OPTN Operations & Safety Committee
Meeting Summary
October 15, 2021
Conference Call

Chris Curran. CPTC, CTBS, CTOP, Chair
Alden Doyle, MD, MPH, Vice Chair

Introduction

The Operations & Safety Committee (the Committee) met via Citrix GoTo Meeting teleconference 10/15/2021 to discuss the following agenda items:

1. Public Comment Overview: Data Collection to Evaluate Organ Logistics and Allocation
2. Research Update: TransNet Dashboard
3. Review & Discussion: Redefine Provisional Yes
4. Project Updates: Mandatory Usage of Offer Filters

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

1. Public Comment Overview: Data Collection to Evaluate Organ Logistics and Allocation

The Committee reviewed their proposal *Data Collection to Evaluate Organ Logistics and Allocation*, and the feedback submitted through Public Comment.

Summary of discussion:

Feedback from Public Comment was overall supportive for the Committee's proposal. Public comments were in support of collecting data in more automated ways, such as through TransNet[SM]. Public comments expressed concerns regarding the collection of organ check-in time in Waitlist[SM] due to the 24 hour timeframe for form completion. Public comments recommended for more clear data definitions for organ check-out time and time of first anastomosis. Data burden was also expressed as a concern through some public comments.

The Committee reviewed post public comment changes based on feedback from the transplant community.

- Organ check-out time will be collected via TransNet[SM]
- Organ check-out time data element will be defined as "time organ begins transit to transplant program following organ acceptance"
- Organ check-in time will be collected via TransNet[SM], and cascade as a display only field onto the Transplant Recipient Registration (TRR) form
- Time of first anastomosis data element will be labeled as *Transplant Time* on Waitlist[SM] for uniformity purposes to complement the Transplant Date data element. Transplant Time will be defined as "an organ transplant begins at the start of anastomosis or the start of an islet transfusion", as this aligns with the data definition for transplant date in OPTN Policy.
- No changes will be made to the kidney pump fields as organ procurement organizations (OPOs) already have the ability to enter multiple values. No further specifications are needed.

A member asked whether the data definition for organ check-out time intends to capture when the organ leaves the OPO to travel to the initial transplant program acceptor, or the final transplant program acceptor. The Chair explained that the data intends to capture the time an organ begins its transit to an accepting program (i.e. initial acceptance). The Vice Chair added that it is hard to capture all of the nuances in organ logistics via data collection, but time of organ check-out will be a step forward in the ability to analyze.

The Committee reviewed a demo of the new data elements within their proposed systems.

The Vice Chair emphasized that the community should continue to adopt technological advancements in order to increase efficiency in the organ allocation system. The Chair explained that requiring the use of TransNet℠ for organ check-in, as well as required tracking of organs during travel is crucial.

The Committee unanimously voted in support of the post public comment changes. The public comment analysis and post public changes reviewed by the Committee will be included in the *Data Collection to Evaluate Organ Logistics and Allocation* proposal and will be submitted to the OPTN Board of Directors for their consideration during the December OPTN Board of Directors meeting.

2. Research Update: TransNet Dashboard

The Committee received an update regarding TransNet℠ data.

Data summary:

Compliance has remained consistently high in the last 2 years. Since March of 2019, the percentage of donors where cases were created/used in TransNet℠ to ship has remained greater than 99 percent each month. While the percentage of transplanted organs shipped using TransNet℠ has remained greater than 90 percent for each day in the past two years.

Summary of discussion:

The Committee has monitored TransNet℠ trends semi-annually since the fall of 2017. Due to the high rates of compliance, and OPOs ability to access their individual monthly TransNet℠ report, Committee leadership has indicated continued semi-annual monitoring of the policy is no longer needed.

Next steps:

Any questions or concerns regarding the policy will be brought to the Committee if they arise.

3. Review & Discussion: Redefine Provisional Yes

The Committee reviewed the progress of the Redefining Provisional Yes project. The Committee further reviewed and discussed recommendations in response to the Match Run Rules Workgroup (the Workgroup) potential policy modification ideas.

Summary of discussion:

The Chair emphasized that the intent of policy modifications is to ensure that the entering of provisional yes is more authentic and meaningful. The Chair explained that policy modifications will help hold transplant programs accountable in reviewing organ offers. The Vice Chair added that the tiered approach to provisional yes could extend beyond primary and back up offers, as well as vary by organ. The Chair added that on average, it takes 120 organ offers to place a kidney.

A member suggested the development of a tiered structure within provisional yes that would be reflective of where OPOs are in the allocation process. The member explained that for a deceased donor with a kidney donor profile index (KDPI) less than 50, with no operating room time set, there should be a different set of expectations for a provisional yes compared to a deceased donor with all the

information available and cross clamp has occurred. The member also added that it would be beneficial to have a "provisional yes with further information" option. The member explained that a transplant program could enter a provisional yes and have the ability to request more information. This would be beneficial to the OPO because they would be aware that if certain lab values of the deceased donor change, then those transplant programs would no longer be interested.

Another member suggested another response should be added between decline and provisional yes, such as reviewed. The member explained this option will allow those who are reviewing organ offers to acknowledge they have received the offer without being held to any expectation as to whether or not they will eventually accept the organ. The member stated if those programs end up in the top tier, then they are re-notified and that is when the transplant program would need to carry out formal expectations set in policy. The Vice Chair asked how many transplant programs would be within that top tier. The member responded five or ten may be feasible. The Vice Chair asked if programs would be removed from the list if they do not respond within the first hour or two of initial organ offer notification. The member responded that they believed that would be appropriate. The member added that the kidney organ offer and acceptance system could be approached similar to expedited liver recoveries. The member explained that once the kidney is cross clamped, the chance to enter a reviewed option is eliminated, and a provisional yes is needed.

A member stated that clarity around primary offers versus back up offers may be needed. The member explained that a primary offer would be defined to outline what a transplant program as primary would be agreeing to, compared to what a back up program would be agreeing to. The Committee agreed.

The Vice Chair stated the Committee needs to consider whether this system will work with all organs. A member responded that thoracic allocation is different based on their experience. The member stated that transplant programs receive thoracic offers but most of the time need to wait for more information. The member added that the review option and provisional yes option need a subcategory for the transplant program to request more information.

A member asked what would happen if a patient consented to accepting a high risk organ and then reversed their decision at the last minute. The Vice Chair responded that transplant programs do not need to be responsible for transplant candidates changing their mind. The Vice Chair stated that the purpose is for transplant programs to do their due diligence ahead of time and have those conversations with their patients. The Vice Chair explained that the formal expectations are not meant to be punitive in one-off circumstances, but to have the ability to recognize those transplant programs that repeatedly prolong allocation time due to not properly reviewing organ offers. Another member added that the entry of a reviewed option will also help mitigate problems such as this. The member explained that provisional yes could be defined as transplant programs engaging in these conversations with transplant candidates, and until the transplant program has been able to talk with their patient, they can enter the review option.

A member suggested that the tiers could be based on organ quality. The member explained that lower quality organs would have more provisional yes while higher quality organs would be required to have fewer provisional yes entries. The Vice Chair suggested that the tiers could also be based on computer modeling, which predicts the chance the organ will be accepted.

The Chair suggested that policy could be modified to include language that states transplant programs should list transplant candidates with parameters they would reasonably consider. The Chair explained that this might help reduce the amount of transplant candidates listed for offers they would not accept. A member responded that sometimes the organ acceptance depends on which surgeon is reviewing the offer.

Policy Modification Idea: Transplant programs must confirm candidate availability

A member stated the feasibility of this expectation is dependent on how provisional yes is defined. The member explained that if provisional yes is defined to apply to the top five programs on a match run, then it would be feasible. The member stated that an expectation to confirm candidate availability would require an increase in personnel for any given transplant program. Members stated that specific considerations for an expectation such as this would include, but are not limited to:

- Can the transplant candidate get to the hospital?
- How is the transplant candidate's overall state?
- Has the transplant candidate had a recent COVID-19 exposure?
- Does the transplant candidate have any current infection?
- Is the transplant candidate already admitted to the hospital?
- How far away the candidate is from the hospital?
- Are the cross matches already performed?
- What specifics need to be reviewed when checking the transplant candidate's electronic medical record?

Another member agreed that confirming candidate availability is only feasible if a tiered approach to provisional yes and associated expectations is utilized. The member emphasized that if confirming candidate availability is implemented as a formal expectation, the Committee will need to be very clear as to what that means. Another member agreed and stated this would also need to be explained to patients.

Policy Modification Idea: Transplant programs must evaluate organ offers to see if the off immediately meets any of their internal refusal reason

The Vice Chair reminded the Committee that these policy modifications ideas are in the framework of a tiered approach to provisional yes and associated expectations.

A member stated that there are transplant programs, which outsource companies to review organ offers. The Vice Chair stated that the companies being used to review organ offers should have access to this information during their review.

Another member stated that in addition to reviewing organ offers for internal refusals, it would be helpful for transplant programs to have the ability to relay to the OPO that they are concerned about certain lab values or need more information.

Policy Modification Idea: Transplant program must assess histocompatibility

A member spoke with their transplant program's human leukocyte antigen (HLA) director to compile additional feedback. The feedback included:

- Including assessment of histocompatibility would be feasible
- Those who enter a provisional yes, based on a tiered approach, should be required to complete a virtual cross match
- Specific considerations include HLA typing, donor HLA typing, HLA antibody profile
- DQ and DP also should be weighed in on zero mismatch in addition to A, B, C, and DR

A member stated that it will be important to have the OPTN Histocompatibility Committee provide input on this idea.

The Chair explained that although it is a requirement for OPOs to enter DPP and DQ alpha for donors, there are no unacceptable antigens related to those in waitlist that would screen candidates. The Chair

stated this is an important consideration and programming component that would be helpful for virtual cross matching.

The Chair added that policy modifications do not need to dictate the specific steps that transplant programs must take in assessing histocompatibility in order to enter provisional yes. The Chair explained that these steps are important for transplant candidates who are sensitized, or have had a sensitizing event, and histocompatibility assessment should be a consideration for those individuals without policy dictating the steps. The Vice Chair agreed and stated that transplant programs, who are in the top tier of provisional yes, should give consideration, to the best of their ability, of histocompatibility.

The Chair asked whether OPOs should be required to send the primary transplant program a specimen if they request it for a cross match, and have obliged to the other outlined expectations. The Vice Chair added that policy language is not up to date with current practices of cross matching.

Policy Modification Idea: Transplant programs must assess whether the candidate is currently, medically suitable

The Vice Chair stated that this idea intends for transplant programs to find out if the transplant candidate is ready for transplant surgery at that moment from a medical standpoint. The Vice Chair added that this would be easily discoverable information through review of the electronic medical record and a phone call with the transplant candidate.

A member stated that the Pacific Northwest needs additional considerations for some of these policy modification ideas due to the large geographic area.

Additional Considerations

A member suggested that an additional policy modification idea could be that transplant programs must provide an approximate time their team could be available for procurement. The member suggested another potential policy modification idea could be that transplant programs must confirm they have an available operating room and bed availability for the transplant surgery. A member agreed and stated it is important for transplant programs to have an idea of timeframe for going into the operating room. The Chair suggested adding a “tentative operating room time” data field in DonorNet so that it is a transparent goal for everyone to view and plan for. Members agreed with this suggestion as it will be beneficial to transplant programs. Another member suggested that utilization of local teams could potentially be part of the solution.

A member stated that if the term provisional yes remains in the system, the definition should be changed to state that, given the current data, that center entering provisional yes would accept the organ. The member stated that provisional yes can become an elevated tier, and an additional tier can be created to be below a provisional yes, which would be called “evaluated” or “notified”. The member stated that an additional option would be to create a new tier above provisional yes, which would be “provisional acceptance”. The member explained this new tier could be entered for transplant programs that have reviewed the organ offer, and are willing to accept the organ barring any new information. The Vice Chair suggested that if a two tiered system is the approach, then there may be value in creating two brand new terms. A member agreed that keeping the term provisional yes may make it difficult for members to transition to a new process and system. Another member suggested “reviewed” and “provisional acceptance”. Members agreed.

Next steps:

The potential policy modification ideas will be placed into various tiers. These recommendations and considerations will be presented to the Workgroup.

4. Project Updates: Mandatory Usage of Offer Filters

The Committee's mandatory usage of offer filters project will begin discussion within a designated Workgroup on October 15, 2015.

Upcoming Meetings

- November 18, 2021 (teleconference)
- December 16, 2021 (teleconference)

Attendance

- **Committee Members**
    - Alden Doyle
    - Audrey Kleet
    - Charles Strom
    - Chris Curran
    - Domonic Adorno
    - Greg Abrahamian
    - Jami Gleason
    - Joanne Oxman
    - Kimberly Koontz
    - Melinda Locklear
    - Melissa Parente
    - Paige Oberle
    - Rich Rothweiler
    - Stephanie Little
    - Susan Stockemer
- **HRSA Representatives**
    - Raelene Skerda
    - Vanessa Arriola
- **SRTR Staff**
    - Katie Audette
- **UNOS Staff**
    - Joann White
    - Katrina Gauntt
    - Kristine Althaus
    - Leah Slife
    - Matt Prentice
    - Meghan McDermott
    - Nicole Benjamin
    - Randall Fenderson