

At-a-Glance

- **Proposal to clarify, reorganize and update OPO policies to align with current practices - Policy Affected: Policy 2.0 - Minimum Procurement Standards for an Organ Procurement Organization**
- **Sponsoring committee: Organ Procurement Organization (OPO) Committee**
- **Summary of proposal**
The proposed changes are a reorganization and clarification of standards for OPOs.
- **Affected groups:**
Lab Directors/Supervisors, OPO Executive Directors, OPO Medical Directors, Directors of Organ Procurement, OPO Procurement Coordinators, Transplant Coordinators and Surgeons
- **Specific requests for comment:**
The Committee would welcome any comments that you may have.

Proposal to clarify, reorganize and update OPO policies to align with current practices

Policy Affected: Policy 2.0 (Minimum Procurement Standards for an Organ Procurement Organization Proposal to Clarify, Reorganize and Update Policy 2.0 - Minimum Procurement Standards for an Organ Procurement Organization)

Organ Procurement Organization (OPO) Committee

Summary and Goals of the Proposal:

The proposed modifications will clarify the policy requirements, eliminate redundancy and align policy with current OPO practices. The changes reorganize the content, eliminate repeated laboratory tests, and update terminology. The proposed policy modifications should clarify policy and reduce OPO confusion in order to reduce the OPO's risk of non-compliance and enhance patient safety.

Background and Significance of the Proposal:

Policy 2.0 lists the minimum standards for organ procurement organizations for such things as laboratory testing, required documentation, verification of death, donor maintenance, obtaining consent, and promoting donor quality. The policy currently lists laboratory tests required for all donors and repeats many of them for organ specific requirements as well. The Committee agreed that this redundant construction is confusing and a potential source for error. There are also several laboratory tests that may be requested but are currently listed as required tests. These are sources of confusion and have been clarified.

The OPO Committee made a commitment to review and revise those policies that may be unclear, repetitive, or not in keeping with current practice in order to improve patient safety and/or identify those policies that will put the OPO at risk for non-compliance. A Policy Review Subcommittee reviewed Policy 2.0 in detail and made recommendations for change to the full Committee. At the June 2008 Committee meeting, the proposed changes were finalized and approved unanimously.

The proposal updates the terminology in the policy language, such as the change from "social-behavioral" history to "medical-behavioral" history. In keeping with the current change to electronic documentation, we removed the term "written" which gives OPOs the opportunity to record their data electronically in the future.

Laboratory tests required for all donors are consolidated into one list and removed from the organ specific test lists to eliminate duplication. There is also a proposed change to no longer require the GGT test for the liver donor and to no longer require the lipase test for pancreas testing. These tests are not always available to OPOs and/or are not routinely conducted. OPOs can request these tests on an individual basis, if desired. Sub-typing of ABO-A donors should be done for all donors, not just liver donors. As such, it was deleted from the liver laboratory testing and moved to the listing of tests for all donors.

Supporting Evidence and/or Modeling:

The changes reflect the Committee's expertise and knowledge about current practice. The Department of Evaluation and Quality (DEQ) provided the subcommittee with a list of the most common potential

policy violations identified by DEQ staff during routine reviews of OPOs.. As such, the subcommittee used those observations to help identify portions of policy that might be misinterpreted or confusing.

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

It is anticipated that by clarifying the policy, OPOs will have a more straightforward and consistent interpretation of the policy. This should result in a more consistent approach to OPO responsibilities and reduce the possibility of non-compliance.

Plan for Evaluating the Policy:

OPOs will be expected to comply with all requirements stated in Policy 2.0 and its subsections. UNOS Department of Evaluation and Quality (DEQ) staff will evaluate member compliance with this policy.

How UNOS will evaluate member compliance with this policy:

UNOS currently monitors member compliance with the existing requirements of Policy 2.0 during OPO site surveys and as part of the allocation review process. UNOS staff forward potential violations of this policy to the Membership and Professional Standards Committee (MPSC) for review. If these revisions are approved and implemented, then UNOS staff would incorporate the new and modified requirements into monitoring procedures.

UNOS also monitors complaints received through its Patient Services Line and the confidential Member Reporting line. Any complaint received through these mechanisms that has the potential to be a policy or bylaw violation is forwarded to the MPSC¹. If the MPSC identifies the need for clarification, education, or additional changes related to this policy, the MPSC will forward its recommendation to the OPO Committee.

Expected Implementation Plan:

UNOS will provide notice of these changes within 30 after being approved by the Board of Directors, and implementation will occur 30 days following notification.

Communication and Education Plan:

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice (summary of all policy changes approved by the board in a PDF format)	OPOs and Transplant Centers	Electronic (email sent from the UNOS Communications mailbox)	30 days after the Board approves the change.

¹The Membership and Professional Standards Committee performs confidential medical peer review, and any recommendations or information reported to the OPO Committee is only reported in aggregate (i.e. non-identified, not case specific) data.

Data Collection:

This proposal does not require additional data collection.

Policy or Bylaw Proposal:

2.0 MINIMUM PROCUREMENT STANDARDS FOR AN ORGAN PROCUREMENT ORGANIZATION (OPO)

The following policies provide the minimum procurement standards for an Organ Procurement Organization (OPO).

2.1 HOST OPO. The Organ Procurement Organization (OPO) responding to an organ donor call from a hospital is the "Host OPO" for that particular donor. The Host OPO is responsible for identifying, evaluating and maintaining the donor, obtaining consent for the removal of organs, ~~verifying pronouncement of death~~ and organ allocation. Additionally, the Host OPO is responsible for ensuring that donor tissue typing information ~~about the donor~~ is entered into the OPTN computer UNetSM and that the approved OPTN organ allocation computer program is executed for each donor organ. Every reasonable attempt shall be made to obtain a ~~social~~ medical/behavioral history from individual(s) familiar with the donor and not restricted to the person granting permission for organ donation. The Host OPO is responsible for organ procurement quality including appropriate preservation, and packaging of the organs, and assurance that adequate tissue typing material is procured, divided, and packaged. The Host OPO is responsible for ensuring that written documentation of donor evaluation, donor maintenance, consent for donation, death pronouncement, and organ procurement quality accompanies the organ as described in Policy 5.0 (Standardized Packaging and Transporting of Organs and Tissue Typing Materials).

2.2 EVALUATION OF POTENTIAL DONORS. The Host OPO is responsible for performing the following activities and communicating this information to the OPO or transplant center for every donor:

2.2.1 Verifying that death has been pronounced according to applicable laws.

2.2.2 Performing pertinent tests including:

- ABO typing;
- FDA licensed Anti-HIV I, II.

~~In addition, the Host OPO shall perform the following evaluations and provide this information to the OPO or transplant center, documenting in the donor record circumstances when such information is not available.~~

2.2.3 The Host OPO must perform the following evaluations and provide this information to the OPO or transplant center, and must document in the donor record circumstances when such information is not available. The Host OPO must ~~determine~~ whether there are conditions which may influence donor acceptance by:

- ~~2.2.4~~ Obtaining the donor's medical/behavioral history.

- ~~2.2.5~~ Reviewing the donor's medical chart.
- ~~2.2.6~~ Performing a physical examination of the donor.
- ~~2.2.7~~ Obtaining the donor's vital signs.

2.2.84 The Host OPO must perform the following performing pertinent tests including; and provide this information to the OPO or transplant center. The Host OPO must document in the donor record circumstances when such information is not available. In all cases, the transplant center will make the clinical decision whether to accept or reject the organ based on the available data or identify the need for additional information. The Host OPO may be requested to provide additional information if possible in addition to the information required on all donors.

2.2.84.1 For all potential donors:

- CBC;
- Electrolytes;
- Hepatitis screen serological testing; including HBsAg, HBcAb, and Anti-HCV;
- VDRL or RPR;
- Anti-HTLV I/II;
- Anti-CMV;
- EBV serological testing;
- Blood, sputum, and urine cultures ~~if the donor is hospitalized 72 hours or longer;~~
- Urinalysis within 24 hours prior to cross clamp; ~~and~~
- Arterial blood gases;
- ABO typing with sub-typing for ABO-A donors;
- Chest x-ray; ~~and~~
- Serum Glucose.

Additional Organ Specific information is required as follows:

2.2.84.2 For potential renal donors:

- ~~Urinalysis;~~
- Creatinine; and
- B.U.N.

2.2.84.3 For potential liver donors:

- AST
- ALT
- Alkaline phosphatase

- ~~GGT~~
- Direct and tTotal bilirubin;
- Direct bilirubin (if requested);
- INR (PT if INR not available);and
- PTT;and
- Blood group subtyping of ABO=A donors.

2.2.84.4 For potential heart donors:

- 12 Lead ECG; and
- Cardiology consult and/or echocardiogram; and
- ~~Blood gases.~~

2.2.84.5 For potential pancreas donors:

- Serum amylase;
- ~~Serum lipase (if requested); and~~
- ~~Glucose.~~

2.2.84.6 For potential lung donors:

- ~~Blood gases, and~~
- Sputum gram stain.

2.3 DONOR MAINTENANCE. The Host OPO must ensure that the deceased donor is maintained as follows and that these actions are documented:

- 2.3.1 Blood pressure is adequate to maintain perfusion of vital organs;
- 2.3.2 Vital signs are monitored;
- 2.3.3 I.V. therapy or drugs are administered as required (i.e. vasopressors, vasodilators; etc.).
- 2.3.4 Antibiotic therapy is administered as required; and
- 2.3.5 Intake and output.

2.4 OBTAINING CONSENT. The Host OPO must provide evidence of consent for donation according to applicable legal authority.

2.5 ORGAN PROCUREMENT QUALITY. Minimum standards of quality shall include documentation of the following:

- 2.5.1 ~~Final urinalysis;~~ All items in section 2.2
- 2.5.2 ~~Monitoring and recording of blood pressure and temperature;~~

2.5.32 Use of standard surgical techniques in a sterile operating environment;

2.5.43 Maintenance of flush solutions and preservation media at appropriate temperatures and recording of flush solutions and additives; organ anatomy, organ flush characteristics, flush solution amount and type, and organ abnormalities or surgical damage if any. The Host OPO is responsible for ensuring that the donor medications are given at appropriate times and that medication administration, including flush solutions and additives, is recorded during the retrieval process.

2.5.54 Each OPO, ~~with and~~ their respective histocompatibility ~~laboratory(s)ies,~~ will ~~establish minimum written requirements~~ define and document the minimum tissue typing material required to generate match runs for local or regional placement of all organs. ~~Organ procurement organizations will establish minimum requirements for tissue typing material required for local disposition of livers, hearts and lungs.~~ In view of the frequent need for regional shipment of pancreas and kidney allografts, however, sufficient specimens for several crossmatches are required. Minimal typing material to be obtained for EACH kidney and pancreas will include the following:

- One 7 to 10ml. clot (red topped) tube for ABO verification, plus
- 2 ACD (~~yellow~~ top) tubes
- 3 to 5 lymph nodes
- One 2 X 4 cm. wedge of spleen in culture medium, if available

For all other organs, the OPO will provide lymph nodes if requested.

2.5.65 Proper packaging of organs for transport (see Policy 5.0); and

2.5.76 Properly packaged ~~paperwork~~ documentation containing complete donor information shall accompany each organ to the recipient ~~institution~~ transplant center.

~~2.5.74~~ **2.5.6.1** Written ~~d~~Documentation accompanying each organ must include:

- ABO typing source documents;
- Serology results;
- Medical/~~Social~~Behavioral History form;
- Donor evaluation;
- Complete record of donor ~~maintenance~~ management;
- ~~Documentation of e~~Consent form; and
- ~~Documentation of e~~Organ quality as described in section 2.5.

~~2.5.87~~—The Host OPO is responsible for ensuring that the donor medications are given at appropriate times and that medication administration, including flush solutions and additives, is duly recorded during the retrieval process. Complete information must be maintained by the Host OPO on

any and all organs recovered, and must include any abnormal anatomy found during the retrieval process. The Host OPO is responsible for ensuring that non-local procurement teams have appropriate transportation to and from the local airport.

2.6 INITIATING ORGAN PROCUREMENT AND PLACEMENT. In order to maximize the number of transplantable donor organs, tissue typing and crossmatching of an organ donor shall commence as soon as possible, ideally pre-procurement. ~~Tissue typing is initiated only after the consent of either the donor by previous designation or the next of kin.~~

2.7 REMOVAL OF NON-RENAL ORGANS. When a non-renal organ is offered for transplantation, the recipient center procurement team must be given the option of removing the non-renal organ unless extenuating circumstances dictate otherwise. ~~Cases in which this option is not given to the recipient transplant team must be reported in writing by the Host OPO and recipient transplant center to the appropriate organ-specific OPTN committee.~~ This policy also applies to non-renal organs from controlled donation after cardiac death (DCD) donors.

2.7.1 Multiple Abdominal Organ Procurement. It is expected that ~~both liver and pancreas~~ all authorized organs should be procured from a donor if each organ is transplantable and/or recipients are identified for each organ. The OPO will document the specific reason for non-recovery of an authorized organ. ~~If both the liver and pancreas are not procured, the OPO should document in writing on the donor form the specific reason(s) for failure to procure both organs.~~ Cooperation between ~~liver and pancreas~~ all organ teams is expected.

2.8 In order to recover organs from a DCD donor, an OPO must follow an established protocol that contains the standards of the DCD Model Elements as adopted in the OPTN Bylaws, Appendix B, Attachment III.

2.89 MULTI-CULTURAL AND DIVERSITY ISSUES. Each OPO must develop and implement a plan to address a diverse population related to organ donation.