OPTN

Briefing to the OPTN Board of Directors on

Data Collection to Evaluate Organ Logistics and Allocation

OPTN Operations and Safety Committee

Prepared by: Joann White, MPH
UNOS Policy and Community Relations Department

Contents

Data Collection to Evaluate Organ Logistics and Allocation

Data instruments affected: *TransNet[SM], Waitlist[SM], TIEDI DDR, TIEDI TRR,*
Sponsoring Committee: *Operations and Safety*
Public Comment Period: *August 3, 2021 – September 30, 2021*
Board of Directors Date: *December 6, 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 that current data collection efforts related to organ logistics and allocation were relevant, the Committee collaborated with the Data Advisory Committee (DAC) to perform a comprehensive review. This review identified necessary data modifications, the removal of several data elements from existing data collection to reduce data burden for areas deemed no longer relevant, and identified new data elements to be collected.

The Committee is proposing several modifications and removals of data elements as well as the inclusion of new data elements related to organ logistics and allocation: organ check-out time (TransNet[SM]), organ check-in time (TransNet[SM] and Transplant Recipient Registration (TRR) form), and time of transplant (first anastomosis) (Waitlist[SM]). The organ check-out time and organ check-in time data elements would complement one another by serving as both documenting chain of custody of organs and as a surrogate for organ transport time. Currently, date of transplant is collected by the OPTN. The addition of collecting time of transplant (time of first anastomosis) as a data element would allow a more detailed account of assessing the timeline from organ recovery to transplant.

The proposal was supported during public comment. Feedback received resulted in changes related to the proposed new data elements, data collection tool (form/system of data collection), and clarity on the data definition for organ check-out time.

Purpose

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

Background

The OPTN 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 qualitative in nature, the information collected revealed great variation in travel patterns. 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 OPTN 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

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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

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 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 OPTN 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.

Proposal for Board Consideration

This proposal includes modifications and removals to current data elements related to organ logistics and allocation as well as the addition of new data elements: organ check-out time, organ check-in time, and time of first anastomosis (time of transplant). Public comments were supportive of the changes proposed to current data elements and provided suggestions on the proposed new data elements that resulted in changes related to the proposed new data elements, data collection tool (system/form of data collection), and clarity on the data definition for organ check-out time. **Appendix A** contains the complete list of current data elements that will also be monitored, but are not being recommended for any modifications.

[5] Executive Summary of the OPTN/UNOS Board of Directors Meeting, December 5-6, 2016.
[6] Ad Hoc System Performance Committee Report, *OPTN Ad Hoc Systems Performance Committee,* June 2019.

Proposed Modifications and Removals

The Committee reviewed and proposed modifications to the following current data elements mentioned below. In reviewing organ disposition data, the Committee reviewed the catalog of "organ not recovered" code responses and proposed that some codes be removed (for a complete list of code responses, see **Appendix B**). A summary of those discussions are summarized below.

Type of Liver machine perfusion

The Committee proposes 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 recognizes that there are current experimental/clinical trials related to liver perfusion. During the development of this proposal, the feedback received from the OPTN Liver Committee agreed with collecting this data element as it would be relevant to collect in order to assess outcomes related to perfusion and complement future data collection efforts related to liver perfusion data.[7] 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.

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 be received on either pump or on ice.

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

The Committee proposed to detail the response fields in collecting the kidney pump values of time, flow, pressure, and resistance to collect the initial, low/peak, and final measurements. The Committee clarified that the collection of these data points aid transplant programs in their assessment and decision making of an organ offer.[8] During public comment, there were questions related to the logistics of collecting this data. The American Society of Transplantation (AST) provided feedback that there should be clarification as to who has the responsibility to put in the final kidney pump numbers in DonorNet, due to variability in the usage of kidney pumps when transporting the organ. There are instances when a kidney is initially on pump but may be shipped on ice to the transplant program and vice versa. If a transplant program is receiving the kidney on pump, it could be the transplant program's responsibility to upload those final values; otherwise, OPOs would need to provide those values.

The Committee considered this and upon further review of how the data elements are currently collected in DonorNet, the OPOs currently have the capability of entering as many values as needed when placing an organ on pump. The initial and final values can be collected without further specificity to the current response field; therefore, the Committee agreed that no modifications are needed for this data element. The data elements will remain as currently collected.

[7] December 15, 2020 Meeting Summary, OPTN Operations & Safety Committee, Broader Distribution Data Collection Workgroup. Available at httsp://optn.transplant.hrsa.gov/.
[8] April 15, 2021 Meeting Summary, OPTN Operations & Safety Committee

No Recipient Located (Organ Not Recovered response code ID #208)

The Committee proposed the removal of the no recipient located, organ not recovered (response code #208) after determining this code response was vague and did not provide a descriptive explanation of the disposition of the organ. The Committee received public comment related to alternative codes to use in the absence of code ID #208.

The Committee considered this feedback, and still concluded that the removal of this code was appropriate and agreed that usually a recipient is not located due to poor organ function (code #200) or the list was exhausted (code ID #'s 215, 216, 217).

POSITIVE – Human T-lymphotropic virus (HTLV-1) (Organ Not Recovered response code ID #211)

The Committee proposed the removal of the positive HTLV-1 organ not recovered response code (code #211) after determining that this code response is no longer relevant as HTLV-1 is no longer required to be tested or collected by the OPTN.

There was support of the removal of this code during public comment. The OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) agreed with the Committee's recommendation and added that since HTLV-1 has been removed from routine screening, and as testing results would not be back in time of organ offer, it seems appropriate to remove this code. The Committee agreed with the feedback received, and concluded that the removal of this code was appropriate.

Table 1 outlines the proposed response field removals of current data elements.

Table 1: Proposed Modifications to Current Data Elements

Field Label	Form	Recommended Changes
Type of Liver Machine perfusion: *(follow up to liver machine perfusion (Y/N))	DDR	**Options Response Field:** Single Selection, Listed Choices: 1 – Normothermic 2 – Hypothermic ~~999- Other/Specify : (write in)~~
Kidney(s) received on:	Kidney-TRR	**Options Response Field:** Single Selection, Listed Choices: Ice Pump ~~N/A~~
Organ Not Recovered Code	DDR	~~ID #208 – No recipient located~~
Organ Not Recovered Code	DDR	~~ID #211 – POSITIVE HTLV-1~~

Proposed New Data Elements and Response Code

During the review of the current data elements, and with consideration from the Committee's fall 2019 request for feedback[9], the Committee identified and proposed new data elements to be included in the data set to provide additional information regarding organ logistics and allocation. Based on public comment received, the Committee made changes to the proposed data collection tools and data definition clarifications for the new proposed data elements. Additionally, the Committee proposed the addition of a new organ not recovered response code. The proposed changes are described in further detail below.

Organ Check-Out Time

The Committee proposes organ check-out time as a data element that would be collected by the OPOs. Organ check-out time would serve as both a surrogate for organ transport time and 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.

During public comment, the majority of comments were related to clearly defining organ check-out time. The Committee originally defined organ check-out time as when the organ leaves the custody of the OPO. The OPTN OPO Committee provided feedback and suggested that organ check-out should be defined as when the organ is en route to the accepting transplant program rather than when the organ leaves the custody of the OPO. There are instances when the organ is transported by OPO staff to the transplant program and is technically still in the possession of the OPO. The OPO Committee discussed and clarified that organ check-out time denotes when the organ transport begins to the accepting transplant program.[10] The Committee considered this feedback and redefined organ check-out time to when the organ begins transit to the transplant program following organ acceptance.

Additionally, the Committee originally proposed and sought feedback on the form/system to collect organ check-out time. The Committee's preference was to collect this data element in either TransNet[SM] or on the deceased donor registration (DDR) form. The public comment received was in support of collecting organ check out time in TransNet[SM] as OPOs have accessibility to upload information electronically through this system. The Committee finalized the proposed form/system of collecting organ check-out time to TransNet[SM].

Organ Check-In Time

To complement the proposed organ check-out time data element, the Committee proposes organ check-in as a data element to serve as both documenting chain of custody of organs as well as a surrogate of transport time when combined with the other data collection included in this proposal. 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.[11] Currently, there is variability among transplant programs in how this information is collected. Including this data element will provide a centralized location to collect and monitor this information.

[9] *Data Collection to Evaluate the Logistical Impact of Broader Distribution,* OPTN Operations & Safety Committee. Available at https://optn.transplant.hrsa.gov/.
[10] August 18, 2021 Meeting Summary, OPTN Organ Procurement Organization Committee
[11] 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), would provide an accurate account from organ recovery to transplantation and could serve as a surrogate of organ transport time and a way to better understand these unique milestones from organ recovery to transplant. The Committee discussed how the collection of organ check-in time could help to delineate between time of transport and time of implant due to the complexities and variations related to organ transport logistics. The collection of organ check-in time would provide baseline expectations that can be utilized to assess outliers and better assess practices across programs[12].

There was support of this data element during public comment, but there was concern regarding collecting organ check-in time in Waitlist[SM]. Members voiced concern in collecting organ check-in within the 24-hour timeframe required in entering data in Waitlist[SM]. The OPTN Transplant Administrators Committee (TAC) recommended the collection of organ check-in time to be collected on the Transplant Recipient Registration (TRR) form. TAC members clarified that there is variation in who performs organ check-in and that the information may not be readily available after transplantation. The submission of data for the TRR form would allow transplant programs 60 days to complete and submit data, which would provide sufficient time for staff to obtain and enter organ check-in time. There were also comments related to collecting this information in TransNet[SM]. Organ check-in time is a current field within TransNet[SM] that can be entered either electronically (scanning) or manually. Transplant programs have the ability to enter this information at the time of organ check-in but cannot enter this retroactively. The Committee made revisions based on the public comment received and agree that in addition to being collected in TransNet[SM], organ check-in date and time would also be added to the TRR form to allow for manual entry if the transplant program does not use TransNet[SM]. Although this data element will be available in both TransNet[SM] and the TRR, this information will only need to be entered once. If organ check-in is entered in TransNet[SM] , it will then be cascaded into a read only display on the TRR form. If the transplant program does not use TransNet[SM], organ check-in would be entered on the TRR form.

Time of First Anastomosis

The Committee initially proposed 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 detailed account of the timeline from recovery to transplant. There were a few questions during the regional meetings as to why first anastomosis was being used instead of another event, such as reperfusion, to assess the timeline from recovery to transplant. As defined by policy, organ transplant begins at the start of anastomosis or the start of an islet infusion.[13] The Committee agreed that this was the most appropriate timing to collect of when organ transplantation occurs. Currently the date of transplantation is collected in Waitlist[SM] and with the addition of time of transplantation added, this will provide a more detailed dataset. The Committee revised the field label name to time of organ transplant to keep the data field labels uniform. The Committee revised the data definition of the time of organ transplant to align with the current OPTN policy definition of organ transplant: an organ transplant begins at the start of anastomosis or the start of an islet infusion.

[12] May 27, 2021 Meeting Summary, OPTN Operations & Safety Committee
[13] OPTN Policy 1.2: *Definitions* (June 2021)

No candidates on the match run (new Organ not recovered code)

The Committee identified a need for OPOs to be able to document those instances where a match is run but no candidates appear. While this happens rarely, it was noted that this does occasionally happen with very small donors and HIV positive donors. There were no public comments related to this change and the Committee agreed the new code was appropriate and would improve the quality of the data collected in this area.

Table 2 summarizes the proposed new data elements, new organ not recovered code, and the post public comment changes made by the Committee.

Table 2: Proposed New Data Elements, Organ Not Recovered Code, and Post Public Comment Changes

Field Label	Proposed Data Collection tool (System/Form)	Post Public Comment Change	Proposed Response Field Description/Data Definition	Post Public Change
Organ Check-out Time	DDR or TransNet[SM]	TransNet[SM]	Enter the date and time of when the organ leaves the OPO. Format: HH:MM **Note**: Time should be in 24-hour format.	Enter the date and time when organ begins transit to transplant program following organ acceptance **Format**: MM/DD/YYYY HH:MM **Note:** Time should be in 24-hour format.

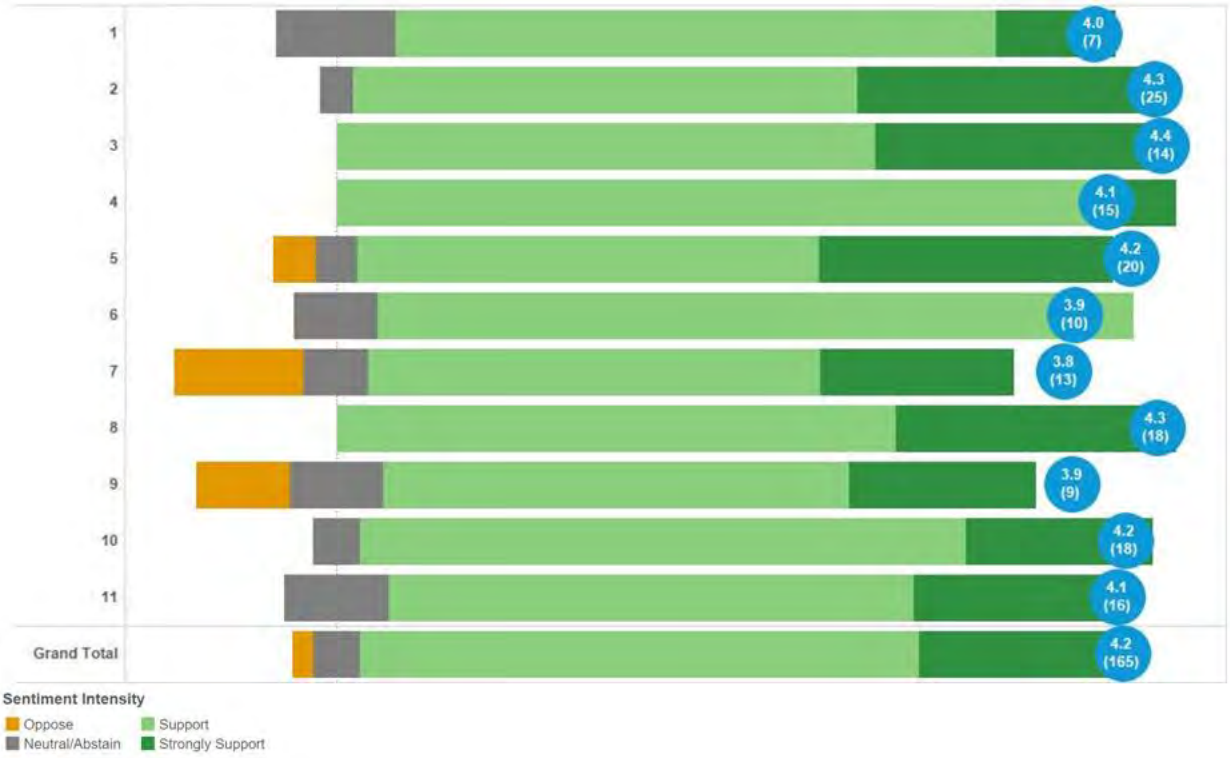
Field Label	Proposed Data Collection tool (System/Form)	Post Public Comment Change	Proposed Response Field Description/Data Definition	Post Public Change
Organ Check-in Time	Waitlist[SM]	TransNet[SM] and Transplant Recipient Registration (TRR) form	Enter the date and time the organ arrives at the transplant center. Format: HH:MM **Note**: Time should be in 24-hour format.	**Data Definition:** Organ check in must be completed any time an organ is recovered outside the facility where the transplant will take place. Organ check in must be competed upon arrival at the transplant hospital prior to opening the organ's external transport container. **Description:** Enter the date and time the organ arrives at the transplant hospital (prior to opening the organ's external transport container). **Format**: MM/DD/YYYY HH:MM **Note**: Time should be in 24-hour format.
Time of first anastomosis	Waitlist[SM]	No Changes	Enter the time of first anastomosis. Format: HH:MM **Note**: Time should be in 24-hour format.	**Field Label:** Time of organ transplant **Data Definition:** An organ transplant begins at the start of anastomosis or the start of an islet infusion **Description:** Enter the time of organ transplant
Organ Not Recovered Code	DDR	No Changes	Add code for "No candidates on the match run"	No Changes

Overall Sentiment from Public Comment

This proposal was issued for public comment from August 3, 2021 to September 30, 2021. The Committee requested feedback on proposed new data elements, specifically if organ check-out time and organ check-in time are good surrogates for organ transport. The Committee also asked for additional feedback on any other data elements that should be considered for inclusion in this data collection effort.

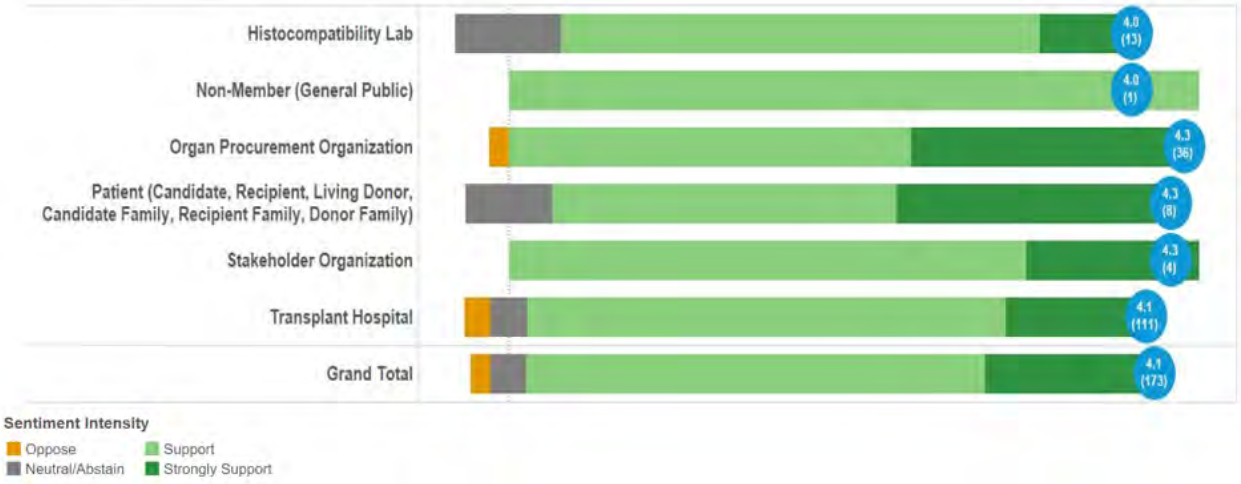
Public comment sentiment indicated support for this proposal. The proposal was on the discussion agenda for the OPTN regional meetings. All eleven regions were in general support of the data collection proposal. **Figure 1** illustrates the support for the proposal at the regional meetings. Gray represents neutral sentiment or abstentions, light green represents general support, and dark green represents strong support. The bar at the bottom of the figure is a representation of the average sentiment score for the proposal across each state. The score is calculated using a scale of 1-5. For example, a "strongly oppose" comment would receive a score of one, "support" would receive a two, "neutral/abstain" would receive a three, "support" would receive a four, and finally, a "strongly support" would receive a five.

Figure 1. Sentiment by Region



There was overall support across member types as shown in **Figure 2**. The scores were calculated in the same manner as Figure 1. There was some opposition from organ procurement organization (OPO) and transplant hospital members related to the new data elements.

Figure 2. Sentiment by Member Type



Compliance Analysis

NOTA and OPTN Final Rule

The Committee submits the following proposal for the Board consideration under the authority of the National Organ Transplant Act (NOTA), which requires the OPTN to "collect, analyze, and publish data concerning organ donation and transplants,"[14] and the OPTN Final Rule, which states, "An organ procurement organization or transplant hospital shall…submit to the OPTN…information regarding transplant candidates, transplant recipients, [and] donors of organs…"[15] The OPTN shall "maintain records of all transplant candidates, all organ donors and all transplant recipients" [16] and shall "…receive…such records and information electronically…[17] 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.

OPTN Strategic Plan

Increase the number of transplants:

This data collection effort will help to monitor and provide insight on patterns related to organ logistics and allocation, which will help to inform future policy development.

OPTN Data Collection Principles

Develop transplant, donation, and allocation policies:

This data collection effort will allow the opportunity to monitor trends related to organ logistics and allocation that could provide additional information that could help in the development of future policy development.

[14] 42 U.S.C. § 274(b)(2)(I)
[15] 42 CFR §121.11(b)(2).
[16] 42 CFR §121.11(a)(1)(ii).
[17] 42 CFR §121.11(a)(1)(iii).

Determine Member-specific performance:

This evaluation of this data can help to analyze and identify the potential impacts of changes seen related to organ logistics and allocation.

Implementation Considerations

Member and OPTN Operations

To implement this proposal, the OPTN will modify data collection instruments and communicate the changes to the transplant community. The OPTN will create help documentation for the new data elements to provide additional instruction for submitting these data, and the Committee will work with the OPTN to continue to refine the data element definitions throughout implementation of this proposal.

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 TransNet[SM] 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, TransNet[SM], Waitlist[SM], and data definitions. This proposal may add additional administrative burden, particularly for collecting organ check-in time and time of transplant. 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 were taken into consideration for final decisions on programming efforts.

This proposal requires the submission of official OPTN data that are not presently 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 will 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.

Projected Impact on Histocompatibility Laboratories

This proposal is not anticipated to have any fiscal impact on histocompatibility laboratories.

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 and time of transplant.

Projected Impact on the OPTN

The OPTN Operations and Safety Committee prepared and managed a number of workgroups to propose new data elements within UNet[SM] to provide insight into organ logistics and patterns, while also informing future policy development. The Committee also made recommendations to modify or remove data elements found to be unnecessary, so as to improve the accuracy and relevancy of collected data.

IT estimates a large number of development hours will be necessary to add the requested data elements and modifications to existing data elements. It is estimated that the changes will impact TIEDI, TransNet, and Waitlist[SM]. Research expects little effort will be required for implementation.

Research expects a minor number of ongoing hours, 80, will be required to compose a report, present to the Committee, and make necessary updates. No other department anticipates anything other than minimal ongoing hours necessary to support the project.

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.

Data Collection Monitoring

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^{SM}). 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

This proposal will allow 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.

From the feedback received throughout the development of this project as well as during public comment, there is support for more information on assessing the trends related to organ logistics and allocation. The proposed new data elements of organ check-out time and organ check-in time will provide insight on organ transport while also allowing for documentation on the chain of custody of the organ.

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 by allowing the OPTN to collect data collection that will further help in gathering more information on organ logistics and allocation as well as allow the opportunity to inform future policy development.

Proposed Changes to Data Fields and Definitions

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

1 **Proposed Changes to Current Data Elements**

Field Label	Form	Recommended Changes
Type of Liver Machine perfusion: *(follow up to liver machine perfusion (Y/N))	DDR	**Options Response Field:** Single Selection, Listed Choices: 1 – Normothermic 2 – Hypothermic ~~999- Other/Specify : (write in)~~
Kidney(s) received on:	Kidney-TRR	**Options Response Field:** Single Selection, Listed Choices: Ice Pump ~~N/A~~
Organ Not Recovered Code	DDR	~~ID #208 - No recipient located~~
Organ Not Recovered Code	DDR	~~ID #211 – POSITIVE HTLV-1~~

Proposed New Data Elements

Field Label	Proposed Data Collection tool (System/Form)	Proposed Response Field Description/Data Definition
Organ Check-out Time	TransNet[SM]	**Data Definition:** Time organ begins transit to transplant program following organ acceptance. **Description:** Enter the date and time when organ begins transit to transplant program following organ acceptance **Format**: MM/DD/YYYY HH:MM **Note:** Time should be in 24-hour format.
Organ Check-in Time	TransNet[SM] and Transplant Recipient Registration (TRR) form	**Data Definition:** Organ check in must be completed any time an organ is recovered outside the facility where the transplant will take place. Organ check in must be competed upon arrival at the transplant hospital prior to opening the organ's external transport container. **Description:** Enter the date and time the organ arrives at the transplant hospital (prior to opening the organ's external transport container). **Format:** MM/DD/YYYY HH:MM **Note**: Time should be in 24-hour format.
Time of transplant	Waitlist[SM]	**Data Definition:** An organ transplant begins at the start of anastomosis or the start of an islet infusion **Description:** Enter the time of organ transplant **Format:** HH:MM **Note:** Time should be in 24-hour format.
Organ Not Recovered Code	DDR	**Add ID code:** No candidates on the match run

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Appendix A: Current Data Elements included in Proposed Data Set (no modifications made)

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.

Data Elements included in data set

Field Label	Systems/Form	Justification/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).
Total time on perfusion: (ST:)	Thoracic - TRR	Relevant in assessing cold ischemic time (CIT).
Total Cold Ischemia Time Left Kidney/Right Kidney/EnBloc: (if pumped, include pump time)	Kidney - TRR	Relevant in assessing cold ischemic time (CIT).
Received on ice:	Kidney-TRR	Relevant in assessing organ preservation practices.

Field Label	Systems/Form	Justification/Rationale
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.
Kidney Pump Values: Time	DonorNet	Relevant to assess organ preservation practices. Helps with decision making of offers.
Kidney Pump Values: Flow (cc/min)	DonorNet	Relevant to assess organ preservation practices. Helps with decision making of offers.
Kidney Pump Values: Pressure (mmHg)	DonorNet	Relevant to assess organ preservation practices. Helps with decision making of offers.
Kidney Pump Values: Resistance	DonorNet	Relevant to assess organ preservation practices. Helps with decision making of offers.
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	Justification/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 Lung/Right Lung machine perfusion intended or performed:	DDR	Relevant to assess patterns related to organ perfusion
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. 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. 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	Justification/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/modifications related to heart perfusion once more information becomes available.
Total organ preservation time from cross clamp to in situ reperfusion (include warm and cold time)	Heart/Heart-Lung - TRR	Relevant in understanding organ preservation and evaluate timeframe from procurement to reperfusion of organ. The Committee will defer to the Heart Committee for further recommendations of additional data collection efforts/modifications related to heart perfusion once more information becomes available.
Left Lung/Right Lung machine perfusion intended or performed:*	DDR	Relevant in understanding perfusion patterns.
Recovery Team # (recommendation by OPO Committee currently out for public comment)*	DDR	Relevant in accessing patterns related to organ recovery.
Organ Disposition	DDR	The six organ disposition codes currently used cover the range of scenarios for organ disposition (see **Appendix C** for look up table of codes)

*Modifications were made to this data element in the OPO Committee's *Modifications to the Deceased Donor Registration (DDR) form* proposal. The Board of Directors approved modifications June 2021.

Appendix B: 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 C: 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