OPTN

Briefing to the OPTN Board of Directors on

Deceased Donor Support Therapy Data Collection

OPTN Operations and Safety Committee

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Deceased Donor Support Therapy Data Collection

Sponsoring Committee: *Operations and Safety*
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Executive Summary

The Operations and Safety Committee ("Committee") has embarked on several projects aimed at increasing the efficiency of organ offer review and acceptance process, 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 June 2023 OPTN Board approved *Optimizing Usage of Organ Offers* proposal.[1]

The offer filters project resulted in the development of this proposal which 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.

The Committee proposed the addition of six data fields. A parent field would specify if any donor support therapies have been initiated. 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. Additionally, the Committee proposes the removal of three current ECMO data fields in the Organ Recovery section of the Deceased Donor Registration (DDR) form in the Data System for the OPTN. The proposal was supported during public comment with some suggestions for modifications and clarifications. The feedback received resulted in changes related to modifications to the parent donor support field question, donor support therapy description field, and data definition. Additionally, this proposal addresses and clarifies questions posed during public comment related to the delineation of this data collection effort and normothermic regional perfusion (NRP) data collection, as well as the ability to collect serial data for instances when the donor support therapies selected are discontinuous.

This proposal for data collection was issued for public comment from July 27, 2023 to September 19, 2023. The Committee reviewed the public comments and made changes to the document to incorporate feedback, discussed below.

[1] https://optn.transplant.hrsa.gov/media/xdvgftub/osc_offer-filters_policy-notice_jun-2023.pdf

Purpose

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.

Background

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]

The Committee reviewed the above findings and agreed that this 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.[5] The Committee reasoned that knowledge of dialysis status, for example, could help provide additional clarity on the creatinine values documented.[6]

[2] November 14, 2022 OPTN Operations and Safety Committee Mandatory Usage of Offer Filters Workgroup meeting summary. Available at https://optn.transplant.hrsa.gov/.
[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.
[5] October 27, 2022 OPTN Operations and Safety Committee meeting summary. Available at https://optn.transplant.hrsa.gov/.
[6] Ibid

The Committee developed a list of donor support therapies and reviewed their relevancy with multiple OPTN Committees (Kidney Transplantation, Organ Procurement Organization (OPO), and Data Advisory).

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

The Workgroup agreed that the data collection proposed by the Committee is beneficial as there currently is no standardized way of collecting this information.[7] It was agreed that this information would be useful for evaluating post-transplant outcomes for recipients of organs from donors supported by these therapies.[8] The Workgroup suggested simple and straightforward data collection and avoiding unnecessary complexity.[9]

The Workgroup reviewed a mockup of the data fields. There was agreement on 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).[10] The Workgroup then reviewed the initial list of donor support therapies proposed by the Committee and suggested the collection of this data be as generalized and simplistic as possible .[11] It was noted that if further level 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.

Overall Sentiment from Public Comment

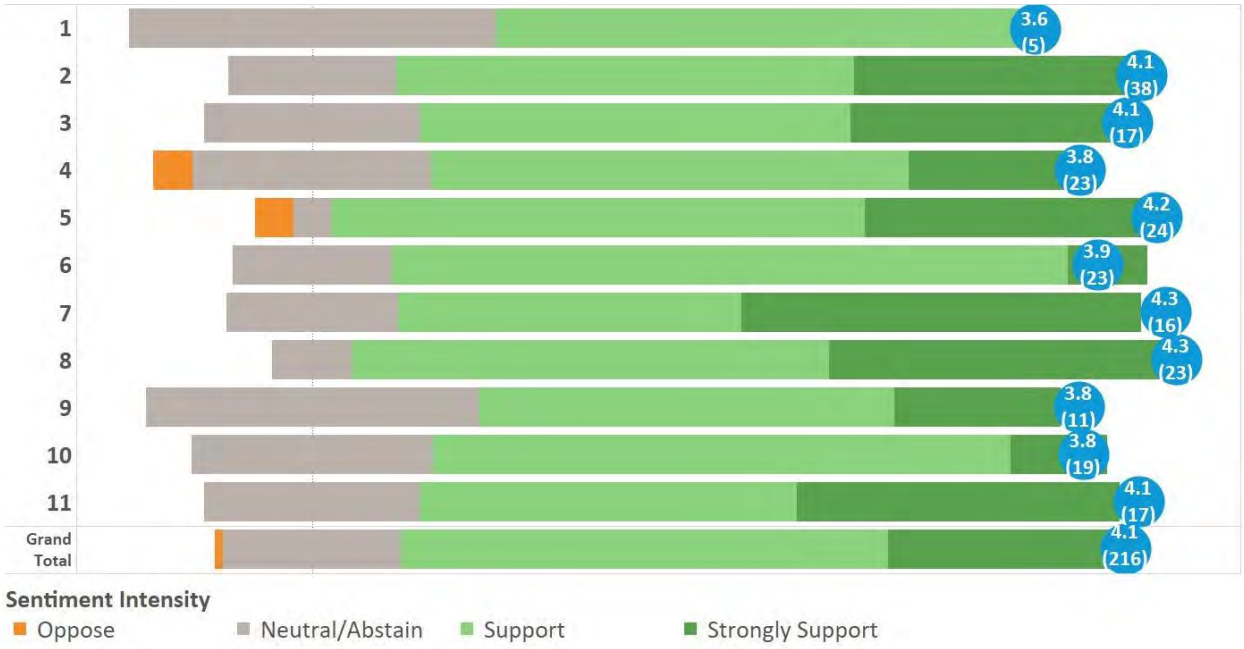
This proposal was issued for public comment from July 27, 2023 to September 19, 2023. Committee members presented the proposal to five other OPTN Committees for feedback, and a video presentation describing the proposal was posted to the OPTN website. Five professional organizations as well as several transplant programs, OPOs, and individuals provided written public comment.

The proposal was on the non-discussion agenda for the OPTN regional meetings. All eleven regions and public comment indicated support with minor opposition to some components of the proposal. Further detail on the feedback and the Committee's changes to the proposal are summarized later in this document.

[7] May 3, 2023 OPTN Operations and Safety Committee Donor Support Interventions Workgroup meeting summary. Available at https://optn.transplant.hrsa.gov/.
[8] Ibid.
[9] Ibid.
[10] Ibid.
[11] Ibid.
[12] Ibid.

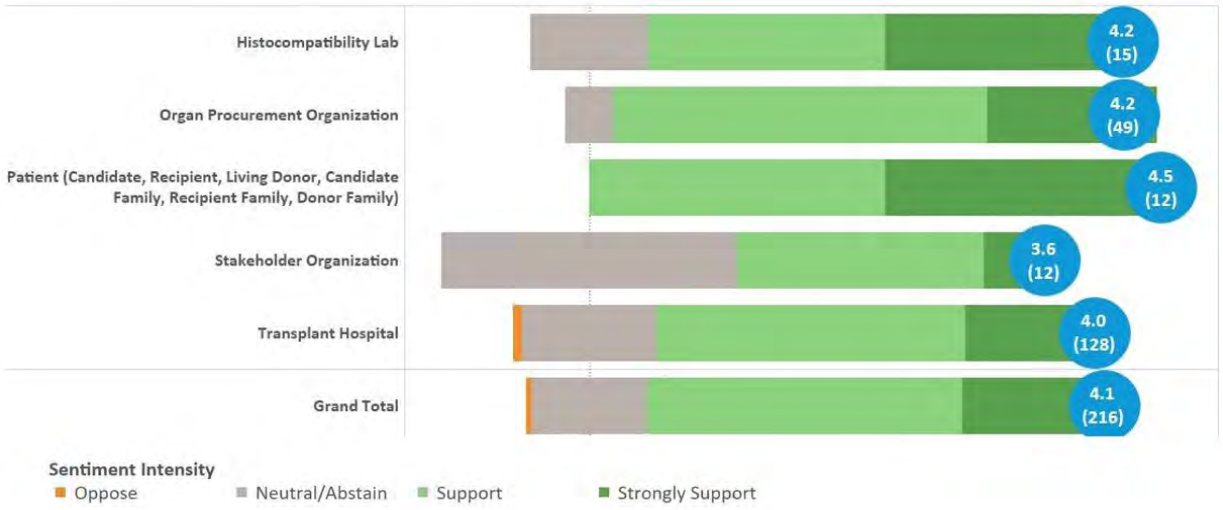
Figure 1 illustrates the sentiment votes for the proposal at the regional meetings. Red represents strong opposition, orange represents general opposition, gray represents neutral sentiment or abstentions, light green represents general support, and dark green represents strong support. The score (indicated by the blue figure at the end of each bar) is calculated using a scale of 1-5. For example, a "strongly oppose" comment would receive a score of one, "oppose" would receive a two, "neutral/abstain" would receive a three, "support" would receive a four, and finally, a "strongly support" would receive a five. There was overall support for the proposal across the 11 regions with some opposition noted from Regions 4 and 5.

Figure 1: Sentiment at Regional Meetings



There was overall support across member types as shown below in **Figure 2**. The scores were calculated in the same manner as **Figure 1**. There was some minor opposition from transplant hospital members. Further detail on the feedback and the Committee's changes to the proposal are summarized later in this document.

Figure 2: Sentiment by Member Type



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. Those responses were reviewed and discussed by the Committee as outlined in further detail in the next section.

Proposal for Board Consideration

The Committee proposes the addition of six 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 support therapies were initiated; a response would be required for sending organ offer notifications. This field would solicit a "yes" or "no" response. A "yes" response 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. Further information regarding the proposed data fields is detailed in **Appendix A**.

Public comments were supportive of the proposed data fields with some suggestions related to additions, removals, and/or modifications of proposed data fields, placement of data collection fields, clarifications, and future considerations for the data collection efforts. A summary of those comments and the Committee's responses are highlighted below.

Public Comment Themes and Considerations

Donor Support Therapy Parent Field: Time of admission

The OPTN OPO Committee inquired how this data field would include instances when a donor is transferred from the admitting hospital to another hospital. Limiting this field to the initial time of

admission would be collecting a subset of this information. The intent of this data is to evaluate the usage of support therapies from the earliest time of admission until cross clamp; the clinical reasoning being that these support therapies affect each organ differently depending on the duration how long they have been on said therapy.

The Committee agreed with this observation and decided to modify the data field to read, "Were any support therapies initiated?". Additional text includes a note to specify that this includes support therapies initiated from the earliest time of admission to time of cross clamp and would be inclusive of any hospital transfers. 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 be required.

Table 1 summarizes the proposed support therapy parent data field.

Table 1: Proposed New Donor Support Therapy Parent Data Field

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

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

Modification to support therapy description field

The Committee proposes five subsequent new data fields that would be in response to the support therapy parent field previously described. The support therapy specific field would require the host OPO to specify the type of therapy/therapies used from a list of options as well as the begin and end date and time the support therapy/therapies were used. OPOs will be able to record multiple begin and end times for a specific support therapy. The Committee initially proposed the following options:

- 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

There was support for keeping the collection of this data as simple as possible, however, there were numerous comments suggesting some granularity to the support therapy options proposed. A comment from the American Society of Transplantation (AST) suggested the addition of a field to capture the reason intervention (support therapy) was discontinued. Another commenter suggested the addition of

a data field to collect ventilator settings. There was another suggestion to include a data field to indicate pre-existing chronic kidney disease/end-stage renal disease. The Committee determined not to include these additional fields as the intent of this data collection effort is to bring awareness to the use of support therapies and support therapy types to improve organ offer assessment.

Commenters also suggested providing granularity to the support therapy options proposed by listing the different types of support therapies. The National Kidney Foundation (NKF), for example, suggested the inclusion of different types of dialysis such as CRRT, intermittent hemodialysis (iHD), and peritoneal dialysis (PD). Another member suggested the addition of sustained low efficiency dialysis (SLED). The Committee reviewed these comments and agreed to extend the list of support therapy options by adding iHD, PD and SLED as suggested; the support therapies were further modified to categorize each option as follows:

- Cardiac device: (LVAD) - Left ventricular assist device
- Cardiac device: (RVAD) - Right ventricular assist device
- Cardiac device: (IABP) - Intra-Aortic Balloon Pump
- Cardiac device: (VV ECMO) - Venovenous Extracorporeal Membrane Oxygenation
- Cardiac device: (VA ECMO) - Venoarterial Extracorporeal Membrane Oxygenation
- Cardiac device: (MCSD) - Temporary mechanical circulatory support devices
- Cardiac device: Left Heart Device: Other
- Cardiac device: Right Heart Device: Other
- Inhaled Therapy: Nitric Oxide
- 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

The intent of the “other” option for each category is to provide an option to capture any other therapies that were not mentioned in the options listed above.

Modification of begin date, begin time, end date and end time data fields

The Committee proposes a begin date and time and end data and time fields to provide additional information of the required support therapy options. To provide further information, the Committee agreed to a modification to the description of these fields to note the begin and end date and time must be before cross-clamp date and time. This notification is to account for scenarios where a therapy might begin and end on the same day as cross-clamp but before the actual time of cross-clamp.

Table 2 summarizes the proposed new data fields for begin date and time and end date and time (including the modifications mentioned above) made by the Committee. The begin date and time fields would be required, while the end date and time fields will be optional in the Donor Data and Matching System but will be required for final data submission in the Data System for the OPTN.

Table 2: Proposed New Data Fields for Begin date and time and End date and time

Data Field	Forms	Description
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.

Removal of "ongoing until cross clamp" option

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".

Upon further review, the Committee discussed the complexities of the "ongoing until cross clamp" field being included in the end time data field. There was concern of this option potentially becoming more of a default option and not providing accurate data. The Committee reasoned that the end date should be available and collected, and therefore decided to remove the "ongoing until cross clamp" option. The end date and time fields will be optional in the Donor Data and Matching System but will be required for final data submission in the Data System for the OPTN.

Table 3 summarizes the proposed new data fields for support therapy specifications (including the modifications mentioned above) made by the Committee. These fields would be required if the parent field response is "yes".

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: Cardiac device: (LVAD) - Left ventricular assist device Cardiac device: (RVAD) - Right ventricular assist device Cardiac device: (IABP) - Intra-Aortic Balloon Pump Cardiac device: (VV ECMO) - Venovenous Extracorporeal Membrane Oxygenation Cardiac device: (VA ECMO) - Venoarterial Extracorporeal Membrane Oxygenation Cardiac device: (MCSD) - Temporary mechanical circulatory support devices Cardiac device: Left Heart Device: Other Cardiac device: Right Heart Device: Other Inhaled Therapy: Nitric Oxide 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

Data Field	Forms	Description
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.

Removal of current Extracorporeal Support (ECMO) data field

The Committee proposes the removal of the current Extracorporeal Support (ECMO, etc.) data collection field found in the Organ Recovery section of the Deceased Donor Registration (DDR) form 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 support therapy data, the current data field should be removed as ECMO data will be included in the proposed data collection effort.[13] Additionally, the Committee discussed whether there was a need to document flow rate and determined for the purposes of this data collection effort, there was not a need. The Committee recommended excluding flow rate information in this data collection effort.[14]

There was overall support for the removal of this current data field, with commenters voicing this recommendation was reasonable and would allow a more centralized location to collect and evaluate this data.

[13] June 22, 2023 Operations and Safety Committee meeting summary. Available at https://optn.transplant.hrsa.gov/.
[14] Ibid.

Table 4 summarizes the proposed changes to the current ECMO data fields.

Table 4. Proposed Changes 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 =~~

Placement of data

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 proposed that the label of the page may need to be changed to reflect the fact it addresses more than medications and fluids.

The public comment received did not show any opposition to the proposed placement of the data collection. There was one comment in agreement to the suggestion of including an additional tab in OPTN Donor Data and Management System labeled Donor Management. The Committee concluded to place the proposed data fields on the "Meds and Fluids" screen in the OPTN Donor Data and Matching System maintain the placement of new data fields as proposed.

Clarifications on data collection

There were comments asking for further clarification on the proposed data fields as well as suggestions to ensure efficient data collection. Those comments and further clarifications are provided below.

Clarification/delineation between normothermic regional perfusion (NRP) data collection efforts

There were several comments asking for further clarification on the potential overlap of this data collection and the collection of NRP data. The OPTN Liver and Intestinal Transplantation Committee suggested including a data field that specifies if therapy was used prior to or after declaration of death, which is a current challenge with ECMO and NRP data. Additionally, the OPTN Transplant Administrators Committee (TAC) suggested there be clarity on whether ECMO data refers to NRP as well, and if not, then fields should be included to collect that information.

The Committee clarifies that this data collection proposal is a separate effort from NRP data collection and note that NRP data collection is addressed by the OPTN Organ Procurement Organization (OPO) Committee's Board approved (December 2022) and recently implemented *Enhancements to OPTN Donor Data and Matching System Data Collection* proposal.[15]

[15] https://optn.transplant.hrsa.gov/media/uk3nv1ku/policy-notice_dn-data-collection_opo.pdf

Collecting multiple begin and end times for therapies

Some commenters asked for clarification on the ability to collect data for instances when therapies have multiple begin and end times. The Committee clarifies that serial data is permissible for these instances and OPOs will be able to enter multiple begin and end times as applicable for the therapies documented.

Additional Considerations

There were additional comments for the Committee's consideration. One comment advised data definitions that are clear and consistent for the therapies outlined in this proposal. The OPTN OPO Committee also advised the Committee to consult and collaborate with vendors to ensure streamlining of data from medical records.

The Committee agreed with these suggestions and will take these comments into consideration for implementation planning.

Future Considerations

Some commenters provided additional considerations related to future iterations of this data collection effort. Those suggestions are as follows:

- "Future versions should include DCD methods of heart resuscitation, heart transport devices, solutions utilized, and local versus transplant program procurement teams."
- "Future expansion of this mechanism to identify other key donor attributes that might be essential for proper allocation (e.g., donor is a previous recipient of allograft)."

The Committee will take these suggestions into consideration if this data collection effort potentially evolves further.

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. NOTA requires the Organ Procurement and Transplantation Network (OPTN) to "collect, analyze, and publish data concerning organ donation and transplants,"[16] and the Final Rule requires the OPTN to receive and maintain records.[17]

The Final Rule also requires OPOs and transplant hospitals "as specified from time to time by the Secretary, to submit to the OPTN...information regarding transplantation candidates, transplant recipients, [and] donors of organs, transplant program costs and performance, and other information that the Secretary deems appropriate."[18] This proposal is in alignment with NOTA and the Final Rule in promoting efficient donor/recipient matching by allowing the OPTN to collect data collection in a

[16] 42 USC. §274(b)(2)(I).
[17] 42 CFR § 121.11(a)(1)(i-iii).
[18] 42 CFR § 121.11(b)(2).

standardized manner that complements other efficiency tools (e.g., offer filters). This proposal also allows for transparency among OPOs and transplant programs on additional donor information that can provide a more comprehensive and efficient review of organ offers.

OPTN Strategic Plan

This data collection aligns with the strategic plan of increasing the number of transplants. Standardizing this type of data collection and its location within the system will promote more efficient donor organ offer review. Programs that do not rule out donors on support therapies can continue their evaluation while other programs that do not utilize donors who have had support therapies will be able to enter a refusal in a more timely manner. This data will also add additional context for efficiency tools, such as offer filters. With the addition of serum creatinine as an offer filter option, information on whether support therapy was used can clarify the values being evaluated better inform a program's decision on organ offers.

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."[19] This proposal includes the collection of this data to standardize already reported data within the OPTN system such that it can promote the efficient allocation of organs; donor suitability interpretation varies widely depending on which support interventions have been initiated.

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 guidance for submitting these data.

Operations affecting Histocompatibility Laboratories

This proposal 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 support therapy data. Educational efforts and training may be needed to ensure staff have a standardized process of documenting the additional data being proposed.

[19] 42 CFR §121.11(b)(2)

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.

Operations affecting the OPTN

This proposal 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.

Resource Estimates

The OPTN contractor estimates 2425 hours for implementation. This will include hours for developing and testing new support therapy fields in the OPTN Donor Data and Matching System and the OPTN Data System. Additionally, creation of targeted member emails, news articles, and web design, and finally, following up on system and policy questions.

The OPTN contractor estimates 330 hours for ongoing support for this project. This will include continued testing of new features, internal discussions and reviews, and completion of six-month and one-year monitoring reports.

Projected Fiscal Impact

The proposal is anticipated to have low fiscal impact on transplant hospitals. It has potential to have some 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 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 60 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 support therapies, to verify that data reported in the OPTN Computer System are consistent with source documentation.

Data Collection Monitoring

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 support therapies that are standardized/uniformly collected, this proposal will provide a standard format for tracking the use of support therapies within the OPTN Donor Data and Matching System.

The feedback received throughout the development of this project as well as during public comment demonstrated strong support for the proposal which provides a more standardized approach for this data collection. There were various comments that voiced strong belief that this data collection effort will improve data sharing and transparency among OPOs and transplant programs by providing more complete donor data when assessing organ offers.

In the Committee's continued efforts to increase the efficient use of organ offers and acceptances and ultimately reducing overall organ allocation time, this data collection effort complements and will improve other efficiency tools, such as offer filters and can also help inform post-transplant outcomes.

Proposed Changes to Data Fields

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 5: Proposed New Data Field (Parent Field) Indicating Initiation of Support Therapy

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

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

Table 6: Proposed New Data Fields for Support Therapy 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: Cardiac device: (LVAD) - Left ventricular assist device Cardiac device: (RVAD) - Right ventricular assist device Cardiac device: (IABP) - Intra-Aortic Balloon Pump Cardiac device: (VV ECMO) - Venovenous Extracorporeal Membrane Oxygenation Cardiac device: (VA ECMO) - Venoarterial Extracorporeal Membrane Oxygenation Cardiac device: (MCSD) - Temporary mechanical circulatory support devices Cardiac device: Left Heart Device: Other

Data Field	Forms	Description
		Cardiac device: Right Heart Device: Other Inhaled Therapy: Nitric Oxide 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 7: Proposed 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 =~~

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Appendix A: Data Definitions

Table 8: Proposed New Data Field Data Definitions

Data	Definition
Were any support therapies initiated? **Note:** This includes support therapies initiated from the earliest time of admission to time of cross clamp; inclusive of any hospital transfers.	Indicate if any support therapies have been initiated. This includes support therapies initiated from the earliest time of admission to time of cross clamp; inclusive of any hospital transfers. Select Yes of No.
Support Therapy	If support therapies have been initiated, indicate therapy type(s).
Cardiac device	Any devices designed to assist cardiac function
Left ventricular assist device(LVAD)	LVADs are mechanical devices designed to improve cardiac output by assisting with the function of the left ventricle
Right ventricular assist device (RVAD)	RVADs are mechanical devices designed to improve cardiac output by assisting with the function of the right ventricle
Intra-Aortic Balloon Pump (IABP)	IABPs are implanted mechanical devices designed to assist cardiac function
Venovenous Extracorporeal Membrane Oxygenation (VV ECMO) Venoarterial Extracorporeal Membrane Oxygenation (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
Left Heart Device	Any devices designed to assist (left) cardiac function
Right Heart Device	Any devices designed to assist (right) cardiac function
Inhaled Therapy	Inhaled therapies include any support therapies delivered through the respiratory system (route of lungs)
Nitric Oxide	1) Nitric oxide is a naturally occurring vasodilator indicated for treatment of persistent pulmonary hypertension 2) Vasodiatic support or treatment of pulmonary hypertension
Renal Replacement Therapy	Any therapies designed to support kidney function
Continuous Renal Replacement Therapy (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

Data	Definition
Intermittent Hemodialysis (iHD)	Intermittent hemodialysis is a faster method of dialysis indicated primarily to support kidney function
Peritoneal dialysis (PD)	A treatment for kidney failure that uses the lining of the abdomen (peritoneum) as the membrane to filter blood
Sustained low efficiency dialysis (SLED)	An intermittent hybrid renal replacement modality in between conventional intermittent hemodialysis (IHD) and continuous renal replacement therapy (CRRT)

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Appendix B: Post-Public Comment Changes

New language that was proposed following public comment is underlined and highlighted (example); language that is proposed for removal following public comment is struck through and highlighted (~~example~~).

Table 5: Proposed New Data Field (Parent Field) Indicating Initiation of Donor Support Therapy

Data Field	Forms	Description of Response Field
Were ~~Have~~ any ~~donor~~ support therapies ~~been~~ initiated? ~~at or after the initial time of admission?~~ **Note:** This includes support therapies initiated from the earliest time of admission to time of cross clamp; inclusive of any hospital transfers.	OPTN Donor Data and Matching System, Data System for the OPTN	Select Yes or No

Table 6: 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: Cardiac device: (LVAD) - Left ventricular assist device Cardiac device: (RVAD) - Right ventricular assist device Cardiac device: (IABP) - Intra-Aortic Balloon Pump ~~(IABP)~~ Cardiac device: (VV ECMO) - Venovenous Extracorporeal Membrane Oxygenation Cardiac device: (VA ECMO) - Venoarterial Extracorporeal Membrane Oxygenation Cardiac device: (MCSD) Temporary mechanical circulatory support devices ~~(MCSD)~~

Data Field	Forms	Description
		Cardiac device: Left Heart Device: Other Cardiac device: Right Heart Device: Other Inhaled Therapy: Nitric Oxide Inhaled Therapy: Other Renal Replacement Therapy: (CRRT) Continuous Renal Replacement Therapy Renal Replacement Therapy: (iHD) Intermittent Hemodialysis ~~Hemodialysis (intermittent kidney replacement therapies (KRT))~~ 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. ~~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~~

Table 7: Proposed Removal to Current ECMO Data Fields

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