OPTN Data Advisory Committee
Refusal Codes & Late Turndowns Workgroup
Meeting Summary
January 21, 2021
Conference Call

Introduction

The Refusal Codes & Late Turndowns Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 1/21/2021 to discuss the following agenda items:

1. Discussion: Refusal Codes
2. Discussion: Late Turndowns

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

1. Discussion: Refusal Codes

The Workgroup members reviewed the draft list of proposed refusal codes. UNOS staff provided project updates.

Summary of discussion:

The list of proposed refusal codes was presented to the Organ Procurement Organization (OPO) Committee and the Data Advisory Committee. This presentation will be given to the Transplant Administrators Committee, Operation and Safety Committee, Transplant Coordinators Committee, Membership and Professional Standards Committee, as well as the Heart, Kidney, Liver and Intestines, Lung, Pancreas, and Vascularized Composite Allograft Transplantation Committees over the next few months.

Next steps:

The feedback received from these committees will be compiled and shared with the Workgroup to guide any additional changes to the proposed list of refusal codes.

2. Discussion: Late Turndowns

UNOS staff provided an overview of the Late Turndowns project problem statement and the expedited placement of liver policy. The Workgroup members discussed how to define late turndowns.

Summary of discussion:

Late turndowns are important to understand as they lead to an increase in both cold time and organ discard. Additional data collection can assist in determining ways to prevent discards. There is currently no data collected relating to late turndowns and the transplant community requires a way to define, report, and monitor this occurrence.

UNOS staff provided background on the development of the expedited placement of liver policy. Sponsored by the OPO Committee, this policy establishes a system for expediting liver offers following the notification that the primary accepting transplant program has declined the liver while the donor is in the operating room (OR) or, in the case of donation after circulatory death (DCD) donors, support has been withdrawn.

In the early phases of the expedited placement of liver policy development, the OPO Committee tried to address both pre-OR and in-OR expedited placement by identifying decision points when the OPO would consider moving to expedited placement. The OPO Committee decided it would be difficult to justify pre-OR timeframes such as 2 or 3 hours prior to the scheduled donor recovery time as these schedules change for a variety of reasons. This led the OPO Committee to ultimately focus on in-OR expedited placement because the criteria is clearer. The following is the criteria that must be met in order to permit expedited placement of livers:

1. The donor has entered the operating room or, in the case of a DCD donor, withdrawal of life sustaining medical support has been initiated, whichever occurs first.
2. The host OPO or Organ Center is notified by the primary transplant hospital that the primary potential transplant recipient will no longer accept the liver.

The term "late turndown" is not included in the expedited placement of liver policy and was not defined by the OPO Committee. A challenge with developing the expedited placement of liver project was the lack of data relating to late turndowns. In addition to anecdotal evidence that this is a problem for livers, there was a study conducted by the Associated of Organ Procurement Organizations (AOPO) supporting that intraoperative declines result in a higher likelihood of discard.

One benefit of the expedited placement of liver policy, when implemented, is that there will be data collected on intraoperative declines. These data elements that will be collected when the two conditions listed above are met and the OPO moves forward with expedited liver placement:

1. Date and time donor entered the operating room or withdrawal of life sustaining medical support was initiated, whichever occurs first.
2. Date and time host OPO was notified by the primary transplant hospital that they will no longer accept the liver offer for the primary potential transplant recipient.
3. Reason for organ offer refusal by the primary potential transplant recipient.

A member commented that his team has had a lot of discussions around the difference between late turndowns and intraoperative declines. One concern with the description of the criteria required for the expedited placement of liver policy is that a late turndown can occur prior to entering the OR, meaning it is preoperative. Late turndowns will still impact the OPO, especially if multiple organs are being procured and the procurement teams are already mobilized, regardless of if the donor has entered the OR.

A member noted that there is a difference in abdominal and thoracic late turndowns. It is extremely difficult to reallocate a cardiothoracic organ as late as 30 minutes prior to the donor entering the OR. Whereas, the member commented, she has had some successful reallocations of abdominal organs, even when declined intraoperatively. She commented that it is harder to coordinate backups for cardiothoracic organs.

A member agreed that not having a backup when an organ is turned down late creates logistical problems. They also agreed that the criteria set forth by the expedited placement of liver policy could be expanded on to apply to other organs.

UNOS staff asked the members if the definition for late turndowns should be organ specific, or if there is a possibility to create one, overarching definition for all organs.

A member commented that another factor to consider is the use of extracorporeal circulation or perfusion devices which would prolong the timeline for placement, although access to these devices is

limited. A member commented that use of these devices are commonly coordinated by transplant programs and not OPOs.

UNOS staff asked if the presence of a perfusion device should be considered for inclusion in the definition of late turndowns. Members commented that they are hesitant to include this in the definition because the use of these devices is still fairly uncommon.

A member suggested creating two late turndown definitions, one for heart and lung, and one for liver and other organs. Hearts and lungs will require similar processes when receiving notification of a late turndown. Different processes are required for abdominal organs. A member commented that a late turndown for kidney is likely when it is out of the body, post cross-clamp.

A member commented that hearts and lungs are more likely to be declined intraoperatively after the organ is visually examined. Other reasons for late turndowns of hearts could be due to the change in hemodynamics or a recipient issue.

When figuring out some parameters to set to define a late turndown, the members agreed that entering the operating room is a clear indicator that a decline at that stage is late, regardless of the organ. A member commented that donor type is also an important consideration. The turndown of an organ from a DCD donor at time of withdrawal is worse than an intraoperative decline of an organ from a donor after brain death (DBD) which is more likely to be reallocated.

A member commented that, ideally, expedited placement would happen for late turndowns for DCD donors hours before entering the OR since more time is needed to reallocate organs from DCD donors. The amount of time needed will vary based on distance between the donor hospital and transplant program, but a range from 2-6 hours prior is needed.

The mock-ups of the data collection tool for the expedited placement of livers policy were shared with the Workgroup. UNOS staff commented that the transplant program must agree that they are willing to accept expedited liver offers that are procured by any recovery team and are also required to enter acceptance criteria for each candidate in order to receive expedited liver offers.

A member asked if the facilitated pancreas policy could be used as a framework for addressing late turndowns. The members commented that they would support applying the facilitated pancreas allocation policy language to all organs except kidneys.

UNOS staff commented that the facilitated pancreas allocation policy language applies to pancreases that have not yet been accepted. A member commented that this language could be applied for cases where there was an acceptance and then a decline but it is within 3 hours of OR time. UNOS Organ Center staff commented that they apply this facilitated policy once within 3 hours of OR regardless of what the match looks like, even with backups.

A member agreed with this 3 hour approach since it is already established by policy. For cardiothoracic organs, the OR may be delayed but if there are time constraints, this would provide an opportunity for placement rather than losing the organ. Members agreed that the 3 hour prior to OR timeframe could be applied for all organs except kidney.

Members considered declines that occur post cross-clamp. A member commented that sometimes livers are declined before cross-clamp because of the visual evaluation. There are also cases where there may be a need for a biopsy and time is needed to receive the results.

UNOS staff shared that in order for transplant programs to receive facilitated pancreas offers, the program must have transplanted a minimum of five pancreas organs recovered from deceased donors from outside of the program’s DSA in the last two years.

A member commented that transplant programs could be asked if they are willing to accept an organ recovered by another program within 3 hours of recovery time and if they are willing to accept an organ post cross-clamp. Members commented that distance should also be considered, as 3 hours may be enough time for a program to send their own procurement team.

The members discussed some of the common reasons for late turndowns. A member commented that livers have the most late turndowns and this may be due to what is found when visually evaluated. Sometimes there are unreported liver lacerations or tumors. Other reasons can be related to size, macrosteatosis, or because the accepting program has accepted multiple offers. The members agreed that the most common reasons for a late decline of livers are size, issues discovered when evaluated visually, issues discovered when biopsied, recipient issues, and multi-organ acceptance. Another reason for turndowns is when another program requests a crossmatch but the recipient is unavailable.

Members discussed how perfusion could factor into expedited placement following a late turndown. A member suggested adding whether a transplant program is willing to accept a perfused organ as an offer filter.

A member commented that because of the decrease in travel due to COVID, transplant programs are relying more on other teams to perform the procurement.

A member commented that the expedited placement of liver policy requires collecting the time of day the primary acceptor declines. There may not be a primary acceptance at 3 hours pre OR. A member commented that scheduled or planned OR time may be a needed data element.

UNOS IT staff commented that there is no collected timing data that drives the 3 hour requirement for facilitated pancreas allocation. There is a field in the donor record that collects OR time and can provide a descriptive note that indicates if the time is tentative or confirmed. If this field was used, the same concept could be applied to DCD planned time of withdrawal. UNOS IT staff commented that collecting this data is challenging since OR times tend to change. The location of this field on the donor record is not convenient for the user when working in the match run which may make this option less efficient. A member agreed that the field should be moved to a different location in order to be more useable.

Next steps:

UNOS staff will send a summary of the discussion to the Workgroup for continued consideration.

Upcoming Meeting

- 3/18/21

Attendance

- **Workgroup Members**
    - Angele Lacks
    - Anna Mello
    - David Marshman
    - Farhan Zafar
    - Jennifer Muriett
    - Kristine Browning
    - Lauren Kearns
    - JoAnn Morey
    - Nick Salkowski
- **HRSA Representatives**
    - Adriana Martinez
- **SRTR Staff**
    - Ajay Israni
    - Bertram L. Kasiske
- **UNOS Staff**
    - Adel Husayni
    - Ben Wolford
    - Kimberly Uccellini
    - Lauren Mauk
    - Leah Slife
    - Melissa Lane
    - Nicole Benjamin
    - Niyati Upadhyay
    - Peter Sokol
    - Robert Hunter
    - Sarah Konigsburg
    - Sarah Taranto
    - Susan Tlusty