OPTN

Notice of OPTN Data Collection Changes

Report Primary Graft Dysfunction in Heart Transplant Recipients

Sponsoring Committee:	**Heart Transplantation Committee**
Data Instruments Affected:	***TIEDI TRR***
Public Comment:	**August 3, 2021 – September 30, 2021**
Board Approved:	**December 6, 2021**
Effective Date:	**Pending implementation and notice to OPTN members**

Purpose of Data Collection Change

The proposal identifies for collection new data elements associated with primary graft dysfunction (PGD) in adult and pediatric heart transplant recipients, and the removal of a data element that is not relevant to heart transplantation. PGD is the leading cause of 30-day mortality post-heart transplantation.[1] PGD also has a considerable negative effect on heart recipients' morbidity.[2] However, the OPTN does not collect post-transplant information that could identify recipients who develop PGD. The lack of data limits the heart transplant community's ability to identify the incidence of PGD among recipients as well as associated post-transplant outcomes. When implemented, the new data collection will support outcome monitoring and permit evidence-based policy development in the future.

Proposal History

The Committee established a subcommittee to lead the effort, and the subcommittee began work on the proposal in August 2020. Their efforts produced a request for feedback document that was submitted for public input from January through March 2021.[3] The feedback document included the recipient-specific data elements, and suggested potential donor-specific data that might also be useful for better understanding PGD. In the document, the Committee also identified potential collection timeframes of 24 hours (±4 hours) and 72 hours (±4 hours) after a recipient's arrival in the ICU, and requested feedback on the advantages and disadvantages of those times, along with suggestions for fewer and/or more collection timeframes. The Committee also identified the data element "Airway Dehiscence" for removal because it is not relevant to heart transplantation.

Community feedback was largely supportive of the identified data elements and collection timeframes. Some commenters expressed concerns that the amount of information requested would unnecessarily burden the transplant programs tasked with collecting and reporting it. However, commenters also

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[1] Sanjeet Singh Avtaar Singh et al., "Primary Graft Dysfunction after Heart Transplantation: A Thorn amongst the Roses," *Heart Failure Reviews* 24, no. 5 (2019): 805-20.
[2] Jon Kobashigawa et al., "Report from a Consensus Conference on Primary Graft Dysfunction after Cardiac Transplantation," *The Journal of Heart and Lung Transplantation* 33, no. 4 (2014): 328.
[3] Develop Measures for Heart Primary Graft Dysfunction, OPTN Heart Transplantation Committee, https://optn.transplant.hrsa.gov/media/4340/develop-measures-for-heart-primary-graft-dysfunction.pdf (accessed December 9, 2021).

suggested that the donor-specific data should be included in this effort because of its potential importance to better defining and addressing PGD.

Using the public's input, the Committee developed a data collection proposal for public comment from August through September 2021. Acknowledging the earlier comments about data burden, the Committee set about making data reporting as efficient as possible by replacing the requirement to report specific data values with value ranges and eliminating the requirement to answer some questions depending on how gatekeeper questions were answered. The Committee also amended some of the data elements being requested to accommodate the measurement methods used for pediatric heart recipients. Additionally, the Committee chose not include any donor-specific data elements as part of the proposal. As with the request for feedback document, public comment was largely supportive of collecting the proposed data elements at 24 hours and 72 hours (±4 hours) after a recipient's ICU arrival. As before, concerns were reported about data burden on the transplant programs and recommendations were made for collecting donor-specific information. The proposal was approved at the December 2021 OPTN Board of Directors meeting.

Summary of Changes

The changes modify the Heart and Heart/Lung Transplant Recipient Registration (TRR) forms in TIEDI to collect new data elements relevant to identifying PGD in heart transplant recipients. The new data elements can be categorized as follows: presence of primary graft dysfunction, hemodynamic values, device support, inotrope and vasopressor support. They will be collected at 24 hours and 72 hours after a recipient's arrival in the ICU. The data element "Airway Dehiscence" will be removed from the post-transplant section of the TRR, as this information is not relevant to heart recipients.

Implementation

Heart transplant program personnel will be required to become familiar with the changes to the Heart and Heart-Lungs TRR forms and data definitions. Transplant programs should also provide personnel responsible for reporting with instructions regarding the location of the data in their medical records.

The changes require information technology implementation in the system. This proposal requires submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through Office of Management and Budget (OMB)-approved data collection forms.[4] Therefore, after OPTN Board approval, the forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

Affected Data Collection

All data elements are new.

New Data Element	Values	Additional Notes
Is Primary Graft Dysfunction (PGD) Present?	Yes, No, Unknown	

[4] 42 CFR §121.11(b)(2).

New Data Element	Values	Additional Notes
PGD – Left Ventricle (PGD-LV)	Yes, No, Unknown	The value will default to "No" if "Is Primary Graft Dysfunction (PGD) Present?" is "No" or "Unknown".
PGD – Right Ventricle (PGD-RV)	Yes, No, Unknown	The value will default to "No" if "Is Primary Graft Dysfunction (PGD) Present?" is "No" or "Unknown".
Left Ventricular Ejection Fraction (LVEF)	• Severely Depressed LV Function / EF <30% • Moderately Depressed LV Function / EF ≥30%--<40% • Mildly Depressed LV Function / EF ≥40%--<50% • Normal LV Function / EF ≥50% • Unknown	Transplant program chooses percentage from a drop down list with the values identified.
Right Atrial Pressure (RAP)	mm Hg, Unknown	
Pulmonary Capillary Wedge Pressure (PWCP) or Left Atrial (LA) Pressure	mm Hg, Unknown	
Pulmonary Artery (PA) Systolic Pressure	mm Hg, Unknown	
Pulmonary Artery (PA) Diastolic Pressure	mm Hg, Unknown	
Cardiac Output (CO)	Liters Per Minute, Unknown	
Support Device	Yes, No, Unknown	
If yes to Support Device	Right, Left, Biventricular, Unknown	The value will default to "Unknown" if "Support Device" is answered "No," or "Unknown".
Type of Support Device	Drop-down list of devices	The value will default to "Unknown" if "Support Device" is answered "No" or "Unknown".
Inotrope Support		
Nitric Oxide Following Transplant?	Yes, No, Unknown	
Epoprostenol Following Transplant?	Yes, No, Unknown	

Inotrope	Dose (mcg/kg/min)	Dose (mcg/min)	Additional Notes
Epinephrine	• None • Low (>0.00 – ≤0.05) • Moderate (>0.05 – ≤0.10) • High (>0.10) • Unknown	---	
Milrinone	• None • Low (>0.00 – ≤0.30) • Moderate (>0.30 – ≤0.50) • High (>0.50) • Unknown	---	
Dobutamine	• None • Low (>0.00 – ≤3.00) • Moderate (>3.00 – ≤7.50) • High (>7.50) • Unknown	---	
Dopamine	• None • Low (>0.00 – ≤3.00) • Moderate (>3.00 – ≤7.50) • High (>7.50) • Unknown	---	

Vasopressor	Dose (mcg/kg/min)	Dose (mcg/min)	Additional Notes
Levo (Norepinephrine – Levophed)	• None • Low (≤0.05) • Moderate (>0.05 – ≤0.10) • High (>0.10) • Unknown	• None • Low (≤5.00) • Moderate (>5.00 – ≤12.00) • High (>12.00) • Unknown	
Neo (Phenylephrine – Neosynephrine)	• None • Low (≤1.50) • Moderate (>1.50 – ≤4.00) • High (>4.00) • Unknown	• None • Low (≤100.00) • Moderate (>100.00 – ≤200.00) • High (>200.00) • Unknown	

Vasopressor	Dose (mcg/kg/min)	Dose (unit per minute)	Additional Notes
Vaso (Vasopressin – Pitressin)	---	• None • Low (≤0.05) • Moderate (>0.05 – ≤0.08) • High (>0.08) • Unknown	