At-a-Glance

- **Proposal to Improve the ABO Verification Process for Living Donors**
- **Affected Policies: 12.3.1 (ABO Identification) and 12.8.1 (Reporting Requirements)**
- **Living Donor Committee**
- This policy proposal improves the ABO verification and matching process for living donors. Currently, the ABO verification and matching requirements for living donors are less stringent than the requirements for deceased donors.
- **Affected Groups**

  Living Donors
  Candidates for Living Donor Organs
  Transplant Administrators
  Transplant Coordinators
  Transplant Physicians/Surgeons
  Transplant Program Directors
  Donor Family Member
  General Public

Proposal to Improve the ABO Verification Process for Living Donors

Affected Policies: 12.3.1 (ABO Identification) and 12.8.1.1 (Reporting Requirements)[1]

Living Donor Committee

Summary and Goals of the Proposal:

This policy proposal improves the safety of living donation through an improved ABO verification and matching process. Currently, the blood type (ABO) verification and matching requirements for living donors are less stringent than the requirements for deceased donors.

Background and Significance of the Proposal:

In June 2008, the Living Donor Committee learned of a living donor transplant in which the living donor kidney was transplanted into an ABO incompatible recipient. The living donor was originally typed as blood type A2. The recipient was typed blood type O. In this case, the kidney of this A2 living donor was transplanted into a recipient with an O blood type; however, the recipient showed immediate signs of accelerated rejection of the transplanted kidney. After repeated blood typing and cross matching, the donor's ABO was typed as A1, and had a positive crossmatch with the kidney recipient's serum.

After considering this case, and reviewing existing OPTN/UNOS policies, the Committee realized that existing policies for ABO verification are more stringent for deceased donors than for living donors. Policies 3.1.4.2 (Waiting List) and 3.2.4 (Match System Access) require deceased donors and candidates for receiving deceased organs to receive two ABO tests; however, no similar policy exists for living donors.

Though the committee is only aware of this single instance of unintentional living donor and recipient ABO incompatibility, it is difficult to determine conclusively if other cases have occurred. Transplants in which the reported donor ABO differed from the reported recipient ABO may represent intentional "blood type incompatible" donation.

According to the experience of transplant professionals serving on the Committee, it is standard practice for most programs to require potential living donors to receive two ABO tests. Therefore, the Committee embarked on an effort to include this requirement in policy to help prevent ABO mismatches in the future. This policy proposal will help protect living donors and the recipients of their organs.

The Committee consulted the OPTN/UNOS Operations, Transplant Administrators and Transplant Coordinators Committees on this case and proposed policy. The Operations Committee and Transplant Administrators Committee both supported developing new and clearly defined policies for ABO typing and verification of a potential living donor and his/her recipient. The Operations Committee questioned why current policy would permit less stringent testing requirements for living donors, and commented that this proposed policy would help improve living donor safety.

[1] On June 22-23, 2009, the OPTN/UNOS Board of Directors approved the relocation of policies related to living donation to the new Policy 12.0 (Living Donation) category. UNOS will communite the existence of this new policy section on July 23, 2009.

Supporting Evidence

To date, the Committee is only aware of this single case of ABO mismatch that occurred between a living donor and his/her recipient.

Although there is limited evidence to demonstrate persistent problems with the ABO verification process in living donation, the Committee determined that even one accidental case of ABO mismatch between a living donor and his or her recipient is unacceptable. The ABO verification process for deceased donors requires two ABO samples sent to two separate laboratories, or two samples from separate blood draws sent to the same laboratory. At present, there is no policy addressing the ABO verification process for living donors. In response, the Committee opined that the ABO verification process for living donor should be as stringent as the process for deceased donors.

Expected Impact on Strategic Plan:

The policy proposal addresses three strategic plan goals:

- Refine allocation policies, incorporating concepts of:
    - donor risk
    - recipient benefit, and net benefit

- Optimize a safe environment for living donor transplantation

- Improve compliance with policies to protect patient safety and preserve public trust

This policy proposal will help protect living donors by reducing the risk of having their organ transplanted into an ABO incompatible recipient. The proposal also benefits the recipient by guaranteeing that he or she will be ABO compatible with the donor. Any reduction in donor risk optimizes a safe environment for living donor transplantation, protects patient safety, and will help preserve public trust.

Plan for Evaluating the Proposal:

The Committee will monitor ABO incompatibility cases involving living donors.

Additional Data Collection:

The transplant center would be required to collect data and follow the established procedures required for ABO verification for organs from living donors.

As proposed, each living donor must be ABO typed on two separate occasions prior to the donation. Two separate occasions are defined as two ABO samples taken at different times, and sent to the same or different laboratories. Additionally, the living donor transplant program must use the documentation from both ABO typings to enter the living donor's ABO on the Living Donor Feedback Form. Additionally, each living donor program must develop, implement, and comply with a procedure to verify that the living donor's ABO was correctly entered on the Living Donor Feedback Form. Transplant programs must document that each ABO entry was performed in adherence to the program's protocol. The program must maintain this documentation, and make it available to UNOS, upon request.

Expected Implementation Plan:

This policy will become effective on August 24, 2009. This date is 30 days after the transplant community receives notification of the OPTN/UNOS Board of Directors' approval of the proposed policy.

The proposed policy will not require programming in UNet[SM].

Communication/Education Plan:

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice	Living Donors Candidates for Living Donor Organs Transplant Administrators Transplant Coordinators Transplant Physicians/Surgeons Transplant Program Directors Donor Family Member General Public members	E-mail	30 days after Board approval

Monitoring and Evaluation:

UNOS Department of Evaluation and Quality (DEQ) staff will evaluate member compliance with this policy.

How members will be expected to comply:

Transplant centers must:

- Obtain ABO typing of each potential living donor on two separate occasions prior to donation, with two samples obtained at different times and sent to the same or different labs;
- Register each living donor through the Living Donor Feedback Form prior to donation;
- Use the source documents for both ABO typings to enter the living donor's ABO on the Living Donor Feedback form;
- Develop, implement and comply with a procedure whereby an individual other than the person who initially entered the donor's ABO data on the Living Donor Feedback Form uses source documents to verify donor ABO in the Living Donor Feedback Form; and,
- Maintain documentation that such separate verification has taken place and make such documentation and source documents available for audit.

How OPTN/UNOS will evaluate member compliance:

The DEQ staff may detect potential violations of this proposed policy by:

- Reviewing medical records for documentation of two ABO typings prior to donation;

- Reviewing Living Donor Feedback Forms;
- Reviewing Member policies, procedures, and processes for verifying the entry of ABO on Living Donor Feedback forms;
- Verifying documentation that ABO entry was performed according to program procedures;
- Investigating reports of complaints;
- Reviewing OPTN data; or,
- Reviewing referrals received from OPTN/UNOS Committees, OPTN/UNOS staff, or OPTN/UNOS Members.

DEQ staff will explore all potential policy violations and forward any results to the OPTN/UNOS Membership and Professional Standards Committee for confidential medical peer review.

Policy Proposal:

12.3 Medical Evaluation of Living Donors

12.3.1 ABO Identification

The member transplant hospital must ABO type each living donor on two separate occasions prior to the donation. Two separate occasions are defined as two ABO samples taken at different times, and sent to the same or different laboratories.

12.8.1 Reporting Requirements

12.8.1.1 The living donor transplant program must use the source documents from both ABO typings to enter the living donor's ABO on the Living Donor Feedback Form. Additionally, each living donor program must develop, implement, and comply with a procedure to verify that the living donor's ABO was correctly entered on the Living Donor Feedback Form. A transplant program must document that each ABO entry was performed in adherence to the program's protocol. The program must maintain this documentation, and make it available to UNOS, upon request.