

OPTN/UNOS Pancreas Transplantation Committee
Meeting Minutes
May 31, 2018
Conference Call

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Introduction

The Pancreas Transplantation Committee (hereafter, the Committee) met via Citrix GoToTraining teleconference on 5/31/2018 to discuss the following agenda items:

1. Pancreas Program Functional Inactivity
2. Changes to Islet Bylaws

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

1. Pancreas Program Functional Inactivity

The Committee reviewed proposed Bylaw changes related to pancreas program functional inactivity and voted to send the proposal out for public comment.

Summary of discussion:

The Committee discussed whether patients should be informed of multiple listing AND transfer of accrued waiting time instead of multiple listing OR transfer of accrued waiting time, which is how it is written in the current Bylaws for other programs and in the draft language. Committee members were concerned that patients should be informed of both the possibility to multi-list and to transfer accrued waiting time. Although "or" is inclusive of "and," the Committee felt the Bylaws should be more explicit that patients have both options. The Committee agreed this change should apply only to letters sent to pancreas patients because of the scope of the project, which is to change and update pancreas program functional inactivity, not those requirements for other programs.

The Committee discussed why programs must inform patients regarding the reason fewer than 2 transplants were performed in the functional inactivity period. This comes from the current Bylaws, which require all programs to explain their functional inactivity to patients. There can be legitimate reasons why no transplants were performed: for example, if the surgeon had a hand injury and was unable to perform surgery for a certain time period. It allows programs to inform patients of any relevant circumstances, and also holds programs accountable to their patients. The changes to the Bylaws would keep this requirement to inform patients about the circumstances of functional inactivity.

After this discussion, the Committee voted 15-0 to send the proposed changes out for public comment in the fall.

Next Steps:

The Committee liaison will draft a public comment proposal, receiving feedback from Committee and UNOS members. The proposal will go out for public comment August 3, 2018.

2. Changes to Islet Bylaws

The Committee reviewed Bylaws language related to this proposal and voted to send the proposal out for public comment.

Summary of discussion:

The Committee discussed the program coverage plan and potential changes to it. In particular, the Committee discussed how patients should be informed of potential staff unavailability, and whether clinical leaders can be on call for programs more than 30 miles apart.

1. Potential staff unavailability – programs must inform patients of the potential unavailability of the transplant surgeon or transplant physician; that is, if the transplant surgeon/physician has no additional surgeons/physicians to cover for that person if they are gone for a period of time. At first, the Committee agreed that the islet Bylaws should refer only to the potential unavailability of the clinical leader and not also the expert medical personnel, because including the latter may be too onerous for islet programs. The Committee discussed that there are various members of the islet transplant program whose unavailability may impact patients, but it would be too onerous and unrealistic to expect islet programs (which are very small) to have back up for each role. Instead, the Committee agreed that islet Bylaws would require that islet programs inform patients if the “level of program staffing” creates instances of “potential unavailability.”

Islet programs have various key roles that could impact patient care, and originally the proposed language indicated that patients be informed if the “clinical leader or expert medical personnel” were “unavailable.” But the purpose of the clause is to inform patients ahead of time, not at the time of absence, that patient care could be impacted. Also, there could be other personnel other than the expert medical personnel who could impact patient care, but having “back up” personnel for all of these individuals would be impractical and an undue burden on islet programs. To address these issues, the new language indicates that patients be informed if “the level of program staffing” (deliberately vague) creates instances of “potential unavailability” (forward-looking) that affect patient care. Below is a summary of the current language, previously proposed language, and the language the Committee voted to send to public comment.

a. Current bylaws:

A transplant program must inform its patients if it is staffed by a single surgeon or physician and acknowledge the potential unavailability of these individuals, which could affect patient care, including the ability to accept organ offers, procurement, and transplantation.

b. Previous islet language:

An islet transplant program must inform its patients if the clinical leader or member of the expert medical personnel defined in *Appendix K.3.B Expert Medical Personnel* is unavailable, which could affect patient care, including the ability to accept organ offers, procurement and transplantation.

c. Voted on language:

An islet transplant program must inform its patients if the level of program staffing may create instances where potential unavailability of certain staff could affect patient care, including the ability to accept organ offers, procurement, and transplantation.

2. On call distance – the Committee previously agreed that clinical leaders could be on call for islet programs more than 30 miles apart, a decision in contrast to other program coverage plan requirements, but stemming from the fact that islet procedures can be scheduled in a way that other transplants cannot. However, “on call” addresses both the

islet transplant and follow up care, including any complications, which of course are not planned. The Committee reviewed whether the requirement that clinical leaders be on call only at programs within 30 miles should be added back into the islet program coverage plan, and agreed it should not be because islet transplant volume is too low to make this a reasonable requirement, the Committee feels that the other program coverage plan requirements provide the adequate level of care for patients and accountability for islet programs, and doing so may limit clinical leaders to one islet program by default since the current islet programs are not within 30 miles of each other.

The Committee reviewed the rest of the changes to the Bylaws and had no comments, but expressed support for the changes. The Committee voted 11-0 to send the proposal out for public comment.

Next steps:

The Committee liaison will draft a public comment proposal, receiving feedback from Committee and UNOS members. The proposal will go out for public comment August 3, 2018.

Upcoming Meetings

- July 17, 2018 (teleconference)