OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

Data Advisory Committee
Meeting Minutes
April 15, 2019
Conference Call

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Introduction

The Data Advisory Committee (DAC) met via Citrix GoToTraining teleconference 04/15/2019 to discuss the following agenda items:

1. Data Lock Principles

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

1. Data Lock Principles

The DAC discussed details and made decisions about a potential data lock.

Data Summary:

The Committee reviewed UNOS analysis comparing Transplant Information Electronic Data Interchange (TIEDI) form submission rates by the expected date of submission, within 90 days of the expected date of submission, and within six months of the expected submission date.

Summary of discussion:

DAC listened to the advantages and disadvantages of locking data. UNOS staff asked the Committee to make a decision on the legitimacy of locking submitted data. A member pointed out that historically there has been no data locking. The member added that she did not think adding a data lock was controversial because it is important for prospective and retrospective work. The Committee members agreed that as a principle, OPTN data should be locked.

Next, UNOS staff presented information about how the information collected on the TEIDI forms is used and why the Committee should consider locking these forms. UNOS staff clarified that the reason for focusing this project on is that they have found data discrepancies in the TEIDI forms. It is also important for these forms to be accurate as this information gets reported back to the members, and is used in policy initiatives. UNOS staff then presented a list of all eight TIEDI forms. Six of these forms are documenting a point in time, and should conceivably contain accurate data at submission. The remaining two forms are transplant recipient and living donor follow-ups, and obtaining data may be more difficult. For example, if a recipient moves away and is no longer seen by the transplant hospital, it may be a challenge to get the necessary information.

UNOS staff asked the Committee if the data elements on the TIEDI forms should be locked at some point following members' submission and validation. A member verbalized support for locking the six TIED forms for data that is likely to be available when the form is due. However, the member was hesitant to do the same with the two follow-up forms. Another member stated that she believes that DAC will find challenges with locking the Transplant Recipient Follow-up (TRF) form because much of the data is not entered onto this form until a later date. The Committee member also questioned how the collected data is being utilized. For this reason, the member suggested a more detailed conversation surrounding the timing of the form's data lock and how it would be locked. Many DAC members agreed but voiced concerns on the

timeframes for locking data. For example, a Committee member was concerned that locking the Living Donor Follow-up form (LDF) too early may inadvertently lead to less data being submitted because transplant hospitals may not receive information until after the initial submission dates. Due to these concerns, the DAC members agreed that there will need to be more discussion about the timeframes for the locks.

Next, Committee members agreed to apply the lock concept for all TEIDI forms, with the understanding that the 'locking' conversation will be different for the two follow-up forms. One point that will have to be considered is the data feed that transplant hospitals get back from SRTR and the cross-referencing against external databases that happen during that cyclical, six-month period of time.

Next, UNOS staff presented the DAC with potential options for changing data after submission. The specific options requiring feedback are as follows: no changes permitted, changes permitted with restrictions, and changes permitted with no restrictions. A Committee member voiced supporting allowing data changes, but requiring restrictions with explanations. Other Committee members suggested examining each form using the specific questions (such as "What are the permissible circumstances?"). In doing this, the DAC can find out if there needs to be locking rules for each form or if there can be one set of locking rules for all forms. There was general agreement by the Committee members to allow data changes, but to require restrictions with explanations.

Another member asked Committee members to think about the process of locking and how they can best prepare those who will be impacted by this change. One Committee member suggested to start analyzing the Deceased Donor Registration form (DDR) and then moving to the Living Donor Registration form (LDR) and Transplant Candidate Registration (TCR). This member also opined that it would be beneficial to examine the Donor Histocompatibility form (DHS) and Recipient Histocompatibility form (RHD) together, as they are both follow up forms. Their reasoning is that it would be important to understand which information is populating from the OPTN waiting list and transferring to TIEDI forms. However, one DAC member commented that changes should be allowed for incorrect demographic information because this information does not have an impact on outcomes and must be accurate.

As the meeting came to a close, a representative from HRSA commented that they attended the in-person histocompatibility meeting. They reported that the histocompatibility Committee voiced their willingness to assist with the data locking process and had specific feedback to share. This representative also shared that she is pleased with the direction DAC is going on data locking. An SRTR representative suggested that DAC might want to have a submission date, followed by a lock date. This will ensure that data has time to be reviewed before it is locked and potentially far more challenging to change.

Next Steps:

DAC will hold another call where they will examine specific TIEDI forms starting with the DDR. This process will help the DAC to understand data lock challenges and develop a plan of action.

Upcoming Meetings
- April 22, 2019
- April 29, 2019
- May 1, 2019 (In-person)