

OPTN Heart Committee Revise Coronary Artery Disease (CAD) and Cardiac Allograft Vasculopathy (CAV) Data Elements Subcommittee Meeting Summary February 3, 2022 Conference Call

Shelley Hall, MD, Chair

Introduction

The Revise Coronary Artery Disease (CAD) and Cardiac Allograft Vasculopathy (CAV) Data Elements Sucommittee met via Citrix GoToMeeting teleconference on 02/03/2022 to discuss the following agenda items:

- 1. Background
- 2. Review and Edit Project Form

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

1. Background

UNOS staff shared the origin of this issue and highlighted why this problem needs to be addressed by the Committee. Currently, the CAD data elemnt appears on the Transplant Recipient Follow-up (TRF) form and the OPTN is not presently collecting data about CAV. The Subcommittee will review the CAD data element and elect to either revise or remove it, and develop a CAV data element.

2. Review and Edit Project Form

Prior to today's meeting, Subcommittee members reviewed and provided feedback on the project form. The Chair walked through the project form and discussed various components of the project.

Summary of discussion:

Purpose

A member suggested using the definition of CAV developed by the International Society for Heart and Lung Transplantation (ISHLT). The Chair expressed concern that included specific definitions could be too nuanced and possibly inconsistent with what the Subcommittee decides to do. Alternatively, a member noted that it could strengthen the Committee's claim that the terminology has changed by highlighting that other organization have made relevant changes. The group agreed it was important to notice the change in the community but wanted to avoid being pigeonholed into pursuing a certain route for the project because of what is included in the project form. At minimum, the ISHLT document will be referenced in a footnote.

The Subcommittee was satisfied with the remainder of the purpose section. This information is necessary to provide context for individuals who do not have thoracic clinical expertise and to highlight how this work will impact the greater transplant community.

Proposal

Members discussed whether or not CAD should be replaced with CAV. The Chair noted that there is donor derived CAD detected at baseline and single vessel CAD that the OPTN ought to track. The Chair suggested adding that 'the Committee intends to develop clear and concise definitions of CAD and CAV.' Member suggested including language about the data collection type to prioritize the use of drop down options when possible.

A member expressed concern that the language 'collection of a new data element,' in the second paragraph, confined the subcommittee to developing a single data element as opposed to multiple data elements that may need to be collected.

The group identified the following potential data elements for CAD:

- 'Yes' or 'no' option to identify if CAD is present
- 'Yes' or 'no' option to indicate if it was 'known prior'
- 'Yes' or 'no' option to indicate if it was 'discovered post transplant'
- Potentially select a grade level

The group identified the following potential data elements for CAV:

- 'Yes' or 'no' option to identify if CAD is present
- Checkbox for 'mode of diagnosis'
- Chckbox to select a grade level

Members discussed the frequency of forms that would collect this information. The TRF forms occur at 6 months, one year, and annually after. There was discussion about the timeframe and if CAD/CAV was identified in the timeframe between forms or if it would be identified in perpetuity. If it were to be identified in also subsequent forms then a carryover function would be preferred.

Member clarified that primary graft dysfunction (PGD) is tied to short-term post-transplant mortality whereas CAD and CAV is tied to long-term (5-20 year) post-transplant mortality. CAD and CAV will not impact donor selection or allocation but it will inform valuable research to improve long-term post-transplant outcomes. It is important to note that while the current heart allocation system does not consider outcomes, there is a chance that the Committee could decide to include outcomes when developing continuous distribution.

Coronary Artery Disease Discussion

The group is in agreement to keep the CAD data element but discussed ways in which it could be defined. The Chair suggested defining it by etiology as 'donor derived,' while a member countered that the pathology of the lesion is unknown and should not be limited to 'donor derived.' Alternatively, the group suggested identifying CAD as either 'known and accepted' or 'developed.' The group also considered limiting CAD as only applicable when accepting the heart for transplant, therefore, all following instances would be defined as CAV.

A member suggested adding a grade to CAD that asks if 'intervention was required' and if intervention is required then it must be CAD first. A member countered that they identify CAV as any lesion identified 5 years or after post-transplant. A member highlighted the challenge with arguing on definitions and ensuring that the community completes these forms with the correct information.

The Chair suggested removing CAD from the recipient forms and leaving it only on the donor form, but this would miss the patients who have a lesion appear during their six-month post-transplant catheterization. UNOS staff shared that there is not a link between the donor form and recipient form to

indicate that if the donor had CAD then the recipient has CAD. There was concern that even if CAD was linked between the donor and recipient forms, their may not be enough information include for that to be a robust variable.

Members discussed the possibility of having CAD only on the 6-month post transplant form and CAV on the annual forms, however some members pushed back on scenarios in which this would not accurately represent the condition of their patient. A member suggested providing 'yes' or 'no' options for 'angiographic detected disease' and 'advanced imagining detected disease' for CAV.

Next steps:

Members are asked to continue to consider ways in which CAD and CAV can be defined. UNOS staff will circulate the updated project form following the inclusion of the edits from today's subcommittee call.

Upcoming Meetings

• To be determined

Attendance

• Subcommittee Members

- o Cindy Martin
- o Cristy Smith
- o David Baran
- o JD Menteer
- o Jose Garcia
- o Shelley Hall
- HRSA Representatives
 - o Marilyn Levi
 - o Raelene Skerda
- SRTR Staff
 - o Katie Audette
 - o Yoon Son Ahn
- UNOS Staff
 - o Eric Messick
 - Keighly Bradbrook
 - o Krissy Laurie
 - o Laura Schmitt
 - o Lauren Mauk
 - o Sara Rose Wells
 - o Susan Tlusty