OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee
Meeting Minutes
March 13, 2018
Conference Call

Cameron Wolfe, MD, Chair
Marian Michaels, MD, MPH, Vice Chair

Introduction

The Ad Hoc Disease Transmission Advisory Committee (DTAC) met via Citrix GoToTraining teleconference on 03/13/2018 to discuss the following agenda items:

1. DTAC Public Comment Proposal: Clarify Informed Consent for Transmittable Conditions
2. Public comment proposal discussion: Reduce reporting burdens and clarify policies on extra vessels

The following is a summary of the work group's discussions.

1. DTAC Public Comment Proposal: Clarify Informed Consent for Transmittable Conditions

Summary of discussion:

The vice-chair reviewed the policy development process noting that public comment remains open through March 23, 2018. Comments received to date were reviewed.

On the feedback question regarding whether patient signature or solely medical documentation of informed consent should be required, the majority of respondents indicated that medical documentation would be sufficient. This sentiment is largely based on the timing of the consent at organ offer which can create challenges in obtaining a patient signature. Some members of the Patient Affairs Committee had strong feelings with opposing views with one committee member strongly supporting a patient signature while another one equally strongly disagreeing. Some respondents (e.g. Region 2 and American Society of Transplantation), including a DTAC member, suggested that neither be put into policy and to let transplant hospitals decide what to do. The current policy contains the requirement for medical documentation. It was noted that without any policy requirement, the community will be confused and that can cause greater problems. In addition, the consent process cannot be monitored without documentation. Therefore the Committee agreed that having documentation of informed consent is a reasonable minimum standard and will be maintained in policy.

Public comment on what conditions should be included in candidate screening, re-execute the match run, and subsequently informed consent policy as proposed has received varied responses. Four regions did express that informed consent for positive cytomegalovirus (CMV) among intestine potential transplant recipients (PTRs) should not be required. Region 11 did not pass the proposal with this stipulation, but voted to pass the proposal without the consent requirement for CMV This region, however, felt that CMV screening for intestinal transplants should be kept in the candidate screening and re-execute the match run policies. The American Society of Transplantation (AST) had varied opinions within its membership as their Kidney Community of Practice believed that consent when using CMV positive organs should be required for all PTRs, whereas the overall organization was supportive of limiting it to CMV intestine PTRs. The Patient Affairs Committee also supported having CMV screening for all PTRs. DTAC will be presenting to the Liver and Intestine and Pediatric Committees later this

month and these committees will be asked to weigh in on the CMV question. Several DTAC members also responded to an earlier survey that they did believe CMV should be excluded.

One DTAC member strongly expressed that CMV had more complications than hepatitis and that hepatitis C (HCV) was now curable. Another member expressed that it has been very challenging to come up with the right mix and balance but it does not seem right to have hepatitis B and C, as well as HIV, be the three infections that we worry about. Another member stated that they had liked the simplicity of tying policy back to candidate screening but that it is understandable why it might need to change. Membership and Professional Standards Committee (MPSC) public comments acknowledge the challenges of developing and maintaining this policy and a desire to be more nimble were shared. Members discussed that infections of concern have changed in the past and might change in the future. In several years the community might not be as concerned about HCV, but at this point in time the community is not quite there.

DTAC leadership discussed this issue, reviewed all the comments and recommends that the proposal be changed to exclude CMV informed consent for intestine PTRs. The rationale is based on public comment and that policy should be the minimum requirement. It is suggested to solely list the conditions in the policy instead of tying them back to candidate screening and re-execute the match run policies. Including exclusions, but referring back to another policy would not be desirable from a clarity and editorial standpoint.

Another public comment received was to clarify the timing language which can be confusing and to develop strong education and best practices that can assist the transplant community.

2. Public comment proposal discussion: Reduce reporting burdens and clarify policies on extra vessels

Summary of discussion:

Highlights of the Operations and Safety Committee's proposal to reduce reporting burdens and clarify policies on extra vessels were shared. The DTAC had provided guidance prior to public comment on what infectious diseases needed to be on the physical extra vessels label versus electronically accessing results. The Operations and Safety Committee proposed what DTAC had recommended. DTAC had no questions regarding the proposal.

Next steps:

The following next steps will be taken:

- Continue to monitor public comment through March 23, 2018
- Revise policy language draft based on discussions
- Send out draft policy language and public comments on March 26, 2018
- Discuss proposal and vote at in-person meeting

Upcoming Meeting

- March 29, 2018 in-person meeting (Richmond, VA)