OPTN

Briefing to the OPTN Board of Directors on

Modifications to the Deceased Donor Registration (DDR)

OPTN Organ Procurement Organization Committee

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Contents

OPTN

Modifications to the Deceased Donor Registration (DDR)

Sponsoring Committee: *Organ Procurement Organization*
Public Comment Period: *January 21, 2021 – March 23, 2021*
Board of Directors Date: *June 14, 2021*

Executive Summary

The Deceased Donor Registration (DDR) is part of the Transplant Information Electronic Data Interchange (TIEDI®), which is part of the Organ Procurement and Transplantation Network (OPTN) data system (UNet℠) for transplant centers, OPOs, and histocompatibility laboratories across the country. The DDR is a record of donor information completed for all deceased donors from whom at least one organ has been recovered for the purposes of transplantation.

The OPTN Organ Procurement Organization (OPO) Committee proposes modifications to the DDR. 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.

This proposal outlines the recommended changes to the DDR based on a comprehensive review of the form as well as feedback from the community. This briefing paper summarizes the recommendations being submitted to the OPTN Board of Directors for approval as well as the data elements that will require additional work by the Committee.

The National Organ Transplant Act of 1984 (NOTA) requires the OPTN to "collect, analyze, and publish data concerning organ donation and transplants."[1] Organ procurement organizations (OPOs) submit data on deceased donors electronically through UNet, a secure web-based data collection system. This proposal also aligns with the Final Rule's requirement that the OPTN and Scientific Registry "[m]aintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors" and "[m]aintain records of all transplant candidates, organ donors, and transplant recipients."[2]

Finally, this proposal aligns with the OPTN Strategic Goal to promote the efficient management of the OPTN by ensuring accurate data is available to evaluate OPO performance, monitor potential disease transmission, and evaluate post-transplant outcomes, among other things.

[1] NOTA, 42 U.S.C. § 274(b)(2)(I)
[2] 42 CFR § 121.11 (a)(1)(i)-(ii)

Background

Under the OPTN Final Rule, OPOs and transplant hospitals are required to submit data to the OPTN.[3] In 2006, the OPTN established the principles of data collection where institutional members must provide sufficient data to allow the OPTN to do the following[4]:

- Develop transplant, donation, and allocation policies – Deceased donor data provides information useful for developing evidence-based allocation policies.
- Determine if OPTN members are complying with policy – This ensures trust in the transplant system by using data to evaluate member compliance with OPTN policies.
- Determine member-specific performance – In collaboration with the SRTR, the OPTN is required to make information on OPO performance publically available.
- Ensure patient safety when no alternative sources of data exist – Clinical information on deceased donors can provide an understanding of potential impacts on patient outcomes and patient safety.
- Fulfill the requirements of the OPTN Final Rule.

Additionally, the OPTN Board of Directors approved the following OPTN Data Vision Statement during its December 5-6, 2016 meeting:[5]

> *The OPTN collects information in accordance with the Final Rule: 1) to characterize the population it serves; 2) to improve the allocation and utilization of organs; and 3) to develop and assess policies and processes to optimize outcomes. The overall intent is to provide value to patients, OPTN members, the organ donation/transplantation community, and the general public.*
>
> • Whenever possible, data collected in hospital or OPO electronic health records, and other databases should be accessible to the OPTN without the need for additional data entry.
> • Variables collected should specifically support the data uses outlined above and should be re-evaluated on a regular basis.
> • Data collected should be accurate (based on clear definitions), complete, timely, and subject to ongoing quality control audits/efforts.

The DDR is an important data collection tool for OPOs to submit information on deceased donors. *OPTN Policy 18.1: Data Submission Requirements*, requires OPOs to submit the DDR within "30 days after the donor organ disposition (feedback) form is submitted and disposition is reported for all organs." It should be noted that this requirement will change to 60 days following implementation of OPTN Board-approved data submission policy changes.[6] The sections of the DDR include:

[3] 42 CFR § 121.11
[4] "Principles of Data Collection," OPTN, accessed December 11, 2020. https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/
[5] https://optn.transplant.hrsa.gov/media/2038/board_executivesummary_201612.pdf
[6] https://optn.transplant.hrsa.gov/media/3459/modify-data-submission-policies-policy-notice.pdf

- Donor Information
- Procurement and Authorization
- Clinical information
- Lifestyle Factors
- Organ Recovery
- Organ Dispositions

The most recent substantive changes to the DDR occurred in 2010 when the Policy Oversight Committee (POC) conducted a comprehensive review of all TIEDI forms. This 2010 project was initiated in order to identify any necessary changes as part of the three-year cycle of review and approval of all OPTN forms by the Office of Management and Budget (OMB). The POC distributed these proposed changes for public comment and the OPTN Board of Directors subsequently approved the changes in November 2010.[7] The proposal resulted in changes to all TIEDI forms and the changes to the DDR included the addition of twenty-five data elements, modification of four data elements, and deletion of nine data elements.

The OPO Committee routinely reviews member questions about the data fields and data definitions that are submitted to the UNOS Research department. The number of questions reviewed during biannual in-person committee meetings has increased over the years, from two in March 2015 to seven in October 2018. The questions also varied in complexity, 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 Committee collaborated with the DAC in developing this proposal. The DAC is an operating committee of the OPTN and oversees all data-related functions, including collaborating with other OPTN committees on additions, modifications, and deletions of data elements collected by the OPTN in order to improve the completeness, accuracy, and timeliness of the data.[8] The joint workgroup, comprised of members from both committees, reviewed each data element to determine the intent, relevancy, reliability, availability, and burden. Workgroup members, in collaboration with SRTR and UNOS Research department staff, used their clinical expertise to develop recommendations for changes to the data elements and definitions. Additional feedback was received from the leadership of several committees, including the Ad Hoc Disease Transmission Advisory Committee, Heart Transplantation Committee, and Liver and Intestinal Organ Transplantation Committee.

Purpose

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 "that the OPTN and Scientific Registry "[m]aintain and operate an automated system for managing information about transplant candidates, transplant recipients, and organ donors," and "[m]aintain records of all transplant candidates, organ donors, and transplant recipients".[9] These changes will also provide OPO staff with improved direction and clarity when entering deceased donor data on the deceased donor registration form.

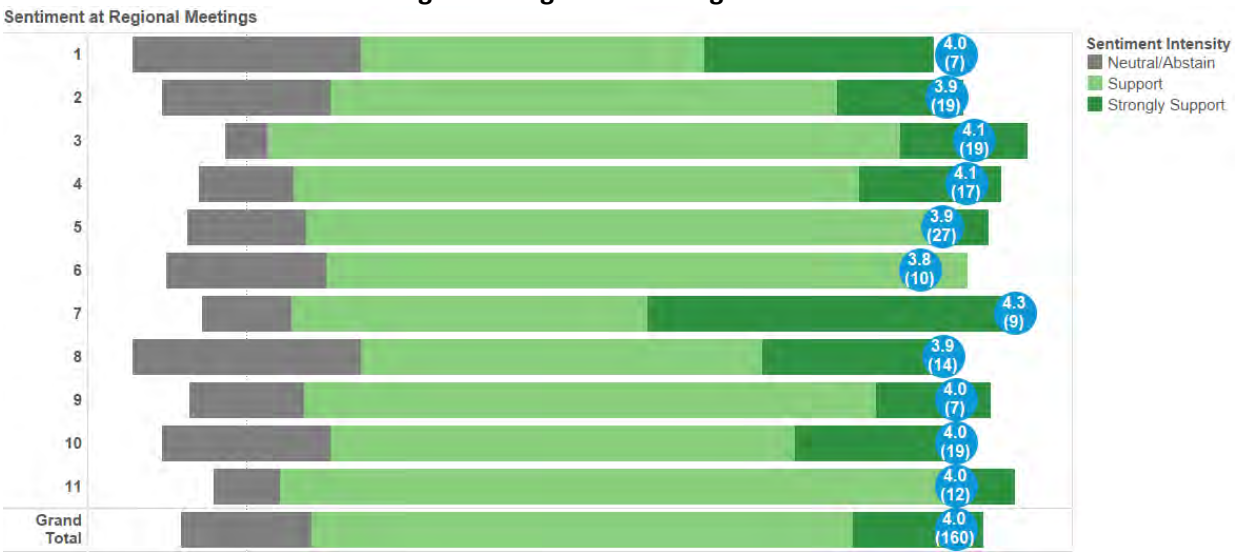
[7] https://optn.transplant.hrsa.gov/media/1799/executivesummary_1110.pdf
[8] https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/
[9] 42 CFR § 121.11(a)(1)(i)-(ii)

Overall Sentiment from Public Comment

This proposal was distributed for public comment from January 21, 2021 to March 23, 2021 and the feedback is described below. The comments received included responses to specific feedback questions regarding citizenship, donor management medications, recovery date, clinical infection confirmed by culture, number of transfusions, drug use, and history of Chagas and tuberculosis.

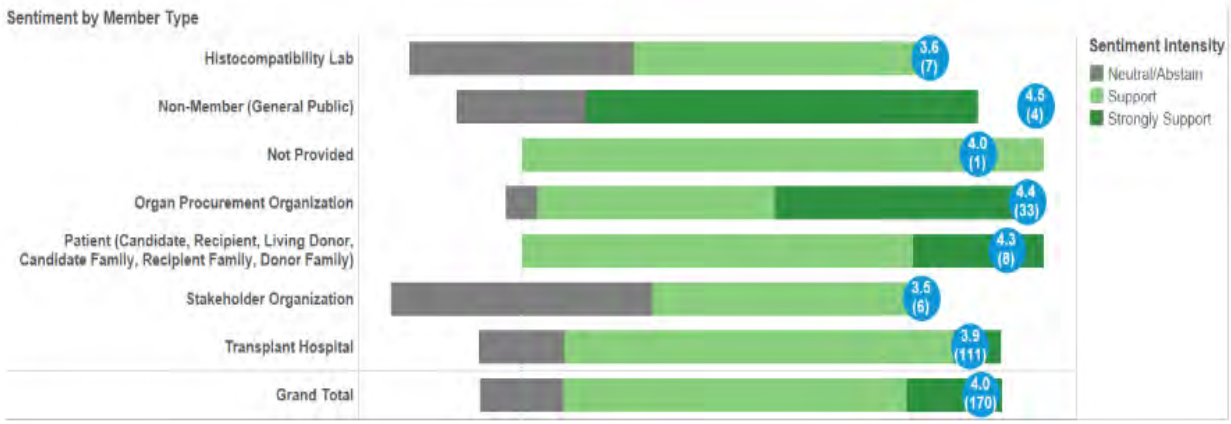
Public comment sentiment indicated support for this proposal across all 11 OPTN regions, as shown in **Figure 1**.

Figure 1: Regional Meeting Sentiment



Public comment sentiment indicated support for this proposal across member types, as shown in **Figure 2**.

Figure 2: Member Type Sentiment



The OPTN Pancreas, Ad Hoc International Relations, Operations and Safety, Ad Hoc Disease Transmission Advisory (DTAC), and Data Advisory Committees reviewed this proposal and provided feedback. There was general support for the proposed changes.

Several professional societies, including American Society of Transplantation (AST), the American Society of Transplant Surgeons (ASTS), the Association of Organ Procurement Organizations (AOPO), and The Organization for Donation and Transplant Professionals (NATCO) provided feedback on this proposal. There was general support from all the organizations for the effort to improve data collection.

Public comments addressed several main topics, most notably responses to the specific feedback requested. There were mixed responses from the community about whether to retain certain data elements or expand on the information collected for each. A summary of the items that garnered comments as well as the Committee's responses are highlighted below. Final recommendations for all data elements can be found in **Table 1**.

- *Citizenship* – There were mixed comments during public comment with more support for removal than retaining. However, the Committee recognized that the Ad Hoc International Relations Committee and other researchers utilize this information and recommend retaining the citizenship information.

- *Donor management (Any medications administered within 24 hours prior to crossclamp)* – AST and ASTS both commented that the current list of medications was comprehensive enough. AST commented that dosages and duration would be helpful information; however, ASTS noted that adding this information would add to member data burden with little clinical impact. There was support for adding dosages and duration as well as support from several commenters for more granular information about the types of medications. The Committee considered the comments and agreed that the current list of medications does not provide adequate information and should be revised. For example, if a donor has received steroids there would not be information about the type of steroid, dosages, and duration. Therefore, the Committee agreed to consider these changes in the future, but not to recommend any changes to this section of the DDR at this time. The Committee will evaluate the list of medications in DonorNet to inform future changes to the DDR that will allow data to cascade without requiring manual entry.

- *Number of transfusions* – The Committee proposed changes that would collect total volume instead of the number of transfusions. They also requested feedback regarding the specific timeframe for reporting transfusions during the terminal hospitalization. Most commenters supported the addition of volume but also supported the continued reporting of the number of transfusions. While there were no comments regarding the timeframe, the Committee determined that establishing a timeframe is important to evaluate the impact of transfusions. Therefore, the Committee is proposing that the number of transfusions and total volume be reported within the following timeframes: Prior to ABO determination and following ABO determination. The Committee also proposes the number of transfusions currently captured as ranges (0-5, 6-10, greater than 10, unknown) be collected as the actual number of transfusions.

- *History of Chagas and TB* – Several commenters recommended no changes to the current collection. However, there were also comments suggesting that additional information to assess risk factors should be considered. The Committee considered the comments and noted that not all OPOs test for Chagas and TB and recommends that the Chagas and TB history data element remain unchanged with yes, no, and unknown response options.

- *Clinical infection confirmed by culture* – There was support for the collection of more granular data, although ASTS noted that it could be difficult to do so in the DDR format. The DTAC requested that the OPO Committee consider the utility of this data collection without more granularity. The Committee agreed with the DTAC's assessment that more information would be beneficial and recommended continued work to evaluate and make future changes to this data element.

- *Cancer free interval* – The Committee recommended the removal of this data element from the DDR. There was concern about the reliability of this information because it is dependent on a historian knowledge of cancer treatment and the timeframe since treatment. The AST recommended retaining this data element because it is relevant for acceptance and post-transplant monitoring. The Committee noted that the information is still available to transplant centers and can be provided by the OPO at the time of the offer. They also noted that the information in the DDR is not due until 30 days after organ procurement. Therefore, the Committee still recommends the removal of this data element.

- *Coronary angiogram* – The Committee recommended changes that would clarify the meaning of "normal" and "abnormal" results. Normal would include results that indicate no evidence of coronary artery disease and not normal include results showing some evidence of coronary artery disease. The AST recommended additional responses that include abnormal results that are either non-obstructive or obstructive as determined by the presence of stenosis of less than or greater than 70%. The Committee accepted these recommendations.

- *DCD serial data* – The Committee requested feedback about whether this information should still be collected on the DDR, and if so, at what intervals should the information be recorded. Currently, the information is collected every 5 minutes between withdrawal of support and the start of agonal phase, then every 1 minute between the start of agonal phase and circulatory standstill or death. There was general support for maintaining the current data efforts. The Committee noted that OPOs collect this information in greater detail within their electronic donor records and provide the information to transplant centers by uploading attachments into DonorNet. The information is also not a required field in the DDR and creates additional work for OPO staff to enter this information with no clear benefit. Therefore, the Committee recommends removing this data collection from the DDR.

- *Cocaine and other drug use* – In order to improve data collection, the Committee proposes using language similar to the universal donor risk assessment interview questions (UDRAI). OPO staff typically use this standardized document when completing the DDR. This will provide more useful information than the current yes, no, or unknown response options. There was general support for these proposed changes.

The Committee also agreed that, whenever possible, updates to other data collection tools such as DonorNet should align with TIEDI forms to allow for the transfer of data to mitigate data burden and reduce errors or inconsistencies.

While there was significant support for removing recovery date from the DDR, this will require additional work in order to modify the following policies that utilize recovery date to determine extra vessel storage requirements:

- *5.8.C: Additional Pre-Transplant Verification Requirements for Extra Vessels*
- *16.3.D: Internal Labeling of Extra Vessels*
- *16.6.B: Extra Vessels Storage*

Proposal for Board Consideration

The Committee is proposing modifications to the DDR and the data definitions, as outlined in **Table 1.**

Proposed Modifications

Table 1: Proposed Modifications to the DDR and Data Definitions

Data Element	Recommended Changes
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. Based on the recommendations to move "cardiac arrest since neurological event that led to declaration of death" and "date and time of pronouncement of death" to the organ recovery section, the information collected in this section focuses on authorization for donation.

Data Element	Recommended Changes

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
	
	Current:
	Medical examiner/coroner:
	• No
	• Yes, Medical examiner consented
	• Yes, Medical examiner refused consent
	
	Proposed changes:
	• 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	Recommended Changes
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 first measured weight of the donor after hospital admission 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). This will provide better guidance about when the patient weight is measured. This will mitigate the impact of medical treatment and donor management on weight values since fluids and medications can affect weight.

Data Element	Recommended Changes
Terminal lab data	The intent of this change is to mitigate inconsistencies when additional lab tests are performed in the donor OR. 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. The intent of this change is to mitigate inconsistencies when additional lab tests are performed in the donor OR. For each of the laboratory tests enter the value, in the units indicated, from tests performed <u>during donor management and prior to the donor entering the operating room.</u> ~~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/<u>Equivocal</u>, Negative, Not Done, Positive, or Unknown). These fields are required.
NAT results	Recommendation: Include NAT results in the "Infectious Disease Testing" section (previously labeled "serology")
Inotropic medications at time of cross clamp	Update field label to include "<u>or at time of withdrawal of life-sustaining medical support</u>" in order to capture this information for donation after circulatory death (DCD) donors.

Data Element	Recommended Changes

Number of transfusions	*Proposed changes:*
	• Transfusions during terminal hospitalization? – yes or no
	• If yes, total volume
	Final recommendations:
	• 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	Remove "on the date of referral"
Cancer free interval	Remove from DDR. Reliability is a concern and dependent on historian knowledge of cancer treatment and timeframe since treatment.

Data Element	Recommended Changes
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	Recommended Changes
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	If the donor had a coronary angiogram, select Yes, Yes - normal or Yes - not normal from the list. If the donor did not have a coronary angiogram, select No. This field is required. • No • Yes, normal (no evidence of coronary artery disease) • Yes, not normal (some evidence of coronary artery disease) *Post public comment change* • 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	Update this data element to include measurements obtained by minimally invasive monitoring methods, which are becoming more common. *Recommendation:* Were advanced hemodynamic parameter data obtained? • If yes, indicate the method (pulmonary artery catheter or minimally invasive monitoring) and report one set of measurements

Data Element	Recommended Changes
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.
Lung (right and left) bronchoscopy	Add an additional response option for "abnormal-other" results and remove "unknown if bronchoscopy performed" since OPOs will know whether a bronchoscopy was performed. *Proposed responses:* • No Bronchoscopy • Bronchoscopy Results normal • <u>Bronchoscopy Results, Abnormal-other</u> • 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 to specify that when multiple bronchoscopies are performed, enter the last results prior to the donor entering the operating room. *Updated data definitions:* If a lung was recovered or transplanted, select the results of the bronchoscopy procedure from the drop-down list. <u>If multiple bronchoscopies are performed, enter the results from the last bronchoscopy performed prior to the donor entering the operating room.</u> 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	Delete "intended or" and only collect if actually performed since intended perfusion does not provide useful data.

Data Element	Recommended Changes
<u>For each organ disposition:</u> If DCD, date/time organ recovered or removed from donor	Remove "If DCD" so this information is captured for both DCD and DBD donors on all organs.
Recipient social security number for each organ transplanted	Remove from DDR since OPOs and transplant centers typically use the name and waitlist ID and there are concerns about the use of social security numbers as a form of identification.
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	Retain type of initial flush solution but remove "volume" requirement for liver and pancreas since volume is not relevant information to collect for flush solutions.
Back table flush solution and volume	Retain type of back table flush solution but remove "volume" requirement for liver and pancreas since volume is not relevant information to collect for flush solutions.

NOTA and Final Rule Analysis

NOTA requires the OPTN to "collect, analyze, and publish data concerning organ donation and transplants."[10] The OPTN requires OPOs to submit data on deceased donors electronically through UNet, a secure web-based data collection system, to fulfill this requirement. The Final Rule requires the OPTN and Scientific Registry to "maintain and operate an automated system for managing information and records of all transplant candidates, organ donors, and transplant recipients."[11] These modifications will ensure that the OPTN provides more accurate and better quality data on deceased donors.

[10] NOTA, 42 U.S.C. § 274(b)(2)(I)
[11] 42 CFR § 121.11(a)(1)(i)-(ii)

Alignment with OPTN Strategic Plan[12]

This proposal aligns with the OPTN Strategic Goal to promote the efficient management of the OPTN by ensuring accurate data is available to evaluate OPO performance, monitor potential disease transmission, and evaluate post-transplant outcomes, among other things.

Implementation Considerations

Member and OPTN Operations

Operations affecting Organ Procurement Organizations

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

Operations affecting Transplant Hospitals

This proposal is not anticipated to affect the operations of transplant hospitals.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of Histocompatibility Laboratories.

Operations affecting the OPTN

This proposal will require programming in UNet^{SM} as reflected in **Table 1**. These modifications will ensure that the OPTN provides improved accuracy and quality of data on deceased donors.

This proposal will require modifications to official OPTN data currently 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.

Projected Fiscal Impact

OPOs

The process for completing the DDR may vary among OPOs, but staff time and potential (minimal) cost savings per case may result due to a more succinct and streamlined form. The updated form should improve the completion process for any OPO, regardless of internal workflow. This could potentially reduce administrative burden, as OPO staff will spend less time trying to interpret how the data should be entered or reaching out to the OPTN for assistance.

[12] For more information on the goals of the OPTN Strategic Plan, visit https://optn.transplant.hrsa.gov/governance/strategic-plan/.

Minimal implementation time is necessary to educate staff and update internal workflow.

Transplant Hospitals

There is no expected impact for transplant hospitals.

Histocompatibility Laboratories

There is no expected fiscal impact for histocompatibility laboratories.

Projected Impact on the OPTN

A significant development effort was facilitated by Policy and Community Relations, including committee and workgroup meetings, as well as internal team meetings to ensure alignment across IT, Research, and other internal stakeholders.

A Large IT implementation effort, estimated at approximately 1,620 hours, involves numerous changes in DonorNet® including data field removals, additions, and edits, as well as removals, additions, and edits to response options. These modifications will require subsequent updates to help documentation. Research estimates 150 hours of work to update analysis datasets and the OPTN website, and Member Quality estimates 100 hours to update monitoring processes and train staff.

Research anticipates a Very Small effort in routine monitoring to develop reports and map old to new values.

Post-implementation Monitoring

Member Compliance

This proposal will not change the current routine monitoring of OPTN members. Site surveyors will continue to review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported in the DDR is consistent with source documentation.

Data Collection Monitoring

These data modifications will be formally evaluated approximately 6 months, 1 year, and 2 years post-implementation. The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available (appropriate lags will be applied, per typical OPTN conventions, to account for time delay in institutions reporting data to UNet) and compared to an appropriate pre-implementation cohort: summary statistics, distributions, and missing data for modified data elements *(Table 1)* will be compared pre- and post-implementation.

Conclusion

Improvements to data collection tools are imperative to promote more consistent and accurate data collection by clarifying the data elements and updating the associated data definitions. These changes support the OPTN's task to collect transplant data according to regulatory requirements and the OPTN

contract. Accurate data collection is important for performance improvement, evaluation of transplant system performance, and assessment of how the transplant system is performing.

The proposal aligns with the Final Rule's requirement that the OPTN and Scientific Registry to "maintain and operate an automated system for managing information…..and records of all transplant candidates, organ donors, and transplant recipients."

Data Element Changes

RESOLVED, that the changes to the Deceased Donor Registration form and data definitions, as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.

Data Element	Recommended Changes
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.

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

Data Element	Recommended Changes
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.
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.

Data Element	Recommended Changes
Weight	Update data definition to specify that the weight entered should be the first measured weight following admission to the hospital. • Enter the first measured weight of the donor after hospital admission 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).
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.

Data Element	Recommended Changes
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.

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	Recommended Changes
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	Recommended Changes
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	Recommended Changes
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	Recommended Changes
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~~

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