

Public Comment Proposal

Enhancements to OPTN Donor Data and Matching System Clinical Data Collection

OPTN Organ Procurement Organization Committee

*Prepared by: Robert A. Hunter
UNOS Policy and Community Relations Department*

Contents

Executive Summary	2
Purpose	3
Background	3
Overview of Proposal	4
Compliance Analysis	6
Implementation Considerations	6
Post-implementation Monitoring	8
Conclusion	8
Considerations for the Community	9
Appendix A: Proposed Data Fields	10
Appendix B: Proposed Data Definitions	11



Public Comment Proposal

Enhancements to OPTN Donor Data and Matching System Clinical Data Collection

Data Collection System Impacted: *OPTN Donor Data and Matching System*
Sponsoring Committee: *Organ Procurement Organization*
Public Comment Period: *August 3, 2022 – September 28, 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 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 DCDs 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, and cold ischemic time. 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

	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

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

recommendation focused on increasing transplants from donors after circulatory death “to at least 45 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. More efficient evaluation will similarly streamline allocation, reducing cold ischemic times and supporting an increase in DCD transplants, and so an overall increase in transplants.

Overview of Proposal

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

Withdrawal of Life Sustaining Medical Support, Date/Time

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 to note the beginning of the agonal phase, once systolic blood pressure and oxygen saturation parameters are met.⁶ 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.⁷

Cessation of Circulation, Date/Time

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.⁸ Inadequate oxygenation of the organs poses risk of irreversible ischemic injury, making warm ischemic time an

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.

⁶ <https://optn.transplant.hrsa.gov/patients/glossary/#W>

⁷ 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>

⁸ <https://academic.oup.com/bjaed/article/11/3/82/257079>

important piece of clinical information for organ evaluation. Longer warm ischemic times can be a contributing factor on outcomes.⁹

Flush Time (in situ), Date/Time

Cold perfusion, or organ “flush,” denotes the end of warm ischemic time and the start of cold ischemic time, when cold perfusion solution is administered through cannula insertion.¹⁰ Cold perfusion is used to slow tissue metabolism, reducing the rate of ischemic injury and preserving the organs for recovery.¹¹ 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.¹²

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 is 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 (single point in time, hourly, or minimum/maximum).

Proposed Data Collection Development and Other Considerations

The Committee also discussed additions and modifications to other hemodynamic information such as echocardiograms. However, after consulting with the OPTN Heart Transplantation Committee, the Committee is not including any changes with this proposal. The OPTN Heart Transplantation Committee agreed that the proposed changes to hemodynamic information would not help with the evaluation of organ offers. Currently collected information provides enough detail to help determine whether to

⁹ Vinson, Amanda J. MD1; Rose, Caren PhD2,3,4; Kiberd, Bryce A. MD1; Oduyayo, Ayodele MD5,6; Kim, S. Joseph MD7,8; Alwayn, 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

¹⁰ Ibid.

¹¹ Ibid.

¹² [https://www.kidney-international.org/article/S0085-2538\(15\)30070-3/fulltext](https://www.kidney-international.org/article/S0085-2538(15)30070-3/fulltext)

search for additional information, such as the echocardiogram reports, in order to make decisions about the offers.

An OPO would only report “Withdrawal of Life Sustaining Medical Support” and “Cessation of Circulation” for donors meeting DCD criteria. Because of this, the Committee discussed the inclusion of a validator question, which would prevent OPOs from reporting “withdrawal” or “cessation” date and time for brain dead donors, for whom the question would not be applicable. In this instance, the validator question would reflect the donor’s DCD status, such as “controlled DCD?” with a binary yes/no response option. The inclusion of a validator question would improve data quality and reduce administrative burden by aligning the proposed data collection with current DCD data collection in the deceased donor registration form (DDR), allowing that information to cascade into the DDR. The Committee is seeking community input on the addition of such a validator question.

Compliance Analysis

NOTA and Final Rule Analysis

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,”¹³ 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...”¹⁴, and “maintain records of all transplant candidates, all organ donors and all transplant recipients.”¹⁵ 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, transplant program costs and performance, and other information that the Secretary deems appropriate.”¹⁶ 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.

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.

¹³ 42 U.S.C. §274(b)(2)(I)

¹⁴ 42 CFR §121.11(a)(1)(i)

¹⁵ 42 CFR §121.11(a)(1)(ii)

¹⁶ 42 CFR §121.11(b)(2)

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.

Operations affecting the OPTN

This proposal would require programming changes 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.

Potential Impact on Select Patient Populations

This proposal has no known impact on specific patient populations.

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.¹⁷

Projected Impact on the OPTN

This proposal would require implementation of system changes, additional monitoring, and communication to members.

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

¹⁷ OPTN Transplant Administrators Committee Meeting Summary. May 26, 2021. Available at https://optn.transplant.hrsa.gov/media/4658/20210526_tac_meeting-summary.pdf

(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.

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 Evaluation

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 data fields did not exist prior to their implementation. Summary statistics, distributions, and missingness for added data elements (**Appendix A**) 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 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. This proposal will streamline communication between OPOs and transplant hospitals and improve efficiency of offer evaluation. This will improve allocation efficiency, which will reduce cold ischemic times and encourage increased DCD transplantation, encouraging an increase in transplantation overall.

Considerations for the Community

1. Are there additional data fields that could improve offer evaluation for DCD donors?
2. Should a validator question, such as “controlled DCD?” be included, to reduce administrative burden and streamline data reporting?
3. Will the proposed data collection be burdensome for OPOs to report? How can implementation be eased for OPO members?
4. Should a new, separate page be created within the donor summary in the OPTN Donor Data and Matching System to report DCD progression information, including vitals such as heart rate, blood pressure, and oxygen saturation?

Appendix A: Proposed Data Fields

OPTN Donor Data and Matching System Addition

ADD: Withdrawal of life-sustaining medical support, date/time

- Format: MM/DD/YYYY and HH:MM

ADD: Cessation of circulation, date/time

- Format: MM/DD/YYYY and HH:MM

ADD: Abdominal aorta flush time (in situ), date/time

- Format: MM/DD/YYYY and HH:MM

ADD: Portal vein flush time (in situ), date/time

- Format: MM/DD/YYYY and HH:MM

ADD: Thoracic aorta flush time (in situ), date/time

- Format: MM/DD/YYYY and HH:MM

ADD: Pulmonary artery flush time (in situ), date/time

- Format: MM/DD/YYYY and HH:MM

ADD: Oxygen saturation (SpO₂)

- Format: Text field (Range: 0-100)
- Format: MM/DD/YYYY and HH:MM

Appendix B: Proposed Data Definitions

- **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