OPTN

Public Comment Proposal

Deceased Donor Support Therapy Data Collection

OPTN Operations & Safety Committee

Prepared by: Joann White, MPH & Isaac Hager
UNOS Policy and Community Relations Department

Contents

OPTN

Deceased Donor Support Therapy Data Collection

Sponsoring Committee: *Operations & Safety*
Data Collection Affected: *OPTN Donor Data and Matching System, Data System for the OPTN*
Public Comment Period: *July 27, 2023 – September 19, 2023*

Executive Summary

This proposal seeks to create new data collection within the OPTN Donor Data and Matching System that standardizes the reporting of donor continuous renal replacement therapy (CRRT), dialysis, and extra-corporeal membrane oxygenation (ECMO) interventions. The proposed multi-option data field would improve the effectiveness of the offer filters tool by providing more data that would inform decisions for future offer filters. 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 also 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.

Purpose

This data collection will improve the effectiveness of the offer filters tool when screening based on donor-specific laboratory values (e.g. creatinine). In addition, it 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.). Finally, this data will allow for the evaluation of post-transplant outcomes for those recipients who received donor organs managed by a support therapy.

Background

The Operations and Safety Committee ("Committee") has embarked on several projects aimed at increasing the efficient use of organ offers and acceptances and ultimately reducing overall organ allocation time. One of those projects focused on optimizing the usage of the kidney offer filters tool and increasing the number of transplants by getting to organ offer acceptance faster, as outlined in the Committee's January 2023 *Optimizing Usage of Organ Offers* proposal.[1]

This proposal was initiated during the development of the offer filters project. The Operations and Safety Committee's Mandatory Usage of Offer Filters Workgroup recommended that donor dialysis and CRRT status be tracked such that programs can use this information to better filter their offers.[2] During the donation process, some donors may require interventions to preserve organ quality, or to allow for short-term organ damage to heal. Within the OPTN Donor Data and Matching System, donor support interventions are not tracked in one standardized field or format. This requires transplant team members who review offers to spend extra time reviewing free text fields, reviewing donor attachments, or calling the offering Organ Procurement Organization (OPO) to determine what, if any, therapies have been applied.

As noted by Marklin et al., "It is estimated that as many as 24% - 36% of [Brain Dead] donors experience acute kidney injury (AKI)", and "continuous renal replacement therapy (CRRT) is the standard of care for severe AKI in critical patients".[3] The study authors acknowledge that CRRT is infrequently started after the diagnosis of brain death, largely due to cost and resource limitations, but conclude that this procedure does ultimately increase the number of viable donors. In their retrospective study of 27 donors with oligoanuric AKI treated with CRRT, they demonstrate that "CRRT, [...] initiated for AKI in an ORC [organ recovery center] after diagnosis of BD [brain death], is not only feasible but beneficial". In addition, they strongly support more OPOs initiating CRRT on donors with AKI. This work corroborates with that of Sanders et al., who, in an earlier study, concluded that "Potential donors with AKI provide an additional pool of kidney donors. It is important that clinicians in the intensive care and donation care sectors do not dismiss potential donors with severe AKI as unsuitable to donate kidneys for transplantation. It is also important that renal transplant physicians consider utilizing such offered organs for transplantation and that systems exist to target the offer of these kidneys to recipients who are most able to benefit from them."[4]

[1] *Optimizing Usage of Offer Filters* proposal, OPTN Operations and Safety Committee, January 2023.
[2] November 14, 2022 OPTN Operations and Safety Committee Mandatory Usage of Offer Filters Workgroup meeting summary.
[3] Marklin GF, Ewald L, Klinkenberg WD, Joy CM, Bander SJ, Rothstein M. The benefits of initiating continuous renal replacement therapy after brain death in organ donors with oligoanuric acute kidney injury. Clin Transplant. 2022 Sep;36(9):e14764. doi: 10.1111/ctr.14764. Epub 2022 Jul 14. PMID: 35776069.
[4] Sanders JM, Opdam HI, Furniss H, Hughes PD, Kanellis J, Jones D. Frequency and outcomes of kidney donation from intensive care patients with acute renal failure requiring renal replacement therapy. Nephrology (Carlton). 2019 Dec;24(12):1296-1303. doi: 10.1111/nep.13601. Epub 2019 Jun 10. PMID: 31081209.

The Committee reviewed the above findings and agreed that this data would be complementary and helpful in informing decisions for offer filters and decided to proceed with a data collection proposal.[5] The Committee developed a list of donor support therapies and reviewed their relevancy with multiple OPTN Committees (Kidney Transplantation Committee, Organ Procurement Organization (OPO) Committee, Data Advisory Committee (DAC)).

A Donor Support Interventions Workgroup ("the Workgroup") was developed to review and provide feedback on the proposal and proposed list of donor support therapies mentioned below. The Workgroup was comprised of representation from the following OPTN Committees: DAC, Kidney Transplantation Committee, Pancreas Transplantation Committee, Lung Transplantation Committee, Liver & Intestinal Transplantation Committee, Heart Transplantation Committee and OPO Committee.

The Workgroup agreed that the data collection proposed by the Committee is beneficial as there currently is not a standardized way of collecting this information.[6] It was agreed that this information would be useful for evaluating post-transplant outcomes for recipients of organs from donors supported by these therapies.[7] The Workgroup suggested simple and straightforward data collection and avoiding unnecessary complexity.[8]

The Workgroup reviewed a mockup of the data fields. There was agreement in a parent field inquiring if a donor support therapy is being used and a second field that specifies which support intervention therapy is being used (with the ability to add as many therapies as applicable).[9] The Workgroup then reviewed the initial list of donor support therapies proposed by the Committee. These are further defined below:

- Venovenous (VV) Extra-corporeal membrane oxygenation (ECMO)
- Venoarterial (VA) Extra-corporeal membrane oxygenation (ECMO)
- Impella* (*edited to Temporary mechanical circulatory support devices (MCSD))
- Continuous Renal Replacement Therapy (CRRT)
- Right ventricular assist device (RVAD)
- Left ventricular assist device (LVAD)
- Balloon pump
- Nitric Oxide* (*edited to inhaled therapies by the Workgroup)

The Workgroup suggested generalizing some of the proposed donor support therapies. For example, it was suggested that Nitric be simplified to "inhaled therapies".[10] The Committee discussed this further and ultimately decided that "inhaled therapies" was exclusive to Nitric Oxide. There was also the suggestion of including hemodialysis as an additional donor support therapy.[11] The Workgroup discussed whether there should be specifications about the indication for CRRT for fluid management or creatinine management purposes. It was decided that the usage of CRRT for fluid management is infrequent and ultimately the Workgroup decided that this field should be as simplistic as possible and not include the indication for the therapy (fluid vs. creatinine management.) It was noted that if that

[5] October 27, 2022 OPTN Operations and Safety Committee meeting summary.
[6] May 3, 2023 OPTN Operations and Safety Committee Donor Support Interventions Workgroup meeting summary.
[7] May 3, 2023 OPTN Operations and Safety Committee Donor Support Interventions Workgroup meeting summary.
[8] May 3, 2023 OPTN Operations and Safety Committee Donor Support Interventions Workgroup meeting summary.
[9] May 3, 2023 OPTN Operations and Safety Committee Donor Support Interventions Workgroup meeting summary.
[10] May 3, 2023 OPTN Operations and Safety Committee Donor Support Interventions Workgroup meeting summary.
[11] May 3, 2023 OPTN Operations and Safety Committee Donor Support Interventions Workgroup meeting summary.

level of detail was necessary during the organ offer and placement process, transplant programs would be able to follow up with OPO staff to obtain it.[12]

The Committee reviewed and agreed with the suggestions by the Workgroup. The Committee finalized and voted in support of the proposed data fields below [13]:

- VV ECMO
- VA ECMO
    - ECMO is a temporary mechanical assist device that allows for prolonged cardiopulmonary support initiated on donors with respiratory failure
- Temporary mechanical circulatory support devices (MCSD)
    - MCSDs are devices designed to provide mechanical cardiac support when acute illness diminishes cardiac output
- CRRT
    - CRRT describes a variety of methods that provide continuous dialysis and is primarily used to support kidney function, fluid management, or address electrolyte disturbances
- RVAD
    - RVADs are mechanical devices designed to improve cardiac output by assisting with the function of the right ventricle
- LVAD
    - LVADs are mechanical devices designed to improve cardiac output by assisting with the function of the left ventricle
- Hemodialysis (intermittent kidney replacement therapies (KRT))
    - Intermittent KRT is a faster method of dialysis indicated primarily to support kidney function
- Intra-Aortic Balloon Pump (IABP)
    - IABPs are implanted mechanical devices designed to assist cardiac function
- Nitric Oxide
    - Nitric oxide is a naturally occurring vasodilator indicated for treatment of persistent pulmonary hypertension

Further detail is available in **Table 2** below.

Overview of Proposal

The Committee proposes the addition of seven new data fields that would be collected by the host OPO and included in the OPTN Donor Data and Matching System and Data System for the OPTN. The first data field would specify if any donor support therapies have been initiated from the time of admission. This field would solicit a “yes” or “no” response. A “yes” response would populate five subsequent data fields for further specifications on what donor support therapy was used, as well as the date and time the donor support began and ended, respectively. Further information regarding the proposed data fields is detailed in the sections below and outlined in **Appendix A**.

[12] May 3, 2023 OPTN Operations and Safety Committee Donor Support Interventions Workgroup meeting summary.
[13] May 25, 2023 OPTN Operations and Safety Committee meeting summary.

Donor Support Therapy Parent Field

The first new data field proposed by the Committee would indicate if a donor support therapy was initiated at the time of admission. By using the term "Support Therapy", the Committee defines this to mean any of the listed interventions from the "Support Therapy" field being used for donor management purposes as outlined later in the next section (Support Interventions Specific Fields) of this proposal. The Committee debated between the initiation time being at time of admission or time of terminal event. Feedback solicited by the Workgroup suggested the time of the terminal event would provide the most accurate way of determining if the donor support therapy was initiated for donor support.[14] The Workgroup supported this approach by arguing that the field should capture support therapies initiated during the donor process, and that admission date would not account for transfers to a second hospital where the organ donor management and organ recovery may occur. [15] The Committee initially agreed with this recommendation, but after further discussion determined the admission date would be most appropriate. The Committee reasoned that in using admission date, this would maintain consistency with current data fields and definitions. This field would be defined as tracking which donor support therapies are either initiated or ongoing from the initial time of admission and their duration.

Table 1 summarizes the proposed new Donor Support Therapy parent data field.

Table 1: Proposed New Donor Support Therapy Parent Data Field

Data Field	Forms	Description of Response Field
Have any donor support therapies been initiated at or after the initial time of admission?	OPTN Donor Data and Matching System, Data System for the OPTN	Select Yes or No

This would be a parent field that would require a "yes" or "no" response. If the response entered is "no", no further action would be needed. If the response entered is "yes", the support interventions specific field will populate as outlined in the next section.

Support Interventions Specific Fields

The Committee proposes five subsequent new data fields that would be in response to the support interventions parent field previously described. The support interventions specific field would ask the host OPO to specify the type of intervention(s) used as well as the begin and end date and time the support intervention(s) were used. The data fields will allow users the ability to add multiple entries as needed to capture all donor support therapies.

The Committee proposes the removal of the current Extracorporeal Support (ECMO, etc.) data collection field found in the Data System for the OPTN. When selecting yes to the question "Was the donor recovered under DCD protocol?" in the Organ Recovery section of the Data System for the OPTN, a subsequent field asks various questions, including if any extracorporeal support was given (ECMO, etc.), the duration of the therapy and the flow rate. The Committee determined that to avoid redundancy, and to have a more centralized place to collect donor support interventions data, the current data field

[14] May 3, 2023 Operations and Safety Committee Donor Support Interventions Workgroup meeting summary.
[15] May 3, 2023 Operations and Safety Committee Donor Support Interventions Workgroup meeting summary.

should be removed, and the proposed data collection effort will collect ECMO data.[16] Additionally, the Committee discussed the need in documenting flow rate and are recommending excluding this information in this data collection effort.[17] **Table 2** summarizes these proposed changes the current ECMO data fields.

Table 2. Proposed Changes to Current ECMO Data Fields

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

The Committee asks the community for feedback on this recommendation and for additional feedback on how the current ECMO data field is analyzed for further consideration to this recommendation.

The begin and end date data field specifies when the support intervention began and ended. The Workgroup and Committee support limiting the begin and end date to all times before the cross-clamp date.[18] [19] Additionally, the Committee proposes standardization among reporting, requiring a start date/time for all donor support intervention listings in the OPTN Donor Data and Matching System.

The Committee proposed a new data field that will allow the OPO to indicate that the support invention duration is on-going until cross-clamp in both the OPTN Donor Data and Matching System and the Data System for the OPTN. This field would not be required on the OPTN Donor Data and Matching System. In the Data System for the OPTN either the end date and time or the on-going until cross-clamp field must be selected in order to validate the deceased donor registration form. If the checkbox is selected, then the duration will say “ongoing until cross-clamp”.

Table 3 summarizes the proposed new data fields for support intervention specifications made by the Committee.

[16] June 22, 2023 Operations and Safety Committee meeting summary.
[17] June 22, 2023 Operations and Safety Committee meeting summary.
[18] May 3, 2023 Operations and Safety Committee Donor Support Interventions Workgroup meeting summary.
[19] May 25, 2023 Operations and Safety Committee meeting summary.

Table 3: Proposed New Data Fields for Support Intervention Specifications

Data Field	Forms	Description
Support Therapy	OPTN Donor Data and Matching System, Data System for the OPTN	Drop down list of support therapies would include the following options: VV ECMO VA ECMO Temporary mechanical circulatory support devices (MCSD) CRRT RVAD LVAD Hemodialysis (intermittent kidney replacement therapies (KRT)) Intra-Aortic Balloon Pump (IABP) Nitric Oxide
Begin Date	OPTN Donor Data and Matching System, Data System for the OPTN	Must be before cross-clamp date
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	Must be before cross-clamp date
End Time	OPTN Donor Data and Matching System, Data System for the OPTN	Format: HH:MM **Note**: Time should be in 24-hour format. For entries on the Data System for the OPTN, a new data field would allow programs the option to select "Ongoing until Cross-clamp" as the end time

The Committee proposes the "Meds and Fluids" page on the OPTN Donor Data and Matching System to be the appropriate location for these data fields to be displayed but felt that the label of the tab in the donor record may need to be changed to encompass the fact it addresses more than medications and

fluids. The Committee suggests “Donor Management” and welcomes any additional feedback on how best to label this tab (if at all) in the donor record.[20]

Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits this data collection proposal under the authority of the National Organ Transplant Act of 1984 (NOTA) and the OPTN Final Rule. The National Organ Transplant Act (NOTA) requires the Organ Procurement and Transplantation Network (OPTN) to “collect, analyze, and publish data concerning organ donation and transplants,”[21] and states the OPTN shall establish "a national system, through the use of computers and in accordance with established medical criteria, to match organs and individuals included in the list"[22] .

The OPTN Final Rule states “transplant programs shall establish criteria for organ acceptance, and shall provide such criteria to the OPTN and the OPOs with which they are affiliated.”[23] This proposal will allow for a standardized collection of data related to donor support therapies that will further inform and provide a comprehensive evaluation of organ offers.

Implementation Considerations

Member and OPTN Operations

To implement this proposal, the OPTN will modify data collection instruments and communicate the changes to the transplant community. The OPTN will create help documentation for the new data elements to provide additional instruction for submitting these data.

Operations affecting Histocompatibility Laboratories

This would not affect histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

This proposal 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 proposal may add additional administrative burden in collecting the donor support interventions data. Educational efforts and training may be needed to ensure staff have a standardized process of documenting the additional data being proposed.

Operations affecting Transplant Hospitals

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

[20] June 22, 2023 Operations and Safety Committee meeting summary.
[21] 42 USC. §274(b)(2)(I)
[22] 42 U.S.C. §274(b)(2)(A)(ii)
[23] 42 CFR 121.6(c)

Operations affecting the OPTN

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, 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.

Potential Impact on Select Patient Populations

There is no impact on select patient populations. The proposed data collection aims to further enhance and inform decisions for offer filters and assessing outcomes in a continued effort to improve efficiency in organ placement.

Projected Fiscal Impact

The proposal is anticipated to have low fiscal impact on transplant hospitals. It has some potential to slightly increase impact on the OPOs who collect this data. There is no expected fiscal impact for histocompatibility labs. The potential impact on the OPTN could be slightly higher due to necessary IT changes being made to the OPTN Computer System, online reporting systems, and the offer filters model.

Projected Impact on Histocompatibility Laboratories

There is no expected fiscal impact on Histocompatibility Laboratories.

Projected Impact on Organ Procurement Organizations

This proposal has the potential to increase the data collection burden on OPOs; however, the burden would not outweigh the positive outcomes relating to expedited organ review and/or placement. There is the possibility of an increase in data entry and input requirements for OPOs and an increased need for staff training. The staff training is expected to be short-term and no additional hiring is anticipated.

Projected Impact on Transplant Hospitals

This proposal does not have a significant increase in burden on transplant hospitals. There might be additional training for staff, as needed, but the majority of the data input and review would fall on OPOs. This proposal is expected to facilitate more efficient review of organ offers by transplant teams.

Projected Impact on the OPTN

IT estimates an effort at 2,300 hours, which would include changes to the OPTN Donor Data and Matching System and the Data System for the OPTN.

Research anticipates an effort estimated at 70 hours. Most of these hours are to develop routine monitoring and to present monitoring results to the committee at 6- and 12-months post implementation.

Post-implementation Monitoring

Member Compliance

At OPOs, site surveyors will continue to review a sample of donor records, and any material incorporated into the medical record by reference to include donor support therapies, to verify that data reported in the OPTN Computer System are consistent with source documentation.

Policy Evaluation

Usage of the newly added data fields will be presented to the committee at 6 months and 12 months following implementation. The following descriptive metrics will be calculated:

1. Number and percent of donors where "Yes" was selected in the parent field.
2. For each individual support therapy option, the number and percent of donors with that support therapy selected.
3. Distribution of the duration for each support therapy option. Distribution metrics include the average, minimum, maximum, median, 25th percentile, and 75th percentile of durations.
4. (Organ specific) The number and percent of kidney donors with CRRT and Hemodialysis support therapies.

As noted in the Background section, some therapies like CRRT are thought to be infrequently utilized for organ donation. Thus, low usage of support therapy options will not necessarily be interpreted as unsuccessful data collection. The committee will review results to determine if the data collection is sufficient or needs further adjustment.

Conclusion

Improving the efficiency of organ placement is vital to ensuring that the right organs get to the right patients in a timely manner. In complementing the Committee's efforts on optimizing the usage of offer filters, this proposal will further enhance these efforts by helping to inform decisions for future offer filters as well as allow for the assessment of outcomes. Additionally, with there being no current data on donor support interventions that is standardized/uniformly collected, this proposal will provide a standard format for tracking the use of donor support interventions with the OPTN Donor Data and Matching System.

Considerations for the Community

In reviewing this proposal, readers are encouraged to provide feedback on all aspects of the paper, and to consider the following question:

- Are there any other donor support interventions not mentioned that should be considered?
- Are there any additional data elements that could be added or eliminated related to this effort?
- Is the recommendation to remove the current ECMO data and instead use this data collection effort to collect this information instead appropriate?
    - Is the recommendation of excluding the flow rate data field appropriate?
    - How does your respective program currently use/evaluate this data?

- Do you agree with the recommendation to display the proposed data fields in the Meds and Fluids page of the OPTN Donor Data and Matching System?
    - Is there another label that would be more appropriate (ex. the Committee suggested a tab labeled “Donor Management”)?

Proposed Changes to Data Fields and Data Definitions

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

Table 4. Proposed New Data Field (Parent Field) Indicating Initiation of Donor Support Therapy

Data Field	Forms	Description of Response Field
Have any donor support therapies been initiated at or after the initial time of admission?	OPTN Donor Data and Matching System, Data System for the OPTN	Select Yes or No

Table 5. Proposed New Data Fields for Support Intervention Specifications

Data Field	Forms	Description
Support Therapy	OPTN Donor Data and Matching System, Data System for the OPTN	Drop down list of support therapies would include the following options: VV ECMO VA ECMO Temporary mechanical circulatory support devices (MCSD) CRRT RVAD LVAD Hemodialysis (intermittent kidney replacement therapies (KRT)) Intra-Aortic Balloon Pump (IABP) Nitric Oxide
Begin Date	OPTN Donor Data and Matching System, Data System for the OPTN	Must be before cross-clamp date
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	Must be before cross-clamp date

End Time	OPTN Donor Data and Matching System, Data System for the OPTN	Format: HH:MM **Note**: Time should be in 24-hour format. For entries on the Data System for the OPTN, a new data field would allow programs the option to select "Ongoing until Cross-clamp" as the end date/time

Table 6. Proposed Changes to Current ECMO Data Fields

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

Appendix A: Data Definitions

Table 7. Proposed New Data Field Data Definitions

Data	Definition
Have any donor support therapies been initiated at or after the initial time of admission?	This field tracks which donor support therapies are initiated at or after the initial time of admission of the donor to the donor hospital; offers a yes or no response option.
Support Therapy	Any of the listed interventions from the "Support Therapy" field being used for donor management purposes.

#