OPTN

Public Comment Proposal

Modifications to the Deceased Donor Registration (DDR) Form

OPTN Organ Procurement Organization Committee

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OPTN

Modifications to the Deceased Donor Registration (DDR) Form

Affected Policies: *N/A*
Sponsoring Committee: *Organ Procurement Organization*
Public Comment Period: *January 21, 2021 – March 23, 2021*

Executive Summary

The Deceased Donor Registration (DDR) is part of the Transplant Information Electronic Data Interchange (TIEDI®), which is part of the OPTN data entry system (UNet[sm]) for transplant centers, OPOs, and histocompatibility laboratories across the county that also includes DonorNet® and Waitlist[sm]. The DDR is a record of donor information completed for all deceased donors from whom at least one organ has been removed for the purposes of transplantation. This information is used to evaluate OPO performance, monitor potential disease transmission, and evaluate post-transplant outcomes, among other things.

In this proposal, the OPTN Organ Procurement Organization (OPO) Committee proposes changes to the DDR. These recommendations are a result of a comprehensive review of the DDR as well as the data definitions.

This proposal will promote more consistent and accurate data collection by modifying, removing, or relocating data elements. The intent of these proposed changes is to improve the quality of data and provide OPO staff with improved direction and clarity when entering deceased donor data into the DDR.

The National Organ Transplant Act of 1984 (NOTA) requires the Organ Procurement and Transplantation Network (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. The 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]

[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 centers 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 center 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] A copy of the DDR can be found in **Appendix A.** 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

- Clinical information
- Lifestyle Factors
- Organ Recovery
- Procurement and Authorization
- Donor Information
- 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 DAC charge to review all OPTN data collection tools.

The Committee collaborated with the OPTN Data Advisory Committee (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 provided input on the draft DAC Data Element Standard of Review Checklist shown in **Appendix B**. This draft checklist was a collaborative effort by SRTR, UNOS Research, and UNOS Information Technology staff as well as DAC members. The purpose of this checklist is to provide a tool to ensure a consistent and systematic approach to aid OPTN Committees in the assessment of data they seek to add, modify, or remove.

UNOS staff developed a data review worksheet using the checklist. Workgroup members reviewed each data element and completed the worksheet using the criteria outlined in the checklist. UNOS staff reviewed the completed worksheets to determine which information required further discussion. 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.

[7] https://optn.transplant.hrsa.gov/media/1799/executivesummary_1110.pdf
[8] https://optn.transplant.hrsa.gov/members/committees/data-advisory-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]

Overview of Proposal

The Committee is proposing modifications to the DDR and the data definitions. The Committee is also seeking specific feedback on several data elements, including citizenship, donor management medications, transfusions, clinical infections confirmed by culture, cocaine and other drug use, and Chagas/TB history.

Proposed Modifications

Table 1 outlines the proposed modifications to the DDR.

Table 1: Recommended Changes to the DDR

Data Element	Recommended Changes
Home city	Add the option to enter "unknown." This is important due to situations where OPOs are unable to collect and report this information.
Home State	Add the option to enter "unknown." This is important due to situations where OPOs are unable to collect and report this information.
Home Zip code	Add the option to enter "unknown." This is important due to situations where OPOs are unable to collect and report this information.
Procurement and Authorization (section title)	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.

[9] 42 CFR § 121.11(a)(1)(i)-(ii)

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. ***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?	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?
Terminal lab data	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. 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

Data Element	Recommended Changes
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.
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.
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” to make the question clearer.

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 If DCD, total urine output during OR recovery phase 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 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 < 80mmHg or O2 sat. < 80% sustained): Remove this data element because this is difficult to collect/measure and is not used to assess kidney function during the recovery procedure. Remove "If yes," so the core cooling information is collected on both donation after brain death (DBD) and DCD donors. Replace "core cooling" with a more commonly used terminology such as perfusion or flush "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.
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. 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
Liver Biopsy: % macro vesicular fat	Align the terminology with the upcoming programming for the expedited placement of livers, which will include 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	Update data definitions to specify that when multiple bronchoscopies are performed, enter the last results prior to the donor entering the operating room. Add an additional response option for "abnormal-other" results and remove "unknown if bronchoscopy performed" since OPOs will know whether a bronchoscopy was performed. Update the following responses: • 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~~
Lung machine perfusion intended or performed	Delete "intended or" and only collect if actually performed since intended perfusion does not provide useful data.
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.
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.

Data Element	Recommended Changes
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.

Table 2 outlines the proposed modifications to the DDR data definitions.

Table 2: Proposed Modifications to DDR Data Definitions

Data Element	Recommended Modifications to Data Definitions
First name, middle initial, 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.** • Middle Initial: Enter the donor’s middle initial. If the donor identity is unknown, enter the hospital-generated alias.
Weight	Update data definition to specify that the weight entered should be the weight at time of hospital admission. • Enter the weight of the donor at time of 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 Modifications to Data Definitions
Terminal lab data	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) The intent of this change is to mitigate inconsistencies when additional lab tests are performed in the donor OR.
Lung (right and left) bronchoscopy	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.
LV ejection fraction (%) and method	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)

Proposed Removal

Table 3 outlines the data elements the Committee proposes removing from the DDR.

Table 3: Proposed Removal from DDR

Data Element	Recommended Removal
Did the patient have written documentation of their intent to be a donor? If yes, indicate mechanisms	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 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 DDR, this information does not provide value and is difficult for OPOs to collect from family members.
Tattoos	Remove from DDR, this information does not factor into organ acceptance and is not included as a risk factor in the PHS guideline.
Cancer free interval	Remove from DDR. Reliability is a concern and dependent on historian knowledge of cancer treatment and timeframe since treatment. If a donor has a history of cancer, the transplant center will usually call the OPO for additional information.
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.
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.

Relocation

Table 4 outlines the data elements being moved to a different location/section of the DDR.

Table 4: Proposed Relocation of Data Elements

Data Element	Current Location/Section	New Location/Section
Cardiac arrest since neurological event that led to declaration of brain death If yes, duration of resuscitation	Procurement and Authorization	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	Procurement and Authorization	Organ Recovery – The procurement and authorization section is being modified to only collect information about authorization for donation.
NAT results	Clinical information – separate section	Recommendation: Include NAT results in the "Infectious Disease Testing" section (previously labeled "serology")
Clamp date, clamp time, clamp time zone	Organ recovery	Keep in the organ recovery section but move to the beginning of the section, potentially replacing recovery date.

Specific Feedback Requested

The Committee is requesting specific feedback on the data elements shown in **Table 5**. The Committee did not reach consensus on recommendations and therefore requests feedback from the community. Public comment feedback will determine the next steps to address recommended changes. Additionally, some changes could have policy implications and impact other systems within UNet which will require additional evaluation before finalizing recommendations.

Table 5: Specific Feedback Requested

Data Element	Discussion and Recommendation(s)	Specific Feedback Requested
Recovery date	The rationale for proposing the removal of "recovery date" from the DDR is that no significant events occur between entering the OR and cross clamp that need to be captured as a data point. Additionally, if the recovery date is different from the cross-clamp date, there is a greater change for data entry errors.	Should both recovery date and cross clamp date/time be collected?

Data Element	Discussion and Recommendation(s)	Specific Feedback Requested
Citizenship	Citizenship information is also collected on the transplant candidate registration (TCR), however, only the DDR allows an "unknown" option. It can be challenging for OPOs to collect citizenship information from family members when evaluating deceased donors.	Should donor citizenship still be collected on the DDR?
Donor management (Any medications administered within 24 hours of cross clamp) ○ Steroids ○ Diuretics ○ T3 ○ T4 ○ Antihypertensives ○ Vasodilators ○ DDAVP ○ Heparin ○ Arginine Vasopressin ○ Insulin ○ Other/specify	These data are currently collected as yes, no, or unknown responses and do not provide dosages or identify how long these medications were administered to the donor.	Should the list of medications be updated? Should dosages and duration be collected instead of yes, no, or unknown? Should these medications only be provided at certain time points (for example, time of extubation, initiation of agonal phase, initiation of flush) instead of within 24 hours prior to crossclamp?
Number of transfusions during terminal hospitalization	Recommendation to collect the total volume instead of the number of transfusions. Currently, number of transfusions response option include None, 1-5, 6-10, greater than 10, or unknown. Recommended changes: ○ Transfusions during terminal hospitalization? – yes or no ○ If yes, total volume	Should there be a specific timeframe for reporting transfusions during the terminal hospitalization?

Data Element	Discussion and Recommendation(s)	Specific Feedback Requested
Clinical infection confirmed by culture	This data element is very broad and requires interpretation by data entry staff. Feedback from Ad Hoc Disease Transmission Advisory Committee (DTAC) leadership raised additional questions. For example, the presence of a positive culture does not always indicate an infection. The impact of positive cultures can depend on the specific type of pathogens present as well as symptoms.	Should this field be modified to capture more granular data? Currently, yes, no, unknown response options. If yes, must indicate source (blood, lung, urine, other-specify)

Data Element	Discussion and Recommendation(s)	Specific Feedback Requested
Cocaine use (ever) AND continued in last six months Other drug use (ever) AND continued in last six months	The terms "abused" and "dependent on" are subjective Family members are not always aware of drug use so reliability is an issue "Other drug use" is overly broad. For example, crack, marijuana and prescription narcotics are all listed in the data definitions for this field but they have different effects on organs. Additionally, marijuana is listed as a "street drug" even though it has medicinal use and is legal in many states. There was discussion about the intent of collecting this information, which could include any of the following: • Cause of death due to drug use • Lifestyle factors that increase the risk of infectious disease transmission • Abuse/use that affect organ(s) – For example, cocaine and amphetamine use could have an impact on the heart as well as blood vessels. In order to improve data collection, the Committee proposes using language similar to the universal donor risk assessment interview questions (UDRAI).[10] OPO staff typically use this standardized document when completing the DDR.	Does the information in the proposed changes below provide more useful information on drug use than the current yes, no, and unknown response options? 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)

[10] https://www.myast.org/sites/default/files/pdfs/uniform_drai_donor_12_older.pdf

Data Element	Discussion and Recommendation(s)	Specific Feedback Requested
Chagas and TB (tuberculosis) history	Not all OPOs routinely test donors for Chagas and TB. If there is a documented history of infectious disease, additional information about the diagnosis and treatment would be helpful. DTAC leadership agreed that Chagas and TB information is important but risks could be captured in another way. Such as demographic information (birthplace, long-term residency, travel outside the US) that help identify risk factors.	Should the OPTN collect additional information on Chagas and TB including specific risk factors for each in order to evaluate patient safety and transplant outcomes?
Organ recovery section	If controlled DCD, measures between withdrawal of support and (circulatory standstill or circulatory death. Provide serial data every 5 minutes between withdrawal of support and start of agonal phase, and every 1-minute between start of agonal phase and cardiac standstill (or cardiac death).	Should this information still be collected on the DDR? If so, how often should the systolic blood pressure, diastolic blood pressure, mean arterial pressure, and O2 saturation be reported.

Future Project

The Committee discussed the following data elements collected on the DDR, in DonorNet for allocation, and on the death notification registration (DNR): Cause of death, mechanism of death, and circumstances of death. The Committee is not seeking feedback on these data elements as part of this proposal. The Committee is recommending a separate project to address these data elements.

The available responses can lead to inconsistent entry of this information by OPOs. The categories are broad and difficult for OPO staff to match up based on the circumstances that led to the declaration of death. For example, an accidental overdose might be interpreted a number of ways by different OPOs. Additionally, these categories have been in place for many years without any significant changes. Finally, any future changes will need to be evaluated to determine the potential impact on the SRTR expected yield models.

The Committee also identified two data elements in the organ dispositions section that need to be further evaluated and updated.

- Reason code – These codes include the reason for the following:
  - Reason authorization was not requested
  - Reason authorization was not obtained

    - Reason why organ was not recovered
    - Reason organs was recovered but not for transplant
    - Reason organ was recovered for transplant but not used for a transplant
- Reason organ not transplanted
    - List of discarded codes

NOTA and Final Rule Analysis

NOTA requires the OPTN to "collect, analyze, and publish data concerning organ donation and transplants."[11] 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."[12] These modifications will ensure that the OPTN provides more accurate and better quality data on deceased donors.

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 Histocompatibility Laboratories

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

Operations affecting Transplant Hospitals

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

Operations affecting the OPTN

This proposal will require programming in UNet. Feedback received on the data elements in question will be taken into consideration for final decisions on programming efforts.

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.

[11] NOTA, 42 U.S.C. § 274(b)(2)(I)
[12] 42 CFR § 121.11(a)(1)(i)-(ii)

Potential Fiscal Impact of Proposal

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.

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

Preliminary estimates indicate that this will be a large effort, as over 800 hours may be needed for IT programming, communication, educational efforts, and post-implementation monitoring.

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.

Policy Evaluation

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 missingness for modified data elements *(Table 2)* will be compared pre- and post-implementation.

Conclusion

As discussed throughout the document, 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."[13]

The Committee is proposing modifications, removal, and relocation of data elements. The Committee is also seeking feedback on several data elements.

[13] 42 CFR § 121.11(a)(1)(i)-(ii)

Appendix A: Deceased Donor Registration[14]

Deceased Donor Registration Worksheet

FORM APPROVED: O.M.B. NO. 0915-0157 Expiration Date: 08/31/2023

Note: These worksheets are provided to function as a guide to what data will be required in the online TIEDI® application. Currently in the worksheet, a red asterisk is displayed by fields that are required, independent of what other data may be provided. Based on data provided through the online TIEDI® application, additional fields that are dependent on responses provided in these required fields may become required as well. However, since these fields are not required in every case, they are not marked with a red asterisk.

Donor ID:

Donor Information

OPO:

Donor Hospital:

Referral Date: *

Recovered Outside the U.S.: * ○ YES ○ NO

Country:

Last Name: *

First Name: *

MI:

DOB:

Age: ○ Months ○ Years

Gender: * ○ Male ○ Female

Home City: *

State:

Zip Code:

Ethnicity/Race: *

American Indian or Alaska Native
- ☐ American Indian
- ☐ Eskimo
- ☐ Aleutian
- ☐ Alaska Indian
- ☐ American Indian or Alaska Native: Other
- ☐ American Indian or Alaska Native: Not Specified/Unknown

Asian
- ☐ Asian Indian/Indian Sub-Continent
- ☐ Chinese
- ☐ Filipino
- ☐ Japanese
- ☐ Korean
- ☐ Vietnamese
- ☐ Asian: Other
- ☐ Asian: Not Specified/Unknown

Black or African American
- ☐ African American
- ☐ African (Continental)
- ☐ West Indian
- ☐ Haitian
- ☐ Black or African American: Other
- ☐ Black or African American: Not Specified/Unknown

Hispanic/Latino
- ☐ Mexican
- ☐ Puerto Rican (Mainland)
- ☐ Puerto Rican (Island)
- ☐ Cuban
- ☐ Hispanic/Latino: Other
- ☐ Hispanic/Latino: Not Specified/Unknown

Native Hawaiian or Other Pacific Islander
- ☐ Native Hawaiian
- ☐ Guamanian or Chamorro
- ☐ Samoan
- ☐ Native Hawaiian or Other Pacific Islander: Other
- ☐ Native Hawaiian or Other Pacific Islander: Not Specified/Unknown

White
- ☐ European Descent
- ☐ Arab or Middle Eastern
- ☐ North African (non-Black)
- ☐ White: Other
- ☐ White: Not Specified/Unknown

Citizenship: *
- ○ US Citizen
- ○ Non-US Citizen/US Resident
- ○ Non-US Citizen/Non-US Resident
- ○ Unknown

Home Country:

Cause of Death: *
- ○ ANOXIA
- ○ CEREBROVASCULAR/STROKE
- ○ HEAD TRAUMA
- ○ CNS TUMOR
- ○ OTHER SPECIFY

Specify:

[14] "Deceased Donor Registration", accessed on December 14, 2020: https://unos.org/wp-content/uploads/unos/DDR.pdf

Mechanism of Death:	DROWNING SEIZURE ASPHYXIATION ELECTRICAL STAB SIDS DEATH FROM NATURAL CAUSES DRUG INTOXICATION CARDIOVASCULAR GUNSHOT WOUND BLUNT INJURY INTRACRANIAL HEMORRHAGE/STROKE NONE OF THE ABOVE
Circumstances of Death:	MVA SUICIDE HOMICIDE CHILD-ABUSE Accident, Non-MVA DEATH FROM NATURAL CAUSES NONE OF THE ABOVE

Procurement and Authorization

Medical Examiner/Coroner:	NO YES, MEDICAL EXAMINER CONSENTED YES, MEDICAL EXAMINER REFUSED CONSENT UNKNOWN
Was the patient declared legally brain dead:	YES NO
Cardiac arrest since neurological event that led to declaration of brain death:	YES NO
If Yes, Duration of Resuscitation:	min ST=
Did the patient have written documentation of their intent to be a donor:	YES NO UNK
If yes, indicate mechanisms (check all that apply):	
Driver's license	Donor Card Donor Registry
Durable Power of Attorney / Healthcare Proxy	Advanced Directive
Other Specify	
Was the authorization based solely on this documentation	YES NO
Did the patient express to family or others the intent to be a donor:	YES NO UNK
Date and time of pronouncement of death: (Complete for brain dead and DCD donors):	Date: Time: (military time)
Date and time authorization obtained for organ donation:	Date: Time: (military time)

Clinical Information

ABO Blood Group:	
Height:	ft in cm ST=
Weight:	lbs kg ST=
Terminal Lab Data:	
Protein in Urine:	YES NO UNK
Serum Sodium:	mEq/L ST=
BUN:	mg/dl ST=
Serum Creatinine:	mg/dl ST=

Total Bilirubin:	mg/dl	ST=
SGOT/AST:	u/L	ST=
SGPT/ALT:	u/L	ST=
INR:		ST=
Hematocrit:	%	ST=
Pancreas (PA Donors Only):		
Serum Lipase:	u/L	ST=
Serum Amylase:	u/L	ST=
HbA1c:	%	ST=

Serology:

HIV Serology Results:	Positive Negative Not Done Indeterminate
HIV Ag/Ab Combo Results:	Positive Negative Not Done Indeterminate
HTLV Serology Results:	Positive Negative Not Done Indeterminate
Syphilis Serology Results:	Positive Negative Not Done Indeterminate
Anti-CMV Serology Results:	Positive Negative Not Done Indeterminate
HBsAg Serology Results:	Positive Negative Not Done Indeterminate
HBcAb Serology Results:	Positive Negative Not Done Indeterminate
HCV Serology Results:	Positive Negative Not Done Indeterminate
HBsAb Serology Results:	Positive Negative Not Done Indeterminate

EBV (VCA) (IgG) Serology Results:	Positive Negative Not Done Indeterminate
EBV (VCA) (IgM) Serology Results:	Positive Negative Not Done Indeterminate
EBNA Serology Results:	Positive Negative Not Done Indeterminate
Chagas Serology Results:	Positive Negative Not Done Indeterminate
West Nile Serology Results:	Positive Negative Not Done Indeterminate
Toxoplasma (IgG) Results:	Positive Negative Not Done Indeterminate
Strongyloides:	Positive Negative Not Done Indeterminate
NAT Results:	
HIV NAT Results:	Positive Negative Not Done Indeterminate
HBV NAT Results:	Positive Negative Not Done Indeterminate
HCV NAT Results:	Positive Negative Not Done Indeterminate
HTLV NAT Results:	Positive Negative Not Done Indeterminate

EBV (VCA) (IgG) Serology Results:	Positive Negative Not Done Indeterminate
EBV (VCA) (IgM) Serology Results:	Positive Negative Not Done Indeterminate
EBNA Serology Results:	Positive Negative Not Done Indeterminate
Chagas Serology Results:	Positive Negative Not Done Indeterminate
West Nile Serology Results:	Positive Negative Not Done Indeterminate
Toxoplasma (IgG) Results:	Positive Negative Not Done Indeterminate
Strongyloides:	Positive Negative Not Done Indeterminate
NAT Results:	
HIV NAT Results:	Positive Negative Not Done Indeterminate
HBV NAT Results:	Positive Negative Not Done Indeterminate
HCV NAT Results:	Positive Negative Not Done Indeterminate
HTLV NAT Results:	Positive Negative Not Done Indeterminate

Number of transfusions during this (terminal) hospitalization:*	NONE 1 - 5 6 - 10 GREATER THAN 10 UNKNOWN
Clinical Infection Confirmed by Culture:*	YES NO UNK
Source	
Blood	
Lung	
Urine	
Other	
Other, specify:	

Lifestyle Factors

Cigarette Use (> 20 pack years) - Ever:*	YES NO UNK
AND continued in last six months:	YES NO UNK
Cocaine Use - Ever:*	YES NO UNK
AND continued in last six months:	YES NO UNK
Other Drug Use (non - IV) - Ever:*	YES NO UNK
AND continued in last six months:	YES NO UNK
Heavy Alcohol Use (heavy= 2+ drinks/day):*	YES NO UNK
Tattoos:*	YES NO UNK
According to the OPTN policy in effect on the date of referral, does the donor have risk factors for blood-borne disease transmission:*	YES NO
History of Diabetes:*	NO YES, 0-5 YEARS YES, 6-10 YEARS YES, >10 YEARS YES, DURATION UNKNOWN UNKNOWN
Insulin Dependent:	NO YES, 0-5 YEARS YES, 6-10 YEARS YES, >10 YEARS YES, DURATION UNKNOWN UNKNOWN
History of Hypertension:*	NO YES, 0-5 YEARS YES, 6-10 YEARS YES, >10 YEARS YES, UNKNOWN DURATION UNKNOWN
If yes, method of control:	
Diet:	YES NO UNK
Diuretics:	YES NO UNK
Other anti-hypertensive medication:	YES NO UNK

Appendix B: DAC Data Element Standard of Review Checklist

Standard/Characteristic	Criteria
Purpose and Relevancy	• What is the intent of collecting this specific data element? • Does the data element measure what it intends to measure?
Reliability	• Is the source of information objective and reliable (historian, self-report, EHR)? • Is the element designed to consistently reproduce the same results?
Definition	• Is there an industry standard for this definition? • What are the acceptable forms of documentation (or tests if lab value/results)? • What is the appropriate timeframe for data element (first, initial, serial, last, terminal, highest)? • What are the acceptable responses or response range for this data element? If a category response, can each response be mutually exclusive? • If unknown values (e.g. missing, not reported, unknown) are acceptable responses, is there adequate instruction on when those values are appropriate? • What unit of measurement? • Is this definition suitable for the variety of users providing the data (clinical vs non-clinical)?
Availability, Burden and Interoperability	• Is this element widely available for the population of patients for which it is sought to be collected? • Does this element require additional testing (e.g. invasive procedure) or measurement that is not commonly done? • Are the data easily and readily discovered by a clinical or non-clinical coordinator in EHR? • What calculations or interpretations are required before entering? • Is the data element a candidate for seamless data exchange? ○ Is there an alternative commonly available in an EHR that should be considered?
Alternative Data Sources	• Is this element already available via an external source? • If so, could the OPTN acquire this element rather than programming?
Usability and Conformity	• Is the form usable for members? • Does the arrangement / grouping of fields on the form make sense to the users? • Are the right fields on the right forms? • Is the label, as written, clear to the user with minimal explanation?