## *At-a-Glance*

- **Proposal to Document All Locally Assigned Unique Identifiers in the Donor Record**

- **Affected/Proposed Policy:** Policies 5.4.2 (Tissue Typing Materials) and 12.7.4.2 (Tissue Typing Materials)

- **Organ Procurement Organization (OPO) Committee**

  This proposal will require OPOs and living donor recovery centers to document all unique identifiers used to label any tissue typing specimen in the donor record. This will allow transplant centers to validate the unique identifier information.

- **Affected Groups**
  Directors of Organ Procurement
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Physicians/Surgeons
  Transplant Program Directors
  Transplant Social Workers
  Organ Recipients
  Organ Candidates
  Living Donors
  Donor Family Members
  General Public

- **Number of Potential Candidates Affected**
  This policy change will affect all candidates that require a tissue typing specimen.

- **Compliance with OPTN Strategic Goals and Final Rule**
  The OPTN Strategic Goals affected by the proposal include:
  - Patient Safety – Transplant Centers will be able to validate the unique identifier information provided with tissue samples.

**Proposal to Document All Locally Assigned Unique identifiers in the Donor Record**

**Affected Policy:** Policies 5.4.2 (Tissue Typing Materials) and 12.7.4.2 (Tissue Typing Materials)

**Organ Procurement Organization (OPO) Committee**

**Summary and Goals of the Proposal:**

This proposal will require OPOs and living donor recovery centers to document all unique identifiers that are used to label any tissue typing specimen in the donor record. This will allow transplant centers to validate second the unique identifier information.

**Background and Significance of the Proposal:**

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.

The strength of this proposal is that it 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. One weakness of the proposal is that OPOs and living donor recovery centers will have to modify their practice and protocols if they are not currently entering the unique identifiers that they assign to label tissue typing specimen in the donor record. This policy may require some staff education.

- ***Collaboration:*** Policy language for tissue typing materials also exists in the living donor policies. It was determined that the same requirements for documenting the unique identifiers used to label tissue typing materials should exist in the living donor policies. The Living Donor Committee reviewed the proposal and approved the inclusion of the new language in Policy 12.7.4.2.

**Supporting Evidence:**

The UNOS Department of Evaluation of Quality (DEQ) data revealed that out of 17 policy violations regarding labeling and packaging within the first 6 months of 2011, 7 were related to issues with the unique identifier.

**Expected Impact on Living Donors or Living Donation:**

This policy change will affect all candidates that require a tissue typing specimen.

**Expected Impact on Specific Patient Populations:**

This policy change has no known impact to specific candidates.

**Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:**

The OPTN Strategic Plan goals affected by the proposal include:

- Improve Transplant Patient Safety and Living Donor Safety – Transplant Centers will be able to validate the unique identifier information provided with tissue typing specimens.

**Plan for Evaluating the Proposal:**

Once the policy is implemented, every six months the OPO and Living Donor Committees will review a list of all tissue typing unique identifier documentation errors that have been reported and determine if the documentation of unique identifiers has decreased the number of errors.

- Has there been a decrease in the number of tissue typing unique identifier errors since the requirement to document unique identifiers in the donor record was made a policy requirement for OPOs and living donor recovery transplant centers?
- Can this decrease be attributed to the new documentation requirements? This can be assessed during on-site reviews when the DEQ staff reviews and verifies member policies and procedures, and conducts interviews with staff to ensure compliance with this policy.

**Additional Data Collection:**

No additional data collection is necessary.

**Expected Implementation Plan:**

OPOs and living donor recovery centers must:

- Label each tissue typing specimen with two unique identifiers
- Enter both unique identifiers used to label tissue typing specimen in the donor record that is sent with the organ

OPOs and living donor recovery centers may need to modify their procedures for the generation and documentation of unique identifiers.

This proposal will not require programming in UNet$^{SM}$.

**Communication and Education Plan:**

| Communication Activities | | | |
|---|---|---|---|
| **Type of Communication** | **Audience(s)** | **Deliver Method(s)** | **Timeframe** |
| Policy Notice | Appropriate staff from OPOs and transplant centers | Policy notice within e-newsletter | 30 days after approval at board meeting |
| Article in e-newsletter in the policy-related category | Target appropriate staff at OPOs and transplant centers in headline. | e-newsletter and accessing URL of member archive | Earliest monthly issue after policy change is approved. |

**Compliance Monitoring:**

During on-site reviews, the Department of Evaluation and Quality (DEQ) staff reviews and verifies transplant centers' and OPOs' policies and procedures, and conducts interviews with staff to ensure compliance with this policy.

DEQ staff will request a corrective action plan if the transplant center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for its review.

**Policy Proposal:**

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

**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. The OPO must document in the donor record all unique identifiers used to label tissue typing specimens.

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