OPTN/UNOS Pancreas Transplantation Committee
Meeting Minutes
March 22, 2018
Richmond, Virginia

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Introduction

The Pancreas Transplantation Committee (hereafter, the Committee) met in Richmond on 03/22/2018 to discuss the following agenda items:

1. OPTN/UNOS Strategic Plan
2. Changes to Kidney Pancreas (KP) Waiting Time Criteria
3. Updating Islet Bylaws
4. Broadened Allocation across compatible blood types
5. Pancreas Program Functional Inactivity
6. COIIN (Collaborative Innovation and Improvement Network)
7. Policy Oversight Committee (POC) Update
8. Geography Committee Update

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

1. OPTN/UNOS Strategic Plan

The Committee continued a discussion of the OPTN/UNOS Strategic Plan for 2018-2021 that was originally reviewed during a 2/12/2018 teleconference call.

Summary of discussion:

The Committee asked questions about the new initiatives and metrics associated with the new Strategic Plan, expressing particular interest in the new COIIN project. Later, UNOS staff who work on the COINN project came down to give the Committee more information about the efforts to increase utilization of high Kidney Donor Profile Index (KDPI) kidneys while maintaining good outcomes. The Committee expressed general support for the new strategic plan. In particular, Committee members expressed support for the new resource allocation, and several new initiatives which touch on multiple organs including increasing the center and patient level specificity in donor/recipient matching (i.e. more dynamic matching initiative) and the expanded use of collaborative models such as COINN.

The Committee felt projects falling under these initiatives would improve the efficiency and effectiveness of the OPTN. The Committee also expressed interest in specifically beginning projects that touch on these initiatives. The Committee noted a previous comment that projects are assigned one primary strategic goal even when they impact multiple strategic goals. The public may not be aware of these secondary impacts even if they are important in considering the value of the proposal, and the Executive Committee should consider increasing the visibility of these other strategic goals so the community understands the full impact of a proposed change. The Committee applauds the new more granular structure of identifying broad initiatives and specifying metrics to measure achievement of those goals.

Next steps:

Committee members entered individual responses to the new OPTN/UNOS Strategic Plan through RedCap as part of a new UNOS effort to improve public comment data collection. The

policy liaison noted the Committee's responses and drafted a public comment response to post on the OPTN website.

2. Changes to KP Waiting Time

The Committee reviewed public comment feedback and themes related to the Changes to KP Waiting Time proposal. The Committee discussed options for sending the original proposal or alternative language to the Board.

Summary of Discussion

The Committee reviewed the themes and concerns from public comment, including feedback from the different regions, organizations and individuals. The Committee discussed whether to send the original public comment proposal to the Board or to modify it in response to public comment.

The public comment themes and discussion are reviewed below:

1. Impact on kidney-alone

The Kidney Committee, Minority Affairs Committee, and several regions expressed concern that removing the restriction for C-peptide > 2, high body mass index (BMI) candidates could lead to an increase in Type 2 SPK transplants that decreases the number of offers from being made to local kidney-alone candidates.

The Committee noted that any changes to KP allocation may receive concern from the kidney-alone community. However, the KP waiting time proposal received less opposition to these changes than a previous project broadening allocation that went out for public comment in 2017. A Committee member noted that the number one goal of UNOS is to increase the number of transplants, and the KP waiting time proposal works in alignment with this goal by removing an unnecessary barrier to waiting time. The Committee member noted that KP recipients are still kidney recipients, and that increasing KP transplants could increase the utilization of pancreata. A Committee member noted that the life years from transplant (LYFT) is greater for KP recipients on average, demonstrating the benefit of the pancreas.

2. Concern about gaming

Some commenters expressed concern that programs could "game" the system by accepting a kidney-pancreas for a Type 2 high BMI candidate, decline the pancreas but keep the kidney and transplant it into the candidate. Kidney-alone candidates have longer waiting times, so Type 2 high BMI candidates on the kidney waiting list could be listed for a KP to get a kidney sooner.

The Committee carefully considered this concern and requested data to review whether this type of gaming might occur. However, the Committee reviewed the process of kidney-pancreas and kidney allocation, which indicates that this behavior is unlikely. If a program accepts a kidney-pancreas for a candidate, then discovers the pancreas is not viable for transplant, the program must alert the organ procurement organization (OPO). The OPO decides whether the kidney stays at the center or not. Depending on the cold ischemia time, the OPO may ask that the program send the kidney back. If the cold ischemia time is too long such that additional travel would make the organ unviable, the OPO may accept the program transplanting it into the original candidate. Thus, the program risks damaging its relationship with its local OPO if it repeatedly accepts a kidney-pancreas only to reject the pancreas very late in the process. Also, a program attempting to game the system doesn't get to decide what to do with the kidney; it is up to the OPO to decide.

A Committee member noted that this type of gaming could occur now, but there is no evidence that it does. The Committee is currently looking into how many programs actually transplant just

the kidney after accepting both the kidney and pancreas to see how widespread the opportunity for gaming is. However, the Committee recognized and affirms that kidney-pancreas programs often have legitimate clinical reasons for determining a pancreas is not viable upon examination. Therefore, data indicating that programs sometimes reject the pancreas is in itself not evidence of gaming.

3. Support for an alternative solution – a small increase in the maximum BMI

Some commenters felt that a more cautious approach would be to gradually raise the maximum BMI instead of removing the requirement altogether.

The Committee considered making the BMI a fixed number and eliminating Table 11-1 that requires the BMI to be adjusted depending on the percent of active KP candidates that meet criterion 3.b. Currently, the BMI may fluctuate every 6 months depending on the percentage of active KP candidates that have C-peptide levels > 2 and BMI below or equal to the maximum, 30. The Committee discussed how this system is very confusing for the community in that members of the community may not know what the current BMI is, since policy doesn't specify. There could be scenarios where eligible candidates may not realize they are able to accrue waiting time, and their programs do not list them for a KP transplant.

The Committee felt a fixed BMI would be an improvement on the current system, in which the BMI can fluctuate and programs may not know what constitutes current eligibility for high C-peptide candidates. However, some members of the Committee disagreed that a fixed BMI would adequately address the issues identified by the Committee of inequity, and would still represent an arbitrary restriction on certain clinically appropriate candidates' access to transplant. In a straw poll, Committee members were divided whether to support eliminating the BMI requirement or changing it to a fixed number.

4. Concern about Type 2 outcomes

Although the Committee identified substantial evidence indicating that Type 2 candidates with higher BMIs can have similarly positive outcomes to other SPK recipients, certain commenters still felt concern that transplanting organs in Type 2 high BMI candidates would not be the best utilization of the organs.

The Committee acknowledges that a candidate's BMI is certainly a factor in determining whether the transplant would be successful, but this is true for candidates with C-peptide < 2 as well. Many factors affect whether a candidate would be appropriate for transplant, including BMI, but BMI does not serve as an absolute contraindication for transplant. Factors such as age can be a more significant factor than BMI for predicting technical failures, yet KP waiting time provides no restriction on age to accrue waiting time (nor would that be appropriate).

In addition, Committee members noted that implementation of the pancreas graft failure definition on February 28, 2018 will ensure that programs are reviewed on their pancreas graft outcomes going forward. This serves to encourage a cautious assessment of whether a candidate is clinically suitable for transplant.

5. Concern about removing the insulin requirement

Certain reviewers of the KP waiting time proposal questioned the public comment proposal's change to remove the requirement for a candidate to be on insulin in order to accrue waiting time. For these commenters, being on insulin represented a baseline requirement for a candidate receiving KP offers, and should be reinstated in the waiting time criteria.

The Committee originally considered whether to remove the insulin requirement before public comment, and concluded it was appropriate to remove because certain candidates may not currently be on insulin but still require a KP transplant. These cases are rare but do occur. Most

Committee members supported at least having a history of insulin use as a requirement in the KP waiting time criteria. However, UNOS staff cautioned that doing so might mean modification to Transplant Information Exectronic Data Interchange (TIEDI®) forms, possibly requiring Office of Management and Budget (OMB) approval. In a straw poll to assess support for either keeping or removing the insulin requirement, a large majority of Committee members supported keeping the requirement.

Changing Table 11-1

In addition to the original proposal to remove the 3rd KP waiting time criterion, the compromise to reinstate the insulin requirement, and the compromise to make the maximum BMI a fixed number, the Committee also considered modifying the table in policy to change the percent of active KP candidates. See Table 11-1:

Table 11-1: Maximum Allowable BMI

If the percent of active kidney-pancreas candidates that meet criterion 3.b:	Then the OPTN Contractor will:
Is greater than 15% nationally	Reduce the maximum allowable BMI by 2 kg/m^2
Is less than 10% nationally	Increase the maximum allowable BMI by 2 kg/m^2

The Committee discussed increasing the percentage of active KP candidates that can meet criterion 3.b (on insulin and having a C-peptide level > 2 but a BMI < 30) before the maximum allowable BMI is reduced. However, in a straw poll no Committee members supported keeping the adjustable BMI and modifying the table to change the percentage of KP candidates that meet the criteria. This option was considered confusing and perpetuating a complicated and non-transparent policy.

Next Steps

The Committee will consider reviewing the KP waiting time proposal during a March 28 conference call.

3. Updating Islet Bylaws

The Committee reviewed progress made by the Islet Bylaws Subcommittee to make the islet Bylaws more reflective of islet program needs instead of having these requirements mirror pancreas program requirements.

Summary of Discussion

The Committee reviewed the changes the Subcommittee proposed making to the islet Bylaws and provided feedback. Specifically, the Committee discussed the proposed change to require the islet program leader to have experience in 6 islet transplants prior to leading the program. A Committee member questioned how difficult it would be to get this experience. The Subcommittee representatives noted that the requirement doesn't specify allogeneic or autologous transplant, which may make it easier for an individual to obtain experience. The Subcommittee members agreed to bring back this concern to the Subcommittee.

A Committee member questioned whether the leader of the program should have experience in multiple backgrounds identified by the Subcommittee as suitable for an islet program leader: transplantation immunosuppression management, endocrinology, beta cell management. The

Subcommittee will discuss whether experience with one or more of these backgrounds is sufficient for an islet program leader.

The Committee was generally supportive of the Bylaws allowing islet programs to be free-standing from pancreas programs. However, a Committee member did express concern whether free-standing islet programs would have sufficient access to someone with experience in immunosuppression without ties to a pancreas transplant program. The Subcommittee Chair noted that bone marrow immunosuppression experience would serve a similar function, and that immunosuppression experience may not come from pancreas programs.

Next Steps

The Subcommittee will review the Pancreas Committee's feedback during its next call.

4. Broadened Allocation across compatible blood types

The Committee discussed modifications to a Scientific Registry of transplant Recipients (SRTR) data request to review options for broadening allocation across compatible blood types.

Summary of Discussion

The Committee reviewed the kidney-pancreas simulated allocation model (KPSAM) runs previously requested and analyzed by the SRTR in 2016. The Committee then reviewed the current SRTR data request, which consists of variations on the KPSAM Run 4 request performed by the SRTR in 2016.

The main question discussed by the Committee was whether to request the analysis for allocation at the local level, local and regional, or local, regional and national levels. Most of the allocation would be at the local level, so there would not be much difference between an analysis at the local level and that which goes out to the national level, although these would be different data requests of the SRTR. During the discussion, more Committee members supported a request at every level (local, regional and national) over just at the local level, since the local level request would be substantially similar.

The Committee also discussed modifications regarding the possible combinations for broadening KP blood type compatibility and the impact of each broadening combination on the total number of SPK transplants through four variations on the previous KPSAM Run 4 (R4):

- O to B
- O to B, A2/A2B to B
- O to A and B
- O to A and B, A2/A2B to B

Specifically, for blood type A, the Committee discussed having the allocation only apply to the top 4 classification levels of the Run 4 allocation system – NOT the 5th classification level "local":

Currently in policy, highly sensitized (0-ABDR AND Calculated Panel Reactive Antibodies or CPRA ≥ 80) O to A is already allowed. So, O to A for the first classification level, 3rd classification level, and 4th classification level is already allowed. The Committee discussed O to A for classification level 2: local CPRA ≥ 80. The Committee discussed making this change to the data request because of the concern expressed at the December Board meeting about a potential negative impact by broadening allocation on blood type O candidates. Since most Os would go to A candidates if that compatibility were allowed in allocation, the Committee discussed restricting that allocation to only sensitized candidates. A Committee member suggested that not just O to A, but A to AB, O to AB, and B to AB should be opened up for sensitized candidates at this level (level 2).

Next Steps

The policy liaison will follow up with the SRTR to ensure that the Committee's new request is captured. The Committee may have another discussion about the request before it is submitted, either in a subcommittee call or a full committee teleconference.

5. Pancreas Program Functional Inactivity

The Committee reviewed progress made by the Functional Inactivity Work Group, comprised of members of the Pancreas Committee and the Membership and Professional Standards Committee (MPSC). The Committee reviewed responses to a Work Group survey on a proposed solution to improve review of pancreas programs for functional inactivity.

Summary of Discussion

The Committee agreed with the Work Group that programs flagged multiple times for functional inactivity should be treated differently than programs that are flagged only one time. However, a Committee member suggested that the first flag of a program could require less review by the MPSC than it already does. Instead of being flagged and reviewed by the MPSC, the first flag of a program could precipitate a letter being sent to the candidates at the program about the functional inactivity. Then the second flag could have more significant consequences.

Committee members supported lengthening the functional inactivity for pancreas programs from 1 in 6 consecutive months to 2 in 12 consecutive months. By low volume programs transplanting their candidates efficiently, they may have no candidates on their list later and be

penalized under the 1 in 6 month rule. 2 in 12 months would give these programs more flexibility.

Some members expressed concern about including metrics in the letter to patients such as average waiting time, or using this metric in the definition of functional inactivity. If a program has only one patient on the list, using the program's waiting time average could provide a skewed picture. Another Committee member expressed concern that adding metrics to the letter or functional inactivity definition could encourage programs to delist patients.

Next Steps

The policy liaison will take the feedback from the Committee to the Functional Inactivity Work Group to review.

6. COIIN (Collaborative Innovation and Improvement Network)

The Committee received a brief overview of the COIIN project.

Summary of Discussion

During the Strategic Plan discussion, the Committee expressed interest in learning more about the COINN project, to increase utilization of high KDPI kidneys while avoiding negative transplant outcomes. A member of UNOS COIIN support staff was able to come down and give a brief overview of this project. The Pancreas Committee is interested in pursuing a similar project for increased utilization of pancreata.

Next Steps

The policy liaison will get further information from UNOS staff to pass along to the Committee. The Committee will review this project and its implications for the pancreas community in more detail at a later date.

7. Policy Oversight Committee (POC) Update

The Committee reviewed a POC update and had no comments on it.

8. Geography Committee Update

The Committee reviewed a brief update on the efforts of the Geography Committee. A Committee member questioned whether the efforts to consider geographic locality should refer to "distribution" or "allocation." The Geography Committee refers to distribution because, although geography is part of allocation, allocation is comprised of more than geography and includes clinical considerations as well. The Geography Committee will work on narrowing the guiding principles of geography at its in-person meeting in Chicago. Some of the most important principles include the role of supply and demand and cold ischemia time. It is clear there are discrepancies in waiting time and the Geography Committee seeks to devise principles to address this inequity. The Geography Committee liaison noted that multiple models may be able to meet the principles.

Upcoming Meetings

- April 16, 2018 (teleconference)
- May 14, 2018 (teleconference)