Notice of OPTN Data Collection Changes

Data Collection to Evaluate Organ Logistics and Allocation

Sponsoring Committee:	**Operations and Safety Committee**
Data instruments Affected:	*TransNet^{SM}, Waitlist^{SM}, TIEDI DDR, TIEDI TRR,*
Public Comment:	**August 3, 2021 – September 30, 2021**
Board Approved:	**December 6, 2021**
Effective Date:	**Pending implementation and notice to OPTN members**

Purpose of Data Collection Changes

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.

Proposal History

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.

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[1] https://optn.transplant.hrsa.gov/media/2806/osc_publiccomment_20190122.pdf
[2] Data Collection to Evaluate the Logistical Impact of Broader Distribution, OPTN Operations & Safety Committee. Available at https://optn.transplant.hrsa.gov/.

Summary of Changes

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 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.

Implementation

OPOs will be required 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.

Transplant programs will be required 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. 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.

These changes will require information technology implementation in the system. The OPTN will develop educational material to support the implementation of these data fields. 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.

Affected Policy Language

New language is underlined (<u>example</u>) and language that is deleted is struck through (~~example~~).

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