OPTN Vascularized Composite Allograft Committee
Meeting Minutes
October 9, 2019
Conference Call

Linda Cendales, MD, Chair
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Introduction

The VCA Committee met via Citrix GoTo teleconference on 10/09/2019 to discuss the following agenda items:

1. VCA Charge
2. Discuss Modify Transplant Outcomes (TRR & TRF) project
3. Collecting Data on Children born from Uterus recipient

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

1. VCA Charge

The Committee began discussing how they may modify the current VCA charge based on feedback received by the Executive Committee. The intent is to modify this charge in order to better align it with what the Committee currently does.

Summary of discussion:

There was some confusion from members as to the purpose of the charge and its intended audience. One member was of the opinion that the charge should remain broad if the intended audience is the public and if the charge is posted publically. Also, a broad charge will allow the Committee to not be constrained in which projects they wish to pursue. On the otherhand, the member thought that a more detailed charge may be warranted if the charge was intended for the Executive Board. Still other members were supportive of broadening the charge to include phrases like "we collect data for patient safety and to inform policy decisions-making". All members agreed though that the Kidney Committee charge was maybe too detailed for the VCA Committee to model off of.

Next steps:

UNOS staff will draft a modified VCA charge for Committee leadership. Once Committee leadership agrees to the charge, then this will be circulated to the larger Committee for input and discussion at the in-person meeting in November.

2. Discuss Modify Transplant Outcomes (TRR & TRF) project

The Vice Chair gave a brief update on the Committee's current project, including next steps.

Summary of discussion:

There were no questions or comments from Committee members.

Next steps:

The Committee will vote on sending out this project for Spring 2020 Public Comment in November 2019.

3. Collecting Data on Children born from Uterus Recipients

The Committee discussed the timeframe to collect information on children born from uterus recipients (e.g. at birth, annually etc.) and what data elements should be collected at each time interval.

Summary of discussion:

There was some confusion from members as to why maternal data is being voluntarily collected along with data on the children at birth. One member commented that such data on the mother may already be collected on the TRF. Clarification was provided that maternal data is collected at birth for the purposes of tracking and in case the recipient has a child during a period of time when a TRF is not due. For example, "candidate ID" is requested so that the mother (or recipient) will be associated with the data collected on her child(s) (a child does not have an ID because they are neither a recipient nor donor). Also, a Committee member stated that there is no TRF or TRR for a child, only for the recipient. Currently, centers voluntarily submit data on children via Excel spreadsheet.

There was some confusion as to what will be collected on TRF forms moving forward. For example, a member stated that the number of embryos should be a data element collected by the OPTN. There was acknowledgement that these data elements should be simply collected so as to not increase exponentially the data burden for transplant centers. Clarification was provided stating that under the current project to modify the TRR & TRF forms for VCA recipients, this and similar data elements will be added.

One member suggested that in order to collect data on both the recipient and child, that the forms should be due when the recipient receives the uterus and when the child is born. In this way, it would allow centers to report data immediately instead of having them wait each year for the TRF. Also, having centers input the data at the time of birth will allow for more accurate data reporting and a decrease in data burden. It was concluded that this suggestion should be asked during Spring 2020 public comment for feedback from the community.

In terms of the timeframe in which to collect data, Committee members agreed that data should be collected on children at birth because of monitoring outcomes and patient safety. However, the Committee members were less in consensus about if or when to collect data post-birth. On one hand, some Committee members thought that data should be collected every year until the child is 18 years old. Supporters pointed out that Sweden will soon mandate the collection of data on these children every year until age 18. However, critics cited the fact that there are numerous logistical challenges to collecting this data, and the impact of environmental factors that could prove difficult to link causation. For example, even for living donors, collecting data past two years is infrequent and commonly lost to follow-up. Others agreed, and one member was concerned that "healthy" children will not have their data reported annually, but rather only those children with issues will be reported to the OPTN. In this way, the data may become skewed overtime and thereby limit the OPTN in identifying accurate long term outcomes. Because of the reasons above, some Committee members supported collecting data up to 1 year post-birth, while others (in order to standardize with other OPTN data collection forms) supported collecting data up to 2 years post-birth. One Committee member mentioned transplant centers being cited if they do not report the data.

Another Committee member was concerned that the effects of medications may not be seen until the child is 5 years old. However, another member cautioned against associating effect with causation. Overall, members supported asking for feedback on whether to collect data post-birth during the Spring 2020 public comment cycle.

A suggestion from a HRSA member was to perhaps have the Transplant Pregnancy Registry collect data past birth. After clarification as to whom the registry collects data on, the Committee agreed that this should be a question that is asked for feedback on during Spring public comment 2020.

Lastly, Committee members agreed that data elements should be limited to common data collected if performed annually, and that the rationale for each data element be reasoned and justified.

Next steps:

Staff will compile a list of the data elements to be collected at birth for the Committee to review prior to their in-person meeting in November 2019.

Upcoming Meeting

- November 15 (in person)