# OPTN Data Advisory Committee Refusal Codes & Late Turndowns Workgroup Meeting Summary March 18, 2021 Conference Call

### Introduction

The Refusal Codes & Late Turndowns Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 3/18/2021 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 provided an update that all targeted OPTN committees have received a refusal code presentation and have been solicited for feedback. A request for feedback has been posted to the OPTN website and will remain open until March 21<sup>st</sup>. The feedback received from the committees and the community will be compiled for the Workgroup to review. The goal is to have the Board of Directors (BOD) review and approve the finalized list of refusal codes at the BOD meeting in June.

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

### Refusal due to candidate financial or insurance reason

The Transplant Administrator Committee (TAC) and a survey participant suggested adding a refusal code that describes instances where the candidate is unable to accept an offer due to financial or insurance constraints. The Workgroup members discussed if this level of granularity is necessary. A member suggested combining this reason with the "candidate refused" code. Another member suggested adding this reason to "candidate temporarily medically unsuitable." Members agreed to change "candidate temporarily medically unsuitable." and include the financial and insurance reasons as part of the code's description. This updated code would be inclusive of both medical and financial or insurance reasons that may cause a candidate to be temporarily ineligible for an organ offer.

### Candidate requires different laterality

The Vascular Composite Allograft (VCA) Committee requested that the "candidate requires different laterality" refusal code be hidden from VCA offers. A member commented that this code should remain an option for VCA offers since some VCA transplants are lateral and therefore may be refused for this reason.

### Unavailable vessels

A survey participant suggested adding a refusal code that would describe a refusal due to "unavailable vessels." A member suggested combining this with the code "candidate requires multiple organ transplant." A member commented that a refusal could happen because the right amount or type of vessels are not being offered along with the organ. They commented that this may be too granular and not very common. The members agreed to add "unavailable vessels" into the description for "candidate requires multiple organ transplant" in order to accommodate this reason for refusal.

# No candidate serum for crossmatching/ No donor serum for crossmatching

A survey participant suggested combining the two refusal codes "no candidate serum for crossmatching" and "no donor serum for crossmatching." UNOS staff noted that the Histocompatibility Committee did not make this suggestion when they were presented the proposed codes. A member commented that the intent of keeping these codes separate was to help identify issues relating to testing serum as impacted by the broader sharing of organs. A member agreed that allocation changes relating to geography will drive the importance of having these two codes broken out by donor and candidate.

The Histocompatibility Committee and a survey participant suggested changing these codes to use the term "cells" or "specimen" rather than "serum." A member commented that cells and specimen fall into the same category but are different. She commented that donor cells may be absent from a blood specimen which is different than having no specimen. A member suggested using the term "sample" and then including "cells and serum" in the code's description. The members agreed that the term "specimen" as suggested by the Histocompatibility Committee is broad enough to be applicable for all sample types such as lymph nodes, cells, serum, and blood.

Membership and Professional Standards Committee (MPSC) and a survey participant recommended adding a code to describe refusal due to not having time for a crossmatch or prospective crossmatch. A member suggested that "no donor specimen for crossmatching" or "no candidate specimen for crossmatching" may be the appropriate code to use in this case. A member commented that instances in which there is not current blood available and not enough time to transport a new sample would fall outside of what is intended for the codes "no donor specimen for crossmatching." Members agreed that no specimen or no time ultimately describes the same issue that may result in a refusal.

The members agreed to change the code to "donor cells (or specimen) unavailable for crossmatching." The description for the donor code will be updated to include the timing consideration discussed.

### Crossmatch related reasons category

Based on feedback received, UNOS staff suggested changing the title of this category to "histocompatibility related reasons." Members agreed with this change.

### Number of HLA mismatches unacceptable

The Heart, Histocompatibility, Liver, Pancreas, and Membership and Professional Standards Committees recommended moving "number of HLA mismatches unacceptable" to the "histocompatibility related reasons" category in order to group all of the histocompatibility reasons for refusal. The members agreed to re-categorize this code to "histocompatibility related reasons."

### ABO

Members discussed a suggestion to add a refusal code for ABO. UNOS staff shared that this was a refusal code for liver offers that was very rarely used and was removed from the proposed list. A

member commented that they know of a transplant program that regularly uses the current ABO refusal code. UNOS staff commented that the Liver Committee did not request that this code be added when given a presentation. The members asked if there is data relating to the number of programs using the current ABO code. UNOS staff will provide this information prior to or during the next meeting.

# Positive physical crossmatch

MPSC recommended changing this code to "positive prospective (physical) crossmatch" to increase clarity. UNOS staff commented that the Histocompatibility Committee did not provide this recommendation. The members commented that the crossmatch could be both prospective or retrospective and determined that the code should remain without change.

# Donor infection/positive culture

The Lung Committee and a survey participant recommended adding a textbox to collect more data about the infection such as the location of the infection. A member commented that refusals may occur due to infections such as myocarditis, endocarditis, or other positive blood or fungal cultures. The members commented that trying to include a list of all possible infections would be too lengthy while having a textbox may make analyzing responses more difficult. The members determined that a specify box is unnecessary but will assess if additional granularity is needed when the codes are monitored in the future.

# Public Health Service (PHS) risk criteria or social history

MPSC recommended clarifying if this code should be used for instances in which the candidate may refuse the offer due to PHS risk reasons. The members determined that if the candidate is refusing for any reason, the code "candidate refused" should be used.

The VCA Committee recommended separating this into two codes. The members decided that this should remain one code since the PHS criteria has decreased to a 30-day timeframe, which will reduce the occurrences in which this code would be appropriate. The members decided to add language to this code's definition to guide the user to use "candidate refused" when the candidate refuses, even if relating to PHS risk.

A member commented that using the term "PHS risk factors" rather than "PHS risk criteria" may be better aligned with current terminology.

### Malignancy or suspected malignancy

The members agreed with the recommendation to move the code "malignancy or suspected malignancy" to the "disease transmission risk" category. A member noted that the codes listed in this category all relate to *Policy 15: Identification of Transmissible Diseases.* Due to these reasons, the members chose keep the category titled "disease transmission risk" rather than "infectious disease transmission risk" as recommended by MPSC.

### DCD donor

The members agreed with the recommendation from TAC and the Pancreas Committee to move the code "DCD donor" to the category "donor specific reasons."

The members considered recommendations to split this code into two in order to describe DCD donor refusals for neurological function or general quality reasons. The members decided that this division would be too granular but agreed to add "neurological function" as part of the "DCD donor" description.

# Donor Age

The Kidney Committee suggested retitling the code "donor age" to "donor age mismatch." A member commented that other codes such as "donor height" would also be used due to a mismatch reason. The members agreed that if this code is used for refusal, it is inherently due to a mismatch so the code does not need to be retitled.

### Donor size- weight/ Donor size- height

Multiple committees and survey participants recommended combining the two codes "donor sizeweight" and "donor size- height." A member commented that these two codes should be left separate for VCA offers. A member commented that a donor's weight is evaluated for heart offers.

The members considered recommendations to replace these codes with a code that describes organ size such as "organ size" or "predictive organ size too large/too small." Members suggested "predicted donor/organ size too large or small" or "donor size mismatch." The members will continue discussing this decision at the next meeting.

### Next steps:

The Workgroup members will continue considering the feedback received on the proposed list of refusal codes.

### **Upcoming Meeting**

• April 15, 2021

### Attendance

٠

# • Workgroup Members

- Angele Lacks
- David Marshman
- Jennifer Muriett
- Kristine Browning
- o Lauren Kearns
- Linda Cendales
- HRSA Representatives
  - Adriana Martinez
- SRTR Staff
  - o Bertram Kasiske
  - Nick Salkowski
- UNOS Staff
  - Adel Husayni
  - o Kim Uccellini
  - o Leah Slife
  - Nicole Benjamin
  - Peter Sokol
  - o Robert Hunter
  - Sarah Konigsburg
  - o Sarah Taranto