommended by Membership and Professional Standards Committee (MPSC) and TAC. A member commented that donor height is evaluated for lung transplants and donor weight and occasionally height is evaluated for heart transplants. He commented that heart transplant programs would prefer to have the two codes for both height and weight. UNOS staff shared that the current refusal code in production is "donor size/weight." The members decided to keep the codes separated and readdress if needed.

DCD donor

The members considered feedback from the Liver Transplantation Committee as well as feedback collected from the survey that recommended adding a refusal code to describe instances where a donation after cardiac death (DCD) donor is unlikely to arrest based on their neurological exam. A member agreed with this suggestion. The members agreed to modify this code to "DCD donor neurological function/not expected to arrest." A member commented that this occurs frequently. The description for this refusal code was updated to "donor pronounced dead after cardiac death has unacceptable neurological function and is not expected to arrest in time."

The members considered the feedback to have an additional code for "DCD donor- quality." A member commented that if an organ is being denied for quality reasons, the user should select the most appropriate reason for the refusal from the proposed list, regardless of if the organ is procured from a DCD donor.

Donor instability/high vasopressor usage

The members considered a concern raised by a survey participant that this code could be overused since Vasopressin is occasionally used by OPOs to manage instable donors. A member commented that the code specifies "high vasopressor usage." The member commented that donor instability could also describe donors with poor oxygenation. The members decided keep the code as proposed.

Epidemic/Pandemic – Donor

The Vice Chair of the Data Advisory Committee (DAC) previously recommended moving this code to the Disease Transmission Risk category. The members agreed with this recommendation as it describes a transmission risk.

Suggestions for additional codes for the Donor Specific Reasons Category

The members considered the recommendation to add refusal codes for reasons relating to cause of death. The members agreed that these reasons could be captured in "donor medical history, specify."

The members considered the recommendation from the Vascularized Composite Allograft (VCA) Transplantation Committee to add a code relating to refusals for different skin color, and/or size, and/or sex and/or age between donor and candidate. UNOS staff commented that VCA is currently being programed into UNet but is not live yet. The members agreed to add a code "Graft Appearance/Quality (i.e skin tone, quality of limb, tattoos, scars, etc.)" visible for VCA offers only.

The members considered the recommendation to add a code to describe refusals for high calculated panel reactive antigen (cPRA). The members agreed that the existing proposed codes relating to histocompatibility reasons are adequate, specifically the refusal codes "positive virtual crossmatch/unacceptable antigens" and "number of HLA mismatches."

Donor family time constraint

A survey participant commented that this code is unnecessary and could be insulting to donor families. A member acknowledged that this is not intended to be insulting but describes a situation that can impact the timeline. The members decided keep this code as proposed.

Resource time constraint (OPO, TXC, Donor Hospital, etc.)

The members considered feedback that this code will require education and should include a specify box. UNOS staff shared that members will have access to the list of codes with descriptions. The members agreed to keep this code as proposed.

Transportation unavailable

The members considered feedback from the Heart Transplantation Committee to change this code to "transportation availability." The members agreed to change this code to "transportation availability" to be consistent with the other codes in the "Logistics" category.

The members considered feedback for additional codes relating to logistics. The recommendations included codes to capture refusals for reasons relating to transportation logistics causing cold ischemic time and weather. The members determined that the proposed codes already capture the reasons included in the recommendations and agreed to not add additional codes.

Upcoming Meeting

• April 29, 2021

Attendance

• Workgroup Members

- Angele Lacks
- o Anna Mello
- Farhan Zafar
- o JoAnn Morey
- Kristine Browning
- HRSA Representatives
 - o Adriana Martinez
- SRTR Staff
 - o Bertram Kasiske
 - Nick Salkowski
- UNOS Staff
 - Adel Husayni
 - o Ben Wolford
 - Emily Kneipp
 - Kimberly Uccellini
 - o Lauren Mauk
 - o Ross Walton
 - Sarah Konigsburg
 - o Sarah Taranto
 - o Susan Tlusty