

Briefing to the OPTN Board of Directors on

Enhancements to OPTN Donor Data and Matching System Clinical Data Collection

OPTN Organ Procurement Organization Committee

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Enhancements to OPTN Donor Data and Matching System Clinical Data Collection

Sponsoring Committee: Organ Procurement Organization
Public Comment Period: August 3, 2022 – September 28,
Board of Director's Date: December 5, 2022

Executive Summary

A donation after circulatory death (DCD) donor is a donor who has suffered devastating and non-survivable brain injury and requires ventilator support to sustain life, but does not meet formal brain death criteria.¹ After authorization for donation, the organ recovery process for a DCD donor begins with the withdrawal of life sustaining medical support, with the donor monitored and managed through their progression to death, or cessation of circulation. Once the donor's death has been pronounced, the organs are perfused and recovered for transplantation. Several aspects of the DCD process can influence organ quality and impact projected graft and patient outcomes, making DCD progression information vital to organ offer evaluation information. Although transplants from DCD donors have steadily increased each year, current data collection related to DCD donors within the OPTN Donor Data and Matching System is limited to a single question regarding the donor's DCD status.

The OPTN Organ Procurement Organization (OPO) Committee proposes the addition of several data fields specific to DCD to the OPTN Donor Data and Matching system, in order to streamline communication between OPOs and transplant hospitals and improve the efficiency of offer evaluation. The proposed data collection will provide transplant programs with the necessary clinical information critical to evaluating DCD organ offers. This will streamline communications between OPOs and transplant hospitals and improve efficiency of offer evaluation.

¹ University of California Davis Transplant Center, Donation After Cardiac Death (DCD).
<https://health.ucdavis.edu/transplant/nonlivingdonors/donation-after-cardiac-death.html#:~:text=A%20donor%20after%20cardiac%20death,has%20decided%20to%20withdraw%20care.>

Purpose

The purpose of this data collection proposal is to streamline communication of DCD donor information between OPOs and transplant hospitals, in order to improve efficiency of offer evaluation and allocation efficiency. This proposal will provide key clinical information related to donor progression of death, warm ischemic time, cold ischemic time, and the use of normothermic regional perfusion (NRP). The proposed data collection will support more efficient donor evaluation, as this information will be easily accessible in the OPTN Donor Data and Matching System, which will increase overall allocation efficiency, reducing cold ischemic times and supporting increased DCD transplantation.

Background

In 2020, the OPTN Policy Oversight Committee established several efficient matching workgroups to develop recommendations for projects that would have the biggest impact on increasing the number of transplants and promoting the efficiency of the OPTN. These projects focus on developing strategies for increasing the efficiency of organ placement, and include concurrent work on organ offer filters, addressing the use of provisional yes acceptances, and proposing changes to the OPTN Donor Data and Matching System. With the recent changes to organ allocation policies focusing on broader distribution, the transplant community has identified several logistical opportunities to streamline communications and information sharing.

The OPO Committee’s Technology Tools Workgroup (the Workgroup) initially focused on providing critical user feedback on current Information Technology (IT) projects, such as image sharing, application notifications, the OPTN Donor Data and Matching System mobile application, and chat capabilities. During these discussions, the Workgroup identified several communication enhancements in the OPTN Donor Data and Matching System to promote efficient information sharing, including the addition of several data fields related to DCD. Although this information is critical to DCD organ offer evaluation, there are currently no specific data fields for clinical DCD progression information. Instead, this information is typically relayed verbally or scanned and uploaded as an attachment into the OPTN Donor Data and Matching System.

Furthermore, DCD donations have steadily increased over time; the rate of DCD donations has nearly doubled since 2015, as shown in **Figure 1**.² The increasing relevance of donation after circulatory death further emphasizes the need to accommodate clinical DCD information and facilitate DCD recovery and transplantation through policy and system improvements.

Figure 1: Deceased Donors by Donor Type

	2021	2020	2019	2018	2017	2016	2015
Total Deceased Donors	13,863	12,588	11,870	10,721	10,286	9,971	9,079
Brain Death Donors	9,673	9,364	9,152	8,589	8,403	8,287	7,585
DCD Donors	4,190	3,224	2,718	2,132	1,883	1,684	1,494
% of DCD Donors	30%	26%	23%	20%	18%	17%	16%

In February of 2022, the National Academies of Sciences, Engineering, and Medicine (NASEM) published the *Realizing the Promise of Equity in the Organ Transplantation System* report, with several recommendations to improve the organ transplant system in the United States. One such recommendation focused on increasing transplants from donors after circulatory death “to at least 45

² <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#>

percent of all deceased donors, with no reductions in the numbers of organs procured from donors from neurological determination of death.”³ This recommendation aims to increase the number of transplants by encouraging increased DCD recovery and increased utilization of DCD organs for transplantation. Such an increase in DCD recovery and transplantation will require a collaborative approach between OPOs and transplant hospitals, as well as updates to the OPTN Computer System to facilitate allocation and streamline communication.

DCD progression information is essential for offer evaluation across organ types. In considering DCD livers, a progressive drop in blood pressure and oxygen saturation during an extended withdrawal period presents risk to graft viability.⁴ Similarly, a sustained drop in the donor’s blood pressure or hypoxia can induce ischemic kidney injury.⁵ The addition of these proposed data elements will allow transplant hospitals to better evaluate DCD organ offers by providing more efficient access to DCD progression information. The provision of the proposed DCD clinical data elements will streamline communication between OPOs and transplant programs and improve efficiency of offer evaluation. An increase in evaluation efficiency will streamline allocation, which aims to reduce cold ischemic times and subsequently supports an increase in transplants, specifically DCD transplants.

Overall Sentiment from Public Comment

Committee members presented the proposal to three other OPTN committees and to all eleven OPTN regions for feedback, and a video presentation describing the proposal was posted to the OPTN website. Six professional organizations as well as a number of transplant programs, OPOs, and individuals provided written public comment. The transplant and donation community was generally supportive of this proposal, with a number of comments suggesting the addition of normothermic regional perfusion (NRP) data.

Sentiment is collected on all public comment proposals, and is measured on a 5-point Likert scale from strongly oppose to strongly support (1-5). The proposal collected sentiment from 176 respondents, including 87 written comments (about 49% of all responses).

³ National Research Council. 2022. *Realizing the Promise of Equity in the Organ Transplantation System*. Washington, DC: The National Academies Press. <https://doi.org/10.17226/26364>.

⁴ Hashimoto K. Liver graft from donation after circulatory death donor: Real practice to improve graft viability. *Clin Mol Hepatol*. 2020;26(4):401-410. doi:10.3350/cmh.2020.0072

⁵ Gill J, Rose C, Lesage J, Joffres Y, Gill J, O’Connor K. Use and Outcomes of Kidneys from Donation after Circulatory Death Donors in the United States. *J Am Soc Nephrol*. 2017 Dec;28(12):3647-3657. doi: 10.1681/ASN.2017030238. Epub 2017 Oct 5. PMID: 28982695; PMCID: PMC5698075.

Figure 2 shows the sentiment received from all respondents (regional meeting, online, and email) by their stated member type. Again, there was general support for the proposed data elements, demonstrated by a total sentiment score of 4.2.

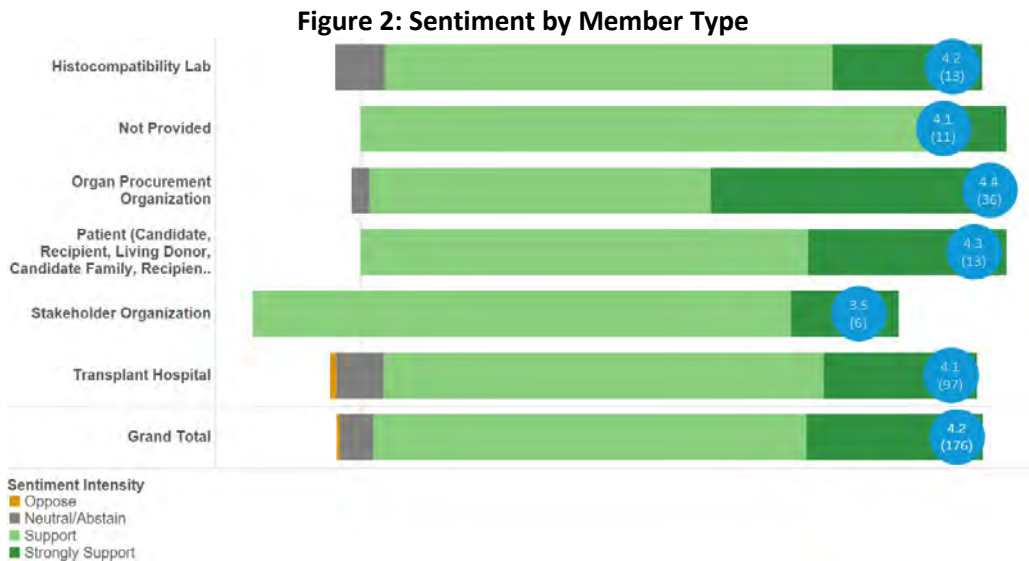
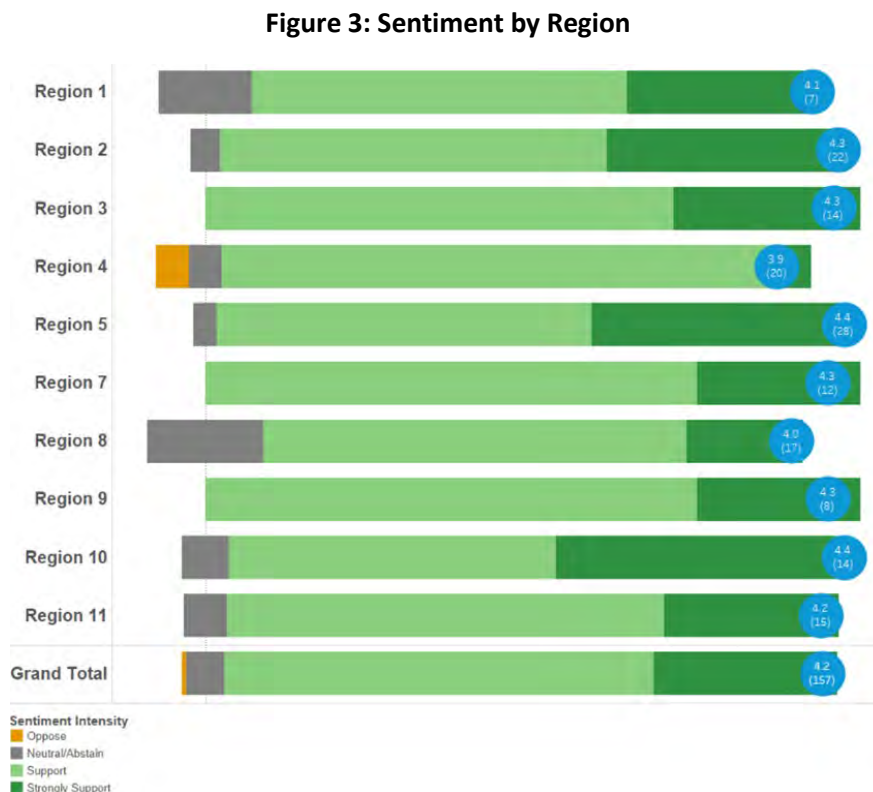


Figure 3 shows sentiment received at regional meetings. Again, overall sentiment was supportive, as indicated by a total sentiment score of 4.2. The lower overall sentiment noted in Region 4 can be attributed to a single “oppose” sentiment. The reason for the opposition is not known since there were no comments indicating a lack of support for the proposal.



In addition to the sentiment score, items out for public comment also provide the opportunity for respondents to submit a substantive written comment. Responses are submitted by members of the public at large, as well as on behalf of regions and committees.⁶

Commenters covered several different topics, including the following main themes. Each theme is described based on the feedback provided and, where able, excerpts from relevant comments are included.

- NRP data collection
- Link between OPO electronic donor records and OPTN Donor Data and Matching System
- Support for a separate page for DCD information

NRP Data

The collection of NRP data was the most common comment throughout the regional meetings and through online submissions on the OPTN website. The transplant community recognizes the increased use of NRP as a method for maintaining solid organ allografts following DCD donation. NRP is used during organ recovery to “maintain the thoracic and organ perfusion to allow organs [donors] to have time to recover from the warm ischemic injury.”⁷ This technique is becoming more common and the OPTN Ethics Committee is currently developing a white paper to address the ethical considerations of NRP. There were several suggestions, in particular from the OPTN Lung Transplantation Committee and the American Society of Transplantation, to include more granular data on NRP such as type, temperature, and amount of flush solution, method of cerebral protection, and peak lactate serum levels. While these clinical elements may be important and provide valuable donor evaluation information, the OPO Committee recommended that data collection, at this time, should only include basic information. This includes whether NRP recovery was performed as well as the date and time of initiation of NRP perfusion.

Link between OPO Donor Records and OPTN Donor Data and Matching System

There was considerable input about the need to provide a seamless flow of information from the OPO’s electronic donor records into the OPTN Donor Data and Matching System. Since much of the data being proposed is already collected by OPOs, this would allow for timely uploads into the OPTN Computer System to ensure the necessary information is available to transplant hospitals. This functionality is currently available and enables users to save data from the OPO’s data system into the OPTN Donor Data and Matching System. This eliminates the need to duplicate data entry, improves data accuracy, and streamlines OPO workflow processes.

⁶ For comments submitted on behalf of the region or committees, the public comment item is discussed at the meeting, OPTN staff draft a summary of the discussion, and the Regional Councillor or Committee leadership review the comment, confirming it is an accurate representation of the discussion that occurred.

⁷ Alamouti-Fard E, Garg P, Wadiwala I J, et al. (June 29, 2022) Normothermic Regional Perfusion is an Emerging Cost-Effective Alternative in Donation After Circulatory Death (DCD) in Heart Transplantation. *Cureus* 14(6): e26437. doi:10.7759/cureus.26437

Separate Page in the OPTN Donor Data and Matching System for DCD Information

The proposal asked the community for feedback on creating a separate page within the system for DCD information. This would allow transplant hospitals to review the information in one location in order to efficiently evaluate organ offers from DCD donors. There was general support for this approach during public comment. The addition of specific data elements will allow transplant centers to review key information about the progression of DCD donors without searching through information provided in attachments within the OPTN Donor Data and Matching System. While this effort would be outside the scope of this proposal, as information about NRP and DCD is expanded, there will be an opportunity to evaluate the best approach to make these changes.

Additional Comments

There was a variety of additional comments provided on this proposal.

- *Standardized definition for the agonal phase* – The Committee noted that there is still variation in the definition amongst transplant programs. The Committee agreed that OPOs should not be defining agonal phase, which is the period in which the donor is progressing to death, instead just providing the information to the transplant programs to make their own interpretation.
- *Explant time for each organ, time from incision to organ flush, and time from flush to placement on perfusion device* – The Committee expressed concern with adding explant time due to a potential conflict with the current definition of recovery date. Additionally, OPOs currently document incision time, initiation of flush, and placement on a perfusion device and this information can be provided as an operative stage report attachment.
- *Extracorporeal membrane oxygenation (ECMO)* – There was a comment about collecting the duration of ECMO. The Committee members noted that ECMO information is currently collected in the deceased donor registration (DDR) but only addresses ECMO support during hospitalization, not as part of the organ recovery process. There was a suggestion to review the DDR definition so that it is clear that the current field in the OPTN Computer System continues to represent ECMO use prior to declaration of death.

Proposal for Board Consideration

The OPO Committee proposes adding the following data elements to the OPTN Donor Data and Matching System related to DCD donors:

Uncontrolled or Controlled DCD

One of the specific requests for feedback from the community was the use of a validator question that would trigger the collection of the proposed DCD donor information. For example, the data fields would only be available in the case of a controlled DCD donation, where organ recovery is planned before circulatory death occurs. There was support for this approach; however, because uncontrolled DCD

donations do occur, the Committee ultimately decided to allow the collection of the DCD information regardless of whether it is an uncontrolled or controlled DCD donation.

Timing of Withdrawal of Life-Sustaining Medical Support

The withdrawal of life sustaining medical support initiates the circulatory death process, and marks the beginning of the donor's progression to circulatory death. Systolic blood pressure and oxygen saturation, along with other key vitals, are monitored throughout this process to note the beginning of the agonal phase, once systolic blood pressure and oxygen saturation parameters are met.⁸ The agonal phase is the period in which the donor is progressing to death. Extended durations of the agonal phase have been found to be associated with an increased risk of delayed graft function for kidney recipients.⁹

Timing of Cessation of Circulation

Cessation of circulation, indicated by cardiac arrest, denotes the end of the agonal phase and the beginning of warm ischemia time. Warm ischemic time measures the period of time for which there is inadequate oxygenation or perfusion of the organs, an inherent aspect of DCD progression.¹⁰ Inadequate oxygenation of the organs poses risk of irreversible ischemic injury, making warm ischemic time an important piece of clinical information for organ evaluation. Longer warm ischemic times can be a contributing factor on outcomes.¹¹ "In DCD, donor warm ischemia time starts with the withdrawal of treatment in the donor, whereafter the vital parameters drop towards asystole and continues until the start of cold perfusion."¹²

Flush Time (In Situ)

Cold perfusion, or organ "flush," denotes the end of warm ischemic time and the start of cold ischemic time, when the donor organ is cross-clamped and cold perfusion solution is administered through cannula insertion.¹³ Cold perfusion is used to slow tissue metabolism, reducing the rate of ischemic injury and preserving the organs for recovery.¹⁴ Although the rate of ischemic injury is significantly reduced during cold perfusion, cold ischemic time can contribute to the risk of organ injury. Extended cold ischemic times have been linked to delayed graft function, graft rejection, and worse outcomes, making cold ischemic time another critical piece of clinical information in organ evaluation.¹⁵

⁸ <https://optn.transplant.hrsa.gov/patients/glossary/#W>

⁹ Peters-Sengers; DCD Donor Hemodynamics as a Predictor of Outcome after Kidney Transplantation, *American Journal of Transplantation*, Volume 18 Issue 8 (January 2018). <https://doi.org/10.1111/ajt.14676>

¹⁰ <https://academic.oup.com/bjaed/article/11/3/82/257079>

¹¹ Vinson, Amanda J. MD1; Rose, Caren PhD2,3,4; Kiberd, Bryce A. MD1; Odutayo, Ayodele MD5,6; Kim, S. Joseph MD7,8; Alwaysn, Ian MD9; Tennankore, Karthik K. MD1 Factors Associated With Prolonged Warm Ischemia Time Among Deceased Donor Kidney Transplant Recipients, *Transplantation Direct*: May 2018 - Volume 4 - Issue 5 - p e342 doi: 10.1097/TXD.0000000000000781

¹² Kalisvaart, Marit MD, PhD1; Croome, Kristopher P. MD, MS2; Hernandez-Alejandro, Roberto MD3; Pirenne, Jacques MD, PhD4; Cortés-Cerisuelo, Miriam MD, PhD5; Miñambres, Eduardo MD, PhD6; Abt, Peter L. MD7. Donor Warm Ischemia Time in DCD Liver Transplantation—Working Group Report From the ILTS DCD, Liver Preservation, and Machine Perfusion Consensus Conference. *Transplantation*: June 2021 - Volume 105 - Issue 6 - p 1156-1164 doi: 10.1097/TP.0000000000003819

¹³ Ibid.

¹⁴ Ibid.

¹⁵ [https://www.kidney-international.org/article/S0085-2538\(15\)30070-3/fulltext](https://www.kidney-international.org/article/S0085-2538(15)30070-3/fulltext)

Different cannulation sites are utilized to flush different organs. The abdominal aorta is typically used for kidney and pancreas procurement, the portal vein for liver procurement, the thoracic aorta for heart procurement, and the pulmonary artery for lung procurement. To capture this, the Committee proposes separate data fields to capture flush time for each cannulation site utilized:

- Abdominal aorta
- Portal vein
- Thoracic aorta
- Pulmonary artery

Separate, cannulation site-specific flush data fields will provide the most accurate information regarding cold ischemic time for specific organs.

Oxygen Saturation

Oxygen saturation, measured as SpO₂, is monitored alongside blood pressure and heart rate for the duration of a DCD donor's progression. This key vital measurement can be used to determine the beginning of the agonal phase, and provides offer-evaluating transplant clinicians a critical and comprehensive understanding of the DCD donor's progression from withdrawal to pronouncement of death. This information will be collected in a similar manner as current vital sign data collection.

Normothermic Regional Perfusion

As noted previously, the most common theme during public comment was the recommendation to include information about normothermic regional perfusion, or NRP. The Committee agreed that collecting whether NRP recovery was performed as well as the initiation of NRP perfusion was an appropriate first step for data collection. The Committee agreed that the technology needs to evolve before committing resources for additional data collection in the system.

The proposed change will collect yes or no for use of NRP recovery as well as date and time of initiation of NRP perfusion.

Compliance Analysis

NOTA and OPTN Final Rule

The OPO Committee submits this proposal under the authority of NOTA, which requires the OPTN to "collect, analyze, and publish data concerning organ donation and transplants,"¹⁶ and the OPTN Final Rule, which requires the OPTN to "maintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors..."¹⁷, and "maintain records of all transplant candidates, all organ donors and all transplant recipients."¹⁸ The Final Rule also requires that "organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN, to the Scientific Registry, as appropriate, and to the Secretary information regarding transplantation candidates, transplant recipients, donors of organs,

¹⁶ 42 U.S.C. §274(b)(2)(I)

¹⁷ 42 CFR §121.11(a)(1)(i)

¹⁸ 42 CFR §121.11(a)(1)(ii)

transplant program costs and performance, and other information that the Secretary deems appropriate.”¹⁹ Organ procurement organizations (OPOs) submit data on deceased donors electronically through the OPTN Computer System, a secure web-based data collection system. This includes the OPTN Donor Data and Matching System, which is used by OPOs to enter deceased donor information for use by transplant programs to evaluate organ offers.

OPTN Strategic Plan

This proposal aligns with the OPTN Strategic Goal to increase the number of transplants.²⁰ One of the initiatives within this goal is to “increase the number of donation after circulatory death (DCD) donor organs recovered and transplanted by encouraging inter-organ and inter-program collaboration and development of best practices.” As noted earlier in this briefing paper, the use of DCD donors has been increasing every year. This proposal will support these efforts by improving the information sharing between OPOs and transplant hospitals during the DCD process. Efficient organ evaluation and placement is important to facilitate the placement of organs from DCD donors.

OPTN Data Collection Principles

This proposal aligns with the following OPTN Data Collection Principle: Fulfill the requirements of the OPTN Final Rule. Section § 121.7(b)(3) states that “an organ offer is made when all information necessary to determine whether to transplant the organ into the potential recipient has been given to the transplant hospital.”²¹ This proposal provides additional information regarding DCD donors that will allow for improved organ offer evaluation. It will allow transplant hospitals to better determine if an offer from a DCD donor is appropriate for their potential transplant recipients.

Implementation Considerations

Member and OPTN Operations

Operations affecting Organ Procurement Organizations

This proposal will provide additional data fields in the OPTN Donor Data and Matching System. This may require OPOs to update their electronic donor records to allow for updated DCD information on active donor cases.

Operations affecting Transplant Hospitals

This proposal is not anticipated to affect the operations of transplant hospitals, however, it will provide additional DCD information in which a transplant hospital can review when evaluating organ offers.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

¹⁹ 42 CFR §121.11(b)(2)

²⁰ <https://optn.transplant.hrsa.gov/about/strategic-plan/goal-1/>

²¹ 42 CFR §121.11(b)(2)

Operations affecting the OPTN

This proposal would require implementation in the OPTN Computer System, specifically, the OPTN Donor Data and Matching System. OPTN Donor Data and Matching System alignment will include updating the mobile Donor Data and Matching System application to display the new fields.

This proposal requires the 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 OMB approved data collection forms. Therefore, if approved by the OPTN Board, 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.

Projected Fiscal Impact

This proposal is projected to have a fiscal impact on the OPTN, organ procurement organizations (OPOs), and transplant hospitals, but it is not anticipated to have any fiscal impact on histocompatibility laboratories.

This fiscal analysis is performed by the OPTN Fiscal Impact Group (FIG). The purpose of the FIG is to gather fiscal impact information to allow the OPTN Board of Directors to consider high level, direct financial implications on OPTN members as part of their decision-making process. FIG members represent transplant programs, OPOs, and histocompatibility laboratories.²²

Projected Impact on Organ Procurement Organizations

OPOs are expected to experience a minimal fiscal impact from the proposed changes associated with collecting the proposed data elements. The information is already collected by OPOs and several data elements, such as flush time, are already reported to the OPTN in the deceased donor registration (DDR). The changes may require some OPOs to make changes to their electronic data reporting systems in order to reduce the data entry burden.

Projected Impact on Transplant Hospitals

There will be minimal to no impact for transplant hospitals. There is no data entry required for the transplant hospital, but hospital staff will be able to view new fields and information available in the OPTN Donor Data and Matching System.

Projected Impact on Histocompatibility Laboratories

There is no expected fiscal impact for histocompatibility laboratories.

Projected Impact on the OPTN

The OPTN Contractor estimates 2115 hours for implementation. Implementation will involve updates to the OPTN Computer System, education and training on the changes, and communication efforts about

²² OPTN Transplant Administrators Committee Meeting Summary. May 26, 2021. Available at https://optn.transplant.hrsa.gov/media/4658/20210526_tac_meeting-summary.pdf

the changes. The OPTN contractor estimates 180 hours for ongoing support. Ongoing support will involve answering member questions, as necessary, and monitoring post-implementation at one year.

Post-implementation Monitoring

Member Compliance

This proposal will not change current routine monitoring of OPTN members. At OPOs, site surveyors will continue to review a sample of donor records, and any material incorporated into the medical record by reference, to verify that data reported in the OPTN Computer System are consistent with source documentation.

Data Collection Monitoring

These data modifications will be formally evaluated approximately 1 year post-implementation. Metrics will be evaluated as data become available (appropriate lags to allow for data submission will be applied, per typical OPTN conventions) as a “point forward” analysis as these are new fields being added to the OPTN Donor Data and Matching System. Summary statistics, distributions, as well as instances of absence of added data elements will be calculated.

Conclusion

This proposal would add several data fields to the OPTN Donor Data and Matching System that will collect important information about DCD donors. The current lack of discrete data fields impacts the ability for transplant hospitals to efficiently assess DCD donors.

This proposal addresses one aspect of the Policy Oversight Committee’s priority to improve efficiency in allocation through streamlined communication and offer evaluation within the OPTN Donor Data and Matching System. The OPO Committee proposes the addition of several DCD-specific data fields to the OPTN Donor Data and Matching System, to improve communication of donor information to evaluating transplant hospitals.

The proposed data collection will provide transplant hospitals with necessary clinical information critical to DCD organ offer evaluation and streamline communication between OPOs and transplant hospitals. It aims to improve the efficiency of offer evaluation and placement, which will reduce cold ischemic times and support the increased use of DCD transplantation.

Proposed Data Elements

- 1 **OPTN Donor Data and Matching System Additions**
- 2
- 3 *ADD:* Controlled DCD, yes/no
- 4
- 5 *ADD:* Withdrawal of life-sustaining medical support, date/time
- 6
 - Format: MM/DD/YYYY and HH:MM
- 7
- 8 *ADD:* Cessation of circulation, date/time
- 9
 - Format: MM/DD/YYYY and HH:MM
- 10
- 11 *ADD:* Abdominal aorta flush time (in situ), date/time
- 12
 - Format: MM/DD/YYYY and HH:MM
- 13
- 14 *ADD:* Portal vein flush time (in situ), date/time
- 15
 - Format: MM/DD/YYYY and HH:MM
- 16
- 17 *ADD:* Thoracic aorta flush time (in situ), date/time
- 18
 - Format: MM/DD/YYYY and HH:MM
- 19
- 20 *ADD:* Pulmonary artery flush time (in situ), date/time
- 21
 - Format: MM/DD/YYYY and HH:MM
- 22
- 23 *ADD:* Oxygen saturation (SpO₂) - Serial
- 24
 - Format: Text field (Range: 0-100)
 - Format: MM/DD/YYYY and HH:MM
- 25
- 26
- 27 *ADD:* NRP recovery, yes/no
- 28
- 29 *ADD:* Initiation of NRP perfusion, date/time
- 30
 - Format: MM/DD/YYYY and HH:MM

Appendix A: Proposed Data Definitions

- **Controlled DCD, yes/no**
 - A controlled DCD donor is a donor whose life sustaining treatment will be withdrawn and whose family gave written consent for organ donation in the controlled environment; a donor awaiting circulatory arrest; patient on intensive care unit with non-survivable injuries who have withdrawal of life sustaining treatment.
- **Withdrawal of life-sustaining medical support, date/time** – Withdrawal of life-sustaining medical support involves the removal of all therapies intended to sustain life. Enter the date and time withdrawal of life-sustaining medical support was initiated.
Date: MM/DD/YYYY
Time: HH:MM
- **Cessation of circulation, date/time** – Cessation of circulation is the permanent and irreversible lack of circulation or heartbeat. Enter the date and time when cessation of circulation was determined.
Date: MM/DD/YYYY
Time: HH:MM
- **Flush time** – Flush time is the start of the infusion of cold preservation solution during organ procurement. Enter the date and time when flush solution was initiated.
Date: MM/DD/YYYY
Time: HH:MM
Note: This definition applies to all four flush entry points (abdominal aorta, portal vein, thoracic aorta, and pulmonary artery)
- **Oxygen saturation (SpO₂)** – SpO₂ is a measure of the amount of oxygen-carrying hemoglobin in the blood relative to the amount of hemoglobin not carrying oxygen. Enter the percentage in the text field.
Date: MM/DD/YYYY
Time: HH/MM
- **NRP recovery** – Normothermic regional perfusion (NRP) is the act of restoring the flow of oxygenated blood to the solid organs following declaration of death and reduce warm ischemic injury in donation after circulatory death (DCD) organ transplantation. Enter yes or no.
- **Initiation of NRP perfusion** – The time that oxygenated blood flow is restored to solid organs following declaration of death. Enter the date/time in the text fields.
Date: MM/DD/YYYY
Time: HH/MM