OPTN

Notice of OPTN Data Collection Change

Modifications to the Deceased Donor Registration (DDR)

Sponsoring Committee:	**Organ Procurement Organization**
Data Collection Affected:	***Deceased Donor Registration (DDR)***
Public Comment:	**January 21, 2021 – March 23, 2021**
Board Approved:	**June 14, 2021**
Effective Date:	**Pending OMB approval, implementation, and notice to OPTN members**

Purpose of Data Collection Change

These changes will ensure the data available to the community and the OPTN provides accurate analyses to meet the requirements in the OPTN Final Rule. Additionally, these changes will provide OPO staff with improved direction and clarity when entering deceased donor data on the deceased donor registration (DDR) form.

Proposal History

The most recent substantive changes to the DDR occurred in 2010 as part of a comprehensive review of all TIEDI forms. The OPO Committee routinely reviews member questions about the data fields and data definitions, which led to the decision to initiate a comprehensive review of the entire data collection form. The timing of this review also corresponds with the OPTN Data Advisory Committee (DAC) charge to review all OPTN data collection tools. The intent of these changes is to promote more consistent and accurate data collection by modifying, removing, or relocating data element as well as providing OPO staff with improved direction and clarity when entering deceased donor data into the DDR.

Summary of Changes

The changes to the DDR, which are listed below, include the following:

- Modification of 19 data elements
- Removal of 6 data elements
- Relocation of 3 data elements

Implementation

Organ Procurement Organizations

This proposal will require OPO staff to become familiar with the changes to the DDR and data definitions.

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Programming will be required to implement the changes in UNet[SM] and will include data field removals, additions, and edits, as well as removals, additions, and edits to response options.

The changes to the DDR, which is an OMB approved data collection form, will also require OMB approval under the Paperwork Reduction Act of 1995. This approval process may impact the implementation timeline.

Affected Data Collection

New language is underlined (example) and language that is deleted is struck through (~~example~~).

Data Element	Change
First name, last name	Update data definition to provide general direction about how to enter information when the donor identity is unknown in order to promote consistency. • Last Name: Enter the donor's last name. **This field is required.** • First Name: Enter the donor's first name. **This field is required.** If the donor identity is unknown, enter the hospital-generated alias.
Home city, state, and zip code	Add the option to enter "unknown" for each of these data elements. This is important due to situations where OPOs are unable to collect and report this information.
Procurement and Authorization	Remove "Procurement and" from the title.

Data Element	Change

Medical examiner/coroner	These recommendations will capture information about how the interaction with the medical examiner/coroner affects authorization for organ donation. Note: Death Notification Registration (DNR) changes required to maintain alignment
	
	~~Medical examiner/coroner:~~
	~~• No~~
	~~• Yes, Medical examiner consented~~
	~~• Yes, Medical examiner refused consent~~
	
	• Did the OPO notify the medical examiner/coroner?
	  ○ Yes
	  ○ No – skip 2 questions below
	  If yes, did the medical examiner/coroner accept the case?
	  ▪ Yes
	  ▪ No
	  If yes, were there any restrictions?
	  • Multi-select menu of all organs

Did the patient have written documentation of their intent to be a donor? If yes, indicate mechanisms	Align with proposed changes to the Death Notification Registration (DNR) by replacing with the following two questions. • Did patient legally document decision to be a donor? • Was authorization obtained for organ donation? Remove mechanisms from DDR since OPOs collect this information and mechanisms, such as driver's license or donor card, are not used by the OPTN.
Was the authorization based solely on this documentation?	Remove from the DDR, this information does not provide relevant information value about authorization for organ donation.
Did the patient express to family or others the intent to be a donor?	Remove from the DDR, this information does not provide value and is difficult for OPOs to collect from family members.

Data Element	Change
Cardiac arrest since neurological event that led to declaration of brain death If yes, duration of resuscitation	*Current location*: Procurement and Authorization *New location*: Organ Recovery – The procurement and authorization section is being modified to only collect information about authorization for donation.
Date and time of pronouncement of death	*Current location*: Procurement and Authorization *New location*: Organ Recovery – The procurement and authorization section is being modified to only collect information about authorization for donation.
Weight	Update data definition to specify that the weight entered should be the first measured weight following admission to the hospital. • Enter the <u>first measured</u> weight of the donor <u>after hospital admission</u> in lbs (pounds) or kg (kilograms). This field is required. • If the donor's weight ~~at the time of recovery~~ is unavailable, select the reason from the status drop-down list (N/A, Not Done, Missing, Unknown).

Data Element	Change
Terminal lab data	If a lab value is unavailable, only allow “not done” option instead of N/A, not done, missing, unknown. Switch the order of serum lipase and serum amylase Update “Na” in DonorNet to align with serum sodium in the DDR Update data definition to specify that the terminal lab values include tests performed during donor management and prior to the donor entering the OR. For each of the laboratory tests enter the value, in the units indicated, from tests performed during donor management and prior to the donor entering the operating room. ~~closest to the time of recovery.~~ These fields are required. If a lab value is unavailable, select the reason from the status (ST) drop-down list (N/A, ~~Not Done,~~ Missing, Unknown). (List of Status codes)
Serology	Rename using the common terminology “infectious disease testing” and delete the separate NAT results section by incorporating NAT results into the same section since these are all infectious disease testing results. Add the word “equivocal” to the response options, as shown below, since lab results can be indeterminate (no clear negative or positive result) or equivocal (cannot be interpreted as negative or positive). For each of the tests listed, select the results from the lists (Cannot Disclose, Indeterminate/Equivocal, Negative, Not Done, Positive, or Unknown). These fields are required.
NAT results	Include NAT results in the “Infectious Disease Testing” section (previously labeled “serology”)
Inotropic medications at time of cross clamp	Update field label to include “or at time of withdrawal of life-sustaining medical support” in order to capture this information for donation after circulatory death (DCD) donors.

Data Element	Change

Number of transfusions	• Transfusions prior to ABO determination: Yes or No
	  • If yes, total number and total volume
	• Transfusions following ABO determination: Yes or No
	  • If yes, total number and total volume

Cocaine use (ever) AND continued in last six months Other drug use (ever) AND continued in last six months	Currently collected as yes, no, or unknown responses Ever use or take drugs, such as steroids, cocaine, heroin, amphetamines, or opioids? • Type of drug • How often and how long was it used? • When was it last used? • Route (inhaled, needles, ingested)
Tattoos	Remove from DDR since this information does not factor into organ acceptance and is not included as a risk factor in the PHS guideline.
According to the OPTN policy in effect on the date of referral, does the donor have risk factors for blood-borne transmissions	According to the OPTN policy in effect ~~on the date of referral~~, does the donor have risk factors for blood-borne transmissions
Cancer free interval	Remove from DDR.

Data Element	Change
Was this donor recovered under DCD protocols?	
If yes, • Controlled? • Date/time of withdrawal of support • Date/time agonal phase begins	Remove option for an unknown response to "If Yes, controlled." The rationale is that OPOs will know whether it was a controlled or uncontrolled DCD and therefore the option of "unknown" is unnecessary. Update the field as shown below: • If Yes, Date and time agonal phase begins (systolic BP < 80<u>mmHg</u> or O2 sat. < 80% <u>sustained</u>):
If DCD, total urine output during OR recovery phase	Remove this data element because this is difficult to collect/measure urine and is not used to assess kidney function during the recovery procedure.
DCD serial data	Remove the collection of DCD serial data
If yes, core cooling used If yes, date/time of • Abdominal core cooling • Thoracic core cooling • Portal vein core cooling • Pulmonary artery core cooling	Remove "If yes," so the core cooling information is collected on both donation after brain death (DBD) and DCD donors. Replace "core cooling" with "flush" which is more commonly used terminology "Gray out" the remaining fields (abdominal, thoracic, portal vein, and pulmonary artery) if the initial response to use of core cooling is "no."
History of MI	Add this data element to DonorNet so the information can cascade to the DDR.

Data Element	Change
LV ejection fraction (%) and method	*Updated data definitions:* Provide the left ventricular ejection fraction, if known. This should be the final measurement collected prior to the donor entering the operating room. If the left ventricular ejection fraction is unavailable, select the reason from the status (ST) drop-down list (N/A, Not Done, Missing, Unknown).This field is required. Method: Select the left ventricular ejection method from the drop-down list. If a value is entered for LV ejection fraction, this field is required. (List of LV Ejection Method codes) • Echo (echocardiogram) • MUGA (multiple gated acquisition scan) • Angiogram
Coronary angiogram	• No • Yes, normal (no evidence of coronary artery disease) • Yes, ~~not normal~~ abnormal but non-obstructive (all stenosis determined to be < 70%) • Yes, abnormal and obstructive (presence of any stenosis determined to be > 70%)
Was a pulmonary artery catheter placed? If yes, initial and final preoperative measurements	Were advanced hemodynamic parameter data obtained? • If yes, indicate the method (pulmonary artery catheter or minimally invasive monitoring) and report one set of measurements
Biopsy (heart donors only)	Remove from DDR since heart biopsies are typically not performed on deceased donors. Only two “yes” responses entered for deceased donors recovered between July 2018 - June 2019.
Liver Biopsy: % macro vesicular fat	Align the terminology with the recent programming for the expedited placement of livers, which included the collection of macrosteatosis percentage, if available. This will remain an open numeric field in both DonorNet and the DDR.

Data Element	Change
Lung (right and left) bronchoscopy	• No Bronchoscopy • Bronchoscopy Results normal • Bronchoscopy Results, Abnormal-other • Bronchoscopy Results, Abnormal-purulent secretions • Bronchoscopy Results, Abnormal-aspiration of foreign body • Bronchoscopy Results, Abnormal-blood • Bronchoscopy Results, Abnormal-anatomy/other lesion • Bronchoscopy Results, Unknown • ~~Unknown if bronchoscopy performed~~ Update data definitions, as shown below, to specify that when multiple bronchoscopies are performed, enter the last results prior to the donor entering the operating room. If a lung was recovered or transplanted, select the results of the bronchoscopy procedure from the drop-down list. If multiple bronchoscopies are performed, enter the results from the last bronchoscopy performed prior to the donor entering the operating room. If the results were abnormal, select Abnormal with the type of abnormality. If a bronchoscopy was not performed, select No Bronchoscopy. ~~If unknown, select Unknown if bronchoscopy performed~~. This field is required.
Lung machine perfusion intended or performed	Lung machine perfusion ~~intended or~~ performed
For each organ disposition: If DCD, date/time organ recovered or removed from donor	Remove “If DCD” for each organ disposition
Recipient social security number for each organ transplanted	Remove from DDR

Data Element	Change
Recovery team #	Change from 6-digit provider number to 4-digit OPTN center code and 3-digit OPTN center type of the transplant center team recovering the organ. This will provide more accurate data since broader distribution has increased the use of local recovery surgeons. Update data definitions to clarify that if the OPO provides the recovery team the OPO center code and center type must be entered.
Initial flush solution and volume	Initial flush solution ~~and volume~~
Back table flush solution and volume	Back table flush solution ~~and volume~~