OPTN

*Public Comment Proposal*

# Data Collection to Evaluate Organ Logistics and Allocation

*OPTN Operations and Safety Committee*

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## Contents

OPTN

# Data Collection to Evaluate Organ Logistics and Allocation

Affected Policies: N/A
*Sponsoring Committee:* *Operations and Safety*
*Public Comment Period:* *August 3, 2021 – September 30, 2021*

## Executive Summary

The Operations and Safety Committee (the Committee) is charged with improving the quality, safety, and efficiency of the organ donation and transplantation system. To ensure data collection efforts are both current and relevant, the Committee collaborated with the Data Advisory Committee to perform a comprehensive review of current OPTN data collection related to organ logistics and allocation. The proposal includes modifications and removal of several data elements to update existing data collection and reduce data burden for areas of existing data collection deemed no longer relevant. The Committee proposes the inclusion of new data elements related to organ logistics and allocation: check-out time (TransNet[SM] or DDR), check-in time (Waitlist[SM]), and time of first anastomosis (Waitlist[SM]). The check-out time and check-in time data elements would serve as both documenting chain of custody of organs (i.e. period of time when an organ procurement organization (OPO) is in the care of an organ to when the OPO relinquishes custody of the organ to the transplant program) as well as a surrogate for organ transport time. Currently transplant date is collected by the OPTN. The collection of time of transplant (time of first anastomosis) as a data element would allow a more accurate account of the timeline from organ recovery to transplant. The purpose of this proposal is to gain insight into organ logistics and allocation to inform future policy development.

# Background

The Operations and Safety Committee (the Committee) embarked on several projects aimed to better understand the quality, safety, and efficiency of the organ donation and transplantation system. To assess organ logistics (specifically, organ transport), the Committee developed a questionnaire that was used to interview organ procurement organizations (OPOs). Feedback was received from 54 of 58 OPOs on the travel questionnaire. While the data was anecdotal in nature, the information collected revealed great variation in travel patterns among regions. The Committee concluded that the information gathered from their work identified a need to collect additional data to further analyze patterns related to organ logistics and allocation.

The Committee began by including a request for feedback in their spring 2019 guidance document[1] to gauge the transplant community's support of collecting additional data related to organ logistics and allocation. The community expressed support for additional data collection, which resulted in a request for feedback[2] during the fall 2019 public comment period to solicit suggestions on new data elements that should be considered in the development of this data collection proposal. The community suggested the collection of data related to costs, transportation mode, organ recovery, and ischemic time.

The Committee collaborated with the Data Advisory Committee (DAC) in developing this data collection proposal and conducting a comprehensive review of current data elements. The DAC is an operating committee of the OPTN which 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.[3]

In 2006, the OPTN Board of Directors approved the OPTN Principles of Data Collection.[4] The Principles state that institutional members must provide sufficient data to OPTN to allow it to:

a) Develop transplant, donation and allocation policies
b) Determine if Institutional Members are complying with policy
c) Determine Member-specific performance
d) Ensure patient safety when no alternative sources of data exist
e) Fulfill the requirements of the OPTN Final Rule

The OPTN Board of Directors also 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*

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[2] *Data Collection to Evaluate the Logistical Impact of Broader Distribution,* OPTN Operations & Safety Committee. Available at https://optn.transplant.hrsa.gov/.
[3] OPTN Data Advisory Committee. Available at https://optn.transplant.hrsa.gov/members/committees/data-advisory-committee/.
[4] https://bodandcommittees.unos.org/Staff/_layouts/15/WopiFrame2.aspx?sourcedoc=/Staff/Liaison%20Manual/Data%20Collection.docx&action=default
[5] Executive Summary of the OPTN/UNOS Board of Directors Meeting, December 5-6, 2016.

*patients, OPTN members, the organ donation/transplantation community, and the general public.*

- Whenever possible, data collected in center or OPO electronic health records (EHRs), 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.

Additionally, the Ad Hoc Systems Performance Committee[6] identified key metrics to support assessment of system efficiencies in recovery and transportation:

- Offer acceptance rates
- Time from first offer to final organ acceptance
- Time from acceptance to decline (as a potential proxy for number of late declines)
- Time from organ allocation to operating room (OR) entrance
- Transportation time

This proposal aligns with the principles and metrics outlined above as the modifications to existing collection and proposed data elements will support the evaluation of patterns related to organ logistics and allocation and help inform the development of future policy. Additionally, the comprehensive data review, as outlined later in this proposal, aims to ensure efficiencies in data collection efforts that are both current and relevant.

# Project Approach

The Committee created a Broader Distribution Data Collection Workgroup (the Workgroup) that comprised of members from the Operations & Safety Committee, Data Advisory Committee, Heart Transplantation Committee, Kidney Transplantation Committee, Liver & Intestinal Transplantation Committee, Lung Transplantation Committee, Organ Procurement Organization Committee, Pancreas Transplantation Committee, and Transplant Coordinator Committee. Members' expertise included backgrounds in transplant coordinators, transplant administration, transplant physicians and surgeons, organ procurement organization executives, compliance specialists, and transplant quality.

The Workgroup utilized the Data Element Standard of Review Checklist (see **Appendix A**), developed by the DAC in collaboration with Scientific Registry of Transplant Recipients (SRTR)[7], UNOS Research, and UNOS Information Technology staff, to evaluate each data element. The purpose of this tool is to provide a consistent, systematic approach to aid OPTN Committees in the assessment of the data they seek to add, modify, or remove. The Data Element Standard of Review Checklist was created to evaluate data elements to improve the quality, usefulness, and trustworthiness of OPTN data. The Data Element Standard of Review Checklist uses the following criteria to evaluate data elements:

- Purpose, relevancy, and face validity

[6] Ad Hoc System Performance Committee Report, *OPTN Ad Hoc Systems Performance Committee,* June 2019.
[7] The SRTR is the Scientific Registry of Transplant Recipients. They provide statistical and other analytic support to the OPTN for purposes including the formulation and evaluation of organ allocation and other OPTN policies.

- Reliability
- Definition
- Availability, burden, and interoperability
- Alternative data sources
- Usability and conformity
- Implication of removing data element

The Workgroup reviewed current data elements related to organ logistics and allocation within the Deceased Donor Registration (DDR) form, Transplant Recipient Registration (TRR) form, and DonorNet®. The DDR form is a data collection tool for OPOs to submit information on deceased donors. The TRR form is a data collection tool that is generated immediately after a transplant is reported. The TRR is utilized by transplant programs to submit information on transplant recipients and the transplant event. DonorNet® is a system that OPOs and transplant programs use to manage organ offers and acceptances.

During the development of this data collection proposal, feedback was solicited from collaborating OPTN Committees. In addition to feedback from DAC, Ad Hoc Disease Transmission Advisory Committee (DTAC), Transplant Administrators Committee (TAC), Transplant Coordinators Committee, as well as organ-specific committees, the Workgroup also reviewed and considered input received from the Committee's fall 2019 request for feedback.[8]

The Workgroup was conscious of the potential relationships between this data collection proposal and other Committee and research efforts. Additionally, there were some data elements that were under review by other Committee projects during the development of this proposal. For example, the Organ Procurement Organization (OPO) Committee proposed modifications to the Deceased Donor Registration (DDR) form, which included some data elements the Workgroup reviewed. To prevent duplicating efforts, the Workgroup reviewed and included those data elements that were applicable to this proposal, but deferred to the sponsoring Committee on any modifications being proposed. Those projects and specific data elements are outlined in further detail later in this proposal.

# Purpose

The purpose of this data collection proposal is to monitor current data elements and propose new data elements to provide more insight into organ logistics and allocation to inform future policy development. Additionally, the review and recommendations to modify or remove current OPTN data is to ensure efficiencies in data collection efforts that are both current and relevant.

# Overview of Proposal

The Committee is proposing modifications and removals to current data elements as well as the addition of new data elements. Those proposed changes are outlined in further detail in the below sections.

[8] April 20, 2021 Meeting Summary, OPTN Operations & Safety Committee, Broader Distribution Data Collection Workgroup. Available at httsp://optn.transplant.hrsa.gov/.

## Proposed Modifications

The Committee reviewed and proposed modifications to the following current data elements mentioned below. **Appendix B** contains other data currently collected that will also be monitored, but are not being recommended for any modifications. Definitions for data elements are located in **Appendix C**.

### *Type of Liver machine perfusion*

Currently, there are experimental/clinical trials related to liver perfusion. This current data element will be important in the future and would be relevant to collect in order assess outcomes further. The Committee recommends the removal of "other" as an option in the response field as it is believed that the options "normothermic" and "hypothermic" would be sufficient. The Committee will defer to the Liver Committee for further recommendations of additional data collection efforts related to liver perfusion once more information becomes available.

### *Left Lung/Right Lung machine perfusion intended or performed*

This data element was reviewed by the OPO committee in their Modifications to the Deceased Donor Registration (DDR) form proposal.[9] The Committee reviewed and agreed with the proposed modifications made by the OPO Committee to remove "intended or". This modification has since been approved by the Board of Directors and will be included in this data collection effort.

### *Kidney(s) received on*

This data element seeks to determine what the kidney was received on: ice, pump, or N/A. The Committee agreed that this data element is important in assessing organ preservation practices. The Committee recommended to remove "N/A" as an option in the response field as it is believed that kidneys will either be received on pump or ice.

### *Kidney Pump Values: Time, Flow, Pressure, and Resistance*

The Committee agreed that these data elements are relevant in assessing organ preservation practices. It was agreed that the important values to capture would be initial, low/peak, and final measurements. For the initial values, the Committee discussed these values should be collected at least two hours after the organ has been placed on the pump to allow time for the pump to calibrate and reach an equilibrium for an accurate reading.[10] The Committee also agreed that an upload of the final pump report is acceptable to collect this information.

### *Recovery Team #*

This data element was previously reviewed by the OPO Committee and proposed modifications were made in their Modifications to the Deceased Donor Registration (DDR) form proposal.[11] The Committee reviewed and agreed with the now Board approved modifications made by the OPO Committee to 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 modification has since been approved by the Board of Directors and will be included in this data collection effort.

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[9] *Modifications to the Deceased Donor Registration Form*, OPTN Organ Procurement Organization Committee. Available at https://optn.transplant.hrsa.gov/.
[10] April 15, 2021 Meeting Summary, OPTN Operations & Safety Committee. Available at https://optn.transplant.hrsa.gov/.
[11] *Modifications to the Deceased Donor Registration Form*, OPTN Organ Procurement Organization Committee.

**Table 1** outlines the proposed modifications to data elements in further detail.

**Table 1: Proposed Modifications**

| Field Label | Form | Modification |
|---|---|---|
| Type of liver machine perfusion: *(follow up to liver machine perfusion (Y/N)) | DDR | **Options Response Field:**<br><br>Single Selection, Listed Choices :<br>1. Normothermic<br>2. Hypothermic<br>~~999- Other/Specify : (write in)~~ |
| Left Lung/Right Lung machine perfusion intended or performed: | DDR | Left Lung/Right Lung machine perfusion ~~intended or~~ performed:* |
| Kidney(s) received on: | Kidney-TRR | **Options Response Field:**<br><br>Single Selection, Listed Choices:<br>Ice<br>Pump<br>~~N/A~~ |
| Kidney Pump Values: Time | DonorNet | **Options Response Field:**<br><br>Initial Time:<br>Low/Peak time:<br>Final Time: |
| Kidney Pump Values: Flow (cc/min) | DonorNet | **Options Response Field:**<br><br>Initial Time:<br>Low/Peak time:<br>Final Time: |
| Kidney Pump Values: Pressure (mmHg) | DonorNet | **Options Response Field:**<br><br>Initial Time:<br>Low/Peak time:<br>Final Time: |
| Kidney Pump Values: Resistance | DonorNet | **Options Response Field:**<br><br>Initial Time:<br>Low/Peak time:<br>Final Time: |
| Recovery Team # (recommendation by OPO Committee currently out for public comment) | DDR | 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.* |

*Modification has been approved by the OPTN Board of Directors (June 2021) from the OPTN OPO Committee's Modifications to the Deceased Donor Registration (DDR) form proposal[12] will be included in this data collection effort.

[12] *Modifications to the Deceased Donor Registration Form*, OPTN Organ Procurement Organization Committee.

# Proposed removals and addition to Organ Not Recovered Code responses

In reviewing organ disposition data, the Committee reviewed the catalog of "organ not recovered" code responses and proposed the following codes to be removed (for complete list of code responses, see **Appendix D**):

### *No Recipient Located (code #208)*

The Committee determined this code response was vague and did not provide a descriptive explanation of the disposition of the organ. The Committee discussed that usually a recipient is not located due to poor organ function (code #200) or the list was exhausted (codes # 215, 216, 217) and agreed that the purpose of recording the organ reason codes should be to provide a clear depiction of an organ's disposition.

### *POSITIVE – Human T-lymphotopic virus (HTLV-1) (code #211)*

The Committee determined that this code response is no longer relevant as HTLV-1 is no longer required to be tested or collected by the OPTN.

**Table 2** outlines the proposed removals from the organ reason code list.

**Table 2. Proposed Removals from Organ Reason Code Responses**

| Response Field | Form | Recommended Removal |
|---|---|---|
| Organ Not Recovered Code | DDR | 1) Remove code #208 (no recipient located); a recipient is not located because of either poor organ function or the list was exhausted.<br><br>2) Remove code #211 – POSITIVE HTLV-1 |

The Committee also identified and are proposing a new "organ not recovered" response code:

### *No candidates on the match run (new code)*

The Committee identified a need for OPOs to be able to document those instances where a match is run and zero candidates appear.

**Table 3** outlines the proposed addition to the organ reason code list (see **Appendix B**).

**Table 3. Proposed Addition to Organ Reason Code Responses**

| Field Label | Form | Recommended Removal |
|---|---|---|
| Organ Not Recovered Code | DDR | Add code for "No candidates on the match run" |

## Proposed New Data Elements

During the review of the current data elements, and with consideration from the Committee's fall 2019 request for feedback[13], the Committee identified and proposed new data elements to be collected and included in the data set to provide additional information regarding organ logistics and allocation (these data elements are summarized in further detail in **Table 5**).

The Committee reviewed findings from the UNOS Research Department pilot project, "Understanding CIT" Project: Approach to Collecting Transit Data. The pilot focused on understanding and determining what data points can provide an accurate measurement of cold ischemic time. The finding was that transport time as a data collection element is often unreliable. Additionally, transplant time is not currently collected, only transplant date. Therefore, creating transplant time as a data element will be a more useful field for estimating cold ischemic time. Estimates for a more accurate calculation of cold ischemic time could be derived from transplant time and organ check-out time/cross clamp time. The Committee reviewed the results of the pilot project and agreed that transplant time as a data element would allow for more accurate ischemic time calculations. [14] The feedback received was reviewed and considered in the final recommendations presented in this proposal.

### *Organ Check-Out Time*

To complement the proposed organ check-in time data element, the Committee proposes organ check-out time as a data element that would be collected by the OPOs. In order for the organ check-in data element to serve as a surrogate for organ transport time, the Committee determined that the most accurate data point to assess this would be in collecting when the organ is checked-out and leaves the donor hospital. This will also aid in documenting the chain of custody (i.e. period of time when an OPO is in care of the organ to when the OPO relinquishes control to the transplant program) of the organ in combination with organ check-in to have timestamps of when the organ leaves the OPO and arrives at the transplant hospital.

The Committee's primary recommendation is to collect this data element in TransNet[SM] as OPOs have accessibility to upload information electronically through this system. Should there be complexities in collecting this information through TransNet[SM], the Committee recommends an alternative in collecting this data element on the Deceased Donor Registration (DDR) form.

### *Organ Check-in Time*

The Committee proposes organ check-in as a data element to serve as both documenting chain of custody of organs (i.e. period of time when an OPO is in care of the organ to when the OPO relinquishes control to the transplant program) as well as a surrogate of transport time. Organ check-in is required to be completed upon arrival at the transplant hospital prior to opening the organ's external transport container, any time an organ is recovered outside the facility where the transplant will take place per OPTN policy.[15] Currently, there is variability among transplant programs in how this information is collected; including this data element will help to standardize those processes.

[13] *Data Collection to Evaluate the Logistical Impact of Broader Distribution,* OPTN Operations & Safety Committee. Available at https://optn.transplant.hrsa.gov/.
[14] April 15, 2021 Meeting Summary, OPTN Operations & Safety Committee.
[15] OPTN Policy 5.7: *Organ Check-In* (June 2021).

The Committee also felt that this data element, in conjunction with other discrete fields (cross clamp time, organ check-out time, time of first anastomosis), will provide an accurate account from organ recovery to transplantation and could serve as a surrogate of organ transport time. The Committee discussed how the collection of organ check-in time could help to delineate between time of transport and time of implant. This will aid in understanding time relative to travel versus scheduling logistics. Additionally, capturing an accurate transport time allows for expected time of transport to be calculated. These baseline expectations can be utilized to assess outliers and better assess practices across programs[16].

Acknowledging that the use of technological enhancements such as a GPS tracker would measure this information more directly, organ check-in can still provide an estimate of the expected time of transport of an organ.

### *Time of first anastomosis*

The Committee proposes time of first anastomosis as a data element to provide additional information in assessing the intervals from organ recovery to organ transplant. Currently, transplant date is collected by the OPTN in Waitlist[SM]. The collection of the time of transplant (time of first anastomosis) would provide a more accurate account of the timeline from recovery to transplant.

**Table 4** outlines the proposed new data elements that would be included in the data set and evaluation of organ logistics and allocation.

**Table 4. Proposed New Data Elements**

| Field Label | System/Form | Response Options | Description |
|---|---|---|---|
| Organ Check-In Time | Waitlist[SM] | Date and Time | Enter the date and time the organ arrives at the transplant center.<br><br>Format: HH:MM<br>**Note**: Time should be in 24-hour format. |
| Time of first anastomosis | Waitlist[SM] | Time | Enter the time of first anastomosis.<br><br>Format: HH:MM<br>**Note**: Time should be in 24-hour format. |
| Organ Check-Out Time | TransNet[SM] or DDR | Date and Time | Enter the date and time of when the organ leaves the OPO.<br><br>Format: HH:MM<br>**Note**: Time should be in 24-hour format. |

[16] May 27, 2021 Meeting Summary, OPTN Operations & Safety Committee

## Other Data Elements Considered

As previously mentioned, the Committee solicited feedback from the community during the Winter 2019 public comment cycle which included proposed data elements as well as additional input received by the transplant community for further consideration. The list below summarizes those data elements the Committee reviewed and determined would not be included in the data collection proposal:

### *Transportation Mode*

As previously mentioned, the Committee's survey of OPOs demonstrated an increased use of organ transport by planes. The Committee's intent in proposing this data element was to further evaluate the trend of mode for organ transport. Additionally, the Committee believed that transportation mode could serve as a surrogate for costs. Examples included reporting whether staff used their own private vehicles or if the organ was transported by courier.

The Committee agreed with transplant community sentiment that transportation mode was an important data element to collect, but were challenged by how to effectively collect this information while also being cognizant of the data burden the complexities of this data element could create in doing so. The Workgroup discussed how best to collect this data from collecting each leg of an organ's transport to collecting the "most complex mode" of transportation. However, after further discussions the Workgroup agreed that the most complex mode of transportation is not always clear (i.e. two hour helicopter versus five hour airplane travel).

The Workgroup further considered the data burden of collecting transportation mode. The Committee evaluated how OPOs and transplant programs document transportation mode; some programs have the ability to document transportation mode in their electronic health records (EHR), while other programs may not have capability in doing so. It was acknowledged that those who set up travel logistics are often not the same staff who enter form data, which would require case notes documenting each mode of transportation. Additionally, when multiple teams come from out of town, an OPO would not have all the information of travel logistics. Ultimately, the Workgroup reasoned the validity of the information captured from transportation mode is not consistent enough to justify the additional data burden of collecting transportation mode.

After deliberation, the Committee determined that due to variability in the logistics related to organ transport, collecting this information would be too complex and create too great of a data burden for members to collect. Additionally, the Committee agreed that with the testing of technological advancements such as GPS tracking, there will be opportunity to collect this information more efficiently in the future.

### *Costs*

There was an overall consensus from the transplant community that there should be a methodology for cost assessment. The Committee discussed the challenge of capturing this data due to the variation of costs among institutions. The Committee believes costs can be evaluated and assessed by patterns seen in current data elements being proposed.

### *Late turn down data*

There were numerous comments from the request for feedback which suggested collecting data related to unanticipated events that could impact allocation logistics, such as late turndown rates. The DAC is currently working on a project that will define late turn downs and propose data collection efforts that will effectively assess offer and acceptance behavior and processes. The Committee will remain engaged with the DAC to address this further.

## Potential Relationships with other Projects

The Committee was aware of projects that complemented this data collection effort and have been in contact with each respective Committee/team to prevent duplicative efforts in the development of this proposal. The following projects have potential relationships with this data collection proposal:

- **Review of Deceased Donor Registration (DDR) form (OPO Committee):** In the evaluation of the DDR, there was some overlap in a data element being reviewed and out for public comment by the OPO Committee.[17] The Workgroup evaluated and agreed with the recommendations by the OPO Committee on the following data elements:
    - Left Lung/Right Lung machine perfusion intended or performed
    - Recovery Team #

  There were no further overlaps in the Workgroup's assessment.
- **Late Turndown project (Data Advisory Committee (DAC)):** The Workgroup discussed considering data that would characterize delays in the allocation process, in particular late turn downs. The Workgroup was made aware that late turndowns would be evaluated further by the DAC. The Workgroup provided recommendations for the DAC to consider once they begin these efforts and have agreed to help with addressing further on this separate project with DAC.
- **Future technological advancements:** The Committee is aware of discussions and pilots of technological advancements such as GPS trackers, which would be directly related to the efforts of this data collection proposal. Should these advancements become available to the OPTN once the GPS capabilities have been fully evaluated, the Committee can re-evaluate and include this information in a future proposed data set.

# NOTA and Final Rule Analysis

NOTA requires the OPTN to "collect, analyze, and publish data concerning organ donation and transplants."[18] The Committee submits the following proposal for public comment under the authority of the OPTN Final Rule, which states, "An organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN…information regarding transplantation candidates, transplant recipients, [and] donors of organs…."[19] The OPTN shall "maintain records of all transplant candidates, all organ donors and all transplant recipients"[20]and shall

[17] *Modifications to the Deceased Donor Registration Form*, OPTN Organ Procurement Organization Committee. Available at https://optn.transplant.hrsa.gov/.
[18] 42 U.S.C. § 274(b)(2)(I)
[19] 42 CFR §121.11(b)(2)
[20] 42 CFR §121.11(a)(1)(ii)

"receive…such records and information electronically…."[21] This proposal will allow the OPTN to collect more complete data on living and deceased donors and donor organs, and maintain such data in the OPTN dataset.

# Implementation Considerations

## Member and OPTN Operations

### *Operations affecting Histocompatibility Laboratories*

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

### *Operations affecting Organ Procurement Organizations*

This proposal will require OPO staff to become familiar with the changes to the DDR and data definitions. This proposal may add additional administrative burden, particularly for collecting organ check-out time. Educational efforts and training may be needed to ensure staff has a standardized process of documenting additional data being proposed.

### *Operations affecting Transplant Hospitals*

This proposal will require transplant staff to become familiar with the changes to the TRR and data definitions. This proposal may add additional administrative burden, particularly for collecting organ check-in time. Educational efforts and training may be needed to ensure staff has a standardized process of documenting additional data being proposed. Additionally, transplant hospital staff would need to evaluate their current protocols/processes for organ check in per OPTN policy.

### *Operations affecting the OPTN*

This proposal will require programming in UNet[SM]. 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.

## Projected Fiscal Impact

This proposal is projected to have a fiscal impact on the OPTN and a minimal impact on transplant hospitals and organ procurement organizations as the majority of the proposed data elements are already collected. There are no anticipated fiscal impacts on histocompatibility laboratories.

[21] 42 CFR §121.11(a)(1)(iii)

### *Projected Impact on Organ Procurement Organizations*

There is an expected minimal impact to OPOs related to the additional administrative burden of consistently collecting and reporting organ check-out time.

### *Projected Impact on Transplant Hospitals*

There is an expected minimal impact to transplant hospitals related to the additional administrative burden of consistently collecting and reporting organ check-in time.

### *Projected Impact on the OPTN*

Preliminary estimates indicate this will be a large project effort for the OPTN to develop and implement as approximately 1,800 hours may be needed for IT programming, development of help documentation, communication to members and the transplant community regarding these changes, and research support for these efforts.

### *Projected Impact on Histocompatibility Laboratories*

There is no expected impact to histocompatibility laboratories.

# Post-implementation Monitoring

## Member Compliance

The proposed data collection will not change the current routine monitoring of OPTN members. Any data entered into UNet℠ may be reviewed by the OPTN, and members are required to provide documentation as requested.

## Policy Evaluation

Distributions of new and modified existing data elements on the DDR and TRR will be formally evaluated at approximately 6 months, 1 year, and 2 years post-implementation, as well as any other metrics subsequently requested by the Committee. As shown in the proposal, all modified metrics (Table 1), all updates to the organ reason code (Table 2 and 3) and all new metrics (Table 4) 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℠). Appropriate pre- and post-implementation cohorts will be used to describe modified data elements. Only a post implementation cohort will be used to summarize new data elements. Summary statistics, distributions, and missing data for new and modified elements will be evaluated by organ as appropriate as sample size allows.

# Conclusion

The various projects the Committee has embarked on as well as other OPTN Committee efforts mentioned in this document is testament to the need for additional information to better understand the organ donation and transplantation system. Additionally, the proposed modifications, removals and

new data elements intends to ensure efficiencies in data collection efforts that are both current and relevant.

The Committee's comprehensive review of the current data elements detailed in this proposal aligns with the OPTN Principles of Data Collection, OPTN Data Vision Statement, and metrics outlined by the Ad Hoc Systems Performance Committee. Additionally, this proposal is in alignment with NOTA and the Final Rule, as previously mentioned, and will allow the OPTN to collect more complete data on living and deceased donors and donor organs, and maintain such data in the OPTN dataset. This data collection effort will further help in gathering more information on organ logistics and allocation as well as allow the opportunity to inform future policy development.

# Appendix A: Data Advisory Committee (DAC) Data Element Standard of Review Checklist

| | |
|---|---|
| **Purpose, Relevancy, and Face Validity** | • What is the intent or purpose of collecting this specific data element?<br>• Does the data element measure what it intends to measure? |
| **Reliability** | • Is the source of information objective and reliable (historian, self-report, EHR)?<br>• Is the element designed to consistently reproduce the same results?<br>  ○ Are there objective measures that could be considered rather than having a user calculate or interpret information prior to reporting?<br>  ○ If calculation cannot be avoided, are there different methods or calculations used to obtain this data element? If so, is it clear which method/calculation should be used?<br>• Is the data element definition sufficiently clear and precise to enable consistent entry? |
| **Definition**<br>*(these prompts will inform your data element data definition)* | • What is the intent or purpose of collecting this specific data element?<br>• Is there an industry standard for this definition? (CMS, professional society, etc.)<br>• What are the acceptable forms of documentation (or tests if lab value/results)?<br>• What is the appropriate timeframe for data element (first, initial, serial, last, terminal, highest)?<br>• What are the acceptable responses or response range for this data element? If a category response, can each response be mutually exclusive?<br>• If unknown values (e.g. missing, not reported, unknown) are acceptable responses, is there adequate instruction on when those values are appropriate?<br>• What unit of measurement?<br>• 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?<br>• Does this element require additional testing (e.g. invasive procedure) or measurement that is not commonly done?<br>• Are the data easily and readily discovered by a clinical or non-clinical coordinator in EHR?<br>• What calculations or interpretations are required before entering?<br>• Is the data element a candidate for seamless data exchange?<br>  ○ How is this data collected in the EHR? Is there a reason it should be programmed in UNet$^{SM}$ differently?<br>  ○ 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? (e.g. a registry, regulatory body)<br>• If so, could the OPTN acquire this element rather than programming? |
| **Usability and Conformity** | • Is the form usable for members?<br>• Does the arrangement / grouping of fields on the form make sense to the users?<br>• Are the right fields on the right forms?<br>• Is the label, as written, clear to the user with minimal explanation? |
| **Implication of Removing Data Element** | • What are the implications of removing this data element?<br>  ○ What other UNet$^{SM}$ systems would be impacted?<br>  ○ Would removing the data element impact other entities, such as CMS?<br>  ○ Is this data element used by SRTR?<br>• Who would be impacted?<br>  ○ Who uses this information?<br>  ○ Who should be notified?<br>  ○ Describe collaboration that has already occurred |

# Appendix B: Current Data Elements included in Proposed Data Set (no modifications being required)

The Committee evaluated current data elements related to cold ischemic time (CIT), machine perfusion, recovery team documentation, organ disposition and organ reason codes. **Table 5** outlines those data elements that will be included in the data set and the Committee determined would not require modifications to how they are currently being collected.

**Table 5: Data Elements Included in data set**

| Field Label | Systems/Form | Recommendation/Rationale |
|---|---|---|
| Total Cold Ischemia Time Left Kidney/Right Kidney/EnBloc: (if pumped, include pump time) | Kidney -TRR | Relevant to assessing cold ischemic time (CIT). |
| Total Pancreas Preservation Time (include cold, warm and anastomotic time) | Pancreas - TRR | Relevant to assessing cold ischemic time (CIT). |
| Total Ischemic Time (Include cold, warm and anastomotic time) | Liver - TRR | Relevant to assessing cold ischemic time (CIT). |
| Liver machine perfusion:* (has a follow up question) | DDR | There are experimental/clinical trials related to liver perfusion; this data element will be relevant in this assessment. It is anticipated that additional data collection data efforts will be needed, but current data will allow for baseline information. The Committee will defer to the Liver Committee for further recommendations of additional data collection efforts related to liver perfusion once more information becomes available. |
| Lung(s) perfused prior to transplant: | Thoracic - TRR | Relevant in assessing cold ischemic time (CIT). |

| Field Label | Systems/Form | Recommendation/Rationale |
|---|---|---|
| Total time on perfusion: (ST:) | Thoracic - TRR | Relevant in assessing cold ischemic time (CIT). |
| Received on ice: | Kidney-TRR | Relevant in assessing organ preservation practices. |
| Received on pump: | Kidney-TRR | Relevant in assessing organ preservation practices. There is a cost element associated with this; staff must stay with the kidney while it is on the pump and must be knowledgeable about what to do if the pump malfunctions. |
| (If put on pump or stayed on pump) Left/Right Kidney Final resistance at transplant: | Kidney-TRR | Relevant information for data purposes for transplant hospitals and in capturing clinical measures. This data element provides information on efficiency of organ preservation |
| (If put on pump or stayed on pump) Left/Right Kidney Final flow rate at transplant: | Kidney-TRR | Relevant information for data purposes for transplant hospitals and in capturing clinical measures. This data element provides information on efficiency of organ preservation |
| Left/Right: Pump? | DDR | Relevant for data purposes for OPOs. Provides information on sequence of events across the process of transportation (this collected on the OPO side) |
| Left/Right: Final Resistance Prior to Shipping | DDR | Pump parameters from OPO prior to shipping would be important data to evaluate. The final pump value is important in providing transplant programs with preservation information that helps in decision making |
| Kidney Pump Values: Date | DonorNet | Relevant to assess organ preservation practices. |
| Perfusion occurred at: | Lung – TRR | This data element helps evaluate if either the transplant center, the OPO, or a perfusion center perfused the organ. It provides information on how this process is evolving |

| Field Label | Systems/Form | Recommendation/Rationale |
|---|---|---|
| Perfusion performed by: | Lung – TRR | This data element helps evaluate if either the transplant center, the OPO, or a perfusion center perfused the organ. It provides information on how this process is evolving |
| Left Lung/Right Lung received at transplant center: | Lung – TRR | This data element collects valuable information. There should be alignment between organs in order to have the ability to compare different organ systems (a similar data element is asked for kidney, but the fields are more stratified). |
| Left/Right: Specify type of Kidney Pump/Machine (if other/specify) | DDR | After consulting with the Data Advisory Committee, this data will be included; this data element will be very useful once centers/OPOs begin using normothermic or midthermic pumps.<br>Pumps with Oxygenation could also play a role in the near future. |
| Left/Right: Type of Kidney Pump/Machine: | DDR | After consulting with the Data Advisory Committee, this data will be included; this data element will be very useful once centers/OPOs begin using normothermic or midthermic pumps.<br>Pumps with Oxygenation could also play a role in the near future. |
| Transferred to transplant center on pump | DDR | Relevant to assess patterns related to pump usage |
| Kidney Pump Device | DonorNet | Remove this data element. Information not relevant in assessing ischemic time. |
| Kidney Pump Solution | DonorNet | Relevant to assess organ preservation. Type of solution can play a role in obtaining different flow or resistance. |

| Field Label | Systems/Form | Recommendation/Rationale |
|---|---|---|
| Heart machine perfusion | DDR | Heart machine perfusion is currently in the investigation phase only. It is anticipated that additional data collection data efforts will be needed, but current data will allow for baseline information. The Committee will defer to the Heart Committee for further recommendations of additional data collection efforts related to heart perfusion once more information becomes available. |
| Organ Disposition | DDR | The six organ disposition codes currently used cover the range of scenarios for organ disposition (see **Appendix E** for look up table of codes) |

# Appendix C: Proposed Data Definitions/Clarifications

**Table 6** outlines the proposed modifications/clarifications to data definitions of indicated data elements.

**Table 6. Proposed Data Definitions/Clarifications**

| Field Label | Form | Recommendation/Proposed Modifications |
|---|---|---|
| Total Cold Ischemia Time Left Kidney/Right Kidney/EnBloc: (if pumped, include pump time) | Kidney - TRR | Data definition should delineate between transport time and cold ischemic time. Additionally, there should be a delineation between transport time from origin to destination and cold ischemic time from cross clamp to transplant time. |
| Lung(s) perfused prior to transplant: | Thoracic - TRR | Modify the data definition to reflect “machine perfusion” prior to transplant. |
| Kidney(s) received on: | Kidney-TRR | Remove "N/A" in help documentation. “N/A” is not a data field that can be selected. |
| Kidney Pump Values: Time | DonorNet | Final value would be most important to collect. Initial should be collected two hours after organ is placed on pump (to allow for calibration of pump). Upload of final pump report is acceptable.<br><br>Format: HH:MM<br><br>**Note**: Time should be in 24-hour format. |
| Kidney Pump Values: Flow (cc/min) | DonorNet | Initial value should be collected two hours after organ is placed on pump (to allow for calibration of pump). Upload of final pump report is acceptable. |
| Kidney Pump Values: Pressure (mmHg) | DonorNet | Initial value should be collected two hours after organ is placed on pump (to allow for calibration of pump). Upload of final pump report is acceptable. |
| Kidney Pump Values: Resistance | DonorNet | Initial value should be collected two hours after organ is placed on pump (to allow for calibration of pump). Upload of final pump report is acceptable. |

| Field Label | Form | Recommendation/Proposed Modifications |
|---|---|---|
| Total organ preservation time from cross clamp to in situ reperfusion (include warm and cold time) | Heart/Heart-Lung - TRR | Define total organ preservation time as cross clamp to transplant time (observing cross clamp time to time of first anastomosis) rather than defining warm ischemia and cold ischemia time |
| Organ check-in time | Waitlist[SM] | If the organ is recovered outside the facility where the transplant will take place, enter the date and time the organ arrives at the transplant hospital prior to opening the organ's external transport container.<br>Format: HH:MM<br>**Note**: Time should be in 24-hour format. |
| Time of first anastomosis | Waitlist[SM] | Enter the time of first anastomosis.<br>Format: HH:MM<br>**Note**: Time should be in 24-hour format. |
| Organ Check Out Time | TransNet[SM] or DDR* | Enter the date and time the organ leaves the OPO.<br>Format: HH:MM<br>Note: Time should be in 24-hour format. |

# Appendix D: Look Up Table: Organ Not Recovered

| ID | DESCRIPTION |
|---|---|
| 227 | REPLACED/ABERRANT RHA OR CHA TRAVERSING HEAD OF PA (valid only for PA and PA segments) |
| 200 | POOR ORGAN FUNCTION |
| 201 | CARDIAC ARREST |
| 202 | INFECTION |
| 203 | POSITIVE HEPATITIS |
| 204 | POSITIVE HIV |
| 205 | DISEASED ORGAN |
| 206 | ANATOMICAL ABNORMALITIES (not valid for PA or PA segments) |
| 207 | VASCULAR DAMAGE |
| 208 | NO RECIPIENT LOCATED |
| 209 | DONOR MEDICAL HISTORY |
| 210 | DONOR SOCIAL HISTORY |
| 211 | POSITIVE HTLV - 1 |
| 212 | BIOPSY FINDINGS |
| 213 | SURGICAL DAMAGE IN OR |
| 214 | NO LOCAL RECOVERY TEAM |
| 215 | ORGAN REFUSED BY ALL REGIONAL PROGRAM |
| 216 | ORGAN REFUSED BY ALL NATIONAL PROGRAM |
| 217 | ORGAN REFUSED BY ALL PROGRAMS WITH URGENT NEED |
| 218 | RULED OUT AFTER EVALUATION IN OR |
| 219 | RULED OUT DUE TO BIOPSY |
| 220 | EJECTION FRACTION < 50% |
| 221 | Po2 < 200 ON o2 CHALLENGE |
| 222 | HEMODYNAMICALLY UNSTABLE DONOR |
| 223 | TRAUMA TO ORGAN |
| 224 | "+ GRAM STAIN" |
| 225 | TIME CONSTRAINTS |
| 226 | MEDICAL EXAMINER RESTRICTED |
| 295 | DONOR HISTORY- UNDETERMINED- MEDICAL OR |
| 299 | OTHER SPECIFY |
| 228 | IPDA-SMA JUNCTION IDENTIFIED WITHIN 5MM FROM RHA JUNCTION (valid only for PA and PA segments) |
| 229 | IPDA ORIGINATING DIRECTLY FROM RHA (valid only for PA and PA segments) |
| 230 | OTHER ANATOMICAL ABNORMALITY (valid only for PA and PA segments) |
| 296 | Converted anatomical abnormalities (206 for PA and PA seg) - Inactive |

# Appendix E: Look Up Table: Organ Disposition Codes

| ID | DESCRIPTION |
|---|---|
| 1 | Authorization Not Requested |
| 2 | Authorization Not Obtained |
| 3 | Organ Not Recovered |
| 4 | Recovered Not for Tx |
| 5 | Recovered for TX but Not Tx |
| 6 | Transplanted |
| 7 | N/A |