Introduction

The Refusal Codes & Late Turndowns Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 8/19/2021 to discuss the following agenda items:

1. Refusal Codes Update
2. Late Turndowns

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

1. Refusal Code Updates

UNOS Information Technology (IT) staff provided an update on the refusal codes:

- OPTN Board of Directors approved the refusal codes during its June 14, 2021 meeting
- No policy language changes
- Modifications expand current list of 29 refusal codes to a more granular and targeted list of 42 codes
- New numbering sequence—the 800 series will be replaced with a new 700 series that contains eight categories. The categorization will make the codes easier to locate within the DonorNet® user interface.
- Additional “other, specify” codes were added
- Implementation is scheduled to be completed by the end of 2021. The old codes will be phased out based on the match run dates. For example, any match runs prior to the date/time of implementation will allow the use of the 800 series codes, while all match runs after the implementation date/time will only allow the new 700 series codes. There will be a short period of time where the coordinators will be submitting refusals reasons using both the new and old set of codes, depending on when the match run initiated
- Notice to the members will be sent out approximately one month prior to implementation. Educational documents will outline the new codes and provide time for members to submit questions.
- Monitoring will begin 3 months post-implementation

UNOS IT noted that due to the new concept of categorization and navigation around the user-interface, they would like a few volunteers to test the system to ensure the user-interface is clear. They are also going to have a text search feature that will help users find the right code out of the larger list. The test environment will be in mid-October and will require about 1-2 hours of time for user testing. Testing will use different scenarios with fictional organ offers and match runs.

Members were encouraged to volunteer or identify individuals at their institutions. Several workgroup members volunteered.
2. Late Turndowns

UNOS staff provided a recap of the project’s background and purpose. This effort is to identify how to modify current or add new data collection to provide better information on late turndowns and help inform steps to reduce organ discards.

The workgroup members agreed that both pre-operative and intra-operative declines could be considered late. They also acknowledged that both scenarios have the potential to affect organ placement and that reallocation success varies by organ type. Additionally, thoracic and donation after circulatory (DCD) death donors require more time to coordinate reallocation.

UNOS staff highlighted the recommendations from previous workgroup calls, which includes the following:

Collect the following in “one location”
- Authorization date/time
- Operating room (OR) date/time (not required)
- Enter OR date/time (only required for expedited liver)
- Time of death (DCD and brain death)
- Time of withdrawal (if DCD)
- Recovery date (not always the same as cross clamp)

Summary of discussion:
UNOS staff noted that these recommendations were presented to the OPTN Organ Procurement Organization Committee in July 2021 and they agreed that collecting multiple OR times would be beneficial to evaluate how many times it changes. They also noted that there is a variety of reasons for why OR times change.

Other considerations previously discussed by the workgroup includes the following:
- Decline Time After Accept
  - Collected on all organs on match run page
  - Inconsistent, not documented in real time, may not be updated
- Expedited Liver Offers Require:
  - Date and time donor entered the operating room or withdrawal of life sustaining medical support was initiated, whichever occurs first
  - 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
  - Reason for organ offer refusal by the primary potential transplant recipient
- Ad Hoc Systems Performance Committee
  - Recommendation that data collection could be stratified with the following time points:
    - 0-2 hours prior to OR, 2-4 hours prior to OR, intraoperatively, and post-cross clamp

UNOS Research staff presented a proof of concept for how to analyze late turndowns if there was sufficient data. The analysis included a dataset using the first six months of 2021 data. For the analysis, a turndown is defined as when a candidate has the primary acceptance then subsequently gives up that acceptance.

Response Date
This is entered electronically when the transplant hospital responds but can also be manually entered by the OPO. If updated by the OPO, the default is the same as the previous respond date. One issue with the response data is that the records might be updated later, sometimes a long as a month later.

**Timing Between Refusal and Acceptance (Response Dates)**

Research staff presented data that showed the timing between refusal and acceptance response dates. Approximately half of the turndowns indicated that the acceptance and refusal was reported at the same time across all organ types. There was a range between 26.59% and 44.91% for recorded response dates within 24 hours, and a range of 7.87% and 19.02% for recorded response dates occurring greater than 24 hours across the various organ type offers. There is also no way to be certain when the response was changed to a no, particularly when the data is entered later.

One member noted that the challenge in capturing this data and ensuring accuracy is that OPOs will sometimes wait until they set the OR time or actually in the OR. The provisional yes will remain until the donor is in the OR and there is visual evaluation of the organ. Another member noted that the transplant hospital cannot enter an acceptance; they can only enter a provisional yes or refusal. An OPO member supported allowing transplant hospitals to enter acceptances, but acknowledged that there would need to be some sort of notification to the OPO.

One member noted that there needs to be a clear definition of an acceptance because some transplant hospitals will say that the organ is not officially accepted until it is visualized in the OR. It might also be beneficial to include provisional yes acceptances in the analysis.

A member commented that the match run list might show that it was updated 30 days after the fact. This might indicative of changes made following an internal OPO quality assurance (QA) process. Even if the coordinator documents this at two o'clock in the morning, the information could change based on that QA process, similar to how transplant centers have a certain amount of time to validate the data after the OPO.

A member added that a turndown six hours prior to cross clamp might not be considered a late turndown. However, if it is six hours prior to cross clamp but 18 hours after acceptance it might be considered a late turndown because the OPO might have to reset everything they have done in the process, even though it’s six hours before cross clamp.

Another member noted that it is nearly impossible to reallocate cardiothoracic organ if the turndown occurs within six hours of cross clamp. She also commented that another issue with broader distribution is the availability of planes and being able to get a team to the donor hospital efficiently. Previously, the OPO could give the team four hours to get there, but that is not possible today. She further commented that with abdominal organs there is the opportunity for a procurement surgeon to perform the recovery, but this is not common with cardiothoracic organs.

A member noted that another issue OPOs are experiencing relates to multiple acceptances of livers. He suggested looking at a way to correlate late liver turndowns with other acceptances for the same candidate on different match runs.

UNOS Research staff noted that it might be beneficial to expand on the definition of late turndown to include provisional yes acceptances and evaluate concurrent offers. Additionally, based on the issues with the late turndowns for cardiothoracic organs, workgroup members were asked for thoughts about the timeframe for other organ types.

**Late Turndowns and Organ Utilization**
UNOS Research staff presented data on how turndowns pre and post cross clamp impact organ utilization. Is there a better chance of finding another recipient if a turndown occurs well before cross clamp and do the chances decrease significantly well after cross clamp. There is an assumption that donors with late turndowns will have lower utilization rates than donors without late turndowns.

UNOS Research staff noted that if turndowns occur close to cross clamp, the utilization rate is much worse than with donors without late turndowns. However, if the turndown occurs much earlier prior to cross clamp (such as 12 hours prior), it has a much less effect on the utilization rate. This is similar for post cross clamp. If there is a turndown shortly after post clamp, there is a smaller effect on the utilization rate. However, if there is a turndown well after cross clamp, there is a much lower utilization rate. UNOS Research staff reminded the workgroup that this data is not reliable as is. However, there are some meaningful trends.

One member commented that one of the challenges is always going to be when an OPO has to adjust the OR time because of a late turndown. There are a cascade of factors that come into play when an OPO has to reallocate an organ. There are logistical challenges to coordinate recovery teams and transportation. Unless there is a finite endpoint, like family time constraints or other reasons that the OPO must move forward to the OR on time, a late turndown will always require an adjustment to the schedule OR time.

A member added that cross clamp times can be delayed because the recovery team is pausing to allow time for reallocation efforts. Another member noted that OPOs do not have a good place to consistently capture the data. Some electronic medical record (EMR) systems cannot capture the scenario when an organ was turned down and reallocated in the OR.

UNOS staff noted that the OPO Committee recommended the collection of multiple OR times in order to capture when those times change. There have been discussions about the value of recording multiple OR times as well as the reasons why the rescheduling occurred. A member noted that some OPO EMRs might have the capability to capture OR scheduled times and multiple changes.

UNOS Research staff provided the following summary:

- The “late” in late turndowns depends on when the final refusal occurred.
- We do not have reliable data for when refusals after accepts occur
- If we did have reliable data, we could define late turndowns as: turndowns that occur within a timeframe such that outcomes (e.g. utilization rates) are worse than for organs without any turndowns

A member noted that the data only captures when there is an actual acceptance and then a decline, not the provisional yes acceptances.

UNOS Research staff provided the following recommendations:

- Require real-time updates for decline after accept
- When the OPO is updating a response, do NOT auto populate the respond date with the previously recorded time
- When the OPO is changing a response from Yes to No, prompt the user to record the following:
  - If this turndown qualifies as a “Late Turndown”
  - If this turndown was 1) pre-operative 2) intraoperative or 3) post cross-clamp

One member supported the recommendations but added that OPO coordinators should not be trying to define late turndowns in the field. Being specific about the turndown occurring pre-operatively, intra-operatively or post cross clamp is a great way to capture it. Additionally, requiring the real-time update
for the decline after an acceptance is extremely important, but it might be beneficial to require real-time update to go from provisional to acceptance. As mentioned previously, the provisional yes might remain until the operating room because of the OPO practice or the functionality of the system.

UNOS staff asked if a question such as “did the turndown result in operational challenges or rescheduling of the OR time” would be less subjective. A member agreed that without a clear definition of a late turndown, capturing data that does not require interpretation by the coordinators would be the best approach. The goal is to capture whether a turndown had an impact on the process.

UNOS staff revisited an earlier suggestion to allow transplant programs the ability to enter acceptances and subsequent declines. A member commented that there could be value in allowing that. Another member responded that even if transplant centers have the ability to change it to a decline, there still has to be some sort of formal notification to the OPO. The main concern is the loss of communication for when somebody would go into the system to update something and not have any way to realize what had occurred.

One member suggested leaving the current system in place where only the OPO can change an acceptance. Another member noted that real time updates are actually occurring because there is no way to reallocate without entering a decline. He noted that the real issue is capturing the time stamp values. UNOS Research staff agreed but also noted that some updates occur a month later following a QA process.

A member noted that following the OPO’s QA process, the transplant programs also have 30 days to QA and update the refusal code. He asked if there was policy language addressing this and UNOS staff agreed to review the policy language and bring the information back to the workgroup.

Next Steps

UNOS staff reminded the workgroup that the next scheduled conference call on September 16, 2021. Workgroup members were encouraged to submit thoughts via email and identify information that might help guide the conversation during the next meeting.

Upcoming Meeting

- September 16, 2021 (Teleconference)
Attendance

- **Workgroup Members**
  - Jamie Bucio
  - Angele Lacks
  - David Marshman
  - Jennifer Muriett
  - Kristine Browning
  - Sumit Mohan
  - JoAnn Morey
  - Erica Seasor

- **HRSA Representatives**
  - Adriana Martinez

- **SRTR Staff**
  - Bert Kasiske
  - Jon Snyder

- **UNOS Staff**
  - Sarah Konigsburg
  - Carlos Martinez
  - Kim Uccellini
  - Nicole Benjamin
  - Lauren Motley
  - Lauren Mauk
  - Lloyd Board
  - Leah Slife
  - Robert Hunter
  - Samantha Noreen