

OPTN/UNOS Pancreas Transplantation Committee
Meeting Minutes
November 2, 2017
Chicago, IL

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Introduction

The Pancreas Transplantation Committee (the Committee) met in Chicago Illinois on 11/02/2017 to discuss the following agenda items:

1. Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types
2. Guidance on Increasing Pancreas After Kidney (PAK) Transplants
3. Maximum Allowable BMI for KP Waiting Time
4. Updating Islet Bylaws
5. Pancreas Program Functional Inactivity

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

1. Broadened Allocation of Pancreas Transplants Across Compatible ABO Blood Types

The Committee discussed feedback from public comment, options for moving forward, and voted to send the proposal to the Board.

Summary of discussion:

The Chair reviewed the background on the project, its feedback from public comment and post public comment analysis. The SRTR performed additional analysis on transplant rate by blood type due to concern about the impact on blood type O candidates. For both SPK and kidney alone, transplant rates showed small increases for blood types A, AB and B and small decreases for blood type O. This is in line with the analysis performed by the SRTR showing a small (2%) decrease in blood type O kidney alone transplants.

The SRTR also performed analysis for pediatric transplant rate by blood type and transplant by region for pediatric kidney alone. This arose out of concern for pediatric kidney alone candidates, who may receive offers after SPK candidates at the local level. Although the SRTR analysis showed no impact for this population, public comment feedback led the Committee to ask the SRTR to look closer at any regional variation for pediatric kidney alone candidates. A Committee member asked that the ranges for the SRTR slides be removed because they looked like error bars; the SRTR will make the change. The data showed no projected negative impact on pediatric kidney alone transplants, even when regional variation is taken into account.

A Committee member noted that A2/A2B to B transplants are not currently utilized fully by kidney transplants, and they are unlikely to be fully utilized for pancreas transplants as well. The SRTR analysis projected full utilization and so may overestimate any increase due to A2/A2B to B utilization. The policy liaison will follow up with the SRTR representatives about the proportion of A2/A2B to B in the overall increase of SPKs. A Committee member suggested removing the A2/A2B to B compatibility if the Board were concerned with the high cost. Another member suggested removing B to AB compatibility if the Board was concerned about utilization.

A Committee member expressed concern with the projected decrease to blood type O transplants when the waiting time for blood type O kidney alone and SPK candidates is longer than for other blood types. This was a concern that was raised during public comment as well. A

Committee member countered that the greatest benefit the proposal seeks to make is greater local utilization, because one of the impediments to utilization is that shipped pancreata are less likely to get utilized. Another Committee member agreed that encouraging local KP utilization would be extremely beneficial to growing a program and reducing the pancreas discard rate. The Committee member noted that the analysis indicates no significant impact on subpopulations.

The Committee discussed another theme from public comment that the proposal doesn't address a "significant problem." The Committee agreed that the problem was the high discard rate and underutilization for pancreata. The data suggests that the proposed solution would increase utilization and the number of transplants overall, indicating the solution addresses the problem. The Committee recognizes there are several issues related to underutilization and is committed to continuing to address this problem in other projects as well.

The Committee reviewed several options for going forward with the project: sending the proposal with no changes to the Board, modifying the proposal and sending it to the Board, doing a variance project and studying the effects of the changes in a localized setting before sending the proposal to the Board, or doing further modeling before sending the proposal to the Board.

The Committee was concerned about modifying the proposal by removing blood type O compatibility because there may not be an increase in transplants, which is the strategic goal for this project. A Committee member noted that the SRTR modeled five options and the Committee supported the option with the greatest transplant increase that showed a small impact on kidney alone. The Committee expressed concern over pursuing a variance because the results from one region or center may not translate to other centers or other parts of the country. Also, there was concern that because pancreas transplants are low volume, it would be difficult to evaluate any data gathered during a variance or pilot program. The Committee indicated that it would be acceptable if the Board was concerned with the A2/A2B cost to remove that portion of the projected changes since it represents a small subset of the projected changes.

The Committee supported sending the proposal as is to the Board 15 yes, 1 no, 0 abstentions. The Committee member who didn't support the current proposal was concerned about blood type O kidney alone waiting time, and supported either modifying the proposal or doing a variance. The Committee agreed that the increased utilization, decreased discard rate, increase from LYFT and overall increase in transplants overall were worth the projected small decrease in blood type O kidney alone. The Committee also agreed that the SRTR post-public comment analysis indicated that the transplant rates by blood type were in line with the original analysis, and SRTR data confirmed no negative impact on pediatric kidney alone populations, a major theme from public comment.

Next steps:

The Board will review this proposal at its December in-person meeting.

2. Guidance on Increasing Pancreas After Kidney (PAK) Transplants

The Committee discussed the proposal's public comments and voted to send the proposal to the Board.

Summary of Discussion

This proposal was on consent during public comment and supported by all 11 regions and every commenter (including ASTS and IPITA) except for AST. The AST didn't support the proposal, arguing the proposal would be better as a manuscript and suggesting that the analysis should

focus on a comparison with kidney alone candidates, recipients and the PAK waitlist candidates. However, the guidance document was developed because of concern over the comparison used in the JAMA paper, which did not include SPK waitlist as a comparison. The Committee feels this is the appropriate comparison. Also, members of the Committee will independently submit a manuscript from the same data analysis used for the guidance. The Committee feels that providing guidance may encourage a change in behavior that may not be accomplished by publishing a manuscript only.

The Committee discussed the time interval from a pancreas following a kidney transplant, agreeing that a shorter interval is beneficial for outcomes. Further analysis may include data on the interval for PAKs. Additional analyses may be beyond the scope of this guidance document, and is not felt to substantially address the essential question. However, it could be incorporated into the subsequent publication of a manuscript.

The Committee unanimously supported (16-0-0) sending the guidance document to the Board.

Next Steps

The Board will review this proposal at its December in-person meeting.

3. Maximum Allowable BMI for KP Waiting Time

The Committee reviewed the background and evidence in support for this project and discussed next steps.

Summary of Discussion

The Committee reviewed language options for changing the current policy: removing the cap and references to it, changing the cap to another number, or removing the table that dictates the cap is raised or lowered based on the number of candidates with high BMIs and high c-peptides. The Committee could also chose one option but still present the others during public comment.

The Committee discussed different caps that could be pursued instead of the current cap which is 30, if the Committee doesn't support removing the maximum BMI threshold altogether. Some Committee members argued that a lower cap may make it more likely to garner support, while others supported a higher cap that would be more inclusive. Ultimately the Committee agreed that the cap itself was arbitrary and ideally would be entirely removed. A Committee member noted that BMI differs by age, highlighting that the cap is arbitrary.

Next Steps

The Chair will present the proposal to the Kidney Committee so the Committee can review that feedback before making a final decision for spring public comment.

4. Updating Islet Bylaws

The Committee reviewed the project to update the Pancreas and Islet Bylaws to reflect current and appropriate islet program requirements for primary personnel.

Summary of Discussion

The Chair of the Pancreas and Islet Bylaws Subcommittee presented the progress made on this project and the direction the Subcommittee is heading regarding a solution. The Subcommittee has been developing which personnel are essential to an islet program, and determining the characteristics of any primary personnel. The Subcommittee suggested any islet program require access to an abdominal surgeon, interventional radiologist, immunosuppression manager and an endocrinologist. The Subcommittee Chair noted the islet Bylaws would be a major departure from the typical way of having a transplant physician and transplant surgeon.

A Committee member asked about the need for an endocrinologist, since pancreas programs aren't required to have one. Because the aim of the islet transplant is to limit hypoglycemia, the program needs to know the functionality of those islets to supplement with them, leading to the need of an endocrinologist.

The Subcommittee discussed a primary person supervising 10 islet infusions for required experience, but some Committee members expressed concern that observing infusions may not be sufficient experience. Committee members also questioned what "significant training" in islet transplantation meant. The Subcommittee has not yet defined this term.

The Committee discussed whether having a transplant background should be required by the primary person. The Subcommittee supported not having it be a requirement to allow flexibility for islet programs and because the Subcommittee viewed it not a necessary component of islet transplantation. Rather, the necessary experience is in immunosuppression, so if the candidate has experience in immunosuppression but not in transplant, the Bylaws should allow that. However, some Committee members expressed concern with not requiring transplant experience and suggested a primary person would need a transplant fellowship or equivalent to deal with immunosuppression complications.

The Committee discussed what the Bylaws should require regarding the minimum requirement for post-transplant patient care. The Subcommittee suggested 10, but some Committee members suggested a higher number may be more appropriate – 15 or 20. However, other Committee members expressed concern that managing 20 islet patients post-transplant would put a prohibitive burden on new islet programs. The Committee also discussed whether auto islets (islet cells from the patient) should be allowed to count toward the number of post-transplant care. Auto islet care differs from allo islet care in three respects: immunosuppression, preparation of islets, and access to the portal vein. A Committee member suggested the Subcommittee connect with ASTS about a fellowship committee working on getting formal islet transplant training.

A Committee member suggested changing the name of the Pancreas Transplantation Committee to the Pancreas and Islet Transplantation Committee to reflect the work of the Committee to improve islet transplantation.

Next Steps

The Subcommittee will review feedback from the Committee at its next Subcommittee meeting.

5. Pancreas Program Functional Inactivity

The Committee reviewed a data analysis requested by the Pancreas Program Functional Inactivity Work Group (the Work Group) and the solution the Work Group is pursuing.

Summary of Discussion

The research liaison presented the data analysis the Work Group had requested and a summary of its findings. This request examined whether transplant volume had any correlations with a number of factors related to patient access to transplant, transplant performance and patient outcomes. Because pancreas programs are reviewed at a higher rate for functional inactivity, the Work Group is developing unique parameters for the MPSC to use in reviewing these programs. The data analysis is to help inform what parameters or metrics should be used in pancreas program functional inactivity review.

For a graph depicting waitlist removal for large, medium and small volume centers, Committee members asked whether the different reasons candidates are removed from the waitlist could be expanded: including candidates too ill, transfer to another center, center inactivated, and candidate choosing to be removed. A Committee member suggested that the reasons

candidates are removed from the waitlist may differ from large volume centers to small, and detailing the different reasons may elucidate that.

The Committee discussed the slide presenting center volume and kidney-pancreas (KP) complications and technical failure. Technical failure refers to graft failure in an immediate time period following the transplant procedure, while complications may refer to the same characteristics over a longer period of time following the procedure. Both complications and technical failure are reported as separate fields in the transplant recipient registration (TRR) form collected by UNOS. The research liaison noted that missing values for these fields are why the rate of technical failure and pancreas graft failure differ. However, Committee members found this slide confusing and indicated its presentation or the information contained within could be clarified.

The data analysis examined offer acceptance rate by volume level. If a center had 10 offers for 10 patients and accepted 1, then that would be considered a 10% offer acceptance rate. However, some Committee members felt that organ acceptance rate may be a more appropriate measure to include in the analysis. For organ acceptance rate, a center that receives an offer for each of its 10 patients and accepts it for one would have an acceptance rate of 100%. While neither metric is without limitations, having both may show a more complete picture of center acceptance practices.

The Committee discussed additional metrics that could be examined in any future analyses. An SRTR representative noted an abstract on the interval from last pancreas transplant and outcomes indicating the longer interval for PAK and PTA (pancreas alone) transplants, a negative correlation with outcomes was seen. The SRTR representative also suggested transplant rates, in addition to waitlist mortality, may be helpful to review for how centers serve their patient population.

The Committee is aware that the MPSC is concerned about patient safety but also about cutting the number of pancreas programs under review substantially. The Committee briefly discussed how modifications to the proposed criteria for functional inactivity (waitlist, offer acceptance and geography) would change the number of programs the MPSC would review. The Committee generally supported the direction the Work Group was going in terms of creating a composite endpoint from several metrics – waiting time, offer acceptance, and geographic proximity. The Committee also agreed that the solution would require more development than the Spring 2018 public comment timeline would allow, and it would be appropriate to change the timeline to Fall 2018.

The Committee briefly discussed the possibility of creating a related project that would provide guidance to the community on best practices for small volume programs to increase volume and grow their programs. While outside the scope of the current Pancreas Program Functional Inactivity project, the Committee may revisit this idea when more resources are available.

Next Steps

The Work Group will review the Committee's suggestions, questions and feedback during its next teleconference call.

Upcoming Meetings

- November 13 (teleconference)
- January 16 (teleconference)