

**OPTN Data Advisory Committee
Holistic Data Review Workgroup
Meeting Summary
August 25, 2023
Conference Call**

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Introduction

The Holistic Data Review Workgroup (“Workgroup”) met via Citrix GoToMeeting teleconference on 08/25/2023 to discuss the following agenda items:

1. Data Definitions Updates
2. Workgroup Discussion

The following is a summary of the Workgroup’s discussions.

1. Data Definitions Updates

Slide summary:

The Workgroup reviewed 11 changes to data definitions within the OPTN Computer System.

- Patient on insulin
 - Require further clarification
- Source of payment
 - Reword “Public insurance, other government” to provide specific sources of payment (Indian Health Service, Military Health Services, etc.)
 - Further clarity for “Unknown” response
 - Update definition of private insurance to include “commercial insurance through employer or the Affordable Care Act”
 - Reviewed previous list of changes agreed upon at prior meeting:

FROM	CHANGE TO
Private Insurance	Private Insurance (Commercial Health Insurance) *See next slide
Public insurance – Medicare & Choice	Public insurance – Medicare Part C or Medicare Advantage
Self	Self-pay
Free Care	Free Care (Charity Care)
Unknown	Remove unknown

- Date last seen, retransplanted or death
 - “If the recipient died or the graft failed, **submit the expected Transplant Recipient Follow-Up forms. Also, if the death or graft failure occurs before an expected form, submit an interim event by clicking on the Report Interim Event link in the Related Links box in the top right of the page.**”

- Date of discharge from transplant center
 - “The recipient’s acute care stay includes total time spent in different hospital (inpatient) units.”
- Patient on life support
 - “If the recipient was on life support within 24 hours prior to entering the OR, select Yes.”
- Patient on VAD
 - “If the candidate was on a Ventricular Assist Device (VAD) within 24 hours prior to entering the OR, select the type.
- Hemodynamic Measurement
 - “Enter the most recent hemodynamic values within 24 hours prior to OR. The CO value may be collected via thermodilution or the Fick method.”
- Events occurring between listing and transplant
 - “Transfusion: if the recipient received any blood or blood product transfusions between listing and acceptance of organ offer, select Yes.” “
 - Pulmonary Embolism: (Lung only) If the recipient experienced any episode of pulmonary embolism between listing and prior to entering the operating room, select Yes.”
 - “Infection Requiring IV therapy within 14 days prior to the date of transplant: If the recipient experienced any infection requiring treatment with intravenous antibiotics during the two week period between listing and prior to entering the operating room, select Yes.”
 - “Dialysis: If the recipient had any hemodialysis or peritoneal dialysis between listing and prior to entering the operating room, select Yes.”
- Prior Cardiac Surgery
 - “Enter the most recent hemodynamic values within 24 hours prior to OR. The CO value may be collected via thermodilution or the Fick method.”
- Episode of ventilatory support
 - “At time of transplant is defined as prior to entering the operating room.”
- Total Time on Perfusion and Lung Received Fields
 - “Received at the center on ice, put on ice or freezer.”
- Did the patient have any acute rejection episodes between transplant and discharge
 - “If not treated with additional anti-rejection agent. Clinically non-significant, histologic rejection would fall under this category.”

Summary of discussion:

Patient on Insulin

Staff will consult with Pancreas Committee leadership on rewording “Patient on insulin” responses.

There was no discussion surrounding Patient on insulin.

Source of Funding

The Workgroup advocated for defining “Public insurance, other government” with specific instances of other governmental funding for transplant.

The Workgroup advocated for removing “Unknown”. Staff noted that this may be challenging due to its usage rate.

The Workgroup supported the previously discussed language changes.

A member supported retaining “Public insurance, other government” provided there was further clarity on what those sources were. They felt that the best option would be to remove that option and provide a comprehensive list of all instances of government funding that were not covered by other list options, but acknowledged that the easier approach may be to clarify within the existing response option what it covered. They expressed surprise that “Unknown” had as high a usage as it did (2.5% of all responses). A second member suggested that it may reflect a lack of knowledge of the staff member entering the information on where to find the source of payment. Removing “Unknown” may force staff members to determine what the payment source is rather than opting for the easiest option. A member agreed, noting that the data collection including “Unknown” felt like bad data collection. It was also proposed that “Unknown” could become “Patient not seen” to accurately convey a true unknown. Staff replied that “Patient not seen” exists at a higher level than the source of payment field, and if “Patient not seen” is selected, a number of fields become non-required.

A member suggested that health and welfare trust would not fall under free given that it was another form of government-provided insurance. A second member suggested that crowdsourced funds or fundraised funds may need a separate response option. This was rebutted by a member who considered fundraising or crowdsourcing acceptable to classify under “Self-pay”.

Date Last Seen, Retransplanted, or Death

The Workgroup proposed amending the definition to “If the recipient died or the graft failed, ***and there is an available Transplant Recipient Follow-Up form, submit the expected Transplant Recipient Follow-Up forms. If the death or graft failure occurs before an expected form, submit an interim event by clicking on the Report Interim Event link in the Related Links box in the top right of the page.**”

A member noted that the existing definition was a long sentence. They suggested rephrasing the two sentences in more of an “if/then” format.

Date of Discharge from Transplant Center

The Workgroup proposed amending the definition to “The recipient’s **acute care** stay includes total time spent in different ***transplant hospital (inpatient) units.**”

A member felt that the revision to the data definition was still vague. They noted that terminology “hospital (inpatient) units” did not accurately convey the intent of the definition when considering rehabilitation. For example, discharge to a hospital rehabilitation unit would still be considered a discharge even if the unit was in-hospital. Staff noted that this would still be tracked as a discharge and should constitute the end of the acute care stay. A member suggested adding “transplant” in front of “hospital” to try to ensure that only the acute care stay within the transplant hospital is tracked.

Patient on Life Support

The Workgroup proposed amending the definition to “If the recipient was on life support **within 24 hours prior to entering the OR *for transplant**, select Yes.”

A member proposed adding “for transplant” to ensure that there is no confusion about OR entry time.

Patient on VAD

There was no discussion surrounding Patient on VAD

Hemodynamic Measurement

A member wondered if an example of where the information could be found for Hemodynamic measurement. A member responded wondering if that could be overly specific for a definition, noting that not every staff member filling out the form may have the clinical knowledge to choose which to record if it seems are two possibilities for reporting.

Events Occurring between Listing and Transplant

The Workgroup proposed amending the following definitions to:

“Transfusion: if the recipient received any blood or blood product transfusions **between *center listing date and * prior to entering the operating room for transplant**, select Yes.” “

Pulmonary Embolism: (Lung only) If the recipient experienced any episode of **pulmonary embolism between *center listing date and prior to entering the operating room *for transplant**, select Yes.”

“Infection Requiring IV therapy within **14 days prior to the date of transplant**: If the recipient experienced any infection requiring treatment with intravenous antibiotics during the two week period **between *center listing date and prior to entering the operating room *for transplant**, select Yes.”

“Dialysis: If the recipient had any hemodialysis or peritoneal dialysis **between *center listing date and prior to entering the operating room for transplant**, select Yes.”

A member felt that all updates should record events between listing and entering the operating room for transplant. A second member noted that listing should likely be clarified to center listing date. It was suggested that acceptance should not be considered because an organ offer can be accepted significantly before the donor is moved to the operating room.

Prior Cardiac Surgery

There were no comments about prior cardiac surgery.

Episode of Ventilatory Support

The Workgroup proposed amending the field to “if the recipient experienced continuous invasive ventilation between listing and prior to entering the operating room ***for transplant**.”

A member noted that the time of transplant technically referred to the time of anastomosis, and therefore could be inaccurate when capturing ventilatory support as all donors will be on ventilatory support at that time. They suggested changing the text to read time of entering operating room for transplant. Staff noted that this text was intrinsic to the form, and therefore would require sponsorship

from a committee to change. Staff added that the OPTN Heart Committee can be made aware of this request.

Total Time on Perfusion and Lung Received Fields

A member suggested that “center” should be clarified to “transplant center”, as some organs may be received at donor centers. A second member replied that the hard coded text on the form reads “transplant center”, so transplant center may be implied in this field.

Did the patient have any acute rejection episodes between transplant and discharge?

The Workgroup recommended examining the response data for this field at their following meeting.

A member asked if rejection was determined by a biopsy. Staff reported that the OPTN Heart Committee had considered this question and replied that not all rejection was diagnosed with a biopsy. The member noted that, at their program, there were no episodes of rejection that did not receive a biopsy diagnosis. A member asked for a definition of clinically non-significant histologic reaction. Staff replied that it was an autoimmune response that did not require pharmacological intervention. A second member suggested it may be a finding from a routine biopsy that did not require pharmacological intervention. They also added that an asymptomatic rejection would not be considered an acute rejection episode. It was also proposed that the staff completing the form should indicate yes if any biopsy results returned positive signs of rejection, regardless of whether it were treated. No should only be selected there were absolutely no signs of rejection. A member noted that, at their center, a yes was only being indicated if there were proven biopsy results. Staff clarified that, on the form, there were three available options: 1) yes, treated with anti-rejection agents, 2) yes, non-treated with anti-rejection agents, and 3) no, no evidence of rejection. A member proposed investigating how frequently the response option is used.

Next steps:

Staff will follow up on the Workgroup’s recommendations.

2. Workgroup Discussion

This item was not discussed.

Upcoming Meeting

- September 22, 2023

Attendance

- **Workgroup Members**
 - Rebecca Baranoff
 - Ashley Cardenas
 - Colleen Flores
 - Karl Neumann
- **HRSA Representatives**
 - None
- **SRTR Staff**
 - Ajay Israni
- **UNOS Staff**
 - Brooke Chenault
 - Jonathan Chiep
 - Nadine Hoffman
 - Sevgin Hunt
 - Krissy Laurie
 - Elana Liberatore
 - Eric Messick
 - Lauren Mooney
 - Laura Schmitt
 - Divya Yalgoori