OPTN Data Advisory Committee
Refusal Codes & Late Turndowns Workgroup
Meeting Summary
June 17, 2021
Conference Call

Introduction

The Refusal Codes & Late Turndowns Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 6/17/2021 to discuss the following agenda items:

1. Refusal Codes Updates
2. Late Turndowns

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

1. Refusal Code Updates

UNOS staff provided an updates on the refusal codes project:

- OPTN Board of Directors approved the refusal codes during its June 14, 2021 meeting
- Educational offering and communications to members are being developed
- Implementation is scheduled to be completed by the end of 2021
- Monitoring will begin 3 months post-implementation

2. Late Turndowns

UNOS staff provided background information on late turndowns. This included the impact that late turndowns have on both cold ischemic time (CIT) and organ discards, since it creates operational difficulties when organ procurement organizations (OPOs) are forced to reallocate organs. There are currently no data collected on late turndowns, so the workgroup is charged with identifying data to better understand the issue and analyze ways to reduce organ discards.

UNOS staff noted that both pre-operative and intra-operative turndowns could be considered late turndowns as both have the potential to impact the placement of organs. The specific timeframe for "late" can also vary by organ type. For example, thoracic organs and organs from donation after cardiac death (DCD) donors need a larger window pre-operating room (OR) in order to coordinate reallocation than abdominal organs. A member noted that OR times have a tendency to change as OPOs coordinate organ procurement.

UNOS staff presented the following questions to the workgroup:

- Can any existing data elements be modified or made required to provide insights into late turndowns?
- What data elements(s) need to be added to understand the impact of late turndowns on all organ types?
- What operational challenges need to be considered for any proposed data elements?

<u>Summary of discussion:</u>

UNOS IT reviewed the importance of data points to help determine when a turndown is considered "late." This included the identification of two parallel processes, the organ offer and response

dates/times and the organ recovery dates/times. The relationship between the two processes could help identify when an organ decline is considered a late turndown. However, in order to compare the two pathways there needs to be additional data collection.

UNOS IT staff reviewed a list of data elements that are currently being collected in either DonorNet® or TransNet℠.

- ***OR Date/Time*** – This information is collected on the donor summary page in DonorNet® and can be entered as tentative, scheduled, or not set. This information is not required so there is no timeframe for when it should be entered. Therefore, the data is not being collected in a consistent way in order to make a comparison between the two process pathways.

- ***Date/Time Donor Entered OR and Decline Time After Acceptance (If Expedited)*** – This information is collected on the match results page in DonorNet® and is only required if the OPO wishes to send expedited liver offers. A member noted that since OPOs are not required to expedite liver offers, this information would not be consistently collected.

  A member noted that OPOs will frequently leave the provisional yes acceptance until entering the OR so there needs to be some standardization of decline. This is especially true for kidney although kidneys are less susceptible to late declines. However, this can be true for other organs if final acceptance is determined in the OR.

- ***Cross Clamp Date/Time*** – This information is collected on the donor summary in DonorNet® and is not required. There is no timeframe for when the information is entered.

- ***Decline Time After Accept*** – This information is collected on all organs on the match results page. However, there are inconsistent reporting practices because the documentation of acceptance does not always happen in real time. UNOS IT staff noted that a data analysis is needed to determine if OPOs are updating the response date/time with subsequent potential transplant recipient (PTR) updates. For example, when a transplant program originally responds to an offer with a provisional yes, eventually accepts the offer, but subsequently declines.

  A member asked for clarification that this data element is referring to updates to the manual date/time field and not the organ offer history. UNOS IT staff noted that the date/time the record is saved is captured in the system. A member noted that the manual date/time field is probably not updated consistently across OPOs.

- ***Final Label Scan Time (Shipping Label 4) in TransNet℠*** – This information is required since it is part of organ packaging and should be done just prior to placing the organ in the shipping container. UNOS staff noted that the scan time does not imply that the organ is ready to be shipped to the transplant program; it could be going somewhere to be pumped. UNOS IT staff noted that there is a pending proposal by the Operations and Safety Committee to make "organ check out time" required which might provide additional information about when the organ leaves the OPO's possession. UNOS staff noted that the scan time might not be available in real time because some OPOs might be working offline. The organ check in process being used is available in real time, the issue is that a minority of transplant program are using TransNet℠ to check organs in.

- ***Time Shipment Received at Transplant Center*** – This information is collected in TransNet℠ and is not required. There is a pending proposal by the Operations and Safety Committee to make this date/time required.

A member noted that with all these different dates/times, it would be ideal if they were collected in one location. For example, three of the data elements are located on the same page but in two different locations. There are also some data elements collected in the match run, which is logical. The member added that as the workgroup identifies the list of data elements, including data being proposed by the Operations and Safety Committee, there needs to be a discussion about consolidating the information into one location.

UNOS staff noted that any barriers to collecting the data would need to be addressed. A member recommended creating a single nodal location to enter the data. This will assist OPO staff with identifying all the necessary data and visualize if there is any missing information that needs to be entered. There was also a recommendation to make this available in DonorNet® Mobile. Another member agreed and noted that the donor OR is a very hectic time and data entry needs to be easy or it will not be done in real time. If there is a turndown in the OR, the focus is on reallocation and not data entry.

UNOS IT staff asked the workgroup members what key events during the case progression would be important to collect in a single nodal location as well as DonorNet® Mobile. They also noted that this is data about the case and not specific to the donor.

UNOS IT staff inquired about the impact of not reporting OR date/time in real time might have on the evaluation of late turndowns. A member responded that if timeframes could be captured, they could be cross-referenced and provide useful information about what is actually happening during the donor cases.

UNOS staff also asked the workgroup if it would be beneficial to add the actual OR date/time to the currently collected scheduled/tentative OR date/time. A member noted that recovery date is collected although it does not include a time and is not required. It could be used to compare the OR date/time, however, the challenge of changing OR dates/times remains an issue. There is also an issue of a coordinator remembering to update any changes to the OR date/time if it changes due to a late turndown or other logistical reasons.

UNOS staff asked the Workgroup if any of these current data elements add value when trying to analyze late turndowns and their impact on organ placement. A member responded that these are the correct data elements, but the challenge is capturing them in a user-friendly way. There are numerous variables to consider as well. For example, when the donor enters the OR might be different for donation after cardiac death (DCD) donors because they could enter the OR a lot earlier to prepare for withdrawal of life-sustaining support.

UNOS staff asked the Workgroup about the stratified time points recommended by the Ad Hoc System Performance Committee (SPC). For example, collecting turndowns at 0-2 hours prior to OR, 2-4 hours prior to OR, intraoperatively, and post-cross clamp. A member noted that late turndowns would sometimes require a change to the scheduled OR time. Another member added that if the turndown is indicated on the match it might work because even though the OR is rescheduled, there is evidence of when the turndown occurred without having to constantly update the data.

UNOS staff noted that the preliminary stage of this work is evaluate the impact of late turndowns across all organ types to determine where to focus the most attention. For example, late turndowns for kidneys may have less of an impact while a heart turned down 3 hours prior to the OR might have a

huge impact on discards. This information could help inform the development of additional policies or other strategies to help address the issue. UNOS staff noted that literature is limited, except for livers, so the data proposed for collection through this project would help support future changes to reduce the associated problems.

A member noted that with the new kidney allocation system, expedited placement is going to be important as geography plays a major factor. For example, late turndowns can have an impact if you have 25 kidney programs to get through versus two when reviewing the match run. There is value in the data to help evaluate kidney discards because a longer CIT can greatly affect higher kidney donor profile index (KDPI) kidneys. While kidneys might not be "pre-recovery" turndowns, they can definitely be turned down post recovery and being able to compare cross clamp time to turndown time will be important.

UNOS staff again inquired about the information to collect about case progression. A member recommended the following data elements:

- Authorization date/time
- Scheduled OR date/time
- Enter OR date/time
- Time of death (DCD and brain death)
- Time of withdrawal (if DCD)
- Recovery date

A member also suggested adding a question about late turndowns by organ type. For example, what time was the organ accepted and what time was the organ subsequently turned down. Another member expressed concern about the added data burden and commented that there needs to be a clear definition of a late turndown. For example, a liver is placed early but the OPO is still offering thoracic organs for the next 12 hours before an OR time can be scheduled. If the liver is turned down prior to going to the OR, is it a late turndown if the OR time has not been scheduled? She added that 12 hours after the offer seems like a late turndown but that is something OPOs deal with all the time. Another member noted that transplant programs might have two liver acceptances, which is allowed by policy, and one of those offers might eventually become a late turndown. A member commented that there are delays on the thoracic side as well due to additional requests for testing.

A member recommended being clear about the definitions and providing the ability to view/enter information in one location. He also commented that even if the information is entered after the fact, it could still provide useful information to evaluate late turndowns. Another member suggested that the workgroup get feedback from the OPO Committee due to the potential for increased data burden.

Next steps:

UNOS staff will summarize the discussion and solicit feedback from the OPO Committee.

Upcoming Meeting

- July 15, 2021

Attendance

- **Workgroup Members**
  - Farhan Zafar
  - Angele Lacks
  - David Marshman
  - Jennifer Muriett
  - Krishnaraj Mahendraraj
  - Lauren Kearns
  - JoAnn Morey
  - Erica Seasor
- **HRSA Representatives**
  - Adriana Martinez
- **SRTR Staff**
  - Nick Salkowski
  - Bert Kasiske
- **UNOS Staff**
  - Sarah Konigsburg
  - Ben Wolford
  - Lauren Motley
  - Lloyd Board
  - Leah Slife
  - Robert Hunter
  - Susan Tlusty
  - Samantha Noreen