Selected Recommendations of the
OPTN/UNOS Organ Procurement Organization Committee to the
Board of Directors
November 12-13, 2012
St. Louis, MO

Summary

I. Action Item For Board Consideration

- The Board is asked to approve a Proposal to Require All Locally Assigned Unique Identifiers be Documented in the Donor Record (Item 1, Page 2)

II. Other Significant Items

- The Committee discussed the Proposal to Update and Clarify Language in the DCD Model Elements (Item 2, Page 3)

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Richard Pietroski, MS, Chair
Sean Van Slyck, MPA/HAS, CPTC, Vice Chair

The following report represents the selected recommendation of the Organ Procurement Organization Committee to the Board of Directors.

I. Action Item for Board Consideration

1. Proposal to Require Documentation of All Unique Identifers Used to Label Tissue Typing Specimens

Policies 5.4.2 and 12.7.4.2 currently require OPOs (for deceased donors) and living donor recovery centers (for living donors) to label every tissue typing specimen with two unique identifiers, one being the UNOS Donor ID. The OPO Committee reviewed two issues related to the policies. 1) The unique identifiers used as the second identifier and 2) documentation of the unique identifiers. The Operations and Safety Committee sought clarification regarding what second identifiers could be used for tissue typing materials and recommended the use of date of birth as a second identifier. The OPO Committee noted that the date of birth is not always known. Each OPO and living donor recovery center, in its individual policies, can determine unique identifiers that can be used to label tissue typing specimens. The OPO Committee determined that developing a list of standardized unique identifiers will not correct the main issue which is the lack of documentation of the unique identifiers.

Currently there is no requirement in policy that the identifiers used on the tissue typing specimen be documented. The UNOS Department of Evaluation of Quality (DEQ) has received complaints from transplant centers regarding the use of unique identifiers that were not documented in the donor record, resulting in the transplant center's inability to validate it. One problem is that no UNOS Donor ID is assigned until the donor data is entered into DonorNet® and this usually occurs after the OPO has sent the tissue typing materials to a lab. The OPO Committee agreed that whatever identifier is used must be documented in the donor record by the Host OPO.

This proposal provides important information in the donor record for transplant centers to validate tissues typing materials received from OPOs or living donor recovery centers. It also reduces the possibility of transplant centers not being able to use tissue typing materials because of lack of validation, which had been reported and posed a risk to patient safety.

This proposal was released for public comment between March 16, 2012, and June 15, 2012. The Committee considered all public comments received on the proposal at its October 11, 2012, meeting. Overall, there was support for the proposal although there was some concern about not specifically defining "donor record." The Commitee noted that this was discussed but the decision was made to not be specific because some

OPOs use electronic records and other use paper records. The Committee did agree to clarify that all unique identifiers need to be documented in the "OPO donor record." The Committee did not agree that requiring documentation in DonorNet should be required since tissue typing specimens can be sent to the lab before a DonorNet record has been created and the fact that this would also requiring changes to DonorNet. Finally, there was also some concern about not requiring standard unique identifiers. The Committee has discussed this previously and agreed to charge a subcommittee with further addressing this issue before proposing any changes to the policy language. All regions and Committees supported the proposal. All comments are provided in the briefing paper (**Exhibit A**). The Resource Assessment and Impact Statement for this proposal can be found in (**Exhibit B**).

The Committee approved the following policy language to be considered by the Board. Committee vote: 13 in favor, 0 opposed, and 0 abstentions.

**** RESOLVED, that Policy 5.4.2 and Policy 12.7.4.2 (Tissue typing materials) set forth below, are hereby approved, effective pending distribution of notice:**

5.4.2 Tissue typing materials

Each separate specimen container of tissue typing material must have a secure label with two unique identifiers, one being UNOS Donor I.D., and one of the following three: donor date of birth, donor initials or locally assigned unique ID, (donor ABO is not considered a unique identifier). Additionally each specimen should be labeled with Donor ABO, date and time the sample was procured and the type of tissue. In the preliminary evaluation of a donor, if the UNOS ID or ABO is not available, it is permissible to use a locally assigned unique ID and one other identifier for the transportation of initial screening specimens. <u>The OPO must document in the OPO donor record all unique identifiers used to label tissue typing specimens.</u>

12.7.4.2 Tissue typing materials

Each separate specimen container of tissue typing material must have a secure label with two unique identifiers, one being UNOS Donor I.D., and one of the following three: donor date of birth, donor initials or locally assigned unique I.D., (donor ABO is not considered a unique identifier). Additionally each specimen should be labeled with Donor ABO and subtyping (when used to determine transplant compatibility, date and time the sample was procured and the type of tissue. In the preliminary evaluation of a donor, if the UNOS I.D. or ABO is not available, it is permissible to use a locally assigned unique I.D. and one other identifier for the transportation of initial screening specimens.

<u>The living donor recovery center must document in the donor record all unique identifiers used to label tissue typing specimens.</u>

2. Proposal to Modify DCD Model Elements

The OPO Committee previously released proposed changes to the Donation after Cardiac Death (DCD) Model Elements. The proposal would clarify and update language for the donation and transplantation community. The Committee continues to work on the proposal and expects to bring the proposal for Board consideration in 2013.

This proposal was distributed for public comment during the March 11, 2011 to June 10, 2011, period and again between March 16, 2012, and June 15, 2012. There was a considerable amount of concern expressed during public comment and the committee continues to work on addressing those comments.