

Request for Feedback

Develop Measures for Heart Primary Graft Dysfunction

OPTN Heart Transplantation Committee

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Contents

Executive Summary	2
Background	3
Suggested Data Elements	5
NOTA and Final Rule Analysis	8
Implementation Considerations	9
Summary	9
Appendix A: ISHLT Consensus Statements on Primary Graft Dysfunction (PGD) and Definition of Severity Scale for PGD	11
Appendix B: List of Mechanical Circulatory Support Devices Associated with Certain Adult Heart Statuses	13

Develop Measures for Heart Primary Graft Dysfunction

Affected Policies: N/A
Sponsoring Committee: Heart Transplantation
Public Comment Period: January 21, 2021 – March 23, 2021

Executive Summary

Primary Graft Dysfunction (PGD) is the leading cause of 30-day mortality post-heart transplantation.¹ However, the Organ Procurement and Transplantation Network (OPTN) does not collect post-transplant information that could identify recipients who develop primary graft dysfunction. The OPTN Heart Transplantation Committee (hereinafter “the Committee”) is requesting input from the community to solicit suggestions and feedback regarding potential data elements to identify PGD in heart transplant recipients and its impact on outcomes.²

This document contains a list of additional data elements the Committee believes are essential to identify PGD. The transplant community is asked to review and assess the comprehensiveness of the data elements, as well as the proposed collection timeframes.

This document is not a proposal, but instead a request for feedback and suggestions concerning new data elements that should be considered. The input received will be used to develop a future data collection proposal that would support the OPTN strategic goal of improving waitlisted patient, living donor, and transplant recipient outcomes. The information that will eventually be collected should allow the Committee to monitor outcomes for recipients with PGD and to aid in future policy development. This project can provide information to assist in developing a continuous distribution heart allocation framework and potential data collection requests in the future.

¹ Singh, Sanjeet, Singh Avtaar, Dalzell, Jonathan R, Berry, Colin, and Al-Attar, Nawwar. "Primary Graft Dysfunction after Heart Transplantation: A Thorn amongst the Roses." *Heart Failure Reviews* 24, no. 5 (2019): 805-20.

² On July 1, 2020, the OPTN Thoracic Organ Transplantation Committee was disbanded and replaced by an OPTN Heart Transplantation Committee and an OPTN Lung Transplantation Committee.

Background

PGD is a leading cause of early mortality post-heart transplantation³ with an incidence that varies from 2.3 percent to 28.2 percent.⁴ PGD presents as ventricular dysfunction occurring within 24 hours post-transplant.⁵ Additionally, there is no identifiable secondary cause such as hyperacute rejection, pulmonary hypertension, or known surgical complications.⁶ A 2013 the International Society of Heart and Lung Transplantation (ISHLT) consensus conference described a classification system to enable a more uniform diagnosis of PGD and improve comparisons between centers in regard to its incidence and treatment options.⁷ The classification system included a severity scale.⁸ **Appendix A** contains the consensus statements and severity scale.

Following the conference, the community has sought to further clarify PGD's reach and impact on recipient mortality. For instance, a study applying the new ISHLT consensus classification showed that severe PGD (i.e. need for mechanical circulatory support following transplantation) is associated with poor outcomes.⁹ This two-center study described a 518 patient cohort with a 14 percent prevalence of PGD and a mortality of 54 percent in patients with severe PGD.¹⁰ In addition, another study evaluating the outcomes of a different cohort of 195 patients found worse 30-day and one-year mortality in patients transplanted who developed moderate and severe PGD as defined by ISHLT criteria compared to those diagnosed with mild PGD or no PGD.¹¹ The patients also experienced increased ICU length of stay, more postoperative bleeding, and increased infections. A consortium of Virginia cardiac transplant programs also examined outcomes and resource utilization following the development of PGF using the ISHLT definition.¹² Of the 718 patients studied, 15.3 percent developed PGD and these patients had longer ICU length of stay, longer duration of intubation, more multi-organ failure, and higher mortality.

Two recent studies from Canada and the United Kingdom also applied the use of the ISHLT PGD criteria to outcomes. In 2019, a study of a 412 patient cohort at the University of Toronto reported significantly elevated hazard ratios of 7.0 and 15.9 one-year mortality for patients with moderate and severe PGD,

³ Singh, Sanjeet, et al. "Primary Graft Dysfunction." 805-20.

⁴ Kobashigawa, Jon, Zuckermann, Andreas, Macdonald, Peter, Leprince, Pascal, Esmailian, Fardad, Luu, Minh, Mancini, Donna, Patel, Jignesh, Razi, Rabia, Reichenspurner, Hermann, Russell, Stuart, Segovia, Javier, Smedira, Nicolas, Stehlik, Josef, and Wagner, Florian. "Report from a Consensus Conference on Primary Graft Dysfunction after Cardiac Transplantation." *The Journal of Heart and Lung Transplantation* 33, no. 4 (2014): 327-40.

⁵ Kobashigawa, Jon, et al. "Report." 337.

⁶ Kobashigawa, Jon, et al. "Report." 337.

⁷ Kobashigawa, Jon, et al. "Report." 327-40.

⁸ Kobashigawa, Jon, et al. "Report." 327-40.

⁹ Sabatino, Mario, Vitale, Giuseppe, Manfredini, Valentina, Masetti, Marco, Borgese, Laura, Maria Raffa, Giuseppe, Loforte, Antonio, Martin Suarez, Sofia, Falletta, Calogero, Marinelli, Giuseppe, Clemenza, Francesco, Grigioni, Francesco, and Potena, Luciano. "Clinical Relevance of the International Society for Heart and Lung Transplantation Consensus Classification of Primary Graft Dysfunction after Heart Transplantation: Epidemiology, Risk Factors, and Outcomes." *The Journal of Heart and Lung Transplantation* 36, no. 11 (2017): 1217-225.

¹⁰ Sabatino, Mario, et al. "Clinical Relevance." 1217-225.

¹¹ Squiers, John J, Saracino, Giovanna, Chamogeorgakis, Themistokles, MacHannaford, Juan C, Rafael, Aldo E, Gonzalez-Stawinski, Gonzalo V, Hall, Shelley A, DiMaio, J Michael, and Lima, Brian. "Application of the International Society for Heart and Lung Transplantation (ISHLT) Criteria for Primary Graft Dysfunction after Cardiac Transplantation: Outcomes from a High-volume Centre." *European Journal of Cardio-thoracic Surgery* 51, no. 2 (2017): 263-70.

¹² Quader, Mohammed, Hawkins, Robert B, Mehaffey, J. Hunter, Mazimba, Sula, Ailawadi, Gorav, Yarboro, Leora, Rich, Jeffrey, Speir, Alan, Fonner, Clifford, Wolfe, Luke, and Kasirajan, Vigneshwar. "Primary Graft Dysfunction after Heart Transplantation: Outcomes and Resource Utilization." *Journal of Cardiac Surgery* 34, no. 12 (2019): 1519-525.

respectively.¹³ Similarly, a 2019 study examined the incidence, risk factors and outcomes following PGD in all adult heart transplant patients in the United Kingdom from October 2012 to October 2015 using the ISHLT consensus definition¹⁴. For the 450 adults included in this study, the incidence of PGD was 36.2 percent with an increased one-month mortality with the highest mortality in the severe PGD group.

Many donor, recipient, and procedural risk factors have been found to be associated with the development of PGD.¹⁵ These include donor age, recipient age, recipient inotropic support, and pre-transplant mechanical support.¹⁶ Ischemia time is also considered an independent risk factor.¹⁷ Nonetheless, it is difficult to definitively establish the risk factors, according to researchers, because of the variability in the studies that have been performed. When the OPTN Thoracic Committee considered a PGD project in 2014, there were concerns that there might be a rising incidence of PGD at that time. However, research studies suggest that it is difficult to determine whether there has been an increase or decrease.^{18,19} Furthermore, it is difficult to know whether future allocation changes, such as the continuous distribution of hearts, may impact the rate of PGD. An understanding of the gravity of the problem is needed.

Presently, transplant programs are reviewed and compared primarily by 30-day, one- and three-year mortality rates. However, PGD adds considerable morbidity in addition to mortality to transplant recipients' outcomes, especially within the first year following transplant. It is important for a patient to be aware of what the chances are that mechanical support post-transplant will be required, which usually means longer ICU stays, more complications, slower recovery, long hospitalizations, more need for rehabilitation, or additional prolonged care. Because the OPTN does not collect post-transplant data specific to PGD, it is not possible to make program-level comparisons. This project is a first step at addressing this knowledge gap.

Currently, analysis of PGD is limited due to the lack of available data. The Committee had twice before started projects addressing PGD. In 2014, the Committee was contacted by the Membership and Professional Standards Committee (MPSC) with information suggesting that the incidence of PGD may have greater occurrences than acknowledged because the OPTN did not collect sufficient data for tracking it.²⁰ However, the Committee chose to put this effort on hold while the members focused on comprehensively modifying adult heart allocation policy. The Committee again considered a PGD project in 2018. However, the Committee's PGD efforts were put on hold because as they began to analyze the recent adoption of the new adult heart allocation policy, as well as other heart projects.

¹³ Foroutan, Farid, and Ross, Heather J. "Primary Graft Dysfunction: The Devil Is in the Details." *Transplantation* 103, no. 2 (2019): 229-30.

¹⁴ Avtaar Singh, Sanjeet Singh, Banner, Nicholas R, Rushton, Sally, Simon, Andre R, Berry, Colin, and Al-Attar, Nawwar. "ISHLT Primary Graft Dysfunction Incidence, Risk Factors, and Outcome: A UK National Study." *Transplantation* 103, no. 2 (2019): 336-43.

¹⁵ Nicoara, Alina, Ruffin, David, Cooter, Mary, Patel, Chetan B, Thompson, Annemarie, Schroder, Jacob N, Daneshmand, Mani A, Hernandez, Adrian F, Rogers, Joseph G, Podgoreanu, Mihai V, Swaminathan, Madhav, Kretzer, Adam, Stafford-Smith, Mark, Milano, Carmelo A, and Bartz, Raquel R. "Primary Graft Dysfunction after Heart Transplantation: Incidence, Trends, and Associated Risk Factors." *American Journal of Transplantation* 18, no. 6 (2018): 1466.

¹⁶ Nicoara, Alina, et al. "Primary Graft Dysfunction after Heart Transplantation: Incidence, Trends, and Associated Risk Factors." 1466.

¹⁷ Nicoara, Alina, et al. "Primary Graft Dysfunction after Heart Transplantation: Incidence, Trends, and Associated Risk Factors." 1466.

¹⁸ Kobashigawa, Jon, et al. "Report." 328.

¹⁹ Quader, Mohammed, et al. "Primary Graft Dysfunction after Heart Transplantation." 1520.

²⁰ OPTN, Thoracic Organ Transplantation Committee, Meeting summary, September 18, 2014.

Development Process

In August 2020, the Committee identified PGD as a high priority project and sought to identify the most important parameters needed to identify PGD. They acknowledged that current data collection efforts were inadequate to actually define PGD based on the recent consensus definition. Data collection that accurately captures the incidence of PGD will enable the heart transplant community to better assess the impact PGD has on the morbidity and mortality of heart transplant recipients. Information collected as part of this initiative will be used to develop future policy options. Furthermore, PGD-specific data may be beneficial to the Committee as it develops a continuous distribution allocation framework, which is expected to begin in early 2023. This document presents the transplant community with an opportunity to discuss and provide feedback on the information that should be considered for a future data collection proposal.

A Subcommittee was created to address the majority of the work, and tasked with defining the project's scope and identifying potential data elements. It was determined that obtaining community feedback would help them identify the best data elements to consider. As a result, the members developed this Request for Input document as a way to gather such information during the January-March, 2021 public comment cycle. The OPTN Data Advisory Committee was engaged and was told how the project aligns with the OPTN Data Collection Principles and the standard of review checklist. The Heart Committee is approaching the project in two phases; this initial request for input, and a presumed subsequent data collection proposal.

Suggested Data Elements

Based on previous discussions, the Committee is seeking feedback on the following data elements that could potentially be collected on the Transplant Recipient Registration (TRR) form to capture information about PGD. In addition, the Committee is seeking the community's feedback regarding how soon after the transplant the information should be collected. The Committee members decided to include more data elements than just those identified in the ISHLT consensus statement. They agreed that additional elements are needed in order to capture changes in clinical practice and research findings since the consensus statement was released in 2013.

PGD related data elements for assessing associated transplant mortality

The data elements the Committee selects will establish how detailed the future monitoring activities can be. However, the Committee also needs to consider how transplant programs will be impacted by the types of information requested and the volume of data elements that must be reported. The Committee also faces challenges when determining the level of detail to collect about treatments.

The Committee suggests collecting the data elements from all heart transplant recipients at an early time point following transplant. Programs will be asked to provide clinical values for certain PGD-related data. **Table 1 on the following page** reflects the data elements the Committee initially identified. The members chose these elements as if they would pursue an expansive data collection effort. The table also shows the values or ranges associated with the data elements.

In addition to these data elements identified for collection, Body Surface Area will be calculated based on the Dubois method using the entries transplant program staff provide for height and weight and will be measured in meters².

Table 1: Potential Data Elements for Addition to the Transplant Recipient Registration Form (TRR) Associated with Primary Graft Dysfunction (PGD)

Data Element	Values and/or Range
Primary Graft Dysfunction	Yes or no
Left Ventricular Dysfunction	Yes or no
Right Ventricular Dysfunction	Yes or no
Left Ventricular Ejection Fraction	Percentage
Right Atrial Pressure (RAP)	mm Hg
Pulmonary Capillary Wedge Pressure (PCWP)	mm Hg
Pulmonary Artery Systolic Pressure Pulmonary Artery Diastolic Pressure	mm Hg
Cardiac Output ^b	L / min
Support device	Yes or no
If yes to support device	Right, left, or biventricular
Type of device ^c	Drop down list of devices
Inotrope support	Drop down list of drugs (Multiple selections of drug types are acceptable) Dosings (Exact doses or dose ranges)

^a PGD refers to graft dysfunction occurring immediately after transplant, requiring greater than typical medical support, or mechanical support. PGD is graft dysfunction not attributable to hyperacute rejection, acute rejection, antibody mediated rejection, surgical implant issues, or acute infarction.

^b Reported cardiac output will be used to calculate cardiac index in UNetSM.

^c See **Appendix B** for the list of support devices.

The Committee also seeks community feedback regarding the challenges associated with properly capturing PGD. Would programs be able to record vasoactive drug dosages or would a range of dosages be preferable? Should support devices used pre-transplant and continued post-transplant be excluded? The Committee also seeks community feedback regarding collection of data pertaining to the use of pre-transplant therapies that may increase the risk of PGD. While procurement type is included, there are other data elements, such as warm ischemia time, that are not currently collected and may be associated with PGD. Currently, OPTN data includes total ischemic time as a calculated field. Collecting warm ischemia time could be a large challenge for the heart transplant community to identify the appropriate time points and actions within the process.

Defining the timeframe following transplant for data collection

The Committee seeks community feedback regarding when a transplant program should collect PGD information. Monitoring and reporting activities involving PGD-related information will require that the data be collected shortly following transplant, contrasted to current follow-up forms that collect information six months or annually after transplant.

The Committee members discussed different data collection points following the transplant procedure. For example, some members stated that the information should be collected at 24 hours post-procedure, in part because the ISHLT consensus statement requires that a PGD diagnosis be made within that timeframe. Other members countered that a recipient may still be recovering from the surgical impacts at 24 hours. In such cases, it may be difficult to single out PGD from other complications. To address this, some members recommended data collection occur at 72 hours after transplant, or within 72 hours following transplant. This timeframe would be similar to that employed in the Lung TRR forms to collect lung-related PGD data. If data are to be collected within 72 hours, the Committee members discussed whether transplant programs should report the lowest or highest value recorded during the timeframe. The Committee seeks community feedback about the timeframes.

The Committee is also requesting feedback as to the appropriateness of permitting the medical team caring for the patient to determine the postoperative timeframe of hemodynamic and vasoactive medications. Potential postoperative options include: in the operating room; first day in the Intensive Care Unit (ICU), second day in the ICU, etc. Should the worse hemodynamic measurements and highest doses of medications be recorded or should it be at a specific time point?

Consideration of risk factors as potential data elements for collection

The Committee seeks feedback from the community about whether to collect new predictive and operational data elements, potentially associated with PGD, such as details of organ preservation procedure, and warm ischemia time. The members request input as to whether such information would be useful when monitoring outcomes in the future or for assisting with future policy development decisions.

The Committee members discussed that while the type of perfusion solution is collected currently through OPTN data submission, the amount of solution nor the presence or absence of bag pressure is not. The amount of solution used may be helpful in identifying if PGD has occurred or if another complication is present.

The Committee also requests community input about factors associated with procurement as potential data elements. The factors could include whether the organ was procured by a team from the donor hospital or a team from the transplant program, as well as cold, and warm ischemia times. The Deceased Donor Registration (DDR) form collects the data elements: Clamp Date, Clamp Time, and Clamp Time Zone, which are used to determine when cold ischemia time begins. The Committee is also interested in the warm ischemia time associated with hearts procured related to Donation after Cardiac Death (DCD). The heart transplantation community is asked to comment on the advantages and disadvantages associated with collecting warm ischemia time. Furthermore, the Heart Committee requests input to identify the most important time points for collecting warm ischemia information. These might include steps in the process such as removal from cold storage, first anastomosis, and/or reperfusion.

Consideration of eliminating data elements from the Heart-related collection forms

Exhibit 1 shows the post-transplant clinical information currently collected on the adult heart Transplant Recipient Registration (TRR) form. The Committee identified "Airway Dehiscence" for potential removal from the heart TRR because it is not relevant to heart transplants. The Committee also discussed the relevance to heart transplantation of the options included with the Primary Cause of Graft Failure," and whether additional options should be included. The Committee is requesting the community's feedback concerning the removal of airway dehiscence, and the primary causes of graft failure.

Exhibit 1: Adult Heart Transplant Recipient Registration Form

Clinical Information : POST TRANSPLANT

Graft Status: * Functioning Failed
If death is indicated for the recipient, and the death was a result of some other factor unrelated to graft failure, select Functioning.

Date of Graft Failure:

Primary Cause of Graft Failure: Primary Non-Function
 Acute Rejection
 Chronic Rejection/Atherosclerosis
 Other, Specify

Specify:

Events Prior to Discharge:

Stroke: * YES NO UNK

Dialysis: * YES NO UNK

Permanent Pacemaker: * YES NO UNK

~~Airway Dehiscence: * YES NO UNK~~

Source: Heart Transplant Recipient Registration form.

NOTA and Final Rule Analysis

The Request for Input intends to gather feedback from the community about PGD data collection. The document is an initial step towards an official data collection proposal in the future. The Committee submits this Request for Input for consideration under the authority of the OPTN Final Rule, which states, "An organ procurement organization or transplant hospital shall...submit to the OPTN...information regarding transplant candidates, transplant recipients, [and] donors of organs..."²¹ The OPTN shall "maintain records of all transplant candidates, all organ donors and all transplant recipients."²² This Request for Input will help the Committee's consideration of PGD-related data elements to recommend for future collection on heart transplant recipients.

²¹ 42 CFR §121.11(b)(2).

²² 42 CFR §121.11(a)(1)(ii).

Implementation Considerations

Member and OPTN Operations

While the document is only requesting feedback, the operations of the transplant programs, OPOs, histocompatibility labs, and the OPTN should not be affected. At the same time, the Committee encourages feedback describing how the proposed new data collection may cause operational concerns within the transplant community.

Project Fiscal Impact

Minimal or no expected fiscal impact for transplant hospitals, OPOs, or histocompatibility labs. Likewise, there is minimal or no expected fiscal impact for the OPTN. The Committee requests input from the transplant community as to the whether the proposed new data collection would result in a fiscal impact to OPTN members.

Summary

Primary Graft Dysfunction has a substantial effect on the morbidity and mortality of heart transplant recipients. The intent of this request for input is to solicit community feedback on a specific set of new data elements and data-related questions which will help the Committee as it develops a future PGD data collection proposal. The new data elements the Committee is proposing are not currently collected by the OPTN. The Committee knows that several years of data collection may be necessary before there will be enough data for an appropriate analysis, and to promote informed discussions and decisions regarding potential policy development.

The Committee is requesting feedback about the following:

Data elements and timing

- What, if any, data elements should be included?
- Is it appropriate to focus on moderate to severe PGD? Or, should only severe PGD requiring mechanical support be collected?
- How many hours following completion of the transplant should the data be collected? (When should the data be collected? For example, arrival in ICU? 24 hours? 72 hours? Another time?)
- Should the Committee collect an expansive or narrow amount of data?
- What, if any, left ventricular assist device (LVAD)-related information should be collected that would benefit a review of primary graft dysfunction? (How can that information be collected in the most consistent, straightforward way possible?)
- What information should be collected and reported about Donation after Cardiac Death (DCD) donors that could help the Committee better consider the impact of such donors on the incidence of PGD?

Other

- What challenges would this request present for transplant programs responsible for collecting the additional data?

- Do transplant programs have the necessary information to report this data?
- Is the Transplant Recipient Registration (TRR) form the correct data collection tool to use?
- Should the data collection be part of the “Clinical Information: POST TRANSPLANT” section of the TRR, or is there a more appropriate section?
- Are there differences and/or similarities between adult and pediatric PGD the Heart Committee should consider as part of its future reviews?
- How can the Committee ensure the data collection is reported consistently by all transplant programs?
- Do Organ Procurement Organizations have the necessary information about DCD donors that would benefit this project?

Appendix A: ISHLT Consensus Statements on Primary Graft Dysfunction (PGD) and Definition of Severity Scale for PGD

Consensus Statements

1. Graft dysfunction is to be classified into PGD or secondary graft dysfunction where there is a discernible cause such as hyperacute rejection, pulmonary hypertension, or known surgical complications (e.g., uncontrolled bleeding).
2. The diagnosis of PGD is to be made within 24 hours after completion of the cardiac transplant surgery.
3. PGD is to be categorized into PGD-LV or PGD-RV.
4. A severity scale for PGD-LV will include mild, moderate or severe grades based on specified criteria.
5. Risk factors are categorized in terms of donor, recipient, or surgical procedural factors. Optimization of risk factors and improved allocation and matching of donors and recipients may result in decreased incidence of PGD.
6. Medical management with inotropic support should initially be instituted for PGD. The use of levosimendan may also be helpful. For PGD-RV, nitric oxide and phosphodiesterase inhibitors may be helpful.
7. Mechanical circulatory support of PGD such as ECMO is indicated when medical management is not sufficient to support the newly transplanted graft.
8. Retransplantation for severe PGD may be indicated in select patients if risk factors are minimal.
9. All patients in whom mechanical circulatory support is placed directly into the heart should have a biopsy performed at that time.
10. It was recommended that an autopsy should be performed in all patients who are diagnosed with PGD and subsequently expire.
11. Potential future studies include creation of a PGD registry, impact of preservation solutions on PGD, mechanistic studies to understand pathophysiology of PGD, and study of donor management to minimize PGD, among others.

Definition of Severity Scale for Primary Graft Dysfunction (PGD)

1. PGD Left ventricle (PGD-LV):	<i>Mild PGD-LV: One of the following criteria must be met:</i>	LVEF \leq 40% by echocardiography, <i>or</i> Hemodynamics with RAP > 15 mm Hg, PWCP > 20 mm Hg, CI < 2.0 L/min/m ² (lasting more than 1 hour) requiring low-dose inotropes
	<i>Moderate PGD-LV: Must meet one criterion from I and another criterion from II:</i>	I. <i>One</i> criteria from the following: Left ventricular ejection fraction \leq 40%, <i>or</i> Hemodynamic compromise with RAP > 15 mm Hg, PCWP > 20 mm Hg, 20 mm Hg, CI < 2.0 L/min/m ² , hypotension with MAP < 70 mm Hg (lasting more than 1 hour) II. <i>One</i> criteria from the following: i. High-dose inotropes—Inotrope score > 10 ^a <i>or</i> ii. Newly placed IABP (regardless of inotropes)
	<i>Severe PGD-LV</i>	Dependence on left or biventricular mechanical support including ECMO, LVAD, BiVAD, or percutaneous LVAD. Excludes requirement for IABP.
2. PGD-right ventricle (PGD-RV):	Diagnosis requires either both I and ii, or iii alone:	i. Hemodynamics with RAP > 15 mm Hg, PCWP < 15 mm Hg, CI < 2.0 L/min/m ² ii. TPG < 15 mm Hg and/or pulmonary artery systolic pressure < 50 mm Hg, <i>or</i> iii. Need for RVAD

BiVAD, biventricular assist device; CI, cardiac index; ECMO, extracorporeal membrane oxygenation; IABP, intra-aortic balloon pump; LVAD, left ventricular assist device; PCWP, pulmonary capillary wedge pressure; RAP, right atrial pressure; RVAD, right ventricular assist device; TPG, transpulmonary pressure gradient.

^a Inotrope score = dopamine (x1) + dobutamine (x1) + amrinone (x1) + milrinone (x15) + epinephrine (x100) + norepinephrine (x100) with each drug dosed in $\mu\text{g}/\text{kg}/\text{min}$.

Source: Kobashigawa, Jon, Zuckermann, Andreas, Macdonald, Peter, Leprince, Pascal, Esmailian, Fardad, Luu, Minh, Mancini, Donna, Patel, Jignesh, Razi, Rabia, Reichenspurner, Hermann, Russell, Stuart, Segovia, Javier, Smedira, Nicolas, Stehlik, Josef, and Wagner, Florian. "Report from a Consensus Conference on Primary Graft Dysfunction after Cardiac Transplantation." *The Journal of Heart and Lung Transplantation* 33, no. 4 (2014): 337-38.

Appendix B: List of Mechanical Circulatory Support Devices Associated with Certain Adult Heart Statuses

Dischargeable VADs	Non-Dischargeable VADs	Percutaneous Devices	Total Artificial Hearts
Evaheart	Abiomed AB5000	Biomedicus	AbioCor
Heartmate II	Abiomed BVS 5000	Cardiac Assist Tandem Heart	SynCardia CardioWest
Heartmate III	Berlin Heart EXCOR	Cardiac Assist Protek Duo	Other Specify
Heartsaver VAD	Biomedicus	CentriMag (Thoratec/Levitronix)	—
Heartware HVAD	CentriMag (Thoratec/Levitronix)	Impella Recover 2.5	—
Jarvik 2000	Maquet Jostra Rotaflow	Impella Recover 5.0	—
ReliantHeartAssist 5	Medos	Impella CP	—
ReliantHeart aVAD	PediMag (Thoratec/Levitronix)	Impella RP	—
Worldheart Levacor	Terumo Duraheart	Maquet Jostra Rotaflow	—
Other Specify	Thoratec IVAD	PediMag (Thoratec/Levitronix)	—
—	Thoratec PVAD	Other Specify	—
—	Toyobo	—	—
—	Ventricor VentrAssist	—	—
—	Other Specify	—	—

Notes: There are no device brands for Venoarterial Extracorporeal Membrane Oxygenation (VA ECMO) or Intra-aortic Balloon Pump (IABP). The “Other Specify” category is included for instances where a candidate’s device brand is not identified.

Source: OPTN website (accessed on November 8, 2020):

https://optn.transplant.hrsa.gov/media/2457/heart_device_brand_background.pdf