Notice of OPTN Data Collection Changes

Deceased Donor Support Therapy Data Collection

Sponsoring Committee:	**Operations and Safety**
Public Comment:	**July 27, 2023 – September 19, 2023**
Board Approved:	**December 4, 2023**
Effective Date:	**Pending implementation and notice to OPTN members**

Purpose of Data Collection Changes

This data collection will improve efficiency during the allocation phase of organ procurement and transplant by collecting and standardizing the reporting of donor support interventions (e.g., hemodialysis, extra-corporeal membrane oxygen (ECMO), continuous renal replacement therapy (CRRT), etc.). In addition, it will improve the effectiveness of the offer filters tool when screening based on donor-specific laboratory values (e.g., creatinine). Finally, this data will allow for the evaluation of post-transplant outcomes for those recipients who received donor organs managed by a support therapy.

Proposal History

This proposal was initiated during the development of the *Optimizing Usage of Organ Offers* proposal which was passed by the OPTN Board of Directors in June 2023[1]. The Committee determined that support therapy data would be complementary and helpful in providing additional context for offer filters, such as the addition of the serum creatinine, and decided to proceed with a data collection proposal.[2] The Committee reasoned that knowledge of dialysis status, for example, could help provide additional clarity on the creatinine values documented.[3] The Committee developed a list of donor support therapies and consulted with multiple OPTN Committees (Kidney Transplantation, Organ Procurement Organization (OPO), and Data Advisory) during the development of this proposal.

This data collection will create new data collection within the OPTN Donor Data and Matching System to standardize reporting of donor continuous renal replacement therapy (CRRT), dialysis, and extra-corporeal membrane oxygenation (ECMO) interventions. The proposed multi-option data field was developed to obtain information that can provide critical information to improve future versions of the offer filters tool. In addition, this information will be available for coordinators to review alongside donor offers to provide a comprehensive evaluation of the donor and their interventions. These data will be available for programs to evaluate post-transplant outcomes of recipients who received organs from donors who were managed with any of the listed support therapies. This standardization will improve the efficiency of offer review and promote the effective use of the offer filters tool.

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[1] https://optn.transplant.hrsa.gov/media/xdvgftub/osc_offer-filters_policy-notice_jun-2023.pdf.
[2] October 27, 2022 OPTN Operations and Safety Committee meeting summary. Available at https://optn.transplant.hrsa.gov/.
[3] Ibid.

Summary of Changes

The data collection changes include the addition of six data fields. A parent field would specify if any donor support therapies have been initiated. This includes support therapies initiated from the earliest time of admission to time of cross clamp and is inclusive of any hospital transfers. If the response is yes, five subsequent fields would be required to indicate the type of donor support therapies used, and the begin/end date and time of each therapies used.

The support therapy options are broadly categorized and (if applicable) includes additional specifications for the type of therapy within that category (e.g., inhaled therapy: nitric oxide). The "other" option for each category to provide an option to capture any other therapies not included. For each therapy document, a begin/end date and time will be required and must be before cross-clamp date and time.

Additionally, three current ECMO data fields in the Organ Recovery section of the Deceased Donor Registration (DDR) form in the Data System for the OPTN will be removed.

Implementation

The data collection changes will require OPO staff to become familiar with the changes to the OPTN Donor Data and Matching System, Data System for the OPTN, and data definitions. This may add additional administrative burden in collecting the support therapy data. Educational efforts and training may be needed to ensure staff have a standardized process of documenting the additional data being proposed.

Education may be required for transplant hospital staff such that they are aware of the new field and data captured when reviewing organ offers.

The data collection changes requires the submission of data to the OPTN that are not presently collected. 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 the Office of Management and Budget (OMB) approved data collection forms. 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.

Data Collection Changes

New language is underlined (<u>example</u>) and language that is deleted is struck through (~~example~~).

Table 1: New Data Field (Parent Field) Indicating Initiation of Support Therapy

Data Field	Forms	Description of Response Field
<u>Were any support therapies initiated?*</u> **Note:** <u>This includes support therapies initiated from the earliest time of admission to time of cross clamp; inclusive of any hospital transfers.</u>	OPTN Donor Data and Matching System, Data System for the OPTN	<u>Select Yes or No</u>

*Required field. This field is required for sending organ offer notifications.

Table 2: New Data Fields for Support Therapy Specifications

Data Field	Forms	Description
<u>Support Therapy**</u>	OPTN Donor Data and Matching System, Data System for the OPTN	<u>Drop down list of support therapies would include the following options:</u> <u>Cardiac device: (LVAD) - Left ventricular assist device</u> <u>Cardiac device: (RVAD) - Right ventricular assist device</u> <u>Cardiac device: (IABP) - Intra-Aortic Balloon Pump</u> <u>Cardiac device: (VV ECMO) - Venovenous Extracorporeal Membrane Oxygenation</u> <u>Cardiac device: (VA ECMO) - Venoarterial Extracorporeal Membrane Oxygenation</u> <u>Cardiac device: (MCSD) - Temporary mechanical circulatory support devices</u> <u>Cardiac device: Left Heart Device: Other</u> <u>Cardiac device: Right Heart Device: Other</u> <u>Inhaled Therapy: Nitric Oxide</u>

Data Field	Forms	Description
		Inhaled Therapy: Other
		Renal Replacement Therapy: (CRRT) Continuous Renal Replacement Therapy
		Renal Replacement Therapy: (iHD) Intermittent Hemodialysis
		Renal Replacement Therapy: (PD) Peritoneal dialysis
		Renal Replacement Therapy: (SLED) Sustained low efficiency dialysis
		Renal Replacement Therapy: Other
Begin Date**	OPTN Donor Data and Matching System, Data System for the OPTN	Begin date and time must be before cross-clamp date and time
Begin Time**	OPTN Donor Data and Matching System, Data System for the OPTN	Format: HH:MM **Note**: Time should be in 24-hour format.
End Date***	OPTN Donor Data and Matching System, Data System for the OPTN	End date and time must be before cross-clamp date and time
End Time***	OPTN Donor Data and Matching System, Data System for the OPTN	Format: HH:MM **Note**: Time should be in 24-hour format.

** Required field; A "yes" response from the parent field question would require five subsequent data fields for further specifications on what support therapy was used (at least one support therapy needing to be selected), as well as the date and time the support therapy started and ended, respectively.
*** This data collection is optional in the Donor Data and Matching System but is required for final data submission in Data System for the OPTN.

Table 3: Removal to Current ECMO Data Fields

Data Field	Forms	Description
~~Any Extracorporeal Support Given (ECMO, etc):~~	Data System for the OPTN – DDR (Organ Recovery section)	~~Yes/No~~
~~How long? (subsequent field)~~	Data System for the OPTN – DDR (Organ Recovery section)	~~Hrs~~ ~~ST =~~
~~Flow Rate (subsequent field)~~	Data System for the OPTN – DDR (Organ Recovery section)	~~L/min~~ ~~ST =~~