

Deceased Donor Support Therapy Data Collection

OPTN Operations and Safety Committee

Purpose of Proposal

- Collect data on donor support therapies to promote the efficient review of organ offers from donors on support therapies (ex. CRRT, ECMO)
 - This data will provide granular information to complement the ongoing offer filters effort
 - Standardize the reporting of these data
 - This data will allow for the evaluation of post-transplant outcomes

Rationale

- Currently, data on donor support therapies is not collected in a standardized/uniform manner
 - This data can inform decisions on organ offers and help in assessing outcomes
- Goal/Intent: Make data collection as simple as possible
 - For purposes of this data collection effort, intent is to make aware that a donor support therapy was used, type of donor support therapy, and duration
 - Inquiring on additional information on donor support therapies would be at the discretion of the transplant program

Proposal

- The OSC proposes adding seven new fields
 - Parent field: Have any donor support therapies been initiated at or after the initial time of admission? (Y/N)
 - If YES, Collection field: Support therapy, begin date/time, end date/time
 - Data field that would allow the option to select “Ongoing until Cross-clamp” as the end date/time
- This data collection will be within the Donor Data and Matching System and will be populated to TIEDI
- The parent field (Yes/No response) will be required data collection for sending organ offers

Proposal

- Two new data fields are being proposed as follows:
 - Parent Field: Indicates initiation of Donor Support Therapy

Data Field	Forms	Description of Response Field
<u>Have any donor support therapies been initiated or are ongoing from the time of admission?</u>	OPTN Donor Data and Matching System, Data System for the OPTN	<u>Select Yes or No</u>

- If the response is no, no further action would be needed
- If the response is yes, a subsequent field will appear to document further information

Proposal (continued)

Support Intervention Specifications

- If yes is selected on the previous prompt, these details will be collected.

Data Field	Forms	Description
<u>SUPPORT_THERAPY</u>	OPTN Donor Data and Matching System, Data System for the OPTN	<p><u>Drop down list of support therapies, would include the following options:</u></p> <p><u>VV ECMO</u></p> <p><u>VA ECMO</u></p> <p><u>Temporary mechanical circulatory support devices (MCSO).</u></p> <p><u>CRRT</u></p> <p><u>RVAD</u></p> <p><u>LVAD</u></p> <p><u>Hemodialysis (intermittent kidney replacement therapies (IKRT))</u></p> <p><u>Intra-Aortic Balloon Pump (IABP)</u></p> <p><u>Nitric Oxide</u></p>
<u>Begin Date</u>	OPTN Donor Data and Matching System, Data System for the OPTN	<u>Must be before cross-clamp date</u>
<u>Begin Time</u>	OPTN Donor Data and Matching System, Data System for the OPTN	<p><u>Format: HH:MM.</u></p> <p><u>Note: Time should be in 24-hour format.</u></p>
<u>End Date</u>	OPTN Donor Data and Matching System, Data System for the OPTN	<u>Must be before cross-clamp date</u>
<u>End Time</u>	OPTN Donor Data and Matching System, Data System for the OPTN	<p><u>Format: HH:MM.</u></p> <p><u>Note: Time should be in 24-hour format.</u></p>

Data Definitions: Donor Support Therapies

Data	Definition
VA ECMO VV 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

Proposal: Removal of Current ECMO Data Fields

- The Committee proposes the removal of the current ECMO data collection field found in the Data System for the OPTN
 - If response is yes to field asking if donor was recovered under DCD protocol, subsequent field asks if any ECMO support was given (Organ Recovery section of the Data System for the OPTN)
 - Includes duration of the therapy and flow rate
 - To avoid redundancy, the Committee propose to remove this data field and use the proposed data collection effort to collect ECMO data
 - Committee agreed to only collect duration; soliciting further feedback in public comment to proposed change

ECMO Data

- Currently, there is data being collected in the Data System for the OPTN for heart
- The Committee is proposing to remove this field

Organ Recovery	
Recovery Date (donor to OR):*	<input type="text" value="12/14/2022"/>
Was this donor recovered under DCD protocol:*	<input checked="" type="radio"/> YES <input type="radio"/> NO
If Yes, Controlled:	<input type="radio"/> YES <input type="radio"/> NO <input type="radio"/> UNK
If Yes, Core Cooling Used:	<input type="radio"/> YES <input type="radio"/> NO
Pulmonary Measurements:	
ABG Results	
Blood pH:*	<input type="text" value="7.42"/>
PCO ₂ :*	<input type="text" value="41.00"/> mmHg
PO ₂ :*	<input type="text" value="412.00"/> mmHg
PEEP:*	<input type="text" value="5"/> mm/Hg
FIO ₂ :*	<input type="text" value="100"/>
Ventilator mode:*	<input type="text" value="A/C"/> ▾
Was a pulmonary artery catheter placed:*	<input type="radio"/> YES <input checked="" type="radio"/> NO
Biopsy (heart donors only):*	<input type="text" value="NO"/> ▾
Any Extracorporeal Support Given (ECMO, etc.):	<input type="radio"/> YES <input type="radio"/> NO
How Long?	<input type="text"/> hrs ST= <input type="text"/> ▾
Flow rate:	<input type="text"/> L/min ST= <input type="text"/> ▾



Next Steps

- The Committee will review feedback from public comment and make adjustments as needed

What do you think?

- 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?
- Is the recommendation to remove 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?

Data Collection Option

When yes/no question is set to yes then support therapy data collection fields display

Have any donor support therapies been initiated at or after the initial time of admission?

Yes No

Support therapy	Begin date	Begin time	End date	End time	
Select	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	

MEDICATIONS & FLUIDS									
Inotropic Medication	Begin Date	Begin Time	End Date	End Time	Value	Units	Duration (hours)		
Neosynephrine	04/26/2023	00:20	04/26/2023	07:00	1	mcg/kg/min	6:40:00		