OPTN/UNOS Pancreas Transplantation Committee
Meeting Minutes
October 10, 2018
Chicago, IL

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Introduction

The Pancreas Committee (the Committee) met in person in Chicago, Illinois on 10/10/2018 to discuss the following agenda items:

1. Functional Inactivity
2. Update Islet Bylaws
3. Pancreas Facilitated Placement Data Update
4. Liver Proposal
5. KP Work Group Update
6. New Project Ideas

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

1. Functional Inactivity

The Committee discussed the public comment feedback of the functional inactivity project and potential changes to the proposal.

Data summary:

Overall analysis of public comment found that the community was broadly supportive of a change in definition to functional inactivity from no transplant over the course of 6 months, to no 2 transplants over the course of 12 months. Some commenters expressed concern about waiting time and the impact on highly sensitized patients. There was a lack of evidence for the relationship between wait time and poor outcomes.

Summary of discussion:

The Committee chair suggested the Committee discuss the following themes systematically.

- Broad support for definition change – a theme of public comment that expressed broad support for creating a more flexible transplant threshold of 2 transplants in 12 months instead of 1 in 6 months. The Committee had little feedback no this theme, although it was noted as positive feedback and reflecting well on the proposed solution.
- Impact on outcomes and patient safety
    - The Committee reviewed feedback from public comment that there was not a demonstrated connection between longer waiting time and poor outcomes. Committee members noted that some of the confusion comes from including a public comment slide that indicates a correlation between outcomes and volume. That slide served to provide a general justification for MPSC review of functional inactivity because patient safety is the genesis of MPSC review. In general, more low volume pancreas programs have worse pancreas graft survival than higher volume programs, even while the pancreata transplanted at small volume programs are higher quality. However, this is an average of all small volume programs, indicating that some small volume programs do not have an issue with pancreas graft outcomes. While this slide and graph were used in the public

comment proposal and presentations to provide general evidence for the importance of MPSC review of functional inactivity, the Committee agreed that including this information actually hurt an understanding of the proposal by focusing on outcomes, which are not specifically applicable to the proposal. It was recommended to remove this information from future communications and presentations to avoid further confusion.

- Concern about waiting time
    - One concern raised during public comment was about how waiting time center metrics would be affected by highly-sensitized candidates. One committee member commented that typically smaller centers have less highly sensitized candidates. It was re-emphasized that the only programs that have fewer than 2 transplants in a year, as well as a long waiting time, would even be considered for review. One member asked how many centers currently are averaging less than 2 transplants a year. Over a 5 year period, there were 33 centers.
    - One committee member brought up the possibility that centers that realized they were at risk for above-average wait times may choose to de-list the longest waiting candidate for several months before re-listing them, knowing that the candidate's initial waiting time will be counted in their favor but the waiting time will no longer count against the center's average. However, de-listing a patient is more significant than making a patient inactive, and involves a substantive fee and informing the patient as to why they are de-listed. One member asked how the average waiting time was calculated by the PSR and if OPTN/UNOS could do the same. The PSR uses time to transplant, which the Committee agreed would not be appropriate because it would be recipient focused instead of candidate focused. The Committee has consistently focused on candidate impact in attempting to address patients waiting long times at small volume programs, which time to transplant wouldn't address.
    - One committee member felt that if the waiting time metric was based on time to transplant than the longer a candidate waited the less incentivized a program would be to transplant them, knowing that after transplant that recipient's long waiting time would certainly raise the program's metric above national levels. Staff member suggested a modification to the calculation of wait time so as to avoid the issue. Committee member suggested raising the waiting time expectations to possibly one standard deviation above the mean or 75% percentile. The members continued the discussion of how to include waiting time and whether it should be at the median or a higher percentile of the national waiting time. Ultimately, the Committee decided to ask for more data for a range of options from the research liaison and make a decision during the next teleconference call on November 7th. Although the Committee did not make a decision yet, the Committee agreed that the options reviewed should focus on waiting time thresholds that are substantially greater than the median, to reflect a focus on programs with significantly longer waiting times.
    - The Committee also discussed how to best communicate with programs about the proposed changes. One committee member asked how frequently programs would be reviewed and if they would know they were at risk for being flagged. To ensure that programs would be aware if they were at risk for being reviewed, UNOS will generate a report accessible to the centers that details their waiting time and the national waiting time. A committee member clarified that when considering waiting time, any amount over the national average would qualify a center for review, even though that program's waiting time would be essentially equivalent to the national average. The Committee considered it a potentially

beneficial change to raise the waiting time threshold to some percentile of the national waiting time above the national median, in order to focus review on programs that have substantially longer waiting times than the national average. A committee member asked if the 12 month period was dictated by calendar year, it was noted that the period is 12 months rolling from last review, consistent with PSR.

- Suggestion to add regional wait time comparison for the patient letter and/or functional inactivity definition
    - The Committee agreed not to add a comparison by region, especially because of the upcoming changes to geography and the idea that any decisions made based on region are incompatible with the Final Rule. Also, it was noted that some regions may only have similarly functionally inactive programs to compare, or no programs at all.
- Question about pediatric programs
    - There was concern in public comment that this change would negatively impact pediatric pancreas programs. However, the Committee reviewed the Bylaws which indicate that pediatric pancreas programs are reviewed separately from adult programs, and the proposed changes to adult pancreas programs would not impact pediatric pancreas programs. Members agreed that pediatric programs are already reviewed separately and are not impacted by the current proposal.

Next steps:

The Committee liaison will pass feedback regarding changing the waiting time threshold to MPSC, since the two committees worked on this project together. Research will collect further data concerning the amount of programs that currently fall under the various proposed thresholds of the median wait time and the 75% percentile. Next Board Meeting on Dec. 3-4 in Dallas, TX.

2. Updating Islet Bylaws

The Committee discussed the proposed changes to updating the islet Bylaws.

Data summary:

The proposal received comments from ANNA, ASTS, AOPO, AST & ASHI. ASTS was the only organization that opposed because they felt the policy “must require a transplant surgeon with expertise in solid organ procurement” and did not support allowing islet programs to be free-standing. The MPSC had questions about history of connection with pancreas programs and whether risk of complications is accounted for in islet personnel experience, or whether free-standing islet program needs Organ Procurement Organizations (OPOs). AST supports proposal and find current requirements “sufficient” but also suggest adding pharmacists for immunosuppression expertise to the expert medical personnel.

Summary of discussion:

One committee member expressed disagreement with ASTS’s desire for an expert transplant surgeon due to the option of centers receiving already prepared pancreas transplants. The Committee discussed at length whether to include a transplant surgeon, and determined it would not be necessary from a patient safety or outcomes standpoint, and indeed could harm patient access if it prevents islet programs from growing and prevents qualified individuals from supporting islet programs. The Committee considers that the requirements for an abdominal surgeon and individual to handle immunosuppression sufficient to ensure adequate support handling potential post-transplant complications and providing care to the patient. The additional

islet-specific requirements of the clinical leader supports a program having the sufficient collective experience to address patient safety concerns.

One committee member shared information that he had heard regarding a private company that may be given a contract for islets by the FDA. An OPTN/UNOS staff member noted this potential change.

Based on feedback from UNOS staff, the Committee added standard language indicating that the clinical leader's experience of the management and care of patients must be documented in a log. A sentence requiring pre-, peri- and post-transplant care was removed because it was already implied by the direct involvement that the clinical leader must meet. Direct involvement in patient care was clarified to apply cumulatively to the six islet patients.

The Committee voted on language that made consistent the use of "islet transplant program" instead of "islet program" and "islet" instead of "pancreatic islet." The third paragraph in K.1: Program Director and Clinical Leader that specified requiring a report from the hospital credentialing committee on the clinical leader was deleted because it was duplicative of the third requirement in K:2: Islet Transplant Program Clinical Leader Requirements.

With these minor, non-substantive changes to the proposal, the Committee voted unanimously to send the proposed Bylaws language to the Board.

Next steps:

The Committee liaison will draft a communication with islet program directors because no response was received from CITR during public comment. Because this is an important stakeholder, the Committee agreed getting feedback before board approval was important to ensure no unintended consequences.

3. Pancreas Facilitated Placement Data Update

The Committee discussed data analysis of the effects that the updated 2016 pancreas policy has had on centers, donors and transplants. Centers needed to import 5 pancreata within the last 2 years to be on the updated facilitated placement list.

Data summary:

39 programs qualified for facilitated placement between March 1, 2015 and March 31, 2017. 4 programs were removed from the list but 4 programs were added to the list. Facilitated bypass allocation was used 342 times since the new policy was implemented compared to 374 in the pre-policy era. The Organ Center used facilitated bypass allocation 260 times between Aug 18, 2016 and March 17, 2018. 38 OPOs used facilitated bypass pancreas allocation 82 times between Aug 18, 2016 and March 17, 2018. A total of 42 pancreas transplants from facilitated allocation. 21 transplants performed in the pre-policy era out of 374 offers and 21 in the post-era out of 342 offers. In the post-era, 4 out of the 21 transplants were from OPOs. Overall, facilitated bypass allocation and transplants from facilitated is similar pre and post policy change. There will be a final 2 year post-policy monitoring available for review at the Spring 2019 in-person meeting.

Summary of discussion:

One member asked if there could be further analysis as to why the four programs no longer qualified post-policy and evaluate whether there were unintended negative consequences. An OPTN/UNOS staff said that analysis could be included in the final review in the spring. Discussion arose as to how aware the OPOs are of this resource since the number of transplants did not significantly increase. Members questioned whether there was an automatic alert in the system to notify OPOs or if OPTN/UNOS could do more to increase awareness. The

question also came up as to whether or not OPOs who moved on or off the list were alerted to the status change.

Next steps:

There will be a final 2 year post-policy monitoring available for review at the Spring 2019 in-person meeting. Potential new project for increasing collected data during monitoring.

4. Liver Proposal

The Committee reviewed a presentation on the Liver Committee's proposal to change geographic allocation.

Summary of discussion

The following questions were asked by Pancreas Committee members and answered by the Liver Committee analyst:

- How were the percentages of organs flown calculated?
    - The SRTR based the LSAM estimate on distance, specifically, on the distance at which driving would switch to flying. There will be variation based on differences in population density in the country.
- Will the changes result in a significant change in SLK transplants?
    - There is not estimated to be a significant change in SLK transplants. The same qualifications will exist to be considered for an SLK transplant; it will not change the order in which an organ is offered according to geographic distribution.
- What will be the effect on small liver programs – could some shut down because they do fewer transplants?
    - There will be variation in how individual programs respond to the changes; some program volume may increase while other programs may see volume shrink. It is important to note that the modeling cannot account for changes in behavior that may result from changes in allocation.

Next Steps

The Committee liaison will summarize from the discussion, which will be posted for public comment. Individual Committee members can submit comments through the Redcap form which will be distributed.

5. KP Work Group Update

The Committee discussed the issue with current organ distribution policies. The Donation Service Areas (DSAs) and regions are based on prior transplant program relationships, and the Kidney/Pancreas (KP) work group is looking for a more data-driven, evidence based solution that is consistent with the Final Rule.

Data summary:

The kidney and pancreas organ distribution policies use DSA and regions which are not good proxies for geographic distance between donors and transplant candidates. The disparate sizes, shapes and populations of DSAs and regions as drawn today result in an inconsistent application for all candidates. This presents a potential conflict with the OPTN Final Rule. The KP work group has chosen to submit for modeling of a concentric circle model and a hybrid model of concentric circles/continuous distribution.

Concentric Circles

→ 150 nautical miles & 300 nautical miles circles

→ 250 nautical miles & 500 nautical miles circles

Hybrid

→ 500 nautical mile steep line
→ 500 nautical mile shallow line
→ 500 nautical mile single circle (no points)

Summary of discussion:

The Committee discussed the feasibility of flying procurement teams for pancreas transplants. Some members felt that procuring for pancreas transplants faced greater barriers due to cost and ischemic time, while others suggested that it in certain parts of the country those are barriers aren't as evident. Several members expressed a desire to separate pancreas policies from kidney due to the differences. It was suggested that the Committee could draft "Pancreas Principles" to guide the creation of pancreas policies, specifically, the elements of the Final Rule that have different applications for pancreas procurement methods and barriers due to ischemic time than kidney transplantation may face. This document may be helpful in reviewing the KP modeling options, which are due back early December. The members broadly agreed.

Next steps:

An OPTN/UNOS staff member will draft general "Pancreas Principles" as they relate to the Final Rule. The Committee will receive the modeling data on December 7th and review the options for public comment in January.

6. New Project Ideas

The Committee broke into groups to discuss new project ideas.

Summary of discussion

Below is a list of new project ideas the Committee discussed:

- Best practices for growing pancreas programs
- COIIN project for pancreas
- Guidance on when to transplant a type 2 diabetic candidate
- Mathematical optimization of pancreas allocation: using a score system (e.g., including CIT, diabetes acuity score, surgical risk score, patient preferences for islet or pancreas, biological match, etc.)
- Increased access for sensitized pancreas candidates
- Vessel sharing practices and impact on pancreas discard rate

Next Steps

OPTN/UNOS staff will document new project ideas in project forms. The Committee will review the new ideas again at their next in-person meeting.

Upcoming Meeting

- Teleconference call on November 7, 2018