OPTN/UNOS Data Advisory Committee
Meeting Minutes
February 11, 2019
Conference Call

Sandy Feng, MD, PhD, Chair
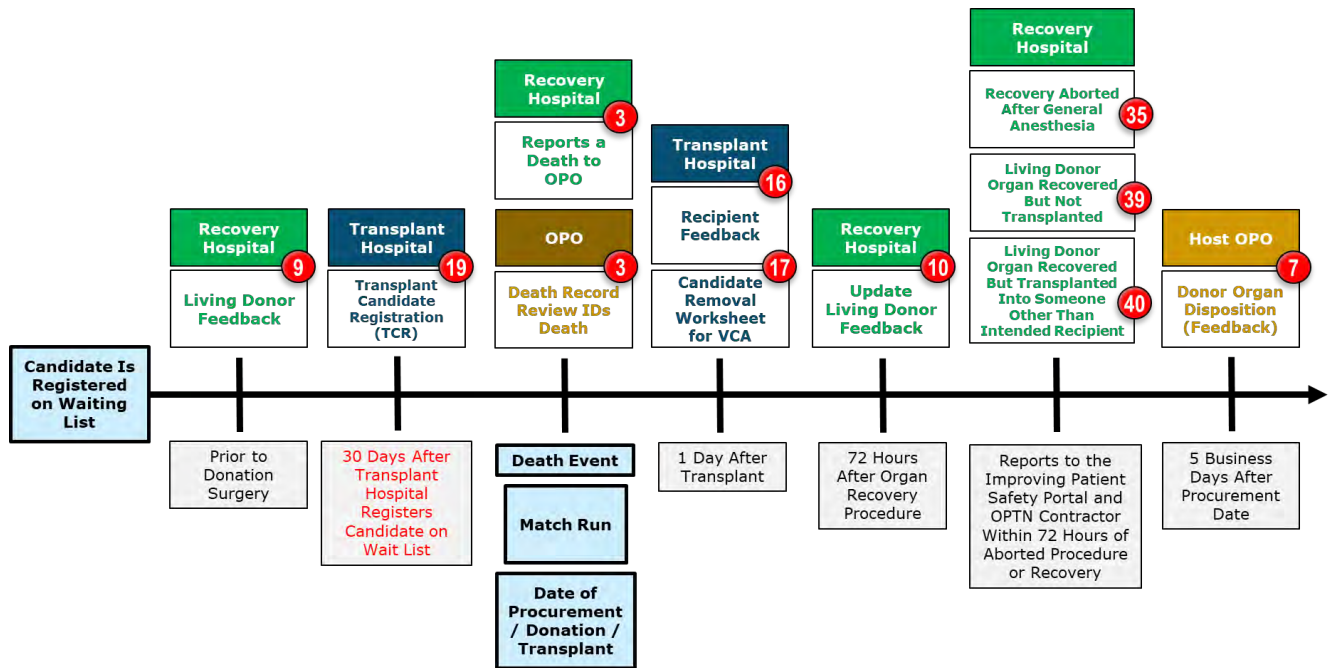**Rachel Patzer, MPH, PhD, Vice Chair**

Introduction

The Data Advisory Committee (DAC) met via Citrix GoTo teleconference on 02/11/2019 to discuss the following agenda items:
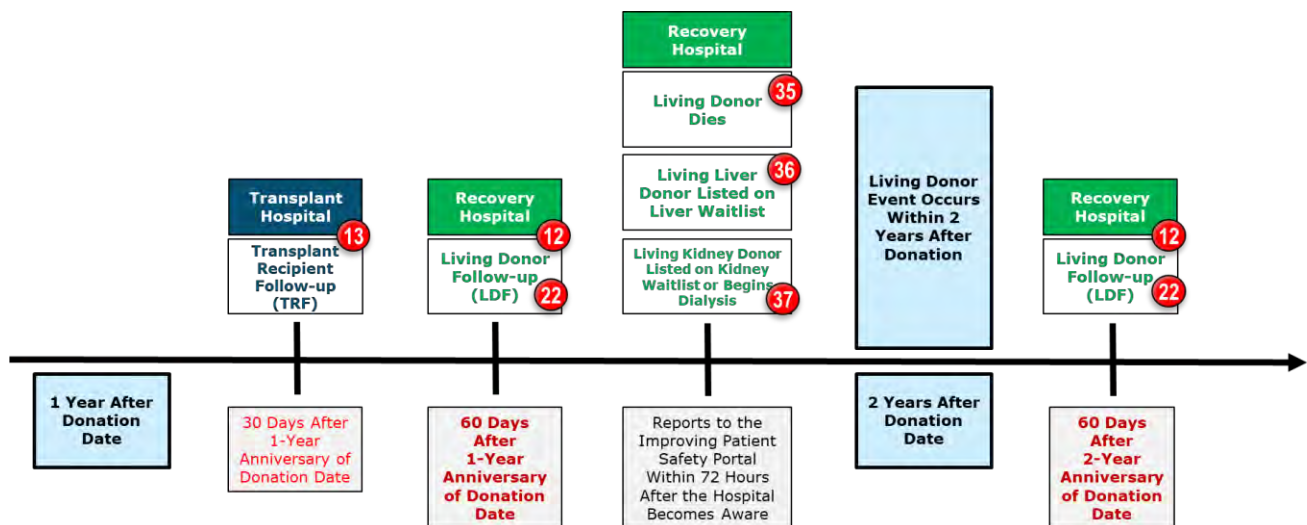
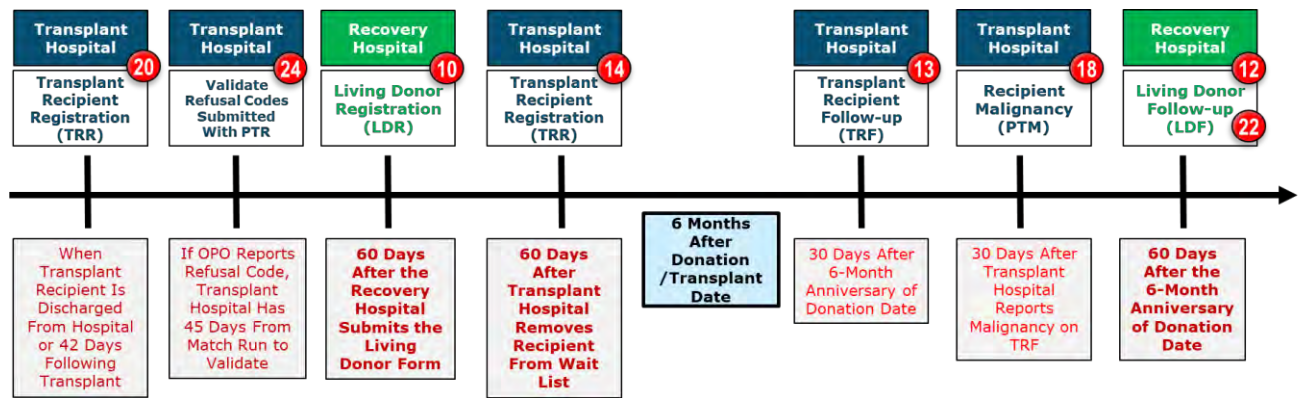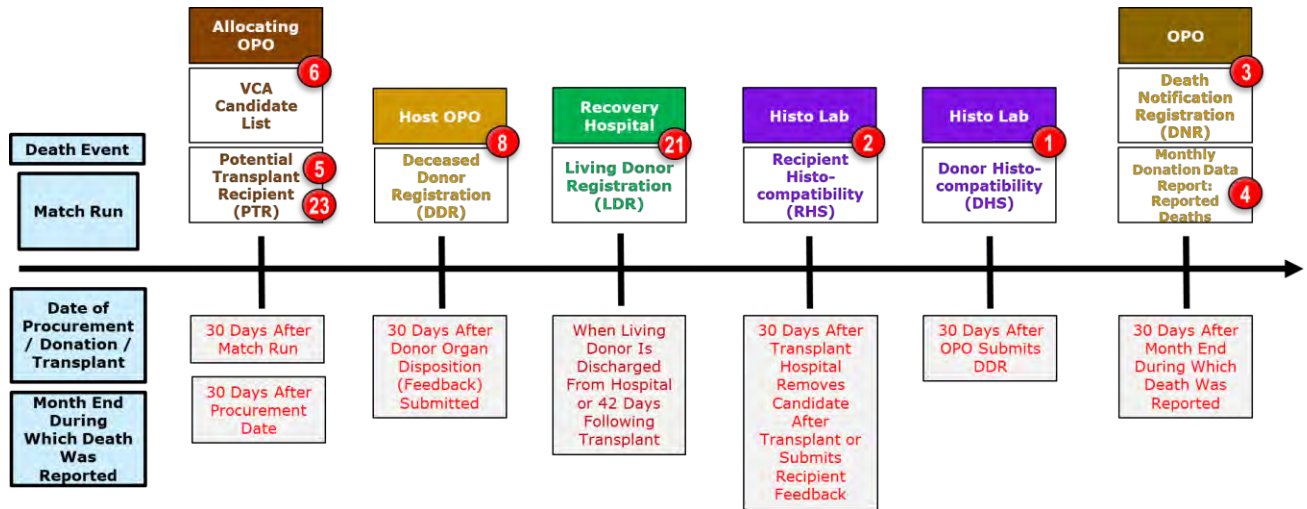1. Data Submission Timeframes
2. Policy Language Clarifications

The following is a summary of the Committee's discussions.

1. Data Submission Timeframes

UNOS staff presented a graphical timeline reflecting when members submit data to the OPTN as outlined under current OPTN Policy 18: *Data Submission Requirements* (see below). There was no further discussion of the timeline by Committee members.

Timeline 1

Left markers: Death Event · Match Run · Date of Procurement / Donation / Transplant · Month End During Which Death Was Reported

Role	Form	Deadline
Allocating OPO (6)	VCA Candidate List; Potential Transplant Recipient (PTR) (5)(23)	30 Days After Match Run; 30 Days After Procurement Date
Host OPO (8)	Deceased Donor Registration (DDR)	30 Days After Donor Organ Disposition (Feedback) Submitted
Recovery Hospital (21)	Living Donor Registration (LDR)	When Living Donor Is Discharged From Hospital or 42 Days Following Transplant
Histo Lab (2)	Recipient Histo-compatibility (RHS)	30 Days After Transplant Hospital Removes Candidate After Transplant or Submits Recipient Feedback
Histo Lab (1)	Donor Histo-compatibility (DHS)	30 Days After OPO Submits DDR
OPO (3)	Death Notification Registration (DNR); Monthly Donation Data Report: Reported Deaths (4)	30 Days After Month End During Which Death Was Reported

Timeline 2

Role	Form	Deadline
Transplant Hospital (20)	Transplant Recipient Registration (TRR)	When Transplant Recipient Is Discharged From Hospital or 42 Days Following Transplant
Transplant Hospital (24)	Validate Refusal Codes Submitted With PTR	If OPO Reports Refusal Code, Transplant Hospital Has 45 Days From Match Run to Validate
Recovery Hospital (10)	Living Donor Registration (LDR)	60 Days After the Recovery Hospital Submits the Living Donor Form
Transplant Hospital (14)	Transplant Recipient Registration (TRR)	60 Days After Transplant Hospital Removes Recipient From Wait List
	6 Months After Donation / Transplant Date	
Transplant Hospital (13)	Transplant Recipient Follow-up (TRF)	30 Days After 6-Month Anniversary of Donation Date
Transplant Hospital (18)	Recipient Malignancy (PTM)	30 Days After Transplant Hospital Reports Malignancy on TRF
Recovery Hospital (12)	Living Donor Follow-up (LDF) (22)	60 Days After the 6-Month Anniversary of Donation Date

Timeline 3

Left marker: 1 Year After Donation Date

Role	Form	Deadline
Transplant Hospital (13)	Transplant Recipient Follow-up (TRF)	30 Days After 1-Year Anniversary of Donation Date
Recovery Hospital (12)	Living Donor Follow-up (LDF) (22)	60 Days After 1-Year Anniversary of Donation Date
Recovery Hospital	Living Donor Dies (35); Living Liver Donor Listed on Liver Waitlist (36); Living Kidney Donor Listed on Kidney Waitlist or Begins Dialysis (37)	Reports to the Improving Patient Safety Portal Within 72 Hours After the Hospital Becomes Aware
	Living Donor Event Occurs Within 2 Years After Donation · 2 Years After Donation Date	
Recovery Hospital (12)	Living Donor Follow-up (LDF) (22)	60 Days After 2-Year Anniversary of Donation Date

2. Policy Language Clarifications

UNOS staff presented a series of proposed policy language changes to the Committee. The Committee discussed the proposed changes, including language that should either be eliminated or added to OPTN Policy 18: *Data Submission Requirements*.

<u>Summary of discussion:</u>

UNOS staff began discussion by reviewing the following information that was discussed during the previous full Committee teleconference call held on January 28th:

- Scheduled bi-weekly Committee calls
- Proposed eliminating OPTN Policy 18.4: *Data Submission Standard*
- Proposed additional smaller revisions and amendments
- Agreed to address issues related to data submission timeframes before data lock
- Discussed addressing Histocompatibility representation

Next, UNOS staff highlighted the three main problems this project will address:

1. Language inconsistencies leading to member confusion
2. Inconsistent timeframes for data submission
3. Instability of submitted data following validation

Staff also presented the following background information:

- 2000: Final Rule addressed importance of data collection, reporting and sharing
- 2002: New OPTN contract included new data submission standard- 95% of expected forms within 3 months and 100% within 6 months
- 2005: Substantial UNOS effort to reduce unnecessary data collection and reporting
- 2007: CMS adopted OPTN's data submission standard for Transplant Centers (In UNOS staff's PowerPoint presentation, this was misidentified as Organ Procurement Organizations (OPOs).
- 2016: UNOS staff effort to review OPTN Policy 18: *Data Submission Requirements*, including identifying potential changes

A Committee member clarified that the adoption of the OPTN's data submission standards by CMS included both OPOs and transplant hospitals.

UNOS staff then presented options for removing references to "recipient Feedback" within OPTN policy (Table 1). In recommending the changes, staff cited that currently, there is no recipient feedback form and members do not access the recipient feedback webpage. UNOS staff presented the following options to the Committee for consideration regarding recipient feedback:

Table 1: Recipient Feedback

	The member:	Must submit:	Within:	For:
(2)	Histocompatibility Lab	Recipient Histocompatibility (RHS)	~~Either: *~~ 30 days after transplant hospital removes candidate from WL because of transplant~~, or * 30 days after transplant hospital submits *recipient feedback*~~	Each heart, intestine, kidney, liver, lung, or pancreas transplant recipient typed by the laboratory
(15)	Transplant hospitals	Liver Post-Transplant Explant Pathology	60 days after transplant hospital ~~submits the recipient feedback form~~ removes candidate from waiting list	Each liver recipient transplanted by the hospital
(16)	Transplant hospitals	~~Recipient feedback~~ Waiting List Removal	1 day after the transplant	Each heart, intestine, kidney, liver, lung, or pancreas recipient transplanted by the hospital

*The red portions that are struck through are sections that UNOS staff recommends striking from policy language, whereas the language underlined in green represents recommended verbiage to add to OPTN policy.

Starting with the first row in Table 1 ("Recipient Histocompatibility- RHS"), Committee members questioned if a member from the Histocompatibility Committee had verified the timeframe of 30 days after transplant. UNOS staff clarified that the focus of this meeting's discussion is to clean-up the policy language, and that the issues of data submission timelines and data locks will be addressed at future Committee meetings. However, Committee members still wanted to know how it was previously determined that RHS forms should be submitted within 30 days after removal of candidate from the waitlist. UNOS staff informed the Committee that the deadline for submitting RHS forms has been in policy for many years, and was implemented when recipients of living donor transplants were not required to be registered on the waiting list. At the time, this was the only method for collecting information for these recipients.

With the clarification shown in Table 1, Committee members indicated that (from a transplant center perspective), striking the language from the RHS form was appropriate since now all living donor recipients must be registered on the waiting list. In terms of gaining an Organ Procurement Organization (OPO) perspective on this issue, Committee members agreed to garner their feedback specifically on the timeframes listed in Table 1 at a future Committee meeting (e.g. 30 days).

Next, discussion focused on the submission of liver post-transplant explant pathology forms. Committee members stated that these forms are already being submitted by transplant hospitals within 60 days of removing a candidate from the waiting list. As such, Committee members agreed to strike the "recipient feedback form" language, and to adopt the verbiage "removes candidate from waiting list" (see Table 1).

The last item the Committee discussed in Table 1 was the submission of a waiting list removal form 1 day after transplantation. Committee members were concerned whether it was necessary or appropriate to include verbiage relating to wait list removal in the above table. Specifically, OPTN Policy 3.9: *Removing Candidates from the Waiting List* contains the following verbiage:

> *If a candidate receives a transplant or dies while awaiting a transplant then the registering transplant hospitals must remove the candidate from the hospital's organ waiting lists and notify the OPTN Contractor within 24 hours of the event.*

However, Committee members were concerned that there are a variety of reasons why a candidate may be removed from the waiting list outside of being transplanted as listed in Table 1. Committee members stated that new policy language should not inadvertently omit or

4

exclude other reasons why a candidate may be removed from the waitlist. The Committee recommended that "waiting list removal" either be stricken, or expanded upon in Table 1 to include more reasons why transplant hospitals would remove a candidate from the waitlist within 1 day. In the end, Committee members agreed that "recipient feedback" should be removed from the language, but that future Committee meetings need to focus on the necessity of having "waiting list removal" in Table 1.

Currently, there is no living donor form, and Help Documentation includes instructions for updating the webpage with relevant data. From a transplant perspective, Committee members agreed that since the living donor form is no longer in use, then the verbiage referencing this can be stricken from Table 2 as shown below.

Table 2: Living Donor Feedback

The member:	Must submit:	Within:	For:
(10) Recovery Hospitals	Living donor feedback ~~Members must amend the form or contact the OPTN Contractor to amend this form according to Policy 18.6: Reporting of Living Donor Adverse Events~~	72 hours after the donor organ recovery procedure	Any potential living donor who received anesthesia but did not donate an organ or whose organ is recovered but not transplanted into any recipient

*The red portions that are struck through are sections that UNOS staff recommends striking from policy language, whereas the language underlined in green represents recommended verbiage to add to OPTN policy.

Currently, OPTN Policy 18.1: *Data Submission Requirements* does not specify the data submission of donor histocompatibility (DHS) for living donors. UNOS staff noted that TIEDI does provide instructions and functionality for submitting living donor information. Committee members questioned whether DHS data is being submitted for living donors, because they do not want to inadvertently add a requirement unto transplant centers to submit this data. UNOS staff clarified that the OPTN system is currently generating a DHS form when the system recognizes that a living donor organ has been recovered. In essence, adopting the policy language in Table 3 would align with current practices performed by histocompatibility labs. Committee members continued discussion by questioning why the policy included language concerning "recovered not for transplant" in Table 3. UNOS staff clarified that this language deals with deceased donors, and agreed that living donor organs would not be recovered for therapeutic reasons. Committee members suggested that the proposed policy language only include "recovered for transplant, not transplanted" and "transplanted".If UNOS staff corrects the proposed language, then Committee members agreed that the proposed policy language will be acceptable since members are already submitting the DHS forms.

Table 3: Donor Histocompatibility (DHS)

The member:	Must submit:	Within:	For:
(1) Histocompatibility Lab	Donor Histocompatibility (DHS)	30 days after the OPO submits the deceased donor registration or living donor feedback is entered in TIEDI and at least one organ disposition is: **Recovered not for Tx, Recovered for Tx not not Tx, or Transplanted**	Each heart, intestine, kidney, liver, lung, or pancreas donor typed by the lab

*The red portions that are struck through are sections that UNOS staff recommends striking from policy language, whereas the language underlined in green represents recommended verbiage to add to OPTN policy.

Next, UNOS staff focused the discussion on defining or clarifying "recovery date" versus "procurement date". Currently, the term "recovery date" appears in Policy 18.1 associated with living donor feedback, whereas "procurement date" is associated with the vascular composite allograft (VCA) candidate list and donor organ disposition. In summary, neither term is defined in OPTN policy. However, TIEDI defines "recovery date", and both terms are used in the TEIDI Help Documentation both terms are used. In practice, the DDR label contains the term "recovery date (donor to operating room)," but differences can occur between entering the operating room and an organ being procured.

Committee members opined that overall, transplant centers use both terms interchangeably to mean the same date. Committee members suggested that clarification needs to be made surrounding "recovery date" versus the date the donor is entering the operating room because this may cause issues for both OPOs and transplant centers when managing vessels. For example, a 1 day difference can determine if a transplant center is being compliant with the disposition of extra vessels. From the OPO perspective, a member stated that both terms are being used interchangeably to mean the "cross-clamp date and time". The reasoning behind this is that cross-clamping is seen as the initializing of organ cold ischemic time. Furthermore, from an OPO perspective, using "recovery date" to mean "donor to operating room" is not frequently used, if at all. In fact, some members define "recovery date" to mean when organs are removed from the body following cross-clamping.

UNOS staff clarified that the term "cross-clamp date and time" is not mentioned in OPTN Policy 18: *Data Submission Requirements*, though it may be mentioned in other areas of policy. Furthermore, though TEIDI Help Documentation defines the term "recovery date" to mean donor to operating room, many members associate this term to mean "cross-clamp date and time". It was mentioned that previously the OPTN Operations and Safety Committee was working on changing the term "recovery date" to "cross-clamp date", and reported that this policy language change would be widely support by the transplant community.

If Committee members had to choose between either term to be used consistently in policy, members supported using the term "recovery date" since this term is already defined in TEIDI Help Documentation. Furthermore, Committee members opined that the OPTN Operations and Safety Committee should be the ones to define "recovery date" since they have already worked on this issue. However, the Committee also strongly suggested that the term "cross-clamp date" be used over "recovery date" if possible, because this term is less ambiguous, currently being used clinically to calculate cold ischemic time and has greater timeframe specificity. The Committee members agreed that the suggestion to use "cross clamp time and date" also be referred for consideration to the OPTN Operations and Safety Committee.

In focusing the last discussion item, UNOS staff presented on overview of how the OPTN/UNOS defines "transplant date" versus "donation date". Currently, Policy 18.2: *Timely Collection of Data* uses both terms when referencing living donors. Transplant date can be found on transplant recipient follow-up form (TRF), recipient feedback form, candidate removal worksheet for VCA, transplant recipient registration form (TRR), and living donor registration (LDR). In terms of "donation date", this definition is used on the living donor follow-up forms (LDF). Furthermore, both the OPTN policy and TIEDI defines "transplant date", but does not define "donation date". In OPTN Policy 18.1: *Data Submission Requirements*, "donation" is used when referring to living donors and "transplant" is used when referring to recipients.

Committee members opined that the term "cross-clamp date and time" can be used for both living donors and deceased donors. As such, time points that occur in the living donation process should correspond to time points that occur in the deceased donor process. Both processes measure cold ischemic time, and therefore both processes should reference "cross-

6

clamp date and time". Committee members also expressed doubt that there is a need to capture OPTN data relating to when a donor enters the operating room. Another Committee member viewed "transplant date" as related to the recipient, and that "donation date" is frequently referenced in connection with living donors. The Committee agreed to refer this issue to the OPTN Operations and Safety Committee and recommended that "cross-clamp date and time" be used when referring to living donors and deceased donors respectively. However, if the OPTN Operations and Safety Committee will not address the term "donation date", then the DAC should look at defining this term.

<u>Next steps:</u>

UNOS staff agreed to relay the Committee's suggestions about "cross-clamp date and time" to the OPTN Operations and Safety Committee.

Upcoming Meeting

- February 25, 2019
- April 11 (in-person meeting)