

**OPTN/UNOS Membership and Professional Standards Committee (MPSC)**  
**Report to the Board of Directors**  
**June 28-29, 2011**  
**Richmond, VA**

**Summary**

**I. Action Items for Board Consideration**

- The Board of Directors is asked to approve the following center-specific actions. (Item 1, Pages 4-5):
  - Fully approve 1 new transplant hospital;
  - Fully approve 2 new histocompatibility laboratories;
  - Fully approve 1 new program in a new transplant hospital;
  - Fully approve 3 new programs in existing transplant hospitals;
  - Approve 1 new business member;
  - Approve 1 new public organization member;
  - Approve changes in program status:
    - Fully approve 1 program previously under conditional approval;
    - Approve 8 programs to reactivate.

The committee will also notify the board of directors that 19 programs inactivated and four other members/programs withdrew from membership.

- The Board of Directors is also asked to approve the proposals listed below, which will amend the bylaws. Each of the proposals has completed the public comment process:
- The Bylaws, Appendix B, Attachment I, XIII, (2) (Living Donor Related Bylaws). This modification to change the) will provide surgeons who perform living donor kidney recoveries an additional means for meeting the open donor nephrectomy qualifications and more closely align the bylaws with current practice (Item 3, Pages 5-10).
- Bylaws, Appendix B, Attachment I, Section XIII, D (3) (Qualifications for Director of Liver Transplant Anesthesia). This proposal adds a new bylaw that describes qualifications for directors of liver transplant anesthesia. (Item 4, Pages 10-13).
- OPTN and UNOS Bylaws, Appendix B, Section I (Organ Procurement Organizations). This proposal introduces OPO performance metrics that will help to maximize the utilization of organs (Item 5, Pages 13-15).

## I. Other Significant Items

- Proposal to Clarify which Transplant Program has Responsibility for Elements of the Living Donation Process and to Reassign Reporting Responsibility for Living Donation from the Recipient Transplant Program to the Transplant Program Performing the Living Donor Nephrectomy or Hepatectomy: The Committee co-sponsored this proposal with the Living Donor Committee. During the March meeting, the Committee agreed to support the amendments to the Bylaws and Policies. (Item 6, Pages 15-16).
- Program-Related Actions and Personnel Changes: The Committee reviewed 66 and approved 55 key personnel change applications during its October meeting, and reviewed 55 and approved 53 during its March 2011 meeting. The Committee was also notified that 19 programs inactivated, 4 members/programs withdrew from membership; (Item 7, Page 17).
- Update of Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data): As required in Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data), transplant programs must report all instances of live donor deaths and failure of the live donor's native organ function within 72 hours after the program becomes aware of the live donor death or failure of the live donors' native organ function. The Committee reviewed two reported instances. (Item 9, Page 17).
- Modified Flagging Methodology: The Committee reviewed the SRTR simulation results regarding small volume outcome triggers and requested additional investigation into small and medium volume programs. This review was conducted by the Performance Analysis and Improvement Subcommittee (PAIS) and reported to the MPSC during its March 2011 meeting. (Item 10, Page 17).
- Composite Pre-Transplant Metric (CPM): The Committee was apprised of the CPM Work Group's progress. During the October 2010 MPSC meeting, the Committee recommended piloting CPM; the work group will meet in the coming months to discuss the pilot. (Item 11, Pages 17-18).
- Separate Transplant Hospitals Seeking Single Program Approval Together: A work group reviewed this matter in August. It recommended to the Committee that each transplant hospital facility, at which a same organ type transplant is being performed, must have the required organ transplant program designation approved for that facility. The Committee endorsed this recommendation and instructed the work group to propose revised language defining transplant hospital and transplant program. This endorsement was communicated to HRSA. (Item 12, Page 18).
- Patterns and Trends of Member Compliance and MPSC Actions: The Committee reviewed types of allocation deviations found during allocation analysis. In addition, staff introduced to the Committee other ways in which potential policy violations are reported to UNOS and a review of Committee actions on past potential policy violations. The Committee formed a workgroup to develop a possible path for future trend analysis. (Item 13, Page 13).
- Review of Living Donor Kidney Pilot Surveys: The Committee reviewed the second

group of five pilot surveys of living donor kidney transplant programs. The Committee provided input to the staff on the pilot survey methodology and the format of the pilot survey reports. The Committee formed a workgroup to explore and develop options to provide living donor kidney programs with further education regarding Bylaws and Policies pertaining to living donor programs and dissemination of best practices to those programs. (Item 14, Page 18).

- Recommendation to Change Committee Appointment Terms: The Committee discussed changing the terms of its at large members to three rather than two years. (Item 16, Page 19).
- Review Bylaws for Currency: The Committee discussed the bylaws pertaining to primary surgeon and primary physician qualifications and agreed that the work group previously tasked with reviewing the nephrology training requirements should also review the bylaws pertaining to urology board certification and the physician experience pathways. (Item 17, Pages 19).

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**John R. Lake, M.D., Chair**  
**David C. Mulligan, M.D., Vice Chair**

I. Regular Committee Meetings. The Membership and Professional Standards Committee (MPSC) met on October 27-28, 2010, and March 10-11, 2011 in Chicago, Illinois; and on April 18, April 29, and May 16 (separate report), by conference call and Microsoft Live Meeting. The committee's deliberations and recommendations are provided below.

1. Membership Application Issues: The Committee is charged with determining that member clinical transplant programs, organ procurement agencies, histocompatibility laboratories, and non-institutional members meet and remain in compliance with membership criteria. During each meeting, it considers actions regarding the status of current members and new applicants. The Committee took the actions reported below during its meetings.

The Committee recommends that the Board of Directors approve one new transplant hospital, two new histocompatibility laboratories, and 3 new programs (including living donor) in existing member centers.

In addition to considering applications for institutional membership, the Committee reviewed applications for new and continued membership for existing non-institutional members and recommends that the Board approve these individuals, medical/scientific and public organizations, and business for membership.

The Committee reviewed the following changes in status and recommends approval by the Board of Directors:

- Approve 8 programs to reactivate; and
- Approve 1 conditional program as a fully approved program.

On February 18, 2011, the Executive Committee approved the following recommendations retroactive to the November 9, 2010, Board of Directors' meeting, based on a request from the MPSC.

- Fully approve one new transplant center for heart transplantation;
- Fully approve two new programs in existing transplant centers;
- Conditionally approve one transplant program for 12 months;
- Approve changes in program status:
  - Approve a 12-month extension for 1 conditionally approved program
  - Approve four programs to reactivate to full active status.

This recommendation for Executive Committee action was made because of the long period between the MPSC meeting in October 2010 and the Board meeting in June 2011.

2. Overview of Annual Committee Projects: Updates were provided to the committee on the projects that were approved to be undertaken in 2010-2011. A list of the projects is provided below, and most are addressed in more detail later in this report.
- OPO Performance Metrics – Completion of publication of initial model, dissemination to broader community improvement, use by MPSC for OPO evaluation (Item 5).
  - Review the living donor program requirements for currency and relevance and to determine if the original goal of the requirements (to improve the process of living donation and transplantation through standardized levels of experience and quality) is being met (Items 3 & 6).
  - Develop and consider use of pre-transplant program performance metrics for flagging (Item 11).
  - Develop criteria for Directors of Liver Transplant Anesthesiology (Item 4).
  - Revise bylaws to better define “transplant hospital” (Item 12).
  - Develop qualification criteria for Pediatric Organ Transplant Program approval. (Under development by the Pediatric Transplantation Committee)
  - Develop and implement Intestinal Transplant Program requirements in conjunction with the Liver and Intestinal Organ Transplantation Committee. (Under development by the Liver and Intestinal Organ Transplantation Committee).
  - Modify bylaws related to flagging methodology (Item 10).
  - Review bylaws pertaining to program certification and key personnel for currency and relevance (Items 3,6, &17).
  - Create a pathway for kidney transplant programs to qualify as the primary kidney physicians who have completed a transplant nephrology research fellowship (Item 17).
3. Living Donor Related Bylaws: Several issues arose over the past few years that made it apparent that the current bylaws and policies pertaining to program requirements for living donor transplantation were in need of review.

The initial bylaws were developed through the committee and public comment process during 2002-2003; and ultimately approved by the Board of Directors in June 2004. During subsequent years, the area of living donation has continued to evolve and some of the requirements no longer correspond with current practice. These changes became most apparent when the MPSC was reviewing the hospital’s applications for living donor kidney transplantation in 2009. The percentage of cases performed laparoscopically increased from 69.7% to 92.4% between 2002 and 2008 and many hospitals are no longer performing open nephrectomies.

As a result, the MPSC Chair appointed a joint work group in April 2009. This work group was comprised of members of the Kidney, Liver and Intestine, Living Donor, Pediatrics, and Membership and Professional Standards Committees to review the living donor bylaws. The charge given to the work group was to determine whether the bylaws remain current, relevant,

and effective in specifying requirements for programs to care for living donors and/or the recipients of living donor transplants. The MPSC asked the work group to address the certification related to donation surgical competencies.

The Committee recommended changing the bylaws and subsequently approved a proposal for public comment (10/1/2010 to 2/15/2011). The following proposed changes will make the requirements more relevant to the current practice of living kidney donation:

- The proposal recommends removing the requirement that programs demonstrate expertise and receive separate approval to perform open nephrectomies, in order to also be approved to perform laparoscopic recoveries. The committee agreed that this change was appropriate because performing 10 open nephrectomies is not relevant training for doing a conversion from laparoscopic to open procedure. Surgeons can already demonstrate experience through deceased donor nephrectomies in the current bylaws.
- The proposal recommends removing the requirement that the open donor recovery surgeon have performed 10 open donor nephrectomies within the 5-year period prior to their designation as a primary surgeon in an application. Removing the five-year currency requirement will allow senior surgeons who have experience, but who have not performed living donor recoveries in the last 5 years, to qualify.
- The proposal recommends removing the language that specifies that if laparoscopic and open nephrectomy expertise resides within different individuals then the program must demonstrate how both individuals will be available to the surgical team. Time is of the essence when converting from a laparoscopic to an open nephrectomy procedure. The recovery team is not likely to seek the involvement of the second surgeon, who may already be engaged in performing the recipient surgery.
- The laparoscopic expertise requirement currently states that the surgeon must have acted as primary surgeon or first assistant on at least 15 laparoscopic nephrectomies within the prior 5-year period. The proposed amendment will further specify that seven (7) of the procedures must have been performed as a primary surgeon. Some programs may only have one individual who has the training/experience to perform the donor recovery. For this reason, the Committee agreed that it was important for that surgeon to have functioned as the primary in at least seven (7) of the 15 required cases. Recognizing that a transplant surgery fellow may not be listed as the primary/attending surgeon on the operative note for billing reasons, the committee proposed adding a requirement for submission of a letter from the fellowship program director, which could document the actual role of the transplant fellow in the donor operation.
- This proposal adds language that specifies that the donor procedure log that is included in applications for primary surgeons must include the type of procedure (open or laparoscopic). This information is already requested in the OMB approved application forms so this change should not result in additional burden.

During its March meeting, the Committee considered the recommendations received during the public comment period and agreed to make two amendments to the original proposal.

- Under Item D,(2), the word transplant was changed to “recoveries.”
- Under iii (1) the language was amended to include kidney paired donation.

Other changes noted in double underline/double strikeout make this proposal consistent with the proposal that is jointly sponsored by the Living Donor Committee and the MPSC and is also being presented to the Board of Directors for approval in June. That proposal will clarify which transplant program has responsibility for elements of the living donation process and to reassign reporting responsibility for living donation from the recipient transplant program to the transplant program performing the living donor nephrectomy.

A copy of the Briefing Paper, which addresses the details of the proposal, is attached as Exhibit A of this report.

The Committee agreed to forward this amended proposal to the Board for their consideration.

**\*\* RESOLVED, that the following modifications to the UNOS Bylaws, Appendix B, Attachment I, Section XIII, D (2); having been distributed for public comment and subsequent reconsideration by the Committee, are approved pending notice.**

The Committee Voted 33 For, 0 Against, 0 Abstention.

## **ATTACHMENT I TO APPENDIX B OF UNOS BYLAWS**

### **Designated Transplant Program Criteria**

#### **XIII. Transplant Programs.**

A. – C. [no change]

D. In addition to the foregoing requirements, to qualify for membership in UNOS, a transplant program must have a clinical service which meets the following criteria.

(1) **No Changes**

(2) **Kidney Transplant Programs that Perform Living Donor Kidney Recoveries**  
**~~Transplants:~~** Kidney transplant programs that perform living donor kidney ~~transplants~~ recoveries must demonstrate the following:

a. **Personnel and Resources:** Kidney recovery hospitals ~~transplant programs that perform living kidney transplants~~ must demonstrate the following regarding personnel and resources:

(i) That the ~~center~~ kidney recovery hospital meets the qualifications of a kidney transplant program as set forth above; and

(ii) In order to perform open donor nephrectomies, a qualifying kidney donor surgeon must be on site and must meet ~~either~~ one of the criteria set forth below:

(1) Completed an accredited ASTS fellowship with a certificate in kidney;  
or

(2) Performed no fewer than 10 open donor nephrectomies (to include deceased donor nephrectomy, removal of polycystic or diseased

kidneys, etc.) as primary surgeon or first assistant ~~within the prior 5-year period. or~~

- (3) Qualified under the section below (iii)(1) to perform laparoscopic donor nephrectomies.

(iii) If the ~~center~~ hospital wishes to perform laparoscopic donor nephrectomies, a qualifying kidney donor surgeon must be on site and must have:

- (1) Acted as primary surgeon or first assistant in performing no fewer than 15 laparoscopic nephrectomies within the prior 5-year period, seven (7) of which were performed as a primary surgeon. Role of the surgeon could be document by a letter from fellowship program director.

~~If the laparoscopic and open nephrectomy expertise resides within different individuals then the program must demonstrate how both individuals will be available to the surgical team.~~

It is recognized that in the case of pediatric living donor or kidney paired donation transplantation, the living organ donation may occur at a hospital center that is distinct from the approved transplant hospital center.

All surgical procedures identified for the purpose of surgeon qualification must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, ~~and~~ the role of the surgeon in the operative procedure, and the type of procedure (open or laparoscopic).

(iv) The kidney recovery hospital center ~~center~~ must have the resources available to assess the medical condition of and specific risks to the potential living donor;

(v) The psychosocial assessment should include an assessment of the potential donor's capacity to make an informed decision and confirmation of the voluntary nature of proceeding with the evaluation and donation; and

(vi) That the kidney recovery hospital center ~~center~~ has an independent donor advocate (IDA) who is not involved with the potential recipient evaluation, is independent of the decision to transplant the potential recipient and, consistent with the IDA protocol referred to below, is a knowledgeable advocate for the potential living donor. The goals of the IDA are:

- (1) to promote the best interests of the potential living donor;
- (2) to advocate the rights of the potential living donor; and
- (3) to assist the potential living donor in obtaining and understanding information regarding the:
  - (a) consent process;
  - (b) evaluation process;
  - (c) surgical procedure; and
  - (d) benefit and need for follow-up.

**b. Protocols:** Kidney transplant programs that perform living donor kidney transplants must demonstrate that they have the following protocols:

- (i) Living Donation Process: ~~Kidney recovery hospitals transplant programs that perform living donor kidney transplants~~ must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the evaluation, pre-operative, operative, post-operative care, and submission of required follow-up forms at 6 months, one-year, and two-years post donation.

~~Transplant centers~~ ~~Member~~ Kidney recovery hospitals must document that all phases of the living donation process were performed in adherence to the hospital's center's protocol. This documentation must be maintained and made available upon request.

- (ii) Independent Donor Advocate: ~~Kidney recovery hospitals transplant programs that perform living donor kidney transplants~~ must develop, and once developed, must comply with written protocols for the duties and responsibilities of Independent Donor Advocate (IDA) that include, but are not limited to, the following elements:

- (1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure the IDA:
  - (a) promotes the best interests of the potential living donor;
  - (b) advocates the rights of the potential living donor; and
  - (c) assists the potential donor in obtaining and understanding information regarding the:
    - (i) consent process;
    - (ii) evaluation process;
    - (iii) surgical procedure; and
    - (iv) benefit and need for follow-up.

- (iii) Medical Evaluation: ~~Kidney recovery hospitals transplant programs that perform living donor kidney transplants~~ must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors that must include, but are not limited to, the following elements:

- (1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult renal and infectious disease and medical comorbidities, which may cause renal disease;
- (2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion;
- (3) screening for evidence of transmissible diseases such as cancers and infections; and
- (4) anatomic assessment of the suitability of the organ for transplant purposes.

- (iv) Informed Consent: ~~Kidney recovery hospitals transplant programs that perform living donor kidney transplants~~ must develop, and once developed, must comply

with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Nephrectomy, which include, at a minimum, the following elements:

- (1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;
- (2) assurance that all communication between the potential donor and the Transplant ~~center~~ Hospital will remain confidential;
- (3) discussion of the potential donor's right to opt out at any time during the donation process;
- (4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;
- (5) disclosure by the ~~member kidney recovery hospital transplant center~~ that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor; and
- (6) the telephone number that is available for living donors to report concerns or grievances through the OPTN.
- (7) documentation of disclosure by the ~~Member kidney recovery hospital Transplant center~~ to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record.

*[Approved with amendments by the Board on June 28, 2011]*

4. Qualifications for Directors, Liver Transplant Program Anesthesiology: Presently, the bylaws only require that transplant programs provide evidence that experts in the field of anesthesiology are involved with the program. The bylaws do not provide a description of the qualifications this expert must possess or describe their expected level of involvement.

The MPSC first began discussing the development of specific requirements for transplant anesthesiologists after the issue was referred to it in 1999 by the Liver and Intestinal Organ Transplantation Committee. The committee agreed then that it was not the right time to develop minimal requirements for liver transplant anesthesiologists as proposed in the initial referral letter. The MPSC did however agree that the best approach was to amend the transplant program application to include an anesthesia related question.

In 2004, the Committee added an anesthesiologist to its roster as a representative of the American Society of Anesthesiology (ASA) committee, which was formed to address the qualifications for liver transplant program anesthesiologists. This ASA committee consists of anesthesiologists from across the nation with representation from all specialties of organ transplantation. That same year the ASA submitted a paper entitled "Anesthesia Expertise and Liver Transplantation" to the MPSC for its input. The ASA and the MPSC had an ongoing dialog for the next two years

and in 2006 they agreed that the development of qualifications for the directors would need to be deferred until outcome data were available. The MPSC agreed that the ASA should continue to develop its recommendations and keep the MPSC apprised of its work. In the meantime, the OPTN/UNOS membership applications for liver transplant programs were further amended in 2008 to include additional questions regarding anesthesia support.

In August 2009, the MPSC received a memorandum from the ASA, which suggested specific qualifications for the directors of liver transplant anesthesia. This recommendation was based on peer reviewed papers that showed that liver transplant programs have better outcomes when they utilize an anesthesiologist experienced in liver transplantation. The MPSC used the recommendations provided by the ASA as the basis for the proposal. The executive committee of the ASTS also considered a draft of the MPSC's proposal and made suggestions regarding the items might be mandatory versus suggested qualifications.

The Committee contemplated whether the requirements should be mandatory and the director role treated the same as a primary transplant surgeon, physician, or laboratory director. After discussing the resources required for monitoring it was agreed that the role would be required but that the qualifications section would be proposed as recommendations that would provide guidance to the liver transplant programs. The Committee agreed that it might consider proposing that the director qualifications become required in the future and that it would consider similar proposals for cardiothoracic organs if the community indicated strong support for this concept. Once the bylaw is approved, existing liver transplant programs will be asked to validate information that is currently on file or to collect missing information about their directors.

The Committee recommended changing the bylaws and subsequently approved a proposal for public comment review (10/1/2010 to 2/15/2011). The proposed changes as shown below will make the requirements more relevant to the current practice of liver transplantation:

Upon implementation each existing liver transplant program will be asked to validate or provide the name and credentials of a proposed director of liver transplant anesthesiology. From this process, a baseline for current practices can be established. New program and re-activation applications already include questions pertaining to the anesthesiology support in the program but they will need to be amended slightly to capture the precise language of the new bylaws.

A copy of the Briefing Paper, which addresses the details of the proposal, is attached as Exhibit B of this report.

The Committee agreed to forward this amended proposal to the Board for their consideration.

**\*\* RESOLVED, that the following modifications to the UNOS Bylaws, Appendix B, Attachment I, Section XIII, D (3)(c) (Qualifications for Director of Liver Transplant Anesthesia); having been distributed for public comment and subsequent reconsideration by the Committee, are approved effective September 1, 2011.**

The Committee Voted 31 For, 1 Against, 1 Abstention.

Final Proposal

Double underline or double strike out as shown below are those changes made following public comment.

**Attachment I, Appendix B of UNOS Bylaws  
Designated Transplant Program Criteria**

**XIII. Transplant Programs.**

A – C [No changes to these sections]

D. In addition to the foregoing requirements, to qualify for membership in UNOS, a transplant program must have a clinical service which meets the following criteria.

**(3) Liver Transplantation**

(a) Transplant Surgeon [No changes to this section]

(b) Transplant Physician [No changes to this section]

(c) Qualifications for Director of Liver Transplant Anesthesia  
Liver transplant programs shall designate a Director of Liver Transplant Anesthesia who has expertise in the area of peri-operative care of ~~liver~~ ~~transplant~~ the patients undergoing liver transplantation and can serve as an advisor to other members of the team.

The Director of Liver Transplant Anesthesia shall be a Diplomate of the American Board of Anesthesiology (or hold an equivalent foreign certification).

Administrative Responsibilities:

The Director of Liver Transplant Anesthesia should be a designated member of the transplant team and will be responsible for establishing internal policies for anesthesiology participation in the peri-operative care of liver transplant patients. These policies will be developed in the context of the institutional needs, transplant volume, and quality initiatives.

The policy must establish a clear communication channel between the transplant anesthesiology service and services from other disciplines that participate in the care of liver transplant patients. The types of activities to consider include peri-operative consults; participation in candidate selection, and in morbidity and mortality conferences (M&M Conferences); and development of intra-operative guidelines based on existing and published knowledge.

Clinical Responsibilities should include but are not limited to the following:

- Pre-operative assessment of transplant candidates;
- Participation in candidate selection;
- Intra-operative management;
- Post-operative visits;
- Participation on the Selection Committee;
- Consultation preoperatively with subspecialists as needed; and
- Participate in M&M Conferences

Qualifications:

1. The Director of Liver Transplant Anesthesia should have one of the following:
  - a. Fellowship training in Critical Care Medicine, Cardiac Anesthesiology, Liver Transplant Fellowship, that includes the peri-operative care of at least 10 liver transplant recipients, or
  - b. Within the last five years, experience in the peri-operative care of at least 20 liver transplant recipients in the operating room. Experience acquired during postgraduate (residency) training shall not count for this purpose.
2. The Director of Liver Transplant Anesthesia should earn a minimum of 8 hours of credit in transplant related educational activities from the Council for Continuing Medical Education (ACCME®) Category I Continuing Medical Education (CME) within the most recent 3 year period.

**(4) Liver Transplant Programs that Perform Living Donor Liver Transplants.  
[No changes to this section]**

*[Approved by the Board on June 28, 2011]*

5. OPO Performance Metrics: The OPTN (through the MPSC) monitors member performance and identifies opportunities for improvement. Historically these efforts have focused on transplant program performance, primarily through routine reviews of one-year post-transplant graft and patient survival and activity levels. Currently, for OPO assessment the MPSC primarily considers results of site surveys (audits), allocation, and member reports of potential policy violations. In 2008, the Board of Directors charged the MPSC and OPO Committee with identifying performance metrics the MPSC could use to monitor OPO performance. A joint work group that includes the OPO committee and MPSC, in conjunction with the SRTR contractor, was established to work on this project.

During its October 2010 meeting, the MPSC approved the recommended thresholds for flagging OPOs identified by the joint work group in September 2010. These are as follows:

- two-sided p-value < 0.05.
- O/E ratio of observed organs transplanted per donor to expected organs transplanted per donor of < 0.9.
- O-E per 100 donors < -10.

Additionally, the MPSC approved bylaw language to be distributed for public comment in January 2011.

The MPSC met on April 29, 2011, to consider feedback from and draft responses to the comments submitted on the proposal. During that meeting, the Committee approved responses to the feedback received during the public comment period and recommended the proposal proceed to the Board for approval, as resolved below. Details of feedback received during the public comment period can be found in the Briefing Paper, Exhibit C. Of note, the Committee is recommending a modification to the originally proposed bylaw language to clarify the thresholds for flagging, as shown with double underlines in the language below.

**\*\* RESOLVED, that the following modifications to Appendix B, Section I (Organ Procurement Organizations) of the OPTN and UNOS Bylaws, having been distributed for public comment and subsequent reconsideration by the Committee, are approved pending SRTR programming, availability of the donor evaluator tool for use by OPOs, and Member notice.**

The committee voted 16 For, 0 Against, 0 Abstentions.

**APPENDIX B TO BYLAWS  
OPTN**

**Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership**

**I. Organ Procurement Organizations.**

**A. General.** [No change to content, only to numbering convention.]

**B. Key Personnel.** [No change to content, only to numbering convention.]

**C. Plan for Public Education on Organ Donation.** [No change to content, only to numbering convention.]

**D. Communication of Information for Organ Distribution.** [No change to content, only to numbering convention.]

**E. Donation after Cardiac Death:** [No change to content, only to numbering convention.]

**F. Performance:** The Membership and Professional Standards Committee (MPSC) will evaluate all OPOs to determine if the difference in observed and expected organ yield can be accounted for by some unique aspect of the Donation Service Area and/or OPO in question. The evaluation may include a peer visit to the OPO at the OPO's expense.

Those OPOs whose observed organ yield rates fall below the expected rates by more than a specified threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC after distribution to the transplant community and subsequent Board approval.

The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

- A difference of at least ~~11~~ More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10)
- A ratio of observed to expected yield less than 0.90.
- A two-sided p-value is less than 0.05.

All three criteria must be met for an OPO to be identified for MPSC review.

If an OPO's organ yield rate cannot be explained by donor mix or some other unique clinical aspect of the OPO or Donation Service Area in question, the Member, in cooperation with the MPSC, will adopt and promptly implement a plan for performance improvement. The Member's failure to do so will constitute a violation of OPTN requirements.

**APPENDIX B TO BYLAWS**

## UNITED NETWORK FOR ORGAN SHARING

### Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

#### I. Organ Procurement Organizations.

- A. General.** [No change to content, only to numbering convention.]
- B. Key Personnel.** [No change to content, only to numbering convention.]
- C. Plan for Public Education on Organ Donation.** [No change to content, only to numbering convention.]
- D. Communication of Information for Organ Distribution.** [No change to content, only to numbering convention.]
- E. Donation after Cardiac Death:** [No change to content, only to numbering convention.]
- F. Inactive Status.** An organ procurement organization that is voluntarily inactive, declared inactive or withdrawn will no longer be allowed to list patients on the UNOS recipient list or to maintain a local recipient list in any form, and will not be allowed to provide organs to UNOS member transplant centers.

**G. Performance:** The Membership and Professional Standards Committee (MPSC) will evaluate all OPOs to determine if the difference in observed and expected organ yield can be accounted for by some unique aspect of the Donation Service Area and/or OPO in question. The evaluation may include a peer visit to the OPO at the OPO's expense.

Those OPOs whose observed organ yield rates fall below the expected rates by more than a specified threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC after distribution to the transplant community and subsequent Board approval.

The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

- ~~A difference of at least 11~~ More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10)
- A ratio of observed to expected yield less than 0.90.
- A two-sided p-value is less than 0.05.

All three criteria must be met for an OPO to be identified for MPSC review.

If an OPO's organ yield rate cannot be explained by donor mix or some other unique clinical aspect of the OPO or Donation Service Area in question, the Member, in cooperation with the MPSC, will adopt and promptly implement a plan for performance improvement. The Member's failure to do so will constitute a violation of UNOS requirements.

*[Approved by the Board on June 28, 2011]*

6. Proposal to Clarify which Transplant Program has Responsibility for Elements of the Living Donation Process and to Reassign Reporting Responsibility for Living Donation from the Recipient Transplant Program to the Transplant Program Performing the Living Donor Nephrectomy or Hepatectomy. (Goal). In July 2009, the MPSC formed a working group to

review the living donor program bylaw requirements for currency and relevance, determine whether the original goal of the requirements was being met, and recommend bylaw modifications if necessary.

The working group was comprised of members from the Kidney Transplantation Committee, Liver and Intestinal Organ Transplantation Committee, Living Donor Committee, and Membership and Professional Standards Committee. Due to the broad scope of work the working group was later divided, with one work group specifically addressing the issue of responsibility for living donor follow-up. Representatives from the Transplant Coordinators and Transplant Administrators Committees were added to that subcommittee to provide the necessary expertise for the discussion on living donor reporting responsibility. The Living Donor Committee (LDC) took the lead with this work group, which was charged with clarifying which hospital is responsible for pre- and post-donation living donor-related activities.

The work group, with input from the MPSC developed a proposal to amend the Bylaws and Policies. This proposal was circulated for public comment from 10/1/2010 to 2/15/2011. The following proposed changes will make the requirements more relevant to the current practice of living kidney donation.

The purpose of this proposal is to clarify and, in some cases, change which transplant program is responsible for specific elements of the living donation process. Under this proposal, the transplant program that performs the donor nephrectomy (surgical removal of a kidney) or hepatectomy (surgical removal of a portion of the liver) will be responsible for that process, which includes the consent, medical and psychosocial evaluations, peri-operative care, and required follow-up reporting of the donor. The intended goals for this policy include improving living donor follow-up by shifting the responsibility for living donor follow-up to the hospital that has an established relationship with the living donor. Additionally, the revisions may lead to improved living donor safety by requiring that transplant hospitals can only accept living donor organs from transplant programs that have the appropriate protocols and staff in place to recover that type of living donor organ.

The MPSC and LDC recommended changing the Bylaws and Policies subsequently co-sponsored a proposal for public comment (10/1/2010 to 2/15/2011). The full discussion of the proposal can be found in the Living Donor Committee's June 2011 Report to the Board of Directors and its attached briefing paper.

During its March meeting, the Committee reviewed the proposal and comments and agreed to join the LDC in recommending that the Board of Directors approve the proposal.

**\*\* RESOLVED**, that the Committee supports the proposal to amend the following Bylaws and Policies: 7.0 (Data Submission Requirements); 12.6 (Center Acceptance of Living Donor Organs); 12.8 (Reporting Requirement); UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D(2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants; UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (4) Liver Transplant Programs that Perform Living Donor Liver Transplants Recovery.

The Committee voted 33 For, 0 Against, 0 Abstentions.

7. Program-Related Actions and Personnel Changes: The Committee reviewed and accepted programs „changing status by voluntarily inactivating or withdrawing from designated program status. Additionally, during the October and March meetings the committee reviewed 121 and approved 108 Key Personnel Changes.
8. Interviews and Informal Discussions: The Committee conducted interviews and informal discussions with five member transplant hospitals during the October 2010 meeting and five member transplant hospitals and one OPO during the March 2011 meeting.
9. Update on Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data): As required in Policy 12.8.4 (Submission of Living Donor Death and Organ Failure Data), transplant programs must report all instances of live donor deaths and failure of the live donor’s native organ function within 72 hours after the program becomes aware of the live donor death or failure of the live donors’ native organ function.

During the October and March meetings, the committee reviewed three reported living donor kidney adverse events and made the recommendation of no further action for each one.

10. Modified Flagging Methodology: Continuing the Performance Analysis and Improvement Subcommittee’s (PAIS) goal to review existing performance metrics and the ongoing work with the SRTR staff in modifying post-transplant outcome flagging methods, UNOS staff conducted several retrospective analyses of the modified flagging criteria proposed by the SRTR. In summary, the analysis showed that using the proposed method, the committee would flag fewer programs overall, while flagging more medium and high volume programs. The analysis also showed that the proposed method would flag >80% of the programs considered “true positives” using the current flagging method and would flag fewer of the current false positives.

The MPSC reviewed the recent retrospective analysis and recommended before adoption that the SRTR conduct a simulation analysis. The modified flagging method, while capturing some of the small volume programs, will not capture all small volume programs. Five programs that would not have been reviewed if the modified flagging were in use were considered “true positives.” As such, the committee wishes to identify a hybrid flagging model that would utilize the modified flagging methodology with some sort of small volume flag. The SRTR reported the simulation might take up to six months.

The Committee reviewed the SRTR simulation results regarding small volume outcome triggers. The Committee requested additional investigation into small and medium volume programs; this review was conducted by the PAIS and reported to the committee during its March 2011, meeting. The MPSC recommended a study of the modifications to the flagging methodology to determine if changes should be made to the Committee’s thresholds and methodology.

11. Composite Pre-Transplant Metric (CPM): Staff presented an update on the latest data requested by the CPM work group. Reviewed were analyses on the impact of removing the mortality O/E ratio from the CPM for kidney programs, implications for including a “delta CPM” in the flagging algorithm, and the distribution of CPM for single surgeon vs. multiple surgeon programs.

During the March 2011 MPSC meeting, the Committee considered a report from the work group, including a proposal for studying the metric prior to distribution for public comment. This study will facilitate the evaluation of the metric meeting its purpose and to use evidence to determine

flagging thresholds. At the conclusion of the discussions, the Committee unanimously approved proceeding with a study of the metric for one year (33 For, 0 Against, 0 Abstentions).

The work group met by conference call in April 2011 to finalize the survey tool to be used for studying the metric though the tool was not finalized. The work group will continue to meet to codify the study process, study tools, and other logistical matters relating to the metric.

12. Separate Transplant Hospitals Seeking Single Program Approval Together: In August 2010 a MPSC work group was asked to respond to the question "...can the OPTN meet its obligations by allowing separate transplant hospitals to operate under a single program approval?" The work group expressed that it is critically important to have hospital specific data regardless of how hospitals have chosen to organize themselves for business or financial purposes. Since the OPTN is unable to support hospital specific outcome data with its current systems without incurring great expense in resources, the work group recommended that allowing separate hospitals to operate under a single program approval not be permitted. The committee voted unanimously to endorse this recommendation (33 For, 0 Against, 0 Abstentions) and instructed the work group to propose revised language defining transplant hospital and transplant program. HRSA was informed of the recommendation.
13. Patterns and Trends of Member Compliance and MPSC Actions: During the Committee's October meeting, staff presented a summary of issues reviewed by allocation analysts. The allocation information included types of issues the allocation analysts review, the trends in numbers of issues identified, and the methods in which these issues come to the attention of the allocation analysts. In addition, staff presented types of allocation deviations found through other reports to UNOS, as well as Committee actions on past potential policy violations. Staff analyzed data by region and method of reporting. Staff presented a series of questions for future analysis by the Committee. Based on this presentation the Committee suggested forming a work group to examine the data and determine a path forward.
14. Living Donor Pilot Program: During its October meeting, the Committee reviewed the second group of five pilot surveys of living donor kidney transplant programs. The committee provided input to the staff on the pilot survey methodology and the format of the pilot survey reports. The committee formed a work group to explore and develop options to provide living donor kidney programs with further education regarding bylaws and policies pertaining to living donor programs and dissemination of best practices to those programs.
15. Patient Safety and Analysis Process: Dr. Phillip Camp, Chair of the Operations and Safety Committee made a presentation to the Committee. Dr. Camp explained that the charge of the Operations and Safety Committee is to review de-identified transplant and donation-related adverse events and near misses reported to the OPTN in order to identify potential network improvements and revisions to Policies that may prevent future such occurrences. The goal of the Operations and Safety Committee's work is to identify gaps in OPTN policy and processes from a network perspective for the purpose of increasing safety.

Dr. Camp began by describing types of patient safety events that may be reported to the OPTN. The Operations and Safety Committee seeks to look at cases with no harm or near miss cases as an opportunity to learn how this incident could happen, what made the member think this was the right decision, and how the system can prevent it from happening again.

In attempting to examine all reported patient safety related events, the Operations and Safety Committee discovered that many other pathways exist for data or issues that may be safety

related to flow to the OPTN, including through Patient Services, the Member Complaint Line, emails or calls directly from members, and reports on vessel dispositions. The OPTN has created critical processes as it has grown and needs have arisen, however as an unintended result there is no centralized, integrated data collection; no coordinated registration or log of information; no global analysis of data types or trends; and the system responds to events as they happen where ever they enter the system.

The Operations and Safety Committee analyzed the current level of patient safety event reporting and determined that the rate of events was not believable. Compared to the increase in disease transmission reporting in the last 4 years from 12 cases to 180, the Operations and Safety Committee concluded that events are currently under-reported. The Operations and Safety Committee recognized that if the level of reporting of patient safety events improves, it could place larger burden on other committees, especially the MPSC.

The goal of patient safety reporting is quality improvement while improving systems and decreasing errors by using data to solve problems. In hopes of improving the current process, the Operations and Safety Committee wants to collaborate with the MPSC to come to a proposed solution to increase reporting without overburdening the MPSC. The Operations and Safety Committee has created a proposal for a central system through which all data flows. This will provide an opportunity for analysis for each issue that allows for a solution and cross-departmental staff analysis, and should result in more issues being referred to Operations and Safety or other appropriate committees for action without requiring review of every issue by the MPSC. The Operations and Safety Committee expects that this should lead to improved and more realistic reporting of events, create a system that promotes a culture of safety and improved outcomes, promote OPTN-based real-time safety analysis and program-based solution generation, and provide a foundation for program educations and best practice dissemination. The proposal will require further development by staff and review by involved committees. Committee members supported the ideas for the proposal, but agreed that more examination and review is needed for how to determine which issues may not need MPSC review. The Committee voted to support the efforts towards improving the patient safety event analysis process (30 For; 0 Against; 0 Abstentions).

16. Recommendation to Change Committee Appointment Terms: The Committee discussed the terms of its at large members and will make a recommendation to the Board of Directors that the bylaws be amended to describe the terms of at large MPSC members as three, rather than two years. The proposal will be prepared for the Board's review in November 2011. The Committee envisioned this change being effective with the 2012 committee appointment cycle.
17. Review Bylaws for Currency: During its October meeting, the Committee discussed the bylaws pertaining to primary surgeon and primary physician qualifications and agreed that the work group previously tasked with reviewing the nephrology training requirements could also review the bylaws pertaining to urology board certification and the physician experience pathways. The Committee also discussed the criteria for pancreas transplant programs and the conditional pathways for the kidney transplant physicians and agreed that the requirements could be reviewed by the same subcommittee. During its March meeting the Committee reviewed the proposal to amend the bylaws pertaining to the surgeons who recover living donor kidneys and the Committee also agreed that the criteria for surgeon case numbers and foreign training need to be reviewed for currency. It was agreed to add these items to the list of issues the committee will discuss during Phase 2 of the Bylaws rewrite project.

18. Bylaws Rewrite Project: During the October meeting, the staff presented an overview of the planned rewrite of the OPTN and UNOS Bylaws. The rewrite is intended to improve clarity and organization of the bylaws documents. The initial phase will focus on reorganizing in a logical arrangement and using plain language rather than substantive changes. The second phase will focus on changes where there may be contradictions, revisions are needed, and additional provisions are required. The committee formed a work group to review the proposed changes to the Bylaws documents and provide feedback on a set schedule prior to public comment review.

During the Committee's meeting in March, the work group chair and the staff updated the status of the Bylaws rewrite project from its last report at the October 2010 MPSC meeting, and asked the committee to approve the plain language versions of Article I - XI for public comment. The committee discussed proposals for enhancing the public comment process for this project and approved Articles I – XI for public comment.

19. Confidential Medical Peer Review: During the October meeting, the staff presented an overview of the committee's confidential medical peer review system and its legal background. Members who participated in an interview or hearing with the committee in the past three years recently received a letter as a reminder to those Members of the importance of confidentiality to the peer review process. Staff reminded the committee that in the case of OPTN peer review, UNOS holds the privilege, not the MPSC, and not the Member. In case the committee members receive any questions from the community, Staff also included a summary of best practices for maintaining the confidentiality of committee matters.
20. UNOS Actions: The Committee unanimously agreed during October meeting that actions regarding Bylaws, Policy, and program-specific decisions made during the OPTN session would be accepted as UNOS actions.

\*\* RESOLVED, that the committee accepts those program specific determinations made during the meeting as UNOS recommendations. FURTHER RESOLVED, that the committee also accepts the recommendations made relative to Bylaw and Policy changes.

The Committee voted 29 For, 0 Against, 0 Abstentions.

The Committee unanimously approved the same resolution during its meetings on March 10-11, 2011 in Chicago, Illinois; and on April 18, April 29, and May 16.

**Participation at the Membership and Professional Standards Committee Meetings**

NAME	Committee Position	7/28-29, 2010	10/27-28, 2010	3/10-11, 2011	4/18/11	4/29/11
John Lake MD	Chair	X	X	X	X	X
David Mulligan MD	Vice Chair	X	X	X		
Elizabeth Pomfret MD, PhD	Regional Rep.	X	X		X	X
David Klassen MD	Regional Rep.	X	X	X	X	X
Christopher Hughes MD	Regional Rep.	X	X	X		
Marlon Levy MD, FACS	Regional Rep.	X	X	X	X	
David Douglas MD	Regional Rep.	X	X	X	X	X
Michael Mulligan MD	Regional Rep.	X		X		
Dixon Kaufman MD, PhD	Regional Rep.	X	X	X	X	X
Sue Dunn MBA,RN, BSN	Regional Rep.	X	X	X	X	X
Mark Orloff MD	Regional Rep.	X	X	X	X	X
Steven Rudich MD, PhD	Regional Rep.	X	X	X	X	X
Prabhakar Baliga MD	Regional Rep.		X	X	X	
Patricia Adams MD	At Large	X	X	X	X	X
Abbas Ardehali MD	At Large	X	X	X	X	
Sharon Bartosh MD	At Large	X	X	X	X	
Elaine Berg MPA, FACHE	At Large	X	X	X		
A. Michael Borkon MD	At Large	X	X	X	X	
Udeme Ekong MBBS, MRCP	At Large		X	X	X	
Richard Hasz Jr., MFS	At Large	X	X	X	X	X
Marjorie Hunter Esq.	At Large	X		X	X	
Diane Jakobowski MSN, CRNP	At Large	X	X	X	X	X
Lori Markham RN, MSN, CCRN, CPTC	At Large	X	X	X	X	X
David Marshman CPTC,BS	At Large	X	X	X	X	X
Jennifer Milton RN,BSN, MBA, CCTC	At Large	X	X	X		
Claus Niemann M.D.	At Large	X	X	X		
Todd Pesavento MD	At Large	X	X	X	X	
Sean Pinney MD	At Large	X	X	X	X	
Mark Robbins MD	At Large	X	X	X		
Dianne LaPointe Rudow ANP, DrNP, CCTC	At Large	X	X	X		
Shirley Schlessinger MD	At Large	X	X	X	X	
Roshan Shrestha MD	At Large		X	X		X

NAME	Committee Position	7/28-29, 2010	10/27-28, 2010	3/10-11, 2011	4/18/11	4/29/11
Dolly Tyan PhD	At Large	X	X*		X	X
Betsy Walsh J.D., M.P.H.	At Large	X	X	X	X	
Brenda Welsch BSN, CPTC	At Large	X	X	X	X	X
David Zaas M.D., MBA	At Large	X	X	X	X	
Christopher McLaughlin	Ex Officio	X		X	X	X
Robert Walsh	Ex Officio	X	X	X	X	X
Charlotte Arrington	SRTR Liaison	X	X			
David Gilbertson	SRTR Liaison		X			
Ajay Israni	SRTR Liaison	X	X			
Tabitha Leighton	SRTR Liaison	X				
Jon Snyder, Ph.D	SRTR Liaison		X	X		
Eric Weinhandl	SRTR Liaison					X
Dave Zaun	SRTR Liaison		X			
Sally Harris Aungier	Committee Liaison	X	X	X	X	X
David Kappus MAS	Committee Liaison	X	X	X	X	X
Rosey Adorno	Support Staff	X				X
Rebecca Anderson	Support Staff			X		X
Manny Carwile	Support Staff	X	X	X		
Elizabeth Coleburn M.S.	Support Staff	X	X			
Erick Edwards Ph.D.	Support Staff	X	X	X		X
Mary D Ellison, Ph.D.	Support Staff	X	X	X	X	X
Suzanne Gellner JD, CHC	Support Staff	X	X	X	X	X
Sheila Foster	Support Staff					X
Linda Gobis B.S., M.N., J.D.	Support Staff	X	X	X	X	X
Walter Graham	Support Staff		X			
Margaret Kearns	Support Staff			X	X	
Geoffrey MacDonald	Support Staff			X	X	X
Diana Marsh	Support Staff	X				
Joel Newman	Support Staff		X	X		
Jacqueline O'Keefe MBA	Support Staff	X	X	X	X	X
Anne Paschke	Support Staff	X				
Amy Putnam	Support Staff	X	X			
Brian Shepard	Support Staff	X	X	X		
Sharon Shepherd J.D., M.S.N., R.N.	Support Staff	X		X	X	X
Leah Slife	Support Staff			X	X	
Liz TenHoeve	Support Staff		X			

<b>NAME</b>	<b>Committee Position</b>	<b>7/28-29, 2010</b>	<b>10/27-28, 2010</b>	<b>3/10-11, 2011</b>	<b>4/18/11</b>	<b>4/29/11</b>
Robyn Zernhelt	Support Staff		X			
Guests for special presentations only						
Matt Cooper, M.D.	Living Donor Committee Presentation	X*				
Deb Sudan, M.D.	Liver and Intestinal Organ Transplantation Committee Presentation	X*				
Philip Camp, M.D.	Chair, Operations & Safety Committee		X			
John Roberts, M.D.	Incoming MPSC Chair			X	X	
Raelene Skerda	HRSA				X	

***Proposed Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization***

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## **Proposed Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization**

**Affected Bylaw:** OPTN and UNOS Bylaws, Appendix B, Section I: Organ Procurement Organizations

### **Membership and Professional Standards Committee (MPSC), Organ Procurement Organization (OPO) Committee**

#### **Summary and Goals of the Proposal:**

The Organ Procurement Organization (OPO) Committee and the Membership and Professional Standards (MPSC) Committee propose a statistical model to analyze OPO performance. This model utilizes a comparison of observed (actual) to expected organs transplanted per donor (yield) based upon donor specific characteristics in each Donation Service Area (DSA). The model will be used in aggregate (for all organs) in addition to organ specific performance measures, and predicts how many organs would have been recovered and transplanted if the OPO performed at the level of the national average for donors with similar characteristics. The MPSC will use the model to monitor OPO performance, similar to existing practices for monitoring transplant program performance. Through this approach, the MPSC will identify opportunities for improvement at OPOs whose observed performance falls below expected performance by more than a threshold. The bylaw proposal provides information regarding the model's intended use by the MPSC as well as the threshold that will result in MPSC inquiry.

#### **Background and Significance of the Proposal:**

The OPTN (through the MPSC) monitors member performance and identifies opportunities for improvement. Historically these efforts have focused on transplant program performance, primarily through routine reviews of one-year post-transplant graft and patient survival and activity levels. Currently, for OPO assessment the MPSC primarily considers results of site surveys (audits), allocation, and member reports of potential policy violations. In 2008, the Board of Directors charged the MPSC and OPO Committee with identifying performance metrics the MPSC could use to monitor OPO performance. A joint work group that includes the OPO committee and MPSC, in conjunction with the SRTR contractor, was established to work on this project.

- **Collaboration:** The joint work group comprises OPO executive directors, medical directors, directors of procurement/clinical services, quality directors and staff, and an anesthesiologist. Once the work group endorsed the SRTR's statistical model of organs transplanted per donor, many educational opportunities explaining the analysis and its benefits were provided to the OPO community. In January 2010, the statistical model was presented during the AOPO Executive Director Winter meeting in La Jolla, CA. Additionally, in May 2010, OPO Executive Directors were encouraged to send staff to an educational forum in Chicago, IL. Finally, during the June 2010 AOPO Annual Meeting, additional presentations were provided for interested parties. Feedback was gained through all of these venues and considered by the work group.
- **Strengths and weaknesses:** Because OPO performance metrics do not exist in the bylaws, this proposal will provide notice of the MPSC's intent to monitor OPO performance and the thresholds used to identify those OPOs that do not meet the expected yield. One of its strengths is that no

additional data collection is needed. With this proposed flagging algorithm, both the OPO committee and MPSC believe they have identified statistically and clinically relevant thresholds that will serve as an appropriate trigger for further inquiry.

- ***Description of intended and unintended consequences:*** This proposal should result in broader quality improvement initiatives based on statistical analyses of data that historically have not been risk-adjusted to account for donor characteristics from the populations of each specific OPO service area. This renewed focus may result in increased organ recovery and utilization practices. The risk-adjusted metrics that have been developed will define OPO performance on the observed yield of organs transplanted per donor as compared to the expected yield. This model predicts how many organs would have been recovered and transplanted if the OPO performed at the level of the national average for donors with similar characteristics. An unintended consequence of adopting this proposal is the potential for parties outside of the OPTN to begin using the metrics for other than the intended purpose of quality and performance improvement. The MPSC and OPTN can provide suggestions to these outside parties, but ultimately the use of these metrics for purposes other than quality improvement is outside of the purview of the OPTN.

## **Supporting Evidence and Modeling:**

### **Statistical Modeling**

The modeling efforts in support of this proposal by the Arbor Research Collaborative for Health (SRTR contractor from 2000-2010) evolved over a period of several months. After extensive deliberations with the joint work group, the overall organs transplanted per donor (OTPD) was chosen as a key outcome measure for assessing OPO performance. From each donor, up to 8 organs can be transplanted (2 kidney, 2 lungs, 1 liver, 1 heart, 1 pancreas, 1 intestine).

The initial overall model for OTPD was based on all donors from 6/1/2000 – 5/30/2007 from whom at least one organ was recovered and transplanted. Potential donor factors in the model were derived almost exclusively from the OPTN Deceased Donor Registration Form (DDR). Potential factors included donor age, ethnicity, blood type, cause of death, body mass index, history of hypertension, and others. Factors that were considered to be “practice-based” such as machine perfusion of kidneys, chest x-rays, coronary angiograms, and biopsy results were explicitly excluded from the model, as well as factors that were not statistically significant ( $p < 0.05$ ). Individual organ-specific models for OTPD (yield) were also developed that use many of the same factors. Over time, a number of interim models were developed in response to work group requests for refinements to the analysis.

The most recent updated overall model for yield was based on over 32,000 donors procured from 1/1/2006 – 12/31/2009, again incorporating many of the same factors used in the initial model. The c-statistic (a measure of the accuracy of model predictions<sup>1</sup>) from this model was 0.825. The individual organ-specific models were also updated using the same cohort. The c-statistics for these models ranged from 0.78 for liver to 0.90 for lung. For the donor factors used in each model and their impact on yield, see Appendix A.

<sup>1</sup>C-statistics typically range from about 0.5 to 1.0. Values closer to 1.0 are better, while values above 0.7 are considered to be clinically useful.

## Application of the Models

Philosophically, the proposed approach for assessing OPO performance is identical to the current approach used to assess transplant program performance. For transplant programs, the actual (observed) number of organs that fail is compared to the expected number of failures. The expected number of failures is derived from the statistical outcome model for that organ. The difference between the observed and expected number of failures is then assessed for statistical significance.

Similarly, for assessing OPO performance, the observed number of organs transplanted is compared to the expected number of organs transplanted, where the expected number is derived from either the overall OTPD model or the applicable organ-specific model. The expected number of organs transplanted can be interpreted as the number expected if the OPO performed at the level of the national average for donors with similar characteristics. Any difference between the observed and the expected is an estimate of the performance of the OPO, or in statistical terms, the “OPO effect.” Differences greater than zero indicate performance above expected, while differences less than zero indicate performance below expected. P-values attached to the differences provide a measure of statistical significance.

## Flagging Methodology

Factors considered by the work group in identifying a flagging threshold included the length of the assessment period, the level of statistical significance, and a clinical significance threshold. In considering the length of assessment, the work group reviewed results of both a one-year and a two-year cohort. A one-year cohort allows for analysis of the most current performance but is limited in scope. A two-year cohort includes older data, but the longer assessment period may better reflect the OPO’s true potential.

The choice of a two-sided p-value allows the MPSC to identify OPOs that perform both above and below expected levels. A two-sided p-value of less than 0.05 provides strong evidence that the difference in the observed and expected yield is due to more than random chance. In addition, using this criterion, the false positive rate among OPOs with performance below expected is only 2.5%.

Clinical significance factors considered by the work group included the absolute ratio of observed to expected yield, or O/E; the difference in organs transplanted per 100 donors, or O per 100 – E per 100; and the absolute difference in organs transplanted, or O-E. In developing a flagging algorithm, the work group reviewed several potential combinations of statistical and clinical significance and the resulting number of OPOs that are triggered for review in each scenario. Using a two-year assessment period, a hierarchy of importance in the factors was chosen as listed below:

1. Statistical Significance
2. Observed/Expected Ratio (O/E)
3. Observed – Expected per 100 donors (O per 100 – E per 100)
4. Observed – Expected (O-E)

Table 1 shows the number of OPOs flagged for performance below expected (based on the overall yield model applied to a recent 2-year cohort) using several combinations of the above factors and a one-sided p-value. Table 2 shows the same information using a two-sided p-value. Note that choosing a one-sided vs. a two-sided p-value had very little impact on the number of OPOs flagged. Using an O/E

ratio of 0.95 flagged more than twice the number of programs as did an O/E of 0.90. Adding criteria 3 and 4 had only a moderate impact on the results. The work group felt that criterion 3 (O per 100 – E per 100) was more relevant than criterion 4 (O – E) since yield varies substantially across OPOs.<sup>2</sup>

After significant discussion, the work group, the OPO Committee, and the MPSC reached consensus on a flagging algorithm to identify OPOs with observed organ yield rates that fall below their expected rates (both in the aggregate and by organ type). **Each of the following three criteria must be met for an OPO to be identified for MPSC review:**

- A difference of at least 11 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10) ,
- A ratio of observed to expected yield less than 0.90 (O/E<0.90), and
- A two-sided p-value less than 0.05.

The two year cohort will be advanced every six months, similar to the processes and cohorts utilized by the Program Specific Reports for the assessment of transplant outcomes performance.

<sup>2</sup> For example, a deficit of 5 organs may be less troublesome at an OPO that procures 100 donors than it is at an OPO that procures 10 donors.

Table 1. Potential thresholds for triggering MPSC review using a one-sided p-value.

<b>Aggregate Yield Model - One Sided p-value &lt; 0.05</b>							
<b>O/E &lt;</b>	<b># of OPOs</b>	<b>AND O - E per 100 &lt;</b>	<b># of OPOs</b>	<b>AND O - E &lt;</b>	<b># of OPOs</b>		
<b>0.95</b>	<b>12</b>	<b>-5</b>	<b>12</b>	<b>-10</b>	<b>9</b>		
				<b>-25</b>	<b>9</b>		
				<b>-50</b>	<b>5</b>		
		<b>-10</b>	<b>12</b>	<b>-10</b>	<b>12</b>	<b>-10</b>	<b>9</b>
						<b>-25</b>	<b>9</b>
						<b>-50</b>	<b>5</b>
		<b>-15</b>	<b>12</b>	<b>-15</b>	<b>12</b>	<b>-10</b>	<b>9</b>
						<b>-25</b>	<b>9</b>
						<b>-50</b>	<b>5</b>
		<b>-20</b>	<b>9</b>	<b>-20</b>	<b>9</b>	<b>-10</b>	<b>9</b>
						<b>-25</b>	<b>9</b>
						<b>-50</b>	<b>8</b>
<b>0.9</b>	<b>4</b>	<b>-5</b>	<b>4</b>	<b>-10</b>	<b>4</b>		
				<b>-25</b>	<b>4</b>		
				<b>-50</b>	<b>3</b>		
		<b>-10</b>	<b>4</b>	<b>-10</b>	<b>4</b>	<b>-10</b>	<b>4</b>
						<b>-25</b>	<b>4</b>
						<b>-50</b>	<b>3</b>
		<b>-15</b>	<b>4</b>	<b>-15</b>	<b>4</b>	<b>-10</b>	<b>4</b>
						<b>-25</b>	<b>4</b>
						<b>-50</b>	<b>3</b>
		<b>-20</b>	<b>4</b>	<b>-20</b>	<b>4</b>	<b>-10</b>	<b>4</b>
						<b>-25</b>	<b>4</b>
						<b>-50</b>	<b>3</b>

Table 2. Potential thresholds for triggering MPSC review using a two-sided p-value.

<b>Aggregate Yield Model - Two Sided p-value &lt; 0.05</b>							
<b>O/E &lt;</b>	<b># of OPOs</b>	<b>AND O - E per 100 &lt;</b>	<b># of OPOs</b>	<b>AND O - E &lt;</b>	<b># of OPOs</b>		
<b>0.95</b>	<b>11</b>	<b>-5</b>	<b>11</b>	<b>-10</b>	<b>11</b>		
				<b>-25</b>	<b>11</b>		
				<b>-50</b>	<b>7</b>		
		<b>-10</b>	<b>11</b>	<b>11</b>	<b>11</b>	<b>-10</b>	<b>11</b>
						<b>-25</b>	<b>11</b>
						<b>-50</b>	<b>7</b>
		<b>-15</b>	<b>11</b>	<b>11</b>	<b>11</b>	<b>-10</b>	<b>11</b>
						<b>-25</b>	<b>11</b>
						<b>-50</b>	<b>7</b>
		<b>-20</b>	<b>9</b>	<b>9</b>	<b>9</b>	<b>-10</b>	<b>9</b>
						<b>-25</b>	<b>9</b>
						<b>-50</b>	<b>7</b>
<b>0.9</b>	<b>4</b>	<b>-5</b>	<b>4</b>	<b>-10</b>	<b>4</b>		
				<b>-25</b>	<b>4</b>		
				<b>-50</b>	<b>3</b>		
		<b>-10</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>-10</b>	<b>4</b>
						<b>-25</b>	<b>4</b>
						<b>-50</b>	<b>3</b>
		<b>-15</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>-10</b>	<b>4</b>
						<b>-25</b>	<b>4</b>
						<b>-50</b>	<b>3</b>
		<b>-20</b>	<b>4</b>	<b>4</b>	<b>4</b>	<b>-10</b>	<b>4</b>
						<b>-25</b>	<b>4</b>
						<b>-50</b>	<b>3</b>

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

Not applicable.

**Expected Impact on Specific Patient Populations**

There is no known impact to specific patient populations, though it is anticipated that improvement opportunities may result in increased organ yield in the transplant community.

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

Adopting a method for monitoring OPO performance and identifying potential opportunities for improvement will ultimately enhance OPO performance and increase the number of donor organs available for transplant and enhance the efficiency of the transplant system.

**Plan for Evaluating the Proposal:**

Upon implementation, the MPSC will monitor the effectiveness of the flagging methodology annually. The committee will consider adding additional variables to the analysis as practice changes and/or additional data is collected. The committee will also review the information submitted by OPOs identified for review. This additional review will identify common issues as well as opportunities to improve the tools the MPSC uses to evaluate OPO performance.

**Additional Data Collection:**

This proposal does not require additional data collection.

**Expected Implementation Plan:**

This proposal does not require OPOs to do anything differently. This proposal will not require programming in UNet<sup>SM</sup>.

**Communication and Education Plan:**

Many educational opportunities have already occurred regarding the methodology for monitoring OPO performance (see summary of educational activities below). Additional opportunities for education will be considered, for example, sessions at conferences and meetings that OPO personnel attend.

Communication Activities			
Type of Communication	Audience(s)	Delivery Method(s)	Timeframe
Policy Notice	OPO executive directors	eNewsletter	Within 30 days of approval by the Board

Education/Training Activities			
Education/Training Description	Audience(s)	Delivery Method(s)	Timeframe and Frequency
Review of model, including covariates and intended use	OPO executive directors, medical directors, directors of procurement	PowerPoint presentation, with question and answer session	January 2010 APOO Executive/Medical Directors Meeting in La Jolla, CA
	OPO Staff of all levels (attendees were determined by each individual OPO executive director)		May 2010 Educational Forum held in Chicago, IL
	AOPO attendees		June 2010 AOPO Annual Meeting

### Monitoring and Evaluation:

OPOs will be flagged or identified for MPSC inquiry and review based upon the identified flagging algorithm in the aggregate as well as individual organ-specific models. Flagging an OPO for review does not mean there is an issue at the OPO; rather it is an opportunity to start a dialogue to identify potential improvement methods. The responsibility for monitoring OPO performance will fall to the Performance Analysis and Improvement Subcommittee (PAIS) of the MPSC.

The PAIS will follow similar processes used to review transplant program performance. Once an OPO is flagged, a survey will be sent to the OPO that will be used to gather additional information. This information may include questions relating to personnel, Clinical/Medical Advisory Board composition and involvement, the DSA, geographic factors, allocation and practice patterns, meetings between the OPO and hospitals in its DSA, and any other factors the OPO may believe to be relevant to the review. The PAIS may ask OPOs to submit copies of protocols and processes or other additional information as requested by the Subcommittee. In cases where the Subcommittee would like to discuss a particular issue directly with the OPO, the OPO may be requested to participate in an informal discussion. Informal discussions provide the opportunity for real time interaction between the OPO and the PAIS before the committee considers potential adverse actions. These discussions are informal and take place through teleconference in most cases.

In some cases, the PAIS may recommend that the OPO undergo a peer visit at the OPO's expense. Peer visits serve as a quality and performance improvement tool. A team of OPO professionals, approved by the OPTN President or Vice President, will visit with the OPO and conduct interviews, policy and procedure reviews, and donor chart reviews. At the conclusion of the peer visit, the team will provide preliminary feedback to the OPO and compile a report for the MPSC and the OPO to identify opportunities for improvement and specific recommendations where applicable. It is expected that the OPO will adopt a plan for improvement to address the findings contained within the peer visit report.

All OPOs identified for review based upon lower than expected performance may be required to promptly adopt and implement a plan for quality improvement. If the OPO fails to comply with requests for information regarding its progress in implementing its plan for improvement, or if it fails to adopt a plan for improvement, the committee may consider recommending an adverse action against the OPO.

**Bylaw Proposal:**

**APPENDIX B TO BYLAWS  
OPTN**

**Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership**

**I. Organ Procurement Organizations.**

**A. General.** [No change to content, only to numbering convention.]

**B. Key Personnel.** [No change to content, only to numbering convention.]

**C. Plan for Public Education on Organ Donation.** [No change to content, only to numbering convention.]

**D. Communication of Information for Organ Distribution.** [No change to content, only to numbering convention.]

**E. Donation After Cardiac Death:** [No change to content, only to numbering convention.]

**F. Performance:** The Membership and Professional Standards Committee (MPSC) will evaluate all OPOs to determine if the difference in observed and expected organ yield can be accounted for by some unique aspect of the Donation Service Area and/or OPO in question. The evaluation may include a peer visit to the OPO at the OPO's expense.

Those OPOs whose observed organ yield rates fall below the expected rates by more than a specified threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC after distribution to the transplant community and subsequent Board approval.

The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

- A difference of at least 11 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10)
- A ratio of observed to expected yield less than 0.90,
- A two-sided p-value is less than 0.05.

All three criteria must be met for an OPO to be identified for MPSC review.

If an OPO's organ yield rate cannot be explained by donor mix or some other unique clinical aspect of the OPO or Donation Service Area in question, the Member, in cooperation with the MPSC, will adopt and promptly implement a plan for performance improvement. The Member's failure to do so will constitute a violation of OPTN requirements.

## APPENDIX B TO BYLAWS

### UNITED NETWORK FOR ORGAN SHARING

#### Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

##### I. Organ Procurement Organizations.

**A. General.** [No change to content, only to numbering convention.]

**B. Key Personnel.** [No change to content, only to numbering convention.]

**C. Plan for Public Education on Organ Donation.** [No change to content, only to numbering convention.]

**D. Communication of Information for Organ Distribution.** [No change to content, only to numbering convention.]

**E. Donation After Cardiac Death:** [No change to content, only to numbering convention.]

**F. Inactive Status.** An organ procurement organization that is voluntarily inactive, declared inactive or withdrawn will no longer be allowed to list patients on the UNOS recipient list or to maintain a local recipient list in any form, and will not be allowed to provide organs to UNOS member transplant centers.

**G. Performance:** The Membership and Professional Standards Committee (MPSC) will evaluate all OPOs to determine if the difference in observed and expected organ yield can be accounted for by some unique aspect of the Donation Service Area and/or OPO in question. The evaluation may include a peer visit to the OPO at the OPO's expense.

Those OPOs whose observed organ yield rates fall below the expected rates by more than a specified threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC after distribution to the transplant community and subsequent Board approval.

The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

- A difference of at least 11 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10)
- A ratio of observed to expected yield less than 0.90,
- A two-sided p-value is less than 0.05.

All three criteria must be met for an OPO to be identified for MPSC review.

If an OPO's organ yield rate cannot be explained by donor mix or some other unique clinical aspect of the OPO or Donation Service Area in question, the Member, in cooperation with the

MPSC, will adopt and promptly implement a plan for performance improvement. The Member's failure to do so will constitute a violation of UNOS requirements.

**Public Comment Responses:**

**1. Public Comment Distribution**

*Has the proposal been distributed for public comment? Yes*

*Date of distribution: 01/21/2011*

*Public comment end date: 03/18/2011*

<b>Public Comment Response Tally</b>					
<b>Type</b>	<b>Response Total</b>	<b>In Favor</b>	<b>In Favor as Amended</b>	<b>Opposed</b>	<b>No Comment</b>
Individual Comments	51	35 (69%)	0	15 (29%)	1
Regional Comments	11	10 (91%)	0	1 (9%)	0
Committee Comments	11	11 (100%)	0	0	0

**2. Primary Public Comment Concerns/Questions**

Based upon feedback during the public comment period, the MPSC identified the following themes in response to the comments reviewed on the proposal. Responses to Individual, Regional, and Committee comments relating to these themes can be found in this section. Where appropriate, responses to comments that fit into these categories can be found here.

- a) OPO performance is influenced by factors outside of its immediate control, including transplant center acceptance practices.

The Committee recognizes that this model does not encapsulate all factors that influence OPO performance, including the aggressiveness of transplant programs in the DSA. The work group did review analyses of the impact of a local program in that DSA (for example a lung program) and found that some of the top performers were OPOs without a local transplant program of that organ type. Recall that the c-statistics for the models range from 0.78 to 0.9 indicating that many of the donor factors (factors not related to OPO practices) that have an impact on yield are being captured in the model.

The performance of transplant programs in the OPOs DSA will be considered by the MPSC during its course of review. The OPO will have the opportunity to identify potential issues that contribute to its performance. Through the process of review, it is expected that the OPO report to the MPSC all factors influencing performance, both those within and outside of the OPOs control. The MPSC encourages dialogue between the OPO and the transplant programs in its DSA to proactively address issues that impact performance for both the OPO and the transplant program.

The MPSC is currently studying the implementation of a pre-transplant performance metric, that would analyze waiting list mortality rates, transplant rates, and organ/offer acceptance rates.

These data are currently available to the MPSC and will be used as supplemental information for committee members to consider when reviewing OPOs that triggered for review.

All models in use or in development by the MPSC will continue to be reviewed, refined and updated as needed.

- b) Additional factors should be included in the model.

The MPSC considered feedback regarding factors that should be included in the model. The SRTR contractor will be evaluating the potential inclusion of additional factors over the next several months. The committee will consider the results and potential additions to the model. The individual donor model will be available upon implementation of this metric, if not before.

Continual evolution of the model may result in the addition of some new factors for inclusion in the future.

- c) The proposal does not address geography/noncontiguous states, flights and weather issues.

During the development of this model, the work group looked at the location of the donor in relation to the local transplant center. At that time, it was determined that geographic factors would not be accounted for in the model. The MPSC has requested that the SRTR contractor continue considering geographic factors that could be included in the model, including the potential for addressing the noncontiguous states.

As part of the review process, OPOs will be given the opportunity to report to the MPSC/PAIS issues that impact its performance. OPOs that encounter flight and weather issues frequently should report that information to the committee for consideration.

- d) The model does not include a measure of donor potential (by population, # of deaths), consent, or conversion rates.

There are other projects underway to review donor potential, consent and conversion rates. The committee agrees that other metrics can further facilitate OPO performance reviews and will consider inclusion of these metrics in its review process when developed.

- e) How will OPOs that pursue marginal donors be impacted?

The model predicts the number of organs that would have been recovered and transplanted if that OPO performed at the level of the national average for donors with similar characteristics. The output includes an expected and actual number of organs. In DSAs that have a higher percentage of medically complex donors, the model would predict fewer transplants resulting from those donors. Additionally, if an OPO declines to pursue marginal donors, the expected yield would be higher compared to an OPO with the same number of donors that does pursue marginal donors.

- f) The model relies on unverified, self reported data and no standard definitions exist.

Data integrity is an ongoing issue for all OPTN members. OPOs are audited on a routine basis and data accuracy is part of that review. Because of the new emphasis on these data fields, the Committee encourages dialogue with OPO Data Coordinators to facilitate consistent reporting.

g) Pilot/Study of proposal before adoption

The MPSC and OPO Committee, through the Joint Work Group, have been evaluating this metric since 2008. The Committees believe the model was adequately tested and do not see the need for additional study at this time. As with all metrics, the MPSC will continue to evaluate the usefulness of the metric and consider additional measures that could be used to evaluate OPO performance.

h) Concern for costs associated with new oversight

The MPSC believes that the importance of pursuing new performance measures and striving for performance improvement outweighs the burden of additional oversight.

i) The SRTR tool should be available to OPOs at the same time.

The tool for OPOs to use to evaluate the expected yield on a donor-specific basis in real time will be available to OPOs prior to the MPSC’s implementation of the metric.

j) Concern that model will be used for purposes other than improvement; if model will be used by others such as CMS; and if the data will be publicly available.

Currently, on the SRTR website the OPO reports (Table 4) show these results. The model is slightly different in that it uses a one-year cohort and does not include the proposed MPSC flagging criteria. The OPTN, HRSA, and the SRTR will discuss which data will be publicly available.

The MPSC shares the desire for consistency amongst agencies reviewing OPO performance.

**3. Regional Public Comment Responses**

Region	Meeting Date	Motion to Approve as Written	Approved as Amended (see below)	Did Not Approve
1		3	0	1
2	In	3	0	0
3	February, a	4	0	5
4	series of	5	0	3
5	conference	9	0	1
6	calls were	4	0	0
7	convened	4	0	0
8	(2/8, 2/9,	2	0	0
9	2/22, 2/24)	2	0	0
10	for all	4	0	0
11	regions	6	0	1

<p><b>Region 1</b></p>	<p>Regional Votes: 3 yes, 1 no, 0 abstentions  <input checked="" type="checkbox"/> Approved as Written    <input type="checkbox"/> Approved as Amended    <input type="checkbox"/> Not Approved</p> <p>Comments: An assessment of the activities of an OPO’s affiliated transplant centers should be an important component of OPO performance when being reviewed by the PAIS. The definition of DSA includes the OPO and its transplant centers.  The proposal states: “...the PAIS may recommend that the OPO undergo a peer visit”. Is this a recommendation or an offer that cannot be refused? If truly a recommendation, to whom is the PAIS recommending this action – the full MPSC? What are the consequences if the OPO refuses the peer visit? If this is intended to mean that the PAIS can require a peer visit at the OPOs expense, the proposal should state that.  The model should include ischemic time and other codes used in DonorNet to turn down organs. OPO tracking for quality should be done but looking at indicators that reflect OPO activities and not factors that they cannot control.</p> <p><b>Committee Response:</b> Please see <b>Section 2 Primary Public Comment Concerns/Questions</b> for a specific response regarding issues outside of the OPOs control that impact performance and other factors for inclusion in the model.</p> <p>The PAIS is a subcommittee of the MPSC and therefore all recommendations must be reported to the MPSC for approval. The MPSC can modify recommendations, and once the recommendations are approved, they are communicated to the Member. Peer Visits are recommended after the Member has reported information to the PAIS and the PAIS members believe the Member could benefit from external consultation. Members can deny the opportunity to undergo a peer visit, and when doing so should provide reasons for the denial. The MPSC may consider further action in some situations where a Member declines the peer visit, depending on the circumstances.</p>
<p><b>Region 2</b></p>	<p>Regional Votes: 3 yes, 0 no, 1 abstention  <input checked="" type="checkbox"/> Approved as Written    <input type="checkbox"/> Approved as Amended    <input type="checkbox"/> Not Approved</p> <p>Comments:</p>
<p><b>Region 3</b></p>	<p>Regional Votes: 4 yes, 5 no, 0 abstentions  <input type="checkbox"/> Approved as Written    <input type="checkbox"/> Approved as Amended    <input checked="" type="checkbox"/> Not Approved</p> <p>Comments: The model does not address the key issues recognized for non-contiguous states resulting in immediate disadvantage to the OPO, we cannot support the proposal at this time.</p> <p>Do not support the current model as discussed. There needs to be metrics used that look at donor recovery per population base for each OPO/region. There needs to be data collected on efficiency and effectiveness of each OPO procuring tissue and organs expected within a population base and NOT just simply maximizing number of organs/tissues PER individual donor.</p> <p>The use of this tool as a measure is premature. We are opposing because we are concerned that geography has not been properly considered, and we are also concerned that not enough is currently understood about how this will impact OPOs who pursue</p>

	<p>marginal donors. This needs to be tested and studies for a couple of years, then evaluated as opposed to implement it then evaluate it.</p> <p>The availability of flights and weather can impact an OPOs ability to place organs outside of the donor service area.</p> <p><b>Committee Response:</b> Please see <b>Section 2: Primary Public Comment Concerns/Questions</b> for details regarding geography and additional measures of OPO performance.</p> <p>The risk adjustments in the model account for donor factors that impact yield, including marginal donors. OPOs that pursue marginal donors will have a different expected value than those that do not, and the data will provide additional insights into these practices.</p>
<p><b>Region 4</b></p>	<p>Regional Votes: 5 yes, 3 no, 0 abstentions  <input checked="" type="checkbox"/> Approved as Written    <input type="checkbox"/> Approved as Amended    <input type="checkbox"/> Not Approved</p> <p>Comments: This model does not measure how effectively an OPO is identifying, consenting and converting potential donors. This model may also discourage OPOs from aggressively seeking out all potential donors (particularly ECD and DCD donors and single-organ donors) and this methodology continues to rely upon unverified self-reported data.</p> <p>The variance allowed should be decreased from 10 to 5% for review. The statistics must be performed as a one sided test, not two as the idea is to only look at the underperforming OPOs for review.</p> <p>By pushing the organ yield per donor, how does the transplant community ensure that transplant outcomes remain good? Will the quality of the organs be factored in the SRTR expected outcomes for the transplant center?</p> <p><b>Committee Response:</b> Please see <b>Section 2: Primary Public Comment Concerns/Questions</b> for details regarding additional measures of OPO performance and data integrity feedback.</p> <p>The statistical analysis is risk adjusted and therefore OPOs that either do or do not seek out marginal donors will have either a lower or a higher expected number of organs transplanted. Likewise, the models for transplant outcomes take into account donor quality.</p>

<p><b>Region 5</b></p>	<p>Regional Votes: 9 yes, 1 no, 0 abstentions  <input checked="" type="checkbox"/> Approved as Written    <input type="checkbox"/> Approved as Amended    <input type="checkbox"/> Not Approved</p> <p>Comments: Regional comments were received via fax and included the following:</p> <ul style="list-style-type: none"> <li>• Metrics should also include the process of obtaining authorization</li> <li>• Request to include in the equation the absolute number or organs transplanted</li> <li>• Support the concept but would like to see the metrics address the number of donors per million population or the percentage of eligible donors</li> </ul> <p><b>Committee Response:</b> The MPSC agrees that consenting and conversion rates are important. Such metrics are in development. Please see <b>Section 2: Primary Public Comment Concerns/Questions</b> for details regarding additional measures of OPO performance.</p>
<p><b>Region 6</b></p>	<p>Regional Votes: 4 yes, 0 no, 0 abstentions  <input checked="" type="checkbox"/> Approved as Written    <input type="checkbox"/> Approved as Amended    <input type="checkbox"/> Not Approved</p> <p>Comments: While I fully support the concept and intent of this proposal, I would strongly urge the committee to make this a pilot proposal. That way, variables outside the control of the OPO that may adversely affect the OPOs performance metric, such as local clinical practice, can be identified and factored into the metrics before adverse actions against an OPO may be taken. The transplant center processes need to be a part of the analysis. The complexities of organ acceptance need to be factored into the performance metric. Until that is done, the policy should remain in the pilot phase.</p> <p><b>Committee Response:</b> Please see <b>Section 2: Primary Public Comment Concerns/Questions</b> for details regarding additional measures of OPO performance, factors outside of the OPOs control that impact performance, and study of the metric prior to implementation.</p> <p>Adverse actions are only considered in situations where the member is not working with the MPSC to improve or fails to implement and follow a plan for improvement. Adverse actions are not taken on a routine basis for performance matters.</p>
<p><b>Region 7</b></p>	<p>Regional Votes: 4 yes, 0 no, 0 abstentions  <input checked="" type="checkbox"/> Approved as Written    <input type="checkbox"/> Approved as Amended    <input type="checkbox"/> Not Approved</p> <p>Comments:</p>
<p><b>Region 8</b></p>	<p>Regional Votes: 2 yes, 0 no, 0 abstentions  <input checked="" type="checkbox"/> Approved as Written    <input type="checkbox"/> Approved as Amended    <input type="checkbox"/> Not Approved</p> <p>Comments: I think this will be very helpful in performance improvement. I look forward to the tool to utilize in real-time.</p>
<p><b>Region 9</b></p>	<p>Regional Votes: 2 yes, 0 no, 0 abstentions  <input checked="" type="checkbox"/> Approved as Written    <input type="checkbox"/> Approved as Amended    <input type="checkbox"/> Not Approved</p> <p>Comments:</p>

<b>Region 10</b>	Regional Votes: 4 yes, 0 no, 0 abstentions <input checked="" type="checkbox"/> Approved as Written <input type="checkbox"/> Approved as Amended <input type="checkbox"/> Not Approved  Comments:
<b>Region 11</b>	Regional Votes: 6 yes, 1 no, 0 abstentions <input checked="" type="checkbox"/> Approved as Written <input type="checkbox"/> Approved as Amended <input type="checkbox"/> Not Approved  Comments: We are concerned about additional resources (now CMS & UNOS) evaluating performance with different measures. The cost of that will be borne by transplant centers. Also concerned about the potential for blaming poor results on transplant centers setting up an adversarial situation.  <b>Committee Response:</b> The MPSC shares the desire for consistency between agencies and appreciates the feedback.

**4. Committee Public Comment Responses:** includes only those Committees that commented on the proposal.

**Kidney Transplantation Committee**

Following the presentation, the Kidney Transplantation Committee discussed the proposal. One member asked if the model included factors to account for transplant program effects. Since OPOs cannot place organs without transplant program that are willing to accept those organs, the member offered that performance should somehow be adjusted to reflect these circumstances. Another member remarked that the directives for transplant programs and OPOs are quite different. OPOs are instructed to procure “every organ every time” while transplant programs are encouraged to be risk averse due to the program specific reports. Ms. O’Keefe explained that the MPSC had discussed incorporating such a factor to account for transplant program effect, but ultimately determined that some OPOs procure high numbers of organs even without a local program to utilize those organs. Finally, the Committee asked if the MPSC had considered whether public disclosure of this information could lead to unintended consequences such as those observed following the development of program specific reports. Ms. O’Keefe stated that the Committee had carefully considered potential unintended consequences and weighed those against the potential for performance improvement prior to issuing the proposal.

While the Committee understood that the proposal was jointly sponsored by the OPO Committee, it requested that UNOS staff share any formal response from the Association of Organ Procurement Organizations (AOPO). The Committee delayed its decision on the proposal until after the meeting when this information could be shared. AOPO’s formal comment (Exhibit A) was circulated to the Committee on March 23, 2011. Following review of this comment, the Committee electronically voted to support the proposal with a vote of 7 in favor, 0 opposed, and 0 abstaining.

**Committee Response:** The Committee appreciates your comments and support.

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**Liver and Intestinal Organ Transplantation committee**

The Committee reviewed this proposal put forward by the OPO and Membership and Professional Standards Committees. The MPSC is recommending that the OPTN implement a statistical model to evaluate OPO performance to identify opportunities for improving organ yield using a comparison of

observed to expected organs transplanted per donor. Two models are proposed: an overall organs transplanted model and organ-specific yield models. There is no organ-specific yield mode for intestines due to the small numbers involved. The c-statistic for the overall model was 0.83, and ranged from 0.78 to 0.90 for the organ-specific models; a c-statistic greater than 0.7 is generally considered clinically useful. Model outputs include:

- Number of donors
- Observed number of organs transplanted
- Expected number of organs transplanted
- Observed/Expected
- Two sided p-value
- Observed Yield per 100 Donors
- Expected Yield per 100 Donors
- Expected – Observed per 100 Donors

For two metrics, the absolute ratio of observed to expected and the difference in organs transplanted per 100 donors, the sponsoring Committees have selected a 10% difference as being a clinically relevant threshold for flagging (i.e., a ratio of observed to expected of less than 0.90). By applying these criteria to donors from 2008-2009, the models would have flagged seven OPOs out of the current 58: four with the overall model, and an additional three with the organ-specific model. This effort is intended as a trigger to begin a dialog with the OPO, rather than being a punitive action. Once an OPO is flagged, the MPSC will send a survey of inquiry and may follow-up with additional questions during the review. If an OPO does not demonstrate a plan for performance improvement or does not respond to the MPSC's requests, the MPSC may consider taking some adverse action. The OPO community is in support of this, as it is a better predictive model than the SCD/ECD/DCD model that is currently used, which was developed for kidneys and has been applied to other organs.

A Committee member asked why livers are only counted as one organ; the sponsoring committees did not consider split livers in their analyses of organs transplanted per donor (split livers would result in two transplants, but it's still only one organ). After discussion, the Committee indicated its support of the proposal by a vote of 14 in favor, 0 opposed, and 0 abstentions.

***Committee Response:*** The Committee appreciates your comments and support. .

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#### **Living donor committee**

A subcommittee of the Living Donor Committee heard a presentation for this proposal. The subcommittee supports the proposal.

#### **Minority Affairs Committee**

The committee did not identify an inherent minority impact from the proposal but offered general feedback to the Membership and Professional Standards Committee (MPSC).

A suggestion was made that prior to active flagging, the MPSC should develop an interim mechanism for identifying and accounting for specific extenuating circumstances (i.e. location in non-contiguous DSA's, conservatism of transplant centers within the DSA's, etc.) which might impact OPO performance, similar to how the SRTR evaluates programs in order to determine the observed and expected yield. This could potentially save time and resources for the MPSC.

The committee determined that it supported the concepts outlined in the proposed model for assessing the effectiveness of OPO's.

**Committee Response:** Please see **Section 2: Primary Public Comment Concerns/Questions** for details regarding geography and other factors that influence performance that are outside of the OPOs control.

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#### **OPO Committee**

Sponsoring Committee. As a co-sponsor of this proposal, the Committee endorses the model as a means of assessing the effectiveness of OPO performance. At the March 10, 2011 meeting, the Committee reaffirmed its approval and support of the proposal with a vote of 16-0-0.

#### **Pancreas Transplantation Committee**

The Committee considered this proposal on March 17, 2011. The Committee inquired why the organs per donor metric is the chosen metric over other metrics such as donors per capita. The sponsoring committees believe that the data used to calculate the organs per donor metric is more reliable than the data needed for other metrics. Committee members believe that although the data may be better for the chosen metric, a metric related to the conversion rate of donors would be more beneficial to the system as a whole. The Committee was concerned that the risk tolerance of the surgeons using the organs in the donation service area (DSA) would impact the organs per donor metric and was not accounted for in the model. The Committee was concerned that the number of organs recovered per donor was not within the OPO's control and that this metric would result in a disincentive to pursuing a donor who may only be able to donate a smaller number of organs. Committee members noted that some DCD donors could become brain death donors in high-functioning OPOs. Adjusting away the difference between cardiac death and brain death could miss a key performance metric. Committee members commented that they would like to see a statement of how the data used for these models are validated. There was also concern over how these models would be used by groups other than the MPSC. The MPSC cannot control how other groups use the data. The Committee suggested that the MPSC work to make these results protected under confidential medical peer review. Committee members commented that the OPO community is largely supportive of this proposal. The Committee voted to support the proposal (7-Support, 3-Oppose, 3-Abstain)

**Committee Response:** Please see **Section 2: Primary Public Comment Concerns/Questions** for details regarding additional measures of OPO performance and data integrity concerns.

All program performance reviews are conducted under confidential medical peer review protection. The data used in the OPO performance model are available on the public SRTR website, though with a different cohort (1 year). The report on the website does not currently show flagging by the MPSC and this will be discussed with the SRTR contractor as well as HRSA.

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#### **Patient Affairs Committee**

The Patient Affairs Committee heard the presentation of the proposal. After discussion the Committee voted to support the proposal as presented: Yes [16], No [0], Abstentions [0]

#### **Policy Oversight committee**

The POC had some concerns about how transplant centers impact OPO performance and whether the transplant center component was considered. It was noted that the transplant center effect is

something that can be identified as part of the survey tool that will go out when an OPO gets flagged. The survey tool will allow OPOs the opportunity to inform the MPSC of situations that impact their performance that are outside their control, such as issues related to the transplant centers.

Another area of concern is the cost of a peer visit, especially if there is an issue with the transplant center(s) identified that contributed to the OPO getting flagged. There needs to be a mechanism for getting the transplant center or centers within the DSA involved in the initial discussions and, if necessary, some sort of cost sharing between the transplant center(s) and OPOs if a peer visit is deemed necessary by the MPSC. The POC noted that it is clear that the relationship between OPOs and transplant centers can influence outcomes and performance for both organizations and questioned whether OPO performance comes up during the discussions of transplant center performance. It was noted that the MPSC does take that into consideration when reviewing and discussing further action against transplant centers, keeping in mind the need to maintain confidential medical peer review protections.

A committee member noted that CMS (Center for Medicare and Medicaid Services) has developed separate performance measures for the OPOs located in Hawaii and Puerto Rico and wondered if there was consideration given to the unique geographic and infrastructure issues of those areas. It was noted that the MPSC did discuss the issue but was unable to model it because of the numbers; however those factors would be considered by the committee if an OPO is flagged. It was also noted that the committee has not identified a process for the reviews and will be discussing this in the coming months as this proposal moves forward.

There was some concern about how this proposal could potentially impact the number of organs transplanted. This included issues such as the utilization of DCD organs, transplant/acceptance rates, marginal donors, and other factors that could have an impact on OPO performance. While there is a reasonable risk adjustment included in the models, there might be an overall reduction in the number of organs transplanted, particularly if the OPOs believe they do not have control over the utilization of the organs being offered. For example, if you look at the recovery utilization of a pancreas it is an issue of having a pancreas center within your OPO because allocating a pancreas outside the DSA is much more difficult because of the increased cold ischemia time. Additionally, as the Liver and Intestinal Organ Transplantation Committee works toward broader sharing, there is concern about OPOs that perform well sharing organs with underperforming OPOs. The POC provided these additional comments:

- It would be informative to look at the first set of OPOs that are flagged and evaluate important processes that need to be in place.
- There are metrics such as potential donors, donor population, and conversion rates that should be included in any flagging methodology.
- It is important to note that although OPOs might not get flagged with this new methodology, it is important to continue to work on performance improvement and strive to more donors and better donor numbers.

The POC agreed that coming up with an objective way of assessing OPO performance is an important step forward and voted to support the proposal and submit its comments for consideration by the MPSC. Committee vote: 14 in favor, 0 opposed, and 0 abstentions.

**Committee Response:** Upon implementation, the MPSC will evaluate the metric, including the processes used by the Committee to review OPOs as well as new metrics such as conversion rates and will consider incorporating additional analyses into its reviews when appropriate. Additional information is available in **Section 2: Primary Public Comment Concerns/Questions**.

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**Thoracic Organ Transplantation committee**

The Thoracic Committee discussed this proposal during its January 24, 2011 meeting that occurred via telephone and Internet. The following are comments and vote from the Thoracic Committee:

Currently, only the Centers for Medicare and Medicaid Services (CMS) audit an OPO’s performance. The proposed bylaw would allow UNOS to audit an OPO’s performance. Are the proposed model and the one used by the CMS the same? If so, would the proposed model, if approved by the Board, create additional work burden for UNOS staff? Also, neither the proposed OPO model nor the one applied by the CMS address the relationship between OPO performance and transplant outcome. Perhaps it is in the purview of the OPTN to consider this transplant outcome factor.

The Committee approved proposed model: 15-supported; 0-opposed; and, 0-abstained.

**Committee Response:** Currently, CMS uses a different metric for evaluating OPO performance. OPTN leadership and HRSA are involved in discussions with CMS regarding use of the MPSC metric. The MSPC recommends implementing this metric as there is no performance metric currently in use for OPOs. There will be additional work, however the Committee believes this is a necessary effort to improve overall performance of the national system.

Please see **Section 2: Primary Public Comment Concerns/Questions** for details regarding additional measures of OPO performance.

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**Transplant Administrators committee**

The Transplant Administrators Committee discussed this proposal via conference call/Live Meeting on February 23, 2011 and again on March 8, 2011. The Committee did not vote but was in overall support of the proposal. The Committee agrees that this effort will provide a more objective measure of OPO performance that is more data driven and less open for individual interpretation. However, the Committee recommends that the MPSC consider including the following variables in future models:

- Transplant center acceptance rates;
- Incidence of transplantation;
- Size of waitlist by organ;
- Concerned that data is compared against a national mean;
- Patient waitlist characteristics;
- Need further detailed analysis regarding acceptance utilization of DCD organs (Pancreas, Lung and Heart);
- Need to address the relationship between OPO performance and transplant outcomes and;
- Need to consider the following important characteristics for adequate organ function measurements and they are reported through the DDR:

Heart	Liver	Lung	Kidney	Pancreas
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Ejection Fraction	Tbili	Abnormal CXR	Biopsy results	Amylase results
Cardiac enzymes	AST	Chest Trauma		Lipase results
History of cancer	ALT	Chest tube insertion		
History of heavy alcohol use	Liver function studies			
HCV positive	Biopsy results			

The TAC believes this is a step in the right direction but has some concerns regarding how the data will be used in the future and how this model will affect transplant centers overall and in reference to transplant center acceptance rates.

**Committee Response:** The work group intended to avoid variables that an OPO could have control over during the donor management process. Since some data points are not collected on the DDR at the time the OPO takes over the case, there is no way to determine if the OPO had an effect on the value. If it is a variable that the OPO can improve over the course of donor management, then an OPO that performs good donor management could be adversely affected by a higher expected value than would have been warranted. Please see **Section 2: Primary Public Comment Concerns/Questions** for details regarding additional measures of OPO performance and factors outside of the OPOs control that may impact performance.

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**Transplant Coordinators committee**

The Transplant Coordinators reviewed this proposal during their March 8<sup>th</sup> Live Meeting and the following were noted for consideration:

How will this model impact OPOs with CMS’s performance metrics in place too? Additional regulation will increase the fiscal responsibility and could become cost prohibitive. If this new proposal requires different information than CMS the OPOs will become so regulated they won’t survive financially.

Another member commented that this is a great proposal. Additionally, the member noted that the ability to demonstrate the potential of recovering x # organs needs to be in place.

It was asked, how the consent of only 1 or 2 organs will be factored in the metric? It was noted that the expected number of organs transplanted from a donor will be lower if the donor has met certain criteria. The metric will not be able to account for every circumstance but hopefully the model overtime will compensate for multiple vs. single organ transplants.

The possibility of a trial was then discussed and it was opined that not having a trial may be problematic with CMS and for the OPOs.

The Committee approved the proposed policy: 5 For; 4 Against; 2 Abstained.

**Committee Response:** OPOs will not be required to submit any additional data for analysis by this metric. Additional burden may be placed on OPOs that are flagged for MPSC review and must therefore submit information to the MPSC for consideration. The Committee believed this metric

was a first step and will consider adding additional metrics/models to its review process when appropriate. Other projects are already underway to consider donor potential and conversion rates.

Please see **Section 2: Primary Public Comment Concerns/Questions** for details regarding additional measures of OPO performance and piloting the metric prior to implementation.

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## 5. Individual Public Comment Responses

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### **Comment 1:**

*vote: Oppose*

*Date Posted: 03/15/2011*

March 15, 2011 Re: Proposed Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization With a steadfast focus on increasing organ donation and meeting the need for patients on the waiting list, the University of Wisconsin Organ Procurement Organization has the following comments on this proposal. Clinical Significance versus Statistical Significance It is our understanding that data currently submitted by the OPOs was analyzed to determine which covariates had a statistical significance on the outcome of organs recovered and transplanted. Those with statistical significance were used in the model. In our experience, some donor characteristics that are currently not included in the model do have a clinical significance in placing organs with transplant centers. Specifically those characteristics (all of which are currently reported by OPOs) include: ejection fraction for heart, Tbili/AST/ALT for liver, abnormal chest x-ray for lung, and number/amount of inotropic medication all play significant roles in predicting organ usage. It concerns us greatly that these clinical indicators of organ function are not included in the model. Risk of Mis-Use of the Framework The proposed metric has significant risk of being used beyond the intended aim of quality improvement. Specifically, misuse could include using this data as comparative (one OPO versus another) instead of the intended purpose of one OPO's actual performance versus its own expected performance. The second potential mis-use is if the metric is used by CMS or other entities that hold contracts with an OPO. If entities other than UNOS intend or have expressed an intent to use this metric, the OPO community should be aware of that prior to UNOS approval. Potential Unintended Consequences It is concerning to our OPO that there has not been a thorough analysis of the potential unintended consequences that may occur from this public policy. Specifically, it is possible that OPOs may begin adjusting their practice on whether to go on a donor at all if the O/E is negatively affected. Will single organ donors be pursued by an OPO that is flagged with this metric? If an OPO is close to being flagged, will they rule out donors that have a high potential for discard or poor biopsy results? Is there a potential negative incentive created by using this metric? We feel this analysis should be done prior to UNOS approval of the policy.

**Committee Response:** Please see **Section 2: Primary Public Comment Concerns/Questions** for details regarding concerns raised. To the degree possible, the models account for low yield from medically complex donors.

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### **Comment 2:**

*vote: Oppose*

*Date Posted: 02/03/2011*

OPOs are confronted with a profound responsibility, and their dedication to optimum performance is a critical component of the national transplant effort. Despite these efforts, there remains a critical shortage of organs available for transplantation in relation to need. As such, OPO performance is a potentially helpful process. The proposed system for doing so, however, focuses on only one parameter which, while important and relatively concrete from the standpoint of ease of measurement, does not provide a sufficiently comprehensive profile of OPO performance to warrant implementation in its present form. At least equally and perhaps more salient parameters reflecting OPO performance are not included in the present proposal. These are as follows: 1) identification of eligible donors indexed to a population denominator of some sort, 2) ratio of actual to eligible donors, 3) medical examiner-related denials, and 4) ratio of actual to eligible non-multiorgan donors (e.g. kidney only). As such, the proposed system also has the potential for masking underperformance of OPOs and Donor Service Areas from the standpoints of identifying eligible donors and successfully obtaining consents for donation. Regardless of intentions and statistical methodology, it seems to me that the proposed process also carries a potential for compounding disincentives for retrieval from donors that are judged, on the basis of valid clinical considerations, to be kidney only. With these considerations in mind, I believe that approval of the present OPO evaluation process should be withheld pending incorporation of the performance parameters mentioned above.

**Committee Response:** This proposal will allow for the MPSC to begin monitoring performance based on the identified parameter; the Committee will continue to consider additional measures of OPO performance as developed in addition to evaluating the usefulness of this metric. Please see **Section 2: Primary Public Comment Concerns/Questions** for a response to the suggested additional measures.

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**Comment 3:**

*vote: Oppose*

*Date Posted: 03/17/2011*

**OPTN/UNOS PUBLIC COMMENT RESPONSE FORM**

January 21, 2011

Public Comment Deadline: March 18, 2011

**To:** Public Comment Coordinator  
 United Network for Organ Sharing  
 Department of Policy, Membership and Regional Administration  
 P.O. Box 2484  
 Richmond, VA 23218  
 FAX: 804-782-4896  
 Email: publiccomment@unos.org

**From:** Dennis F. Heinrichs, President, COO, LifeLink Foundation

LifeLink of Puerto Rico  
 Daimler-Chrysler Bldg, Suite 100  
 Calle 1, #1, Metro Office Park  
 Guaynabo, Puerto Rico 00968  
 787 277 0900

**Date:** 2/28/2011

Please indicate whether the support or opposition and comments below are your individual position on this proposal or that of your organization.  Organization

I support, oppose, or have no opinion on this proposal as circled below:

Support	Oppose	No Opinion	Proposal Name
	<b>X</b>		1. Proposed Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization (Membership and Professional Standards Committee (MPSC), Organ Procurement Organization (OPO) Committee)

**ATTACH ADDITIONAL SHEETS AS NECESSARY FOR COMMENTS (PLEASE TYPE OR PRINT COMMENTS)**

LifeLink of Puerto Rico recognizes the OPO yield measure currently being utilized by the Centers for Medicare and Medicaid Services (CMS) is based on SCD and ECD donors, which was borne out of kidney specific criteria, and does not accurately evaluate OPO yield on all donors. Because of this we would support an alternate method of evaluating OPO yield. However, because the model does not address the key issues recognized for noncontiguous states resulting in immediate disadvantage to the OPO, we cannot support the proposal at this time.

We would be willing to entertain a model that factors in those issues specific to non-contiguous states. We initially communicated our concerns below during the series of conference calls held by UNOS and while responses were provided, no tangible solution was given. We would like to reiterate the following concerns for your consideration.

**1. Geographic / Demographic / Social Factors Not Addressed in Model**

First and foremost, the model does not consider many factors outside of OPO control that certainly impacts maximizing organs recovered. A significant factor is geographic barriers for non-contiguous OPOs like Puerto Rico and Hawaii. There are no provisions available to address their unique circumstances and the current proposal, while acknowledging there is an issue, would require a continuous corrective action plan (CAP) response cycle versus modifying the measure for these OPOs similar to the current CMS measure. Ultimately OPOs located within close proximity to multiple transplant centers have an advantage not shared by OPOs with fewer transplant centers in close radius.

There is no consideration for OPOs with a significant lack of access to basic medical services, i.e. the ability to do cardiac catheterizations, Swan Ganz monitoring and bronchoscopies. All of these factors impact the ability to maximize organs and are not factored into this model's rationale.

The current model does not factor unique demographics for the island of Puerto Rico, specifically Black / Hispanic. Current model logic factors these individuals as black with no consideration given to their unique Hispanic population characteristics. There should be an opportunity to address same with the model definitions.

There is no consideration for regions with frequent severe weather conditions that might impact the ability for donation teams to travel.

Social factors like homelessness and recent jail time impact the ability to place organs but are not factored into the model. Also, there are only three age splines in most models and none indicated in the lung model which could certainly have a negative impact on the older donor.

## 2. OPO Performance Evaluation Tool Access

In order to make operational decisions to improve OPO efforts, the OPOs must be provided a mechanism to routinely review and validate data used to monitor their performance with this new model. We have been advised that the first reports (currently being discussed and identifying OPOs with significant issues) should be released sometime in March and that a tool is being developed but is not ready. Full release of this tool should be available identifying not only the OPO's individual performance but also those OPOs that are being utilized as a comparative OPO.

## 3. Standardized / Approved Definitions and Rationale

Data utilized for these regression models are self reported in a tool (UNet) developed to facilitate organ placement. There are no methods currently being utilized to ensure data entry is consistent across the OPOs. Key data indicators like history of hypertension, diabetes, and drug use, could certainly be interpreted differently by OPO. Also, current definitions do not support clinical signs of undiagnosed hypertension and diabetes, only a documented history of same, and those donors (representing a significant part of the population for LifeLink of Puerto Rico due to lack of access to healthcare) will negatively impact outcome measures for the OPOs in this model.

A current example of said definition misinterpretation is the definition for "eligible". While there is a published UNOS definition, the ability to self report allows for varied interpretations and ultimately varied reporting of same.

A rationale document should be developed, in conjunction with OPO input, for all data indicators used in the evaluation tool prior to utilization as a measurement tool. Also, a mechanism to verify that data indicators are being recorded appropriately by each OPO must be established to ensure parity and accurate comparison of similar OPOs.

## 4. Expected Impact on OPOs Pursuing Marginal Donors

We understand the primary goal of this proposal is to maximize organs recovered per donor (yield), however we believe this model does not take into consideration key factors that support this goal including OPO efforts to pursue marginal donors. The model addresses organs transplanted and does not evaluate donors recovered per population or death, an irrefutable and not self-reported statistic. It also seems to support OPOs that might limit their efforts to easily obtainable organs from donors placed at geographically convenient transplant centers. While current responses state that the model will adjust for OPOs pursuing these marginal donors, there is no data or tool available to evaluate and support this claim.

The current allocation system (DonorNet) is structured to facilitate placement of standard criteria donors and does not efficiently support the process of placing the marginal or expanded criteria donors. However, the ability to place marginal organs remains a critical component if an OPO is to successfully satisfy the primary goal of this initiative, maximizing yield.

LifeLink of Puerto Rico believes the proposed statistical model represents a first effort to define and delineate the complex issue of OPO performance. However, this model evaluates organs transplanted from donors recovered by an OPO and falls short of determining if an OPO is maximizing organs recovered per donor in its service area.

**We also remain concerned regarding the predictive ability of this model and its premature use as a measurement tool with potentially punitive consequences with the OPTN and potentially CMS. Based on the above, we request further development of this tool to address the above issues prior to implementation.**

**Committee Response:** The SRTR contractor will continue to evaluate the model and potential inclusion of geographic factors. Please see **Section 2: Primary Public Comment Concerns/Questions** for details regarding your concerns.

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**Comment 4:**

*vote: Oppose*

*Date Posted: 03/17/2011*

OPTN/UNOS PUBLIC COMMENT RESPONSE FORM  
 January 21, 2011  
 Public Comment Deadline: March 18, 2011

To: Public Comment Coordinator  
 United Network for Organ Sharing  
 Department of Policy, Membership and Regional Administration  
 P.O. Box 2484  
 Richmond, VA 23218  
 FAX: 804-782-4896  
 Email: publiccomment@unos.org

From: E.A. SANTIAGO DELPIU MD  
 (Name) PUERTO RICO RENAL TRANSPLANT PROGRAM  
 (Organization Name, Address and Phone Number)

AUXILIO MUTUO HOSPITAL

Date: 03.17.11

Please indicate whether the support or opposition and comments below are your individual position on this proposal or that of your organization.  Individual  Organization

I support, oppose, or have no opinion on this proposal as circled below:

Support	Oppose	No Opinion	Proposal Name
	X		1. Proposed Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization (Membership and Professional Standards Committee (MPSC), Organ Procurement Organization (OPO) Committee)

ATTACH ADDITIONAL SHEETS AS NECESSARY FOR COMMENTS (PLEASE TYPE OR PRINT COMMENTS)

THE PROPOSAL IS OPPOSED AT THIS TIME BECAUSE THE METRICS DOES NOT CONSIDER ISSUES WHICH ARE CRITICAL, NOT ONLY FOR PUERTO RICO BUT IN THE DIFFERENT REGIONS IN THE U.S. CULTURAL DIVERSITY, EDUCATION, SOCIO ECONOMIC FACTORS, GEOGRAPHICAL ISSUES INCLUDING ISOLATION, THE INFLUENCE OF THE MEDIA, THE INFLUENCE OF RELIGION. ORGAN DONATION IS VERY COMPLEX AND →

MULTIFACTORIAL  $\alpha$  IS NOT THE RESULT SOLELY OF AN O.P.O.. AN ADDED CONFOUNDING VECTOR IS THE TRIAD OF DIRECTIVES RELATED TO INCREASE IN TRANSPLANTS, MAINTAINING EXCELLENT OUTCOMES AND SYSTEMS, AT DECREASING REIMBURSEMENTS, THIS FROM THE PERSPECTIVE OF PROGRAMS + CENTERS.

PERFORMANCE METRICS ARE VALUABLE, BUT OTHER FACTORS INCLUDING THE ABOVE SHOULD BE GIVEN CONSIDERATION + INCLUSION.



**Committee Response:** Please see response to Comment 3 and **Section 2: Primary Public Comment Concerns/Questions** for details regarding geography and additional measures of OPO performance.

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**Comment 5:**

vote: Oppose

Date Posted: 03/09/2011

John Whelchel, MD  
Medical Director  
LifeLink of Georgia  
2875 Northwoods Parkway  
Norcross, GA 30071

I do not support the current “Proposed Model for Assessing the Effectiveness of Individual OPOs etc.” as presently written.

My concerns include:

1. The final “performance tools” for measuring of an OPO’s performance has yet to be circulated and until that tool is released for review and comment it is impossible to really discuss the “Model’s” effectiveness, merits and/or fairness.
2. A standardize methodology must be proposed and adopted that can be validated to ensure consistent data entry across all OPOs . This includes standard definitions of clinical, pathological and geographic issues that effect both organ procurement and organ utilization and these definitions should not be open to a wide range of interpretations by different OPOs.
3. The model does not appear to address factors that are outside the OPOs control and that may adversely affect the number of organs procured/transplanted per donor and number of donors for a given area. These include issues such as geographic barriers, weather and distance effects, local availability of equipment and facilities to perform necessary diagnostic exams to evaluate specific potential donor organs such as the heart and lungs, population characteristics and social issues. Likewise the aggressiveness of transplant centers served by an OPO often effects the successful placement of donor organs especially ECD donor organs.
4. The Proposal’s primary goal appears to be increasing organ availability for transplantation by maximizing organ yield per donor and increasing the utilization of marginal donor. The Model appears to only measure organs transplanted per donor and not donors per population or death. Although these issues have been recognized, no tool or methodology has been presented to answer such concerns.
5. The current organ allocation system (DonorNet) was crafted for the placement of standard criteria donors and inadequately supports placement of marginal or ECD donors. Since placement of the latter organs is a critical measurement of a OPOs compliance, an appropriate system to support allocation for such donor organs must be developed before further considering the implementation of this measurement.

These are but a few of the issues that need to be addressed and resolved in the “Proposal” before it is circulated for final review and implemented. Included in any revision must be data regarding the probably predictive ability of the final proposal and a appropriate period of testing of that predictability before punitive consequences are placed on the OPOs.

**Committee Response:** The proposal distributed for public comment described the MPSC’s intent to utilize a statistical analysis to review OPO performance. The SRTR contractor is creating the “tool” that OPOs can use in real time, and this tool will be made available to OPOs at the same time, if not earlier, that the MPSC will begin using the analysis to evaluate OPOs. For a response to points 2-5, please reference **Section 2: Primary Public Comment Concerns/Questions**.

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**Comment 6:**

vote: Oppose

Date Posted: 03/09/2011

OPTN/UNOS PUBLIC COMMENT RESPONSE FORM  
January 21, 2011  
Public Comment Deadline: March 18, 2011

To: Public Comment Coordinator  
United Network for Organ Sharing  
Department of Policy, Membership and Regional Administration  
P.O. Box 2484  
Richmond, VA 23218  
FAX: 804-782-4896  
Email: publiccomment@unos.org

From:  
Dennis F. Heinrichs, President, COO, LifeLink Foundation  
LifeLink of Florida  
409 Bayshore Boulevard  
Tampa, Florida  
813 348 6308

Date: 2/28/2012

Please indicate whether the support or opposition and comments below are your individual position on this proposal or that of your organization.  Organization

I support, oppose, or have no opinion on this proposal as circled below:

Support	Oppose	No Opinion	Proposal Name
	X		1. Proposed Model for Assessing the Effectiveness of Individual OPOs in Key Measures of Organ Recovery and Utilization (Membership and Professional Standards Committee (MPSC), Organ Procurement Organization (OPO) Committee)

ATTACH ADDITIONAL SHEETS AS NECESSARY FOR COMMENTS (PLEASE TYPE OR PRINT COMMENTS)

LifeLink of Florida recognizes the OPO yield measure currently being utilized by the Centers for Medicare and Medicaid Services (CMS) is based on SCD and ECD donors, which was borne out of kidney specific criteria, and does not accurately evaluate OPO yield on all donors. Because of this we would support an alternate method of evaluating OPO yield. We believe, with some key changes, this model could provide a more accurate evaluation, but have some key issues identified that would need to be addressed prior to our endorsement. We initially communicated our concerns below during the series of conference calls held by UNOS and while responses were provided, no tangible solution was given. We would like to reiterate the following concerns for your consideration.

1. OPO Performance Evaluation Tool Access

In order to make operational decisions to improve OPO efforts, the OPOs must be provided a mechanism to routinely review and validate data used to monitor their performance with this new model. We have been advised that the first reports (currently being discussed and identifying OPOs with significant issues) should be released sometime in March and that a tool is being developed but is not ready. Full release of this tool should be available identifying not only the OPO's individual performance but also those OPOs that are being utilized as a comparative OPO.

## 2. Standardized / Approved Definitions and Rationale

Data utilized for these regression models are self reported in a tool (UNet) developed to facilitate organ placement. There are no methods currently being utilized to ensure data entry is consistent across the OPOs. Key data indicators like history of hypertension, diabetes, and drug use, could certainly be interpreted differently by OPO. Also, current definitions do not support clinical signs of undiagnosed hypertension and diabetes, only a documented history of same, and those donors (representing a significant part of the population for LifeLink of Georgia and LifeLink of Puerto Rico due to lack of access to healthcare) will negatively impact outcome measures for the OPOs in this model.

A current example of said definition misinterpretation is the definition for "eligible". While there is a published UNOS definition, the ability to self report allows for varied interpretations and ultimately varied reporting of same.

A rationale document should be developed, in conjunction with OPO input, for all data indicators used in the evaluation tool prior to utilization as a measurement tool. Also, a mechanism to verify that data indicators are being recorded appropriately by each OPO must be established to ensure parity and accurate comparison of similar OPOs.

## 3. Expected Impact on OPOs Pursuing Marginal Donors

We understand the primary goal of this proposal is to maximize organs recovered per donor (yield), however we believe this model does not take into consideration key factors that support this goal including OPO efforts to pursue marginal donors. The model addresses organs transplanted and does not evaluate donors recovered per population or death, an irrefutable and not self-reported statistic. It also seems to support OPOs that might limit their efforts to easily obtainable organs from donors placed at geographically convenient transplant centers. While current responses state that the model will adjust for OPOs pursuing these marginal donors, there is no data or tool available to evaluate and support this claim.

The current allocation system (DonorNet) is structured to facilitate placement of standard criteria donors and does not efficiently support the process of placing the marginal or expanded criteria donors. However, the ability to place marginal organs remains a critical component if an OPO is to successfully satisfy the primary goal of this initiative, maximizing yield.

## 4. Geographic / Demographic / Social Factors Not Addressed in Model

The model does not consider many factors outside of OPO control that certainly impacts maximizing organs recovered. A significant factor is geographic barriers for non-contiguous OPOs like Puerto Rico and Hawaii. There are no provisions available to address their unique circumstances and the current proposal, while acknowledging there is an issue, would require a continuous corrective action plan (CAP) response cycle versus modifying the measure for these OPOs similar to the current CMS measure. Ultimately OPOs located within close proximity to multiple transplant centers have an advantage not shared by OPOs with fewer transplant centers in close radius.

There is no consideration for regions with frequent severe weather conditions that might impact the ability for donation teams to travel.

There is no consideration for OPOs with a significant lack of access to basic medical services, i.e. the ability to do cardiac catheterizations, Swan Ganz monitoring and bronchoscopies. All of these factors impact the ability to maximize organs and are not factored into this model's rationale.

The current model does not factor unique demographics for the island of Puerto Rico, specifically Black / Hispanic. Current model logic factors these individuals as black with no consideration given to their unique Hispanic population characteristics. There should be an opportunity to address same with the model definitions.

Social factors like homelessness and recent jail time impact the ability to place organs but are not factored into the model. Also, there are only three age splines in most models and none indicated in the lung model which could certainly have a negative impact on the older donor.

LifeLink of Florida believes the proposed statistical model represents a first effort to define and delineate the complex issue of OPO performance. However, this model evaluates organs transplanted from donors recovered by an OPO and falls short of determining if an OPO is maximizing organs recovered per donor in its service area.

**We also remain concerned regarding the predictive ability of this model and its premature use as a measurement tool with potentially punitive consequences with the OPTN and potentially CMS.**

**Based on the above, we request further development of this tool to address the above issues prior to implementation.**

**Committee Response:** Please see response to Comment 3 and **Section 2: Primary Public Comment Concerns/Questions** for details regarding geography and additional measures of OPO performance.

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**Comment 7:**

*vote: Oppose*

*Date Posted: 03/09/2011*

LifeLink of Georgia recognizes the OPO yield measure currently being utilized by the Centers for Medicare and Medicaid Services (CMS) is based on SCD and ECD donors, which was borne out of kidney specific criteria, and does not accurately evaluate OPO yield on all donors. Because of this we would support an alternate method of evaluating OPO yield. We believe, with some key changes, this model could provide a more accurate evaluation, but have some key issues identified that would need to be addressed prior to our endorsement. We initially communicated our concerns below during the series of conference calls held by UNOS and while responses were provided, no tangible solution was given. We would like to reiterate the following concerns for your consideration.

1. OPO Performance Evaluation Tool Access

In order to make operational decisions to improve OPO efforts, the OPOs must be provided a mechanism to routinely review and validate data used to monitor their performance with this new model. We have been advised that the first reports (currently being discussed and identifying OPOs with significant issues) should be released sometime in March and that a tool is being developed but is not ready. Full release of this tool should be available identifying not only the OPO's individual performance but also those OPOs that are being utilized as a comparative OPO.

2. Standardized / Approved Definitions and Rationale

Data utilized for these regression models are self reported in a tool (UNet) developed to facilitate organ placement. There are no methods currently being utilized to ensure data entry is consistent across the OPOs. Key data indicators like history of hypertension, diabetes, and drug use, could certainly be interpreted differently by OPO.

Also, current definitions do not support clinical signs of undiagnosed hypertension and diabetes, only a documented history of same, and those donors (representing a significant part of the population for LifeLink of Georgia and LifeLink of Puerto Rico due to lack of access to healthcare) will negatively impact outcome measures for the OPOs in this model.

A current example of said definition misinterpretation is the definition for "eligible". While there is a published UNOS definition, the ability to self report allows for varied interpretations and ultimately varied reporting of same.

A rationale document should be developed, in conjunction with OPO input, for all data indicators used in the evaluation tool prior to utilization as a measurement tool. Also, a mechanism to verify that data indicators are being recorded appropriately by each OPO must be established to ensure parity and accurate comparison of similar OPOs.

3. Expected Impact on OPOs Pursuing Marginal Donors

We understand the primary goal of this proposal is to maximize organs recovered per donor (yield), however we believe this model does not take into consideration key factors that support this goal including OPO efforts to pursue marginal donors. The model addresses organs transplanted and does not evaluate donors recovered per population or death, an irrefutable and not self-reported statistic. It also seems to support OPOs that might limit their efforts to easily obtainable organs from donors placed at geographically convenient transplant centers. While current responses state that the model will adjust for OPOs pursuing these marginal donors, there is no data or tool available to evaluate and support this claim.

The current allocation system (DonorNet) is structured to facilitate placement of standard criteria donors and does not efficiently support the process of placing the marginal or expanded criteria donors. However, the ability to place marginal organs remains a critical component if an OPO is to successfully satisfy the primary goal of this initiative, maximizing yield.

4. Geographic / Demographic / Social Factors Not Addressed in Model

The model does not consider many factors outside of OPO control that certainly impacts maximizing organs recovered. A significant factor is geographic barriers for non-contiguous OPOs like Puerto Rico and Hawaii. There are no provisions available to address their unique circumstances and the current proposal, while acknowledging there is an issue, would require a continuous corrective action plan (CAP) response cycle versus modifying the measure for these OPOs similar to the current CMS measure. Ultimately OPOs located within close proximity to multiple transplant centers have an advantage not shared by OPOs with fewer transplant centers in close radius.

There is no consideration for regions with frequent severe weather conditions that might impact the ability for donation teams to travel.

There is no consideration for OPOs with a significant lack of access to basic medical services, i.e. the ability to do cardiac catheterizations, Swan Ganz monitoring and bronchoscopies. All of these factors impact the ability to maximize organs and are not factored into this model's rationale.

The current model does not factor unique demographics for the island of Puerto Rico, specifically Black / Hispanic. Current model logic factors these individuals as black with no consideration given to their unique Hispanic population characteristics. There should be an opportunity to address same with the model definitions.

Social factors like homelessness and recent jail time impact the ability to place organs but are not factored into the model. Also, there are only three age splines in most models and none indicated in the lung model which could certainly have a negative impact on the older donor.

LifeLink of Georgia believes the proposed statistical model represents a first effort to define and delineate the complex issue of OPO performance. However, this model evaluates organs transplanted from donors recovered by an OPO and falls short of determining if an OPO is maximizing organs recovered per donor in its service area.

**We also remain concerned regarding the predictive ability of this model and its premature use as a measurement tool with potentially punitive consequences with the OPTN and potentially CMS.**

**Based on the above, we request further development of this tool to address the above issues prior to implementation.**

**Committee Response:** Please see response to Comment 3 and **Section 2: Primary Public Comment Concerns/Questions** for details regarding geography and additional measures of OPO performance.

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#### **Comment 8:**

*vote: Oppose*

*Date Posted: 03/18/2011*

**From:** Klintmalm, Goran B. [mailto:goran.klintmalm@BaylorHealth.edu]  
**Sent:** Wednesday, February 09, 2011 11:51 AM  
**To:** Shannon F. Edwards  
**Cc:** Marlon Levy  
**Subject:** OPO standards

The conference call this morning was interesting. This would be the first time in more than 15 years any standards have been imposed on the OPO community. Thus, the OPO community will push back. The proposed guide lines are so "easy" so the OPO's will most likely accept this without pushback as they see these requirements in order to avoid something more significant.

The presentation was clear. Based on the statistical formulas and the chosen 10% difference for review only 7 organ programs fell out. It was not presented how many OPO's were involved, but I suspect that that number is far less.

Reality check: of the four OPO's in region 4, two are under performing overall and are at the bottom of the list in the USA. One has good overall donor recovery numbers, but is in the 5<sup>th</sup> percentile in the US for liver procurement. Only one OPO perform as good as or better than expected.

On an even higher scale, a given population has an incidence of end stage organ disease that is set with some variation due to basic population factors. That same population also expected to have a similar set incidence of organ donors. Since UNOS was established certain regions, notably northeast and areas on the west coast who normally claim to be more educated and public minded, clamored and required for "broader organ sharing" as their OPO's are notoriously under performing. The same is true in region 4 where representatives from programs in the previously mentioned underperforming OPO's want to have organs from those who do. – "I think we should all share, since you have more to share than I do".

I suggest that the working committee and the MPSC perform a reality check of the proposed standards. **First**, decrease the variance allowed from 10 to 5 % for review. **Second**, the statistics must be done as a one sided test, not two as we are looking only at the underperforming OPO's for review. I assume we are not going to review the over performing OPO's to make them perform less well..... This is the methodology that CMS uses when it reviews organ transplant programs.

I expect that the OPO community will take a dim view on my comments.

Goran Klintmalm MD, PhD  
Chief and Chairman  
Baylor Simmons Transplant Institute  
Region 4 representative, UNOS Liver and Intestine Committee

**Committee Response:** If the data were in use today, the MSPC triggers would result in 7 OPOs flagged for review; that is out of the 58 OPOs in the country. The MPSC believes it has identified the appropriate thresholds that result in committee review, but will continue to evaluate the metric upon implementation. The immediate use of the metric will be to identify underperforming OPOs; eventually, the MPSC expects to identify OPOs performing better than expected to facilitate the sharing of best practices for all OPOs. Thus, the Committee recommends using a two-sided p-value. The Committee is also considering other metrics of donor procurement for future implementation, but feels that those data are not yet mature enough for public reporting.

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**Comment 9:**

*vote: Oppose*

*Date Posted: 03/14/2011*

DATE: February 24, 2011  
TO: UNITED NETWORK FOR ORGAN SHARING  
FROM: LIFEGIFT ORGAN DONATION CENTER  
HOUSTON, TX

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PUBLIC COMMENT: PROPOSED MODEL FOR ASSESSING THE EFFECTIVENESS  
OF INDIVIDUAL OPOS IN KEY MEASURES OF ORGAN  
RECOVERY AND UTILIZATION

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LifeGift Organ Donation Center (LIFEGIFT) is providing comment on the UNOS Proposed Model for Assessing the Effectiveness of Individual OPOs in the Key Measure of Organ Recovery and Utilization.

This model improves on the current OTPD measurement metrics which stratify OTPD based on SCD, ECD and DCD. This model takes into account many other variables which are associated with higher and/or lower OTPD. In that sense, the model is an improvement over existing reports of OTPD available on the collaborative scorecard. LifeGift concurs with the OPTN's effort to develop such criteria based on donor risk and believes the model will be beneficial in looking at the OTPD metric.

However, LifeGift will comment on the limited utility of the model. Our concerns about the proposal are (1) this model does not measure how effectively the OPO is identifying, consenting and converting potential donors, (2) use of this model will actively discourage OPOs from aggressively seeking out all potential donors (particularly single organ donors, DCD donors and ECD donors), and (3) this methodology continues to rely upon unverified self-reported data.

**The "title"**

The model should be specific about what it measures and what it does not measure. Based on the very narrow element of OPO performance that this model measures, LifeGift suggests that a more appropriate title of this model would be:

PROPOSED MODEL FOR ASSESSING THE EFFECTIVENESS OF INDIVIDUAL OPOS  
ON ORGANS TRANSPLANTED FROM **RECOVERED** DONORS

**OTPD is a single, and not the most important, measurement of OPO performance**

OTPD is one "measure" (not measures as suggested in the title) of organ recovery and utilization. This model says nothing about the most important measure of "effectiveness" of an OPO in serving the patients waiting for organs and that measure is the sheer number and volume of organs transplanted based on the actual size of the donor pool in that DSA. An OPO/DSA can have *decreasing* numbers of organ donors and organs transplanted, *increasing* patient waiting size lists and *increasing* patient acuity and waiting list deaths due to low donor identification rates and consent/conversion rates, therefore low organ production from the donor pool and **not** be flagged for a review based on this model.

Additionally, in looking at the OPOs that fall out on this model, OPOs with high volumes of donors and organs transplanted for their population size (transplants) in the model can be flagged, warranting a visit from UNOS, while OPOs that have had an absolute decrease in donors and organs transplanted during the last decade, along with the inevitable increase patient waiting times for transplants and deaths on waiting lists, will not be flagged and will not be visited. Those OPOs simply need to recover an average number of organs based on the number of donors they do recover.

This proposal proposes visits by the OPTN to flagged OPOs based on one single metric on **recovered** donors. It says nothing about the sheer number of organs transplanted. This is the largest flaw with the idea of the OPTN basing its sole performance metric on one measure that will allow OPOs that stick to the middle to the safe middle ground while others are flagged and visited. Until the OPTN arrives with a volume metric to accompany this much improved OTPD metric, LifeGift opposes visits based on this sole metric.

The point of an effective program is to remove as many patients as possible from the waiting list. OTPD is only one part of that. It is understandable that the OPTN would work with what it has – data that is collected on donors that are recovered. However, there is no consideration for data that is not collected and most importantly, donors that are not recovered and organs that are not transplanted. Choosing this single metric is the easy way out. The OPTN must wrestle with the denominator, - the donor pool. Otherwise, we will continue to be in a situation in which the OPOs collectively are vastly improving their “results” (figures 4,7,8,11) with a stagnant to decreasing number of transplants from deceased donors. (figures 1,8,11). This is not a credible position. A volume metric must accompany the OTPD metric in order for OPOs to be flagged and sited visited. In fact, a low OTPD and high donors per million rate may have some association. LifeGift looks forward to the OPTN further developing OPO performance metrics.

### **Self-reported Data**

LifeGift further suggests that so long as any OPO metric is dependent on unverified self-reported data that metric will remain fatally flawed. Either OPO self-reported data must be verified by an independent party (i.e.; CMS, UNOS, JCAHO), a different metric must be developed whose data can be verified (i.e.; donors per 100 deaths) or a different reporting system must be devised (i.e.; OPOs must report all deaths to a central location as hospitals do now).

Figure 1.

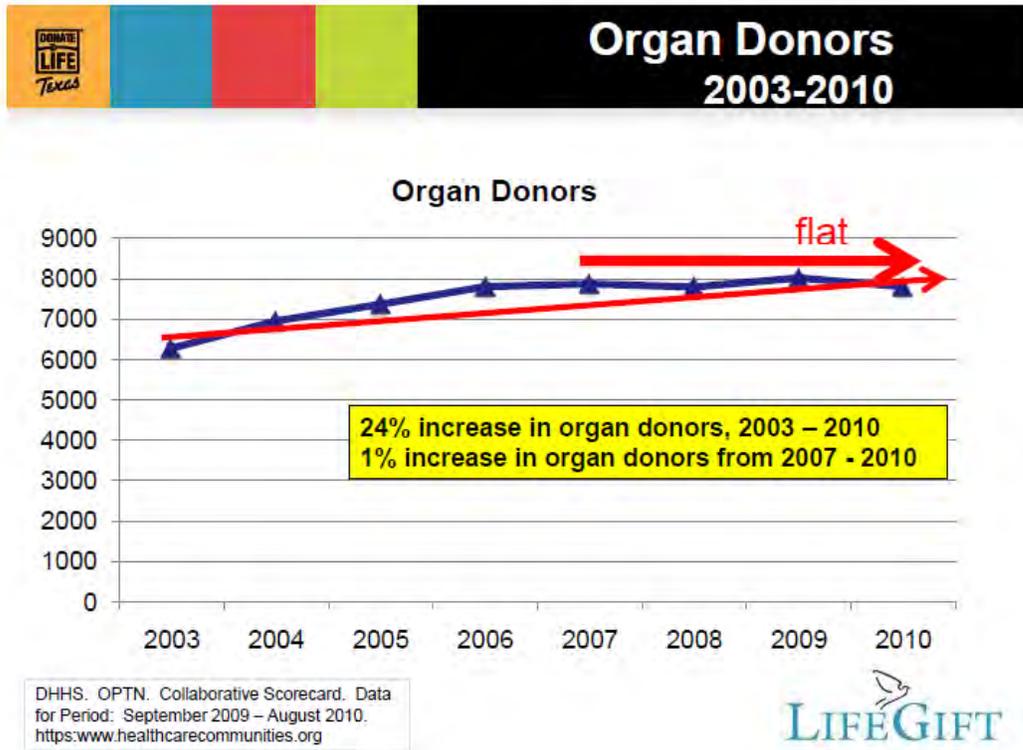


Figure 2.

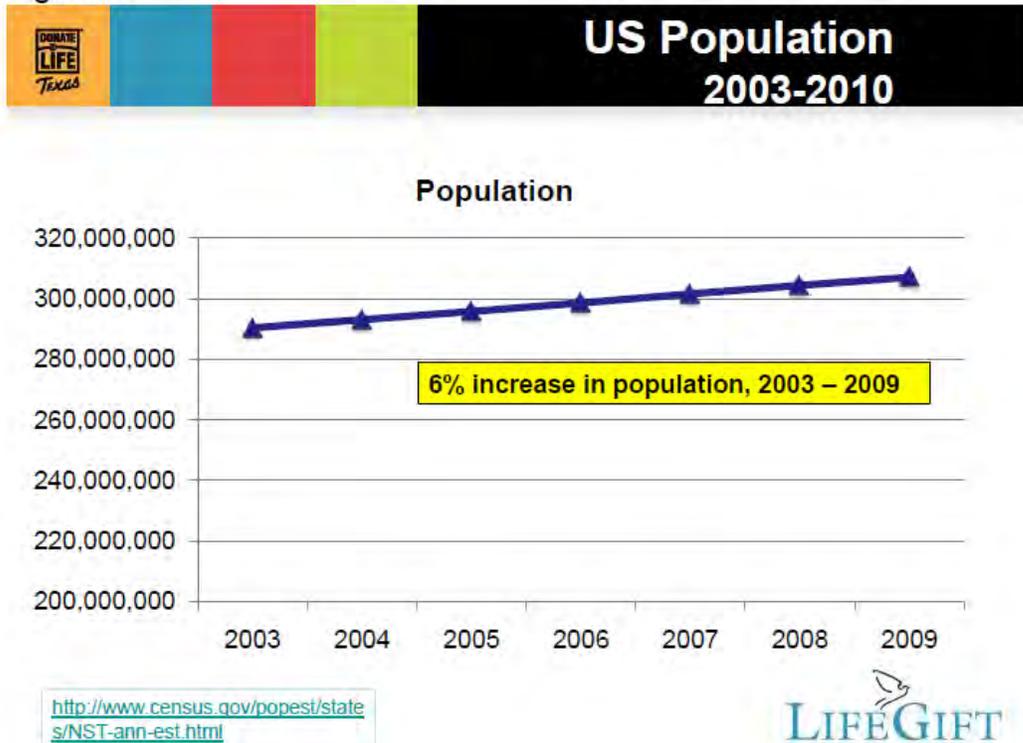
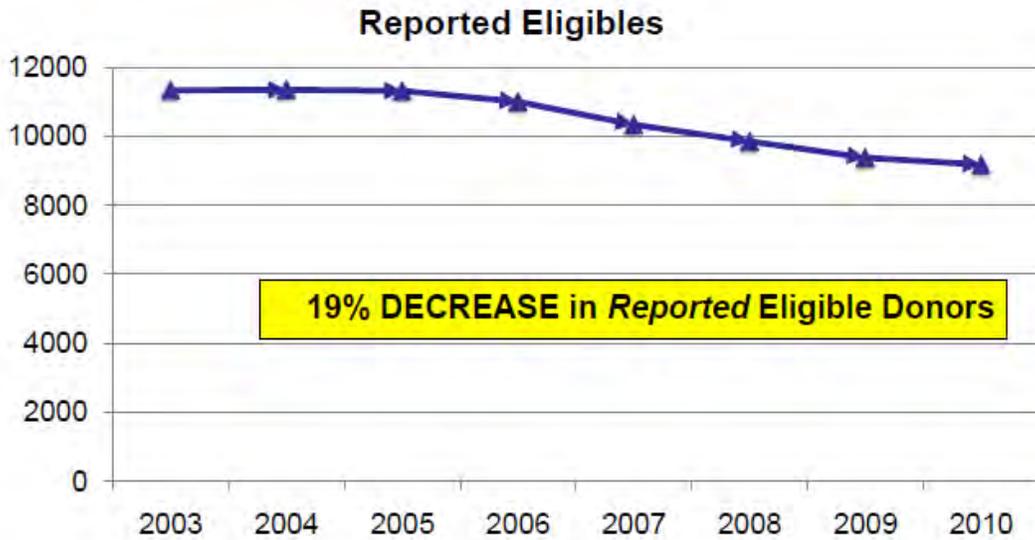


Figure 3.

 **Reported Eligible Donors  
2003-2011**



DHHS. OPTN. Collaborative Scorecard. Data for Period: September 2009 – August 2010. <https://www.healthcarecommunities.org>



Figure 4.

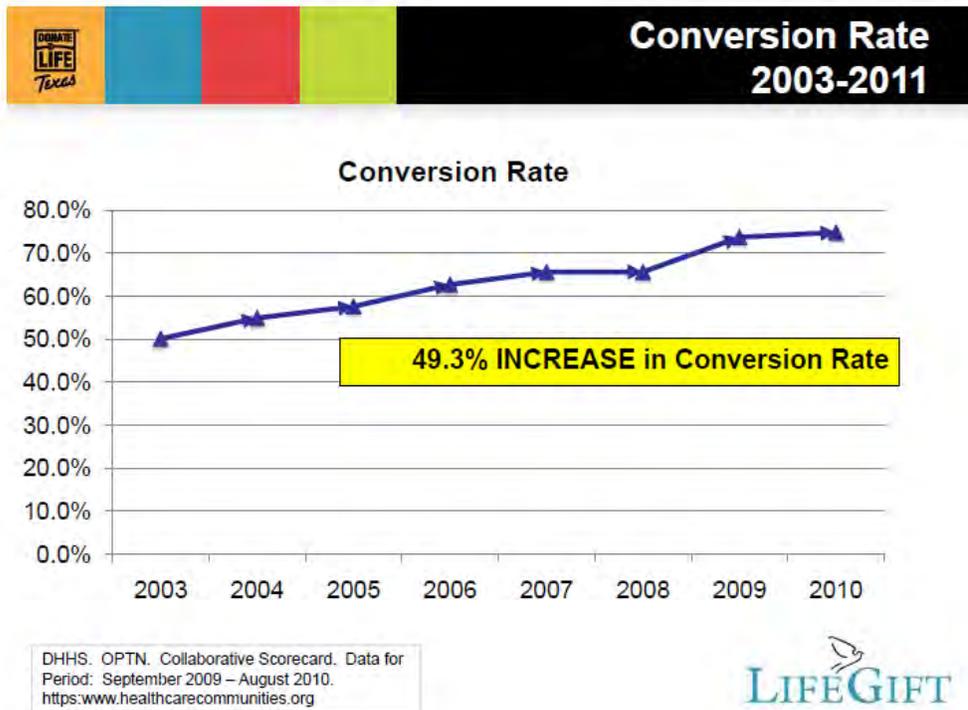


Figure 5.

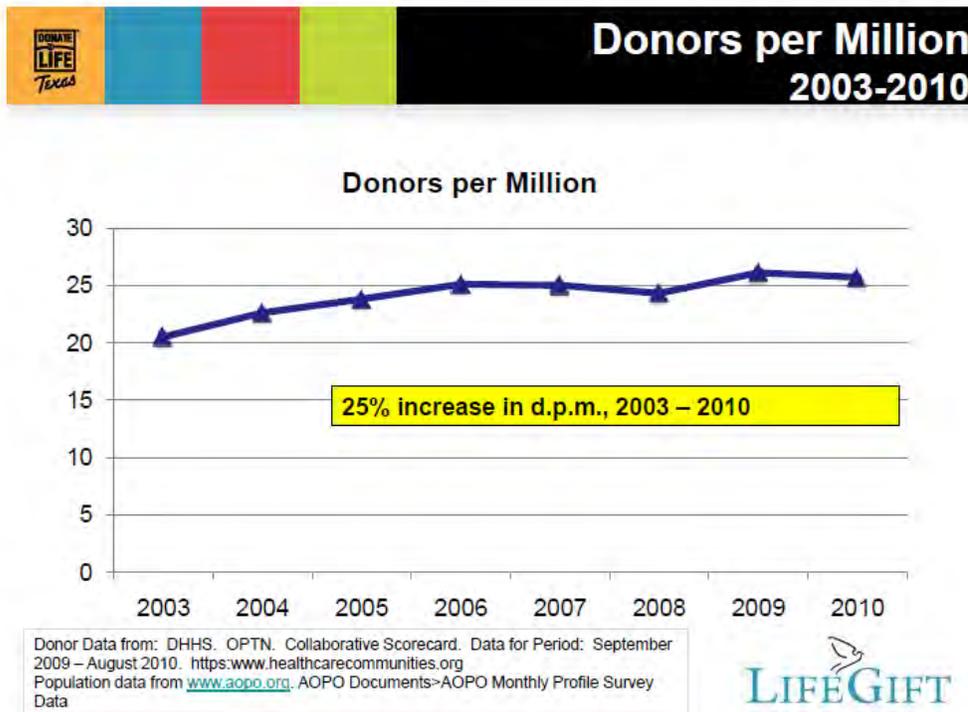


Figure 6.

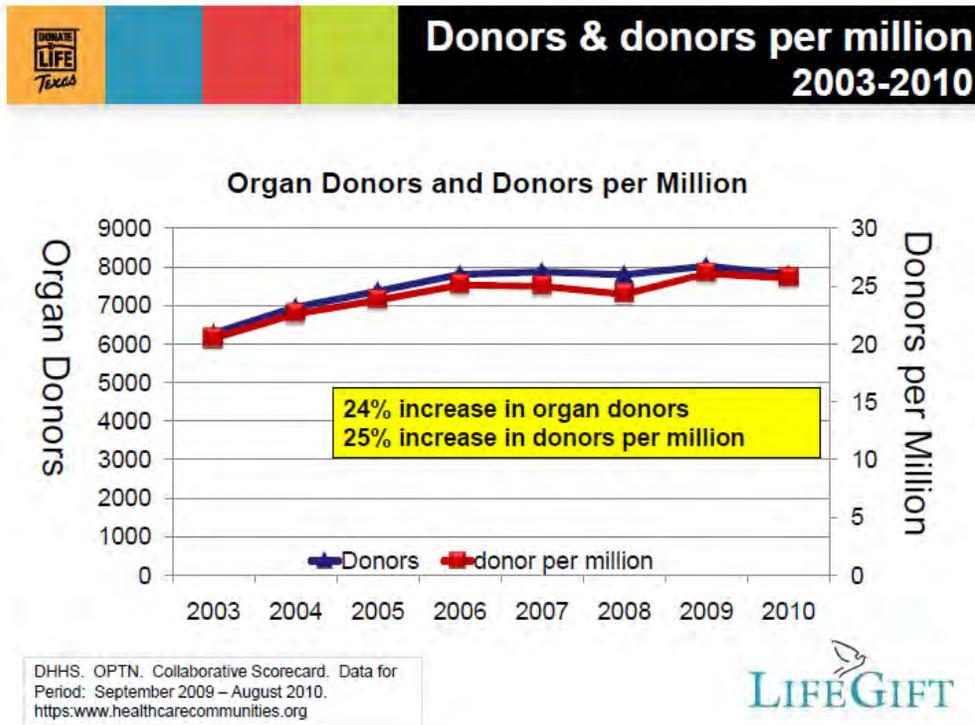


Figure 7.

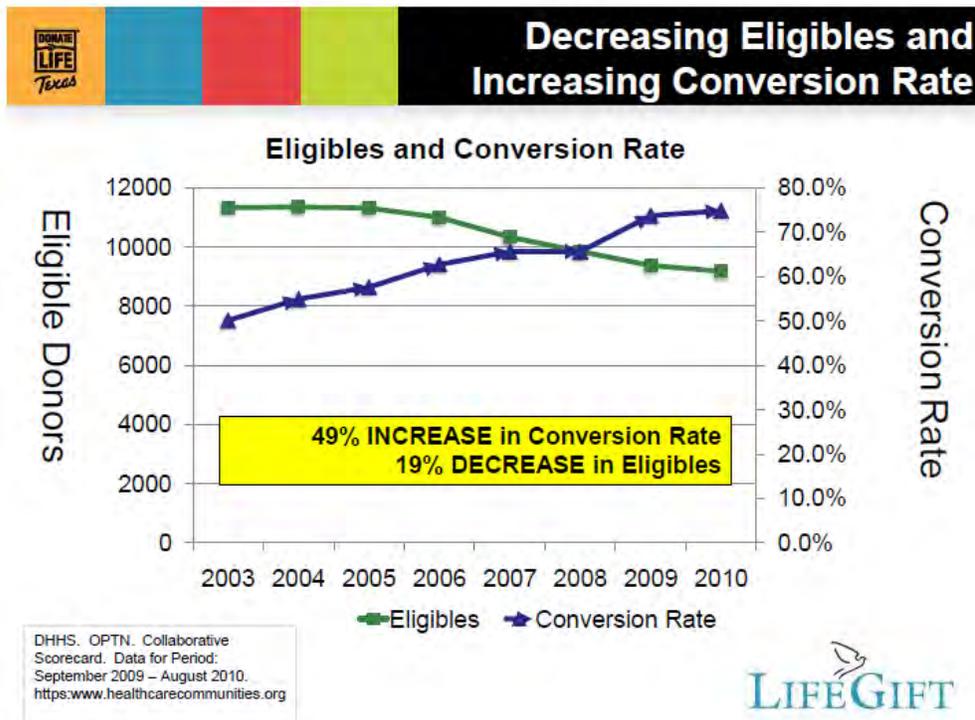


Figure 8.

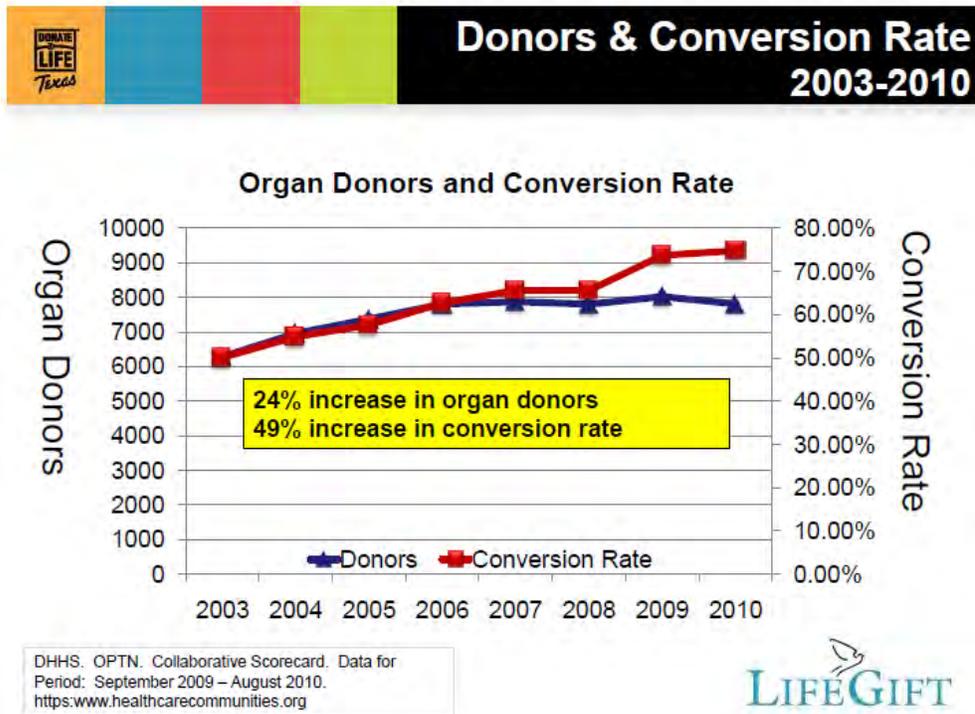


Figure 9.

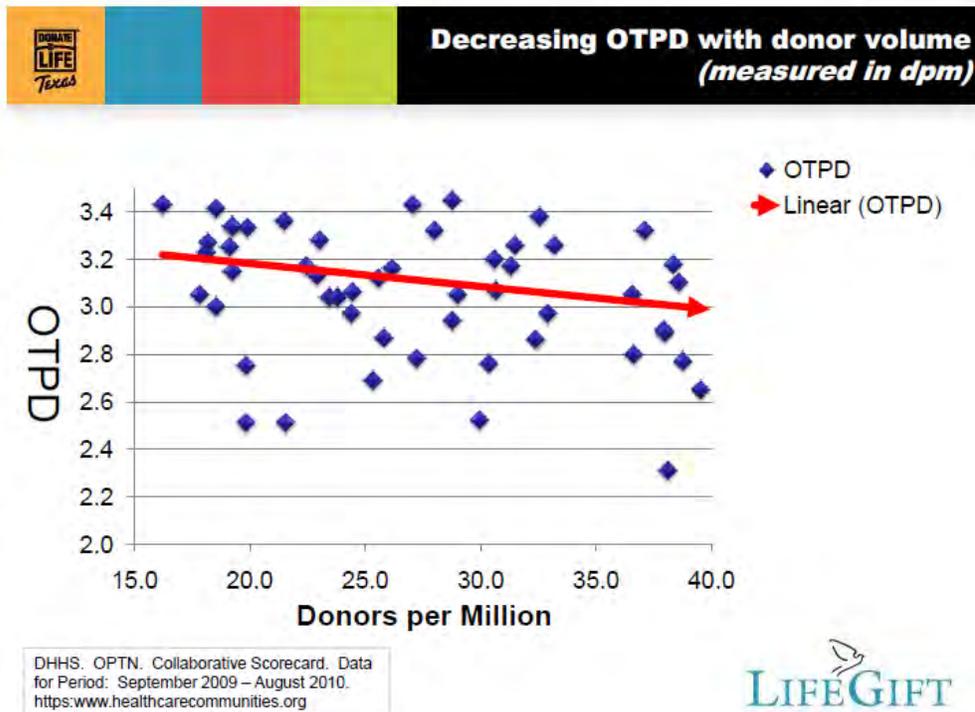


Figure 10.

**Eligible Donors do not represent the donor pool**

- Conversion rate with reported eligibles as denominator are not reliable inter-OPO (between OPOs) performance comparison metric.
- Conversion rate intra-OPO (within OPO) are useful to that OPO to observe current conversion rate against historical conversion rates, given that the OPO did not change its own definitions or measurement strategies.
- Reported Eligibles do not represent the U.S. donor pool, *but we behave as if they do.....*
  - *While there are other problems with the eligible definition, the first step in the wrong direction was excluding donors from the pool who were not officially pronounced dead.....*



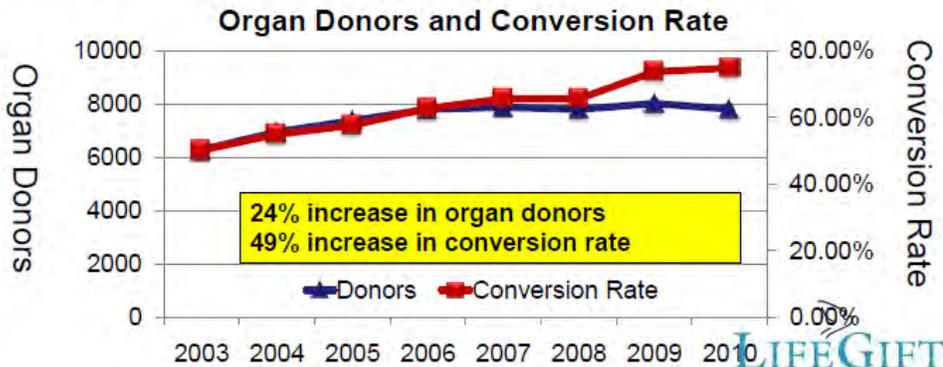
Figure 11.

**An Unsustainable Trend & a need for Renewed Focus**

This is the trend that is not sustainable,- for our patients or for our credibility.....

We can't transplant conversion rate, we can only transplant organs, and sadly, a volume metric is missing from the CMS Outcome Measures.

You get more of what you measure.....and there is no volume metric in the CMS outcome measures.....



**Committee Response:** The title referenced in this proposal is merely the title of the Proposal document. The MPSC agrees that other metrics could also be valuable tools in evaluating OPO performance and will continue to consider additional metrics as developed. For more details in response to your concerns, please see **Section 2: Primary Public Comment Concerns/Questions**, including potential new metrics to analyze pre-transplant performance of transplant programs, including waiting list mortality, transplant rates, and acceptance rate reviews.

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**Comment 10:**

*vote: Oppose*

*Date Posted: 02/08/2011*

Some of this will be captured with your data analysis, however with healthcare as it is, hospital management post admission but (pre)-clinical triggers will have an impact on organ perfusion issues. The other is the acceptance of organs....if your own center has declined, others do follow. If the list is exhausted without placement (& mgmt was acceptable), the OPO has little control over them, but will now be accountable for the 'outcome?' Fully support improvement, but may need to consider other public health data available for the area. Another concern, if I have a referral, but is not an ideal donor...don't pursue. Now is not a donor, does not show at all to count one way or another, and my center is doing a great job....not really. This could be one more dis - incentive to be aggressive in 'every' or 'any' organ every time (my 40 yo smoking dialysis pts) and 'it's all about the ones'. Feel there is a need to examine 'referrals' to get the true OPO performance and then look at OPTD.

**Committee Response:** Please see **Section 2: Primary Public Comment Concerns/Questions** for details in response to your comments.

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**Comment 11:**

*vote: Oppose*

*Date Posted: 01/23/2011*

The great weakness in this proposal is that the greatest determinant of transplantable organs, donors/all deaths in the DSA, is left unreported. There are wide variations in the classification of donor potential, all dependent on self reported data. The OPO's with the lowest organ yield /donor are some of the highest performing OPO's in total number of transplantable organs recovered ( i.e., PADV). This metric places under scrutiny those organizations that pursue every organ donor regardless of yield and rewards those OPO'S that refuse to pursue marginal donors or under report donor potential. An OPO that refuses to pursue DCD's or ECD's, but has good organ/donor yield from SCD's would be an exemplary program under this metric, despite the fact that the donors/ all hospital death rate would be below that of England. There has to be some metric that focuses on the number of donors/ donor potential not reliant on self reported data.

**Committee Response:** Please see **Section 2: Primary Public Comment Concerns/Questions** for details regarding additional measures of OPO performance.

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**Comment 12:**

*vote: Oppose*

*Date Posted: 03/02/2011*

The model does not really solves the problem, maybe it improves yield. What we need a much broader reforms. Iran 'Regulated Paid Model', yes this is the only country where there are no Kidney wait list. <http://cjasn.asnjournals.org/content/1/6/1136.full.pdf+html>

**Committee Response:** The Committee reminds you that it is currently illegal under US law to pay for organs.

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**Comment 13:**

*vote: Oppose*

*Date Posted: 03/11/2011*

The quest to find a true measure of OPO performance is elusive at best. The currently model proposed by the MPSC may be an improvement but I have serious reservations with the model. In order for an OPO to be responsive to a measure, there must be real time feedback. The reporting of a two year cohort advanced each six months may, better reflect the OPOs true potential but can also conceal an evolving trend. In order to be responsive the OPOs will need access to real time data to detect and respond to evolving trends. Before the MELD/PELD system was adopted for liver allocation, the status of patients waiting for a liver was self reported by the transplant centers, could not be independently validated and we suffered through endless discussions of gaming the system. The proposed system for OPO evaluation appears to be based on self reported data with no independent validation. There are broadly divergent methods for reporting eligible even with what some would consider a clear definition. If OPOs are to be evaluated based upon their performance relative to other OPOs then the data must be independently submitted or at least independently validated. As long as the metric includes Organs Transplanted per Donor (OTPD), a very real though unintended consequence may be a decrease in donors and organs available for transplantation. If an OPO has a marginal OTPD will they continue to pursue the marginal donor? A fifty-five year old donor with CAD, ARDS and acute renal failure would be an SCD with one organ recovered. Would an OPO with a dangerously low OTPD pursue that donor? I think not and that liver would be lost. As was made clear in the paragraph titled Description of Intended and Unintended Consequences, although the MPSC intends to use the metrics as process improvement tools, they can not control their use by other outside regulatory agencies. Considering the range and scope of unintended consequences, I can not currently embrace the plan as proposed by the MPSC. I recommend further refinement prior to implementation with the above considerations in mind to avoid worsening the currently unacceptable organ shortage.

**Committee Response:** Please see **Section 2: Primary Public Comment Concerns/Questions** for details regarding data integrity, additional measures of OPO performance, and availability of a tool for real time analysis.

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**Comment 14:**

*vote: Oppose*

*Date Posted: 03/17/2011*

While the University of Wisconsin Hospital & Clinics (UWHC) Transplant program is supportive of having performance measurements established for organ procurement organizations, we have serious concerns with the model that is currently being proposed. The following is a brief summary of these concerns: 1. Lack of Adequate Organ Function Measurements We understand that the data currently in the proposed model, represents covariates only that had a statistical significance on the

outcome of organs recovered and transplanted. Although other covariates may not have statistical significance, we feel strongly that these factors are important and should still be included in the model. Specifically those characteristics include: Ejection fraction and cardiac enzymes for Heart organs; Tbili/AST/ALT and liver biopsy results (if available) for Liver organs; Number/amount of inotropic medication; Abnormal chest x-ray, chest trauma or if a chest tube has been inserted is important for Lung organs; Biopsy results for Kidney organs (if available); While infection is included in all of the organ models with the exception of pancreas, we believe it should also be included in the pancreas model; In addition, H1bA1C and the history of cigarette use should be included and the history of diabetes and insulin dependence would rule-out the use of a pancreas organ. In addition, there are other factors are excluded from the heart model that are included in others. Donor cardiac history (MI, stenting, CABG, other open heart surgery), history of cancer, history of cocaine use ever, history of heavy alcohol use, HBV positive, and HCV positive are all factors incorporated into the decision of accepting a heart organ. 2. Accuracy of Data Reports It is critical that the data released be accurate and we ask how is the data being verified for accuracy? In the proposed model documents sent to the University of Wisconsin Organ Procurement Organization (UW OPO), there was an error in the calculation of the heart organ yield as the calculation included the Donation after Cardiac (DCD) donor deaths. If this information is released to the public and performance evaluated based upon this data, there is no room for inaccuracies and this is not acceptable. 3. Intended Use of Data As we have unfortunately experienced first-hand, the data reports for transplant programs are reviewed by the Centers of Medicare & Medicaid (CMS) and outside payors. For transplant, business decisions are being made based upon these metrics that have a negative impact on patient population when their transplant program is no longer accepted by a payor. Thus, we must anticipate that the proposed model will be viewed by regulatory agencies and other organizations that could possibly result in unintended consequences. For example, OPOs could begin using this data for comparative purposes to show themselves as a better performer while diminishing the collaborative efforts of increasing organ donation across the nation as a whole. In addition, there is a possibility that OPOs could modify their practices to accommodate this model to ensure that they are doing well with the performance measures, while inadvertently decreasing the number of organs recovered. Specifically, if a high-risk donor has the potential of discarded organs, the OPO may choose not to recover organs from this donor. In summary, we respectfully asked that the proposed model be re-visited and consideration of these concerns be given.

**Committee Response:** Please see **Section 2: Primary Public Comment Concerns/Questions** for detailed responses to concerns raised.

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**Comment 15:**

*vote: Support*

*Date Posted: 03/08/2011*

-Encourage development of donor calculator as soon as possible - Continue to reinforce that OPO Performance is one metric of DSA performance

**Committee Response:**

A calculator to determine the expected yield based on donor characteristics will be made available prior to implementation of the metric.

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**Comment 16:**

*vote: Support*

*Date Posted: 02/04/2011*

Agree with need for performance metrics and these appear to be valid and the process simple to make operational. However, it only assesses organ yield, which is dependent on transplant center practice as well as OPO performance. Center practice varies by DSA tremendously. What it doesn't do is measure the number of donors / population which is based on consent and conversion rates. These are measures of OPO performance that are not transplant center dependent. This should be added, and if it cannot be based on OPTN data collection inadequacies I am concerned that this proposal will become a bureaucratic mess in which the OPO and transplant center will trade "blame". We do need a measure to assess OPO performance, however; especially in the environment in which we are considering "regionalizing" allocation of adult liver grafts.

**Committee Response:** Please see **Section 2: Primary Public Comment Concerns/Questions** regarding additional measures of OPO performance.

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**Comment 17:**

*vote: Support*

*Date Posted: 01/24/2011*

As a Transplant Administrator, I am very supportive of this Proposed Model for Assessing the Effectiveness of Individual OPOs. Standardizing these measures and increasing the transparency of outcomes will only enhance our ability to provide opportunities for the patient populations that we serve.

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**Comment 18:**

*vote: Support*

*Date Posted: 01/22/2011*

Excellent plan. Should be implemented.

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**Comment 19:**

*vote: Support*

*Date Posted: 02/08/2011*

Fully support the recommendations of the MPSC

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**Comment 20:**

*vote: Support*

*Date Posted: 01/27/2011*

I feel this is a worthy effort, to finally find a means to evaluate OPOs using uniform data assessments. However there was little said about classification of potential or actual donors. For example, use of ECD or DCD will necessarily reduce the yield of organs/donor. OPOs that aggressively utilize these donors may then be penalized if not factored into the equations. I would also like to see if there is any correlation between donor organ utilization and eventual recipient outcomes, to assess whether overzealous placement of marginal organs to benefit OPO performance is associated with a negative outcome on the recipient side.

**Committee Response:** Please see **Section 2: Primary Public Comment Concerns/Questions** for details regarding additional measures of OPO performance.

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**Comment 21:**

*vote: Support*

*Date Posted: 01/31/2011*

I think it is extremely important that OPOs be held accountable to minimum standards as are the rest of us in the transplant community. However, we are experiencing an unintended consequence of this proposal. Our OPO, Lifenet, underperforms in terms of pancreas retrievals. Lifenet's solution was not to try and work with the transplant programs. Instead, they informed us that they planned on offering all KPs that weren't used locally out for national allocation so that the OPO would have improved pancreas allocation numbers. This would force the local kidney programs to accept payback kidneys (which are never as good as a KP donor kidney). This has temporarily been put on hold due to the outrage of the local kidney programs. Consequently, I think the oversight of this proposal should include making sure OPOs are not doing weird things to make their numbers look good.

**Committee Response:** The MPSC utilizes peer review to evaluate performance. The members of the MPSC will have more than this metric available for their consideration when reviewing an OPO. The Committee appreciates your concerns and support.

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**Comment 22:**

*vote: Support*

*Date Posted: 01/30/2011*

I would like to see a best practices model made available to those OPOs that are found to be less effective. To tell the OPO they are not effective does not provide the tools necessary to remedy the situation. Possessing a degree in Philanthropic Studies, I know of several different approaches that could be standardized and distributed to OPOs in order to facilitate their own best practices.

**Committee Response:** In the future, it is the Committee's intent to identify and disseminate best practices from OPOs that are performing better than expected. This was the purpose for using a two-sided p-value, to identify both over and underperformers with the hope of sharing best practices. The process of MPSC peer review includes providing feedback to the identified programs and OPOs that may benefit from intervention to improve performance.

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**Comment 23:**

*vote: Support*

*Date Posted: 01/30/2011*

It is about time that OPO performance are measured and compared to some standards - this might help increase the donor pool to some degree.

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**Comment 24:**

*vote: Support*

*Date Posted: 03/15/2011*

On behalf of CORE, we support the proposed implementation of this statistical model to analyze OPO performance. We believe that this model will produce much more accurate data because it

utilizes a comparison of observed (actual) to expected organs transplanted per donor (yield) based upon donor specific characteristics in each DSA and the fact that it will be used in aggregate (for all organs) in addition to organ specific performance measures, and predicts how many organs would have been recovered and transplanted if the OPO performed at the level of the national average for donors with similar characteristics.

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**Comment 25:**

*vote: Support*

*Date Posted: 02/24/2011*

OTPD is a function of both the OPO and the transplant programs within a range (distance) that makes organ utilization feasible. When measuring OTPD, it is important to bear in mind that DSA geographic areas (size) and logistics (population density, location and number of local transplant programs, and number of non-local transplant programs in proximity) vary widely, and that this is a limiting factor on an OPO's ability to place organs - especially outside of its "local" service area. For example, fully 50% of the US population resides within 500 miles of Pittsburgh PA (according to the Pittsburgh Visitors Bureau) yet less than 10% of the US population resides within 500 miles of Seattle WA. By extension, the density of transplant programs and patients waiting "nearby" is much greater in Pittsburgh than in Seattle, so the opportunity for transplanting organs "somewhere within 500 miles" is much greater in the former location. In effect, there are OPOs located "on the mainland" that are nearly as (or more) isolated as some OPOs located on islands.

**Committee Response:** Please see **Section 2: Primary Public Comment Concerns/Questions** for details regarding geography.

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**Comment 26:**

*vote: Support*

*Date Posted: 03/07/2011*

Support with reservations: It would be best to do this on a trial basis. We do not want to overburden the OPO's. If this gets to be too much burden, changes hopefully can be made to make this agreeable to all.

**Committee Response:** Please see **Section 2: Primary Public Comment Concerns/Questions** for details regarding a pilot study of the metric.

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**Comment 27:**

*vote: Support*

*Date Posted: 01/22/2011*

The current organization of OPOs in the US is quite dysfunctional; there is no transparency as to donation rates or conversion rates. In addition, there are no consequences for under performance or direct reward for improving donation rates. Thus, the entire system needs an overhaul to provide the next generation of transplant physicians with an expanding base of donors to provide to the large number of recipients that are waiting or who die waiting for an organ transplant.

**Committee Response:** Please see **Section 2: Primary Public Comment Concerns/Questions** for details regarding future development of metrics on donation and conversion rates.

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**Comment 28:**

*vote: Support*

*Date Posted: 03/16/2011*

The Immunogenetics Laboratory supports this proposal as it extends to the OPOs the same monitoring that is applied to transplant programs in terms of performance both within the donor service area and as a comparison of OPO performance on a national basis.

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**Comment 29:**

*vote: Support*

*Date Posted: 03/17/2011*

The National Kidney Foundation endorses the Organ Procurement and Transplant Networks development of a model for assessing the effectiveness of individual OPOs that can be used to facilitate dialogue and thereby identify opportunities for improvement. We agree that this initiative will ultimately enhance OPO performance, increase the number of deceased donor organs available for transplant, and enhance the efficiency of the transplant system. On the other hand, we note that implementation will involve expansion in the scope of work of the Membership and Professional Standards Committee and the contractor for the Scientific Registry of Transplant Recipients and hope that this additional responsibility will not affect the conduct of their ongoing operations. Finally, we are pleased that Membership and Professional Standards Committee will monitor the effectiveness of the methodology annually and will consider adding additional variables to the analysis. Along that line, we suggest that the following issues could affect an OPOs ability to place organs, and might skew OPO performance metrics, and, therefore, (a) ought to be monitored as this program is implemented, and (b) should be considered for inclusion when the model is refined. Those issues include: cold ischemic time, number of times the organ has been turned down, whether or not the organ has been biopsied or pumped.

**Committee Response:** The MPSC appreciates your feedback. In **Section 2: Primary Public Comment Concerns/Questions** there are details regarding the Committee's plans for additional data points to be included in the analysis as well new metrics in development.

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**Comment 30:**

*vote: Support*

*Date Posted: 02/09/2011*

The organ specific criteria could be strengthened by adding specific organ related indicators. For example, Heart - EF; Lungs - O<sub>2</sub> challenge; Liver - enzymes. It appears creatinine is indicated on all the organ specific models and markers more indicative of certain organs would hold more validity.

**Committee Response:** Please see **Section 2: Primary Public Comment Concerns/Questions** for details regarding additional factors for consideration.

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**Comment 31:**

*vote: Support*

*Date Posted: 01/31/2011*

Very important to do this and it should be organ specific as well.

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**Comment 32:**

*vote: No Opinion*

*Date Posted: 03/18/2011*

ASHI has no comment.

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**Comment 33:**

*vote: Support*

*Date Posted: 03/18/2011*



March 23, 2011

Charles Alexander, RN, MSN, MBA, CPTC  
President  
Organ Procurement and Transplantation Network (OPTN)  
United Network for Organ Sharing (UNOS)  
700 North 4th Street  
Richmond, VA 23219

Jeff Orłowski, New York  
*President*  
Tim Brown, Arizona  
*President - Elect*  
Charles E. Wright, MD, Florida  
*Medical Advisor*  
Michael Souter, MD, Washington  
*Medical Advisor - Elect*  
Kent Holloway, Ohio  
*Secretary/Treasurer*  
Teresa Shafer, Texas  
*Member - At - Large*  
Suzanne Conrad, Iowa  
*Immediate Past-President*  
Elling Eidbo, Virginia  
*Executive Director*

Dear Mr. Alexander:

AOPO supports the "Yield Metrics" that are designed to assess one facet of OPO performance, organs transplanted per donor, by using a risk-adjusted model to compare actual to expected OTPD rates. With the understanding that there are currently no statistical models or tools for the OPTN and its responsible committees to utilize for consistent monitoring methodologies, and while there may be opportunities for improvements to this model as new data and trends become available, AOPO sees this as a large step forward. While these metrics demonstrate progress in the ongoing effort to better assess OPO performance, we strongly encourage continued discussion and development of supplementary metrics that in combination with this Yield Metric, encompass OPO performance along the entire donation continuum, from donor referral to organ transplantation.

The Association of Organ Procurement Organizations (AOPO) appreciates the tremendous efforts of the many individuals and committees who have worked so hard to develop this model for donor yield. This two tail approach to a risk-adjusted model will also serve the OPOs community in its pursuit of performance improvement. AOPO also appreciates the opportunity to have many of its members contribute their thoughts and concerns during the development of this tool. Thank you for the opportunity to comment.

Sincerely,

Jeffrey Orłowski  
AOPO President

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8500 Leesburg Pike • Suite 300 • Vienna, VA 22182 • 703-556-4242 • Fax 703-556-4852

**Committee Response:** The MSPC appreciates the support of AOPO on this endeavor.

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**Comment 34:**

*vote:Support*

*Date Posted: 03/18/2011*



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March 18, 2011

Charles Alexander, RN, MSN, MBA, CPTC  
President  
Organ Procurement and Transplantation Network (OPTN)  
United Network for Organ Sharing (UNOS)  
700 North 4th Street  
Richmond, VA 23219

Dear Mr. Alexander:

On behalf of the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST), we submit the following comments in response to the Organ Procurement Organization (OPO) Committee and the Membership and Professional Standards Committee's (MPSC) proposal for the use of a statistical model to analyze OPO performance.

Philosophically, the proposed approach for assessing OPO performance parallels the methodology for evaluating transplant center performance, and at least tries to build in consideration of the donor characteristics. But it seems unlikely that this new methodology for "flagging" potentially substandard OPOs would solve the underlying issue of misaligned OPO and Transplant Center Conditions of Participation (CoP) for Medicare. Since the model is necessarily populated with historical data, and since individual OPO data is compared with the average, the model at least initially may reflect transplant centers' traditional reluctance to transplant substandard organs where there is potential to negatively impact their CMS certification. Generally, the proposal is a step in the right direction towards "risk adjustment" for OPOs, but a misalignment of OPO and Transplant Center incentives will continue to be a major issue. The following summarizes the issue and was sent to CMS Administrator, Donald Berwick, by ASTS, AST, AOPO and UNOS with a request for a meeting in an effort to elevate the issue within CMS.

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## **Transplant Center (TC) and Organ Procurement Organization (OPO) Certification Requirements Should be Modified to Reduce Organ Wastage:**

The misalignment and inconsistencies between CMS outcomes requirements for TCs and OPOs inhibit optimal organ donor strategies and contribute to organ wastage, which is a significant problem in the field of transplantation. In 2009, 3145 kidneys were procured from Expanded Criteria Donors (ECDs); 44% (1372) were discarded of which 75% were donors under the age of 65. This strongly suggests that a large number of these kidneys were potentially transplantable, with good outcomes. Such wastage is inconsistent with the national objective of increasing rates of transplantation.

This problem is exacerbated by CMS certification regulations for TCs and OPOs. CMS regulations encourage OPOs to increase the number of all types of organs from all types of donors (from ideal to marginal, brain dead or DCD). These regulations incentivize OPOs to maximize organ retrieval, without consideration of whether the organs retrieved are appropriate for transplantation or whether transplantation of these organs will result in positive patient outcomes. By contrast, TCs are required to meet stringent transplant recipient outcomes requirements, regardless of donor organ quality: Risk-adjustment methodologies are grossly imperfect and renal-centric and therefore TCs risk losing Medicare certification for accepting and transplanting organs associated with poor outcomes. *Also, TCs are penalized for not accepting and transplanting organs procured and offered to their patients, even though the TC deems the organs clinically unsuitable for transplantation into their particular patient(s).*

The OPO certification regulation not only reflect performance metrics that are inconsistent with those imposed on TCs, but also result in increased Medicare expenditures and increased overall transplantation costs. By pursuing all organs (good and bad – including marginal organs), the OPOs incur significant expenditures as a result of “dry runs” (donor team deployed, but organs not procured and therefore not transplanted), and “discards” (procured organs that are subsequently discarded, i.e. not transplanted). The costs associated with dry runs and discards are allocated to the Standard Acquisition Charge (SAC) for transplanted organs, driving increases in the SACs for transplanted organs and increasing the cost of transplantation. For Medicare beneficiaries, Medicare pays the full SAC and therefore it is CMS that ultimately incurs the additional cost. For non-Medicare beneficiaries (the majority of non-renal transplant recipients), case-rates negotiated with third party payers include the SAC paid by the TC to the OPO for the organ, and therefore the additional cost of dry runs and discards affects TC margins directly and may impact the TC’s ability to negotiate future case-rates with payers. Moreover, additional clinical costs of using marginal organs (not related to SAC; items such as increased recipient length of stay) incurred by TCs result in higher payments by both CMS and third party payers.

These inconsistencies also have resulted in misaligned incentives and therefore increased conflict between TCs and OPOs, adversely impacting the continued success of the Transplant Collaborative and other collaborative efforts.

## Potential Solutions:

### Short Term Options:

- i) Eliminate marginal organs from calculations of both “expected” and “observed” transplant outcome rates. This would require modification of risk adjustment methodologies and CMS Interpretive Guidelines (IGs), but no regulatory change. One potential downside to this solution would be that TCs might be encouraged (incentivized) to increase marginal organ transplantation, without regard to potential outcomes.
- ii) Calculate both “expected” and “observed” rates separately for standard and marginal organs. Again, this would require modification of risk adjustment methodologies and CMS IGs, but no regulatory change. One potential hurdle to this solution would be establishing the “benchmark” for marginal organs, although this could be achieved initially using retrospective data and tweaked further by prospectively analyzed data. Under this model, TC compliance with outcomes criteria would be applied to both standard criteria and marginal organs, but accreditation decisions would be heavily weighted towards standard organs.
- iii) For TCs that are not compliant with CMS outcomes criteria, “expected” and “observed” rates would be separately recalculated to determine whether standard organ outcomes fall in compliance (without consideration of marginal organ outcomes). If so, a condition level determination would not be made by CMS, and the TC would not be publically “tagged” by CMS. Instead, a remediation plan would be provided by the TC to address deficiencies in outcomes for marginal organs. This would result in the application of SRTR data for its intended purpose of remediation, and not the punitive “bright-line” test that it currently serves. Again, no regulatory change and no changes in the IGs would be needed. Instead, this would constitute a slight modification to the “mitigating circumstances” process and guidelines, in line with previous suggestions by the ASTS both during and subsequent to the public comment period.

### Long term Options:

- i) Funding for research to develop improved risk-adjustment methodologies for both standard and (especially) marginal donor and recipient variables.
- ii) Improving the informed consent process, including especially improving effective communication with potential recipients regarding the risks and benefits of accepting marginal organs, the performing center’s outcomes for both standard and marginal organ transplants, and the outcomes of other area transplant centers.
- iii) A unification of the cultures of CMS, HRSA, and the Collaborative that emphasizes a reduction in organ wastage and a focus on linking organ donation initiative metrics (OPO Performance) with transplant outcomes (TC Performance).
- iv) Allocation policy reform with a focus on reducing organ wastage and improving transplant outcomes.
- v) Revise the OPO outcomes requirements to reflect a risk-adjusted model for yield.

The ASTS and AST would also like to comment on transplant hospital representation on OPO governing boards and are therefore including the following statement.

**Joint Statement of the American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) regarding Transplant Surgeon and Transplant Physician Representation on Organ Procurement Organization (OPO) Governing Boards**

It has come to the attention of ASTS and AST that some OPOs have reduced or eliminated transplant hospital representation from their governing boards. Neither Medicare regulations nor OPTN requirements limit transplant surgeon or transplant physician representation on OPO governing boards.

The American Society of Transplant Surgeons (ASTS) and the American Society of Transplantation (AST) embrace the inclusion of community leaders, financial experts, and others with diverse content expertise on the governing boards of Organ Procurement Organizations (OPOs). Diverse perspectives on OPO governing boards enable OPOs to be better equipped to deal with a myriad of issues, develop the OPO budget, and to reach a broader sector of the community. A thorough diversity of skills and perspectives makes for a better and more effective governing board.

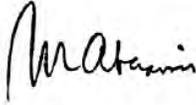
- There is no proscription of transplant surgeons and physicians serving on OPO governing boards by law (NOTA) or regulation (CMS).
- Transplant surgeons and physicians are an essential constituency and content experts for OPOs, and thus play a legitimate role on their governing boards.
- Conflicts of interest (COI) on boards such as OPO governing boards are inevitable, and they should be handled via robust, transparent, and auditable COI disclosure and management policies.
- ASTS and AST have been made aware of instances where individual OPOs have reduced or eliminated transplant surgeons and physicians from their governing boards, and consider this to be inappropriate and counterproductive to the proper discharge of OPO function.

The National Organ Transplant Act (NOTA) mandates the creation of a broadly diverse board whose responsibilities are limited to establishing procurement and other OPO policies. NOTA specifically requires that this policy-making board include a transplant surgeon from each transplant center in the OPO's service area, other physicians with particular types of expertise, and community and hospital representation.

The current OPO Medicare certification regulations and the preamble to these regulations make it clear that CMS anticipates the establishment of at least two OPO boards: The "Advisory Board", which includes surgeon and other physician representation as mandated by NOTA, and the governing board, which may or may not include transplant surgeon or transplant physician representation. In the preamble to the final OPO certification regulations, CMS specifically rejects the suggestion that representatives of transplant centers, such as transplant surgeons and physicians, be excluded from the governing board, and suggests that transplant surgeon/transplant physician/transplant center representation and community member representation on the governing board be balanced.

Neither Medicare regulations nor OPTN requirements require limitation of transplant surgeon or transplant physician representation on OPO governing boards. ASTS and AST strongly oppose any effort by OPOs to systematically remove transplant surgeons and transplant physicians from OPO governing boards or to otherwise limit their involvement in OPO governance.

Sincerely yours,



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**Committee Response:** The MPSC appreciates your support and looks forward to hearing more about developments in the alignment of measures and expectations.

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**Post Public Comment Consideration:** The MPSC identified an issue with the proposed bylaw language after the proposal was distributed for public comment. Specifically, the flagging triggers listed in the bylaws should reflect a difference between the expected and observed number of organs transplanted per 100 donors of more than 10; the language distributed for public comment stated 11 even though the intent was 10. This change was communicated for every presentation of the model, though not to the public at large.

*Board Approval Date: June 28-29, 2011*

*Implementation Date: Pending SRTR contractor programming, donor evaluator tool availability, and notice to OPTN Membership.*

*Revised Bylaw language below:*

## **APPENDIX B TO BYLAWS OPTN**

### **Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership**

#### **I. Organ Procurement Organizations.**

**A. General.** [No change to content, only to numbering convention.]

**B. Key Personnel.** [No change to content, only to numbering convention.]

**C. Plan for Public Education on Organ Donation.** [No change to content, only to numbering convention.]

**D. Communication of Information for Organ Distribution.** [No change to content, only to numbering convention.]

**E. Donation After Cardiac Death:** [No change to content, only to numbering convention.]

**F. Performance:** The Membership and Professional Standards Committee (MPSC) will evaluate all OPOs to determine if the difference in observed and expected organ yield can be accounted for by some unique aspect of the Donation Service Area and/or OPO in question. The evaluation may include a peer visit to the OPO at the OPO's expense.

Those OPOs whose observed organ yield rates fall below the expected rates by more than a specified threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC after distribution to the transplant community and subsequent Board approval.

The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

- ~~A difference of at least 11~~ More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10)

- A ratio of observed to expected yield less than 0.90.
- A two-sided p-value is less than 0.05.

All three criteria must be met for an OPO to be identified for MPSC review.

If an OPO's organ yield rate cannot be explained by donor mix or some other unique clinical aspect of the OPO or Donation Service Area in question, the Member, in cooperation with the MPSC, will adopt and promptly implement a plan for performance improvement. The Member's failure to do so will constitute a violation of OPTN requirements.

## APPENDIX B TO BYLAWS

### UNITED NETWORK FOR ORGAN SHARING

#### Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership

##### I. Organ Procurement Organizations.

**A. General.** [No change to content, only to numbering convention.]

**B. Key Personnel.** [No change to content, only to numbering convention.]

**C. Plan for Public Education on Organ Donation.** [No change to content, only to numbering convention.]

**D. Communication of Information for Organ Distribution.** [No change to content, only to numbering convention.]

**E. Donation After Cardiac Death:** [No change to content, only to numbering convention.]

**F. Inactive Status.** An organ procurement organization that is voluntarily inactive, declared inactive or withdrawn will no longer be allowed to list patients on the UNOS recipient list or to maintain a local recipient list in any form, and will not be allowed to provide organs to UNOS member transplant centers.

**G. Performance:** The Membership and Professional Standards Committee (MPSC) will evaluate all OPOs to determine if the difference in observed and expected organ yield can be accounted for by some unique aspect of the Donation Service Area and/or OPO in question. The evaluation may include a peer visit to the OPO at the OPO's expense.

Those OPOs whose observed organ yield rates fall below the expected rates by more than a specified threshold will be reviewed. The absolute values of relevant parameters in the formula may be different for different organs, and may be reviewed and modified by the MPSC after distribution to the transplant community and subsequent Board approval.

The initial criteria used to identify OPOs with lower than expected organ yield, for all organs as well as for each organ type, will include all of the following:

- ~~A difference of at least 11~~ More than 10 fewer observed organs per 100 donors than expected yield (Observed per 100 donors-Expected per 100 donors < -10)
- A ratio of observed to expected yield less than 0.90,
- A two-sided p-value is less than 0.05.

All three criteria must be met for an OPO to be identified for MPSC review.

If an OPO's organ yield rate cannot be explained by donor mix or some other unique clinical aspect of the OPO or Donation Service Area in question, the Member, in cooperation with the MPSC, will adopt and promptly implement a plan for performance improvement. The Member's failure to do so will constitute a violation of UNOS requirements.

### Exhibit A

Table 1. Overall Ordinal Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.827.

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	8	1	-8.6102	0.2014	1827.5231	<.0001
Intercept	7	1	-5.5884	0.1665	1127.1112	<.0001
Intercept	6	1	-4.4115	0.1643	720.5316	<.0001
Intercept	5	1	-3.3290	0.1631	416.4186	<.0001
Intercept	4	1	-2.0984	0.1623	167.2073	<.0001
Intercept	3	1	-0.1580	0.1621	0.9494	0.3299
Intercept	2	1	1.1047	0.1626	46.1576	<.0001
Intercept	1	1	3.1738	0.1646	371.8649	<.0001
OPO1		1	-0.00712	0.1072	0.0044	0.9470
OPO2		1	0.3150	0.0814	14.9740	0.0001
OPO3		1	0.2608	0.0581	20.1838	<.0001
OPO4		1	-0.1255	0.1149	1.1933	0.2747
OPO5		1	-0.1574	0.0483	10.6107	0.0011
OPO6		1	-0.0451	0.0914	0.2433	0.6218
OPO7		1	-0.1777	0.0862	4.2521	0.0392
OPO8		1	0.1648	0.1440	1.3111	0.2522
OPO9		1	0.2507	0.0878	8.1507	0.0043
OPO10		1	0.1211	0.0914	1.7567	0.1850
OPO11		1	0.1460	0.0793	3.3948	0.0654
OPO12		1	-0.0849	0.0820	1.0707	0.3008
OPO13		1	-0.1991	0.0693	8.2575	0.0041
OPO14		1	-0.1827	0.0585	9.7569	0.0018
OPO15		1	-0.6787	0.1702	15.8934	<.0001
OPO16		1	0.3088	0.1248	6.1239	0.0133
OPO17		1	0.7088	0.0573	153.0782	<.0001
OPO18		1	0.1445	0.0774	3.4845	0.0619
OPO19		1	-0.1745	0.0889	3.8566	0.0496
OPO20		1	-0.1646	0.0762	4.6743	0.0306
OPO21		1	0.2874	0.0633	20.5854	<.0001
OPO22		1	0.5555	0.0822	45.6751	<.0001
OPO23		1	0.2668	0.0541	24.3610	<.0001

Table 1. Overall Ordinal Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.827.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
OPO24	1	0.4444	0.0727	37.3419	<.0001
OPO25	1	-0.0593	0.0743	0.6368	0.4249
OPO26	1	-0.3276	0.1066	9.4476	0.0021
OPO27	1	0.00786	0.0639	0.0151	0.9022
OPO28	1	0.0587	0.0997	0.3469	0.5559
OPO29	1	0.1063	0.0681	2.4383	0.1184
OPO30	1	0.3013	0.1341	5.0446	0.0247
OPO31	1	0.1320	0.0733	3.2459	0.0716
OPO32	1	-0.3486	0.1404	6.1661	0.0130
OPO33	1	-0.2419	0.1242	3.7947	0.0514
OPO34	1	0.0853	0.1333	0.4095	0.5222
OPO35	1	0.1688	0.1349	1.5659	0.2108
OPO36	1	-0.0500	0.0560	0.7991	0.3714
OPO37	1	0.0662	0.1307	0.2569	0.6123
OPO38	1	0.2249	0.0869	6.7061	0.0096
OPO39	1	0.0501	0.1232	0.1653	0.6843
OPO40	1	0.2374	0.0910	6.8085	0.0091
OPO41	1	-0.5000	0.1355	13.6216	0.0002
OPO42	1	-0.5219	0.0984	28.1357	<.0001
OPO43	1	0.0763	0.0960	0.6319	0.4267
OPO44	1	0.00318	0.0491	0.0042	0.9483
OPO45	1	-0.1951	0.0662	8.6754	0.0032
OPO46	1	-0.2561	0.3165	0.6548	0.4184
OPO47	1	-0.1738	0.0715	5.9109	0.0150
OPO48	1	-0.1549	0.0638	5.8966	0.0152
OPO49	1	-0.1681	0.1156	2.1173	0.1456
OPO50	1	-0.3240	0.0546	35.2336	<.0001
OPO51	1	-0.2797	0.0878	10.1576	0.0014
OPO52	1	-0.0719	0.0628	1.3090	0.2526
OPO53	1	-0.0847	0.1028	0.6798	0.4097
OPO54	1	-0.1232	0.0797	2.3869	0.1224
OPO55	1	0.0513	0.0775	0.4376	0.5083

Table 1. Overall Ordinal Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.827.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
OPO56	1	0.2882	0.1014	8.0808	0.0045
OPO57	1	0.6680	0.0796	70.4000	<.0001
Organs recovered outside US	1	-0.5030	0.3262	2.3775	0.1231
Donor age	1	0.0374	0.00294	162.1055	<.0001
Age_spline25	1	-0.0911	0.00461	390.0933	<.0001
Age_spline43	1	-0.0102	0.00513	3.9834	0.0460
Age_spline55	1	-0.0554	0.00531	108.6664	<.0001
Male	1	0.1428	0.0223	40.9450	<.0001
Black (vs White)	1	0.0480	0.0316	2.3149	0.1281
Hispanic (vs White)	1	-0.0909	0.0347	6.8718	0.0088
Other race (vs White)	1	-0.0858	0.0618	1.9252	0.1653
Blood type A (vs O)	1	-0.1773	0.0222	63.9577	<.0001
Blood type AB (vs O)	1	-0.9934	0.0793	156.8312	<.0001
Blood type B (vs O)	1	-0.2701	0.0332	66.2427	<.0001
COD anoxia (vs Stroke)	1	-0.2242	0.0634	12.5230	0.0004
COD head trauma (vs Stroke)	1	0.0654	0.0604	1.1742	0.2785
COD other (vs Stroke)	1	-0.2218	0.0724	9.3895	0.0022
Circ. of death MVA (vs Natural causes)	1	0.1318	0.0505	6.8224	0.0090
Circ. of death Suicide (vs Natural causes)	1	0.1272	0.0652	3.8084	0.0510
Circ. of death Homicide (vs Natural causes)	1	0.1607	0.0678	5.6142	0.0178
Circ. of death Other (vs Natural causes)	1	0.0388	0.0321	1.4594	0.2270
Mech. of death Blunt injury	1	0.0387	0.0573	0.4555	0.4997
Mech. of death GSW (vs Stroke)	1	0.4376	0.0777	31.7438	<.0001
Mech. of death Cardio (vs Stroke)	1	-0.0534	0.0641	0.6938	0.4049
Mech. of death Asphyx (vs Stroke)	1	0.1294	0.0908	2.0311	0.1541
Mech. of death Drug (vs Stroke)	1	-0.0273	0.0836	0.1066	0.7441

Table 1. Overall Ordinal Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.827.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Mech. of death Other (vs Stroke)	1	-0.1512	0.0625	5.8534	0.0155
BMI	1	0.0865	0.00862	100.6804	<.0001
BMI_spline22	1	-0.1135	0.0178	40.6687	<.0001
BMI_spline25	1	-0.0258	0.0191	1.8150	0.1779
BMI_spline30	1	0.0152	0.0119	1.6278	0.2020
BMI missing	1	0.5173	0.1957	6.9892	0.0082
Clinical infection source: Blood (vs No infection)	1	-0.0596	0.0422	1.9964	0.1577
Clinical infection source: Lung (vs No infection)	1	0.1622	0.0255	40.4616	<.0001
Clinical infection source: Urine (vs No infection)	1	-0.0597	0.0397	2.2597	0.1328
Clinical infection source: Other (vs No infection)	1	0.0424	0.0437	0.9401	0.3323
Cigarette use	1	-0.2336	0.0254	84.4726	<.0001
Cocaine use within the last 6 months	1	-0.1234	0.0449	7.5444	0.0060
Heavy alcohol use	1	-0.2672	0.0300	79.3769	<.0001
Meets CDC high risk guidelines	1	-0.4072	0.0408	99.7383	<.0001
History of diabetes	1	-0.5164	0.0436	140.1179	<.0001
Insulin dependence	1	-0.2619	0.0643	16.5902	<.0001
History of hypertension	1	-0.4572	0.0275	276.1260	<.0001
History of cancer	1	-0.4841	0.0681	50.5956	<.0001
DCD	1	-1.9600	0.0383	2623.7252	<.0001
Cardiac arrest after brain death	1	-0.2256	0.0433	27.0971	<.0001
PO2 on FiO2	1	0.00413	0.000079	2733.1721	<.0001
PO2 on FiO2 missing	1	0.4906	0.0585	70.2198	<.0001
Hepatitis B Surface Antigen +	1	-0.9825	0.2990	10.8009	0.0010
Hepatitis B Core Antibody Positive	1	-0.4942	0.0468	111.7161	<.0001
Hepatitis C Antibody Positive	1	-2.6205	0.0577	2066.0598	<.0001
Creatinine	1	-0.4399	0.00873	2541.8058	<.0001
Creatinine missing	1	-1.2840	0.2724	22.2094	<.0001

Table 1. Overall Ordinal Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.827.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Year 2006	1	0.000167	0.0287	0.0000	0.9954
Year 2008	1	0.0237	0.0288	0.6785	0.4101
Year 2009	1	0.0918	0.0290	9.9976	0.0016

Table 2. Lung Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.897.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-4.8281	0.3024	254.8573	<.0001
OPO1	1	-0.1217	0.2032	0.3585	0.5493
OPO2	1	0.3155	0.1481	4.5343	0.0332
OPO3	1	0.2434	0.1019	5.7038	0.0169
OPO4	1	-0.2679	0.2481	1.1666	0.2801
OPO5	1	0.3675	0.0887	17.1859	<.0001
OPO6	1	0.0683	0.1712	0.1591	0.6899
OPO7	1	-0.0755	0.1586	0.2267	0.6340
OPO8	1	-0.0546	0.2881	0.0359	0.8498
OPO9	1	0.4357	0.1659	6.8980	0.0086
OPO10	1	0.00766	0.1666	0.0021	0.9633
OPO11	1	-0.4242	0.1491	8.0976	0.0044
OPO12	1	-0.00588	0.1593	0.0014	0.9706
OPO13	1	-0.2451	0.1291	3.6024	0.0577
OPO14	1	-0.4310	0.1050	16.8391	<.0001
OPO15	1	-4.2873	1.1332	14.3141	0.0002
OPO16	1	0.3449	0.2195	2.4681	0.1162
OPO17	1	1.3852	0.0983	198.7324	<.0001
OPO18	1	0.4128	0.1380	8.9527	0.0028
OPO19	1	-0.1519	0.1751	0.7520	0.3858
OPO20	1	-0.4566	0.1593	8.2133	0.0042
OPO21	1	0.1229	0.1213	1.0264	0.3110
OPO22	1	0.9812	0.1523	41.5181	<.0001
OPO23	1	0.7931	0.0976	66.0626	<.0001
OPO24	1	0.4470	0.1329	11.3196	0.0008
OPO25	1	0.2507	0.1277	3.8530	0.0497
OPO26	1	-0.0399	0.2150	0.0345	0.8527
OPO27	1	0.3091	0.1188	6.7716	0.0093
OPO28	1	-0.0569	0.1691	0.1132	0.7365
OPO29	1	0.3699	0.1233	9.0044	0.0027
OPO30	1	0.1803	0.2535	0.5057	0.4770

Table 2. Lung Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.897.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
OPO31	1	0.0206	0.1455	0.0200	0.8875
OPO32	1	-0.1393	0.2692	0.2677	0.6049
OPO33	1	0.4193	0.2303	3.3134	0.0687
OPO34	1	0.4003	0.2770	2.0893	0.1483
OPO35	1	0.1073	0.2915	0.1355	0.7128
OPO36	1	-0.2783	0.1241	5.0264	0.0250
OPO37	1	-0.1480	0.2993	0.2444	0.6210
OPO38	1	0.6098	0.1460	17.4448	<.0001
OPO39	1	-0.2096	0.2275	0.8482	0.3571
OPO40	1	0.4881	0.1646	8.7963	0.0030
OPO41	1	-0.1813	0.2409	0.5663	0.4517
OPO42	1	-0.6479	0.2120	9.3379	0.0022
OPO43	1	0.5110	0.1645	9.6520	0.0019
OPO44	1	-0.0553	0.0978	0.3196	0.5718
OPO45	1	0.5976	0.1315	20.6646	<.0001
OPO46	1	-0.3970	0.5357	0.5492	0.4587
OPO47	1	-0.1661	0.1248	1.7713	0.1832
OPO48	1	-0.3097	0.1187	6.8030	0.0091
OPO49	1	-0.2791	0.2449	1.2991	0.2544
OPO50	1	0.2646	0.0986	7.1986	0.0073
OPO51	1	-0.3131	0.1518	4.2535	0.0392
OPO52	1	-0.0550	0.1197	0.2114	0.6457
OPO53	1	-0.0905	0.2152	0.1767	0.6742
OPO54	1	-0.3933	0.1483	7.0312	0.0080
OPO55	1	0.3036	0.1384	4.8150	0.0282
OPO56	1	0.1976	0.2065	0.9154	0.3387
OPO57	1	0.3100	0.1714	3.2727	0.0704
Organs recovered outside US	1	-0.7549	0.5572	1.8354	0.1755
Donor age	1	0.0617	0.00557	122.8252	<.0001
Age_spline25	1	-0.0994	0.00837	140.9014	<.0001
Age_spline43	1	0.0130	0.00989	1.7247	0.1891
Age_spline55	1	-0.1363	0.0149	83.4920	<.0001

Table 2. Lung Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.897.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Male	1	-0.2241	0.0417	28.8315	<.0001
Black (vs White)	1	0.0125	0.0562	0.0498	0.8235
Hispanic (vs White)	1	-0.0204	0.0612	0.1117	0.7382
Other race (vs White)	1	0.0380	0.1095	0.1204	0.7286
Blood type A (vs O)	1	-0.1598	0.0411	15.1164	0.0001
Blood type AB (vs O)	1	-0.8707	0.1666	27.2974	<.0001
Blood type B (vs O)	1	-0.3977	0.0629	39.9763	<.0001
COD anoxia (vs Stroke)	1	-0.5790	0.1274	20.6466	<.0001
COD head trauma (vs Stroke)	1	-0.2542	0.1163	4.7777	0.0288
COD other (vs Stroke)	1	0.00331	0.1341	0.0006	0.9803
Circ. of death MVA (vs Natural causes)	1	-0.2519	0.0953	6.9826	0.0082
Circ. of death Suicide (vs Natural causes)	1	0.1704	0.1158	2.1644	0.1412
Circ. of death Homicide (vs Natural causes)	1	0.0915	0.1183	0.5976	0.4395
Circ. of death Other (vs Natural causes)	1	-0.0709	0.0633	1.2555	0.2625
Mech. of death Blunt injury	1	0.0310	0.1070	0.0842	0.7717
Mech. of death GSW (vs Stroke)	1	0.4704	0.1359	11.9835	0.0005
Mech. of death Cardio (vs Stroke)	1	-0.2195	0.1332	2.7133	0.0995
Mech. of death Asphyx (vs Stroke)	1	-0.0706	0.1780	0.1574	0.6915
Mech. of death Drug (vs Stroke)	1	0.0728	0.1581	0.2119	0.6453
Mech. of death Other (vs Stroke)	1	-0.3545	0.1208	8.6097	0.0033
BMI	1	0.0582	0.0157	13.7865	0.0002
BMI_spline22	1	-0.0978	0.0316	9.5569	0.0020
BMI_spline25	1	-0.0436	0.0348	1.5715	0.2100
BMI_spline30	1	0.0321	0.0244	1.7357	0.1877
BMI missing	1	-0.1241	0.4436	0.0783	0.7797

Table 2. Lung Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.897.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Clinical infection source: Blood (vs No infection)	1	-0.1742	0.0839	4.3038	0.0380
Clinical infection source: Lung (vs No infection)	1	0.1611	0.0462	12.1752	0.0005
Clinical infection source: Urine (vs No infection)	1	-0.0952	0.0784	1.4749	0.2246
Clinical infection source: Other (vs No infection)	1	0.00834	0.0844	0.0098	0.9212
Cigarette use	1	-0.7098	0.1146	38.3738	<.0001
Cigarette use within last 6 months	1	-0.3322	0.1222	7.3946	0.0065
Cocaine use	1	-0.1512	0.0639	5.5912	0.0181
Other drug use	1	-0.2304	0.0488	22.3082	<.0001
Meets CDC high risk guidelines	1	-0.5476	0.0767	50.9403	<.0001
Insulin dependence	1	-0.0681	0.1149	0.3517	0.5531
History of cancer	1	-0.2325	0.1517	2.3494	0.1253
DCD	1	-2.3110	0.1346	294.8229	<.0001
Cardiac arrest after brain death	1	-0.2394	0.0841	8.0988	0.0044
PO2 on FiO2	1	0.00869	0.000140	3879.4997	<.0001
PO2 on FiO2 missing	1	1.5110	0.1408	115.1558	<.0001
Hepatitis B Core Antibody Positive	1	-0.8812	0.1102	63.9102	<.0001
Creatinine	1	-0.1005	0.0155	42.2094	<.0001
Creatinine missing	1	-0.3878	0.5103	0.5775	0.4473
Year 2006 (vs 2007)	1	-0.1609	0.0536	9.0112	0.0027
Year 2008 (vs 2007)	1	-0.00656	0.0536	0.0150	0.9027
Year 2009 (vs 2007)	1	0.2014	0.0536	14.1423	0.0002

Table 3. Kidney Ordinal Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.856.

Parameter		DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	2	1	1.1023	0.0835	174.3468	<.0001
Intercept	1	1	1.7344	0.0841	425.5546	<.0001
OPO1		1	0.0316	0.1600	0.0391	0.8432
OPO2		1	0.2600	0.1311	3.9356	0.0473
OPO3		1	0.2700	0.0887	9.2615	0.0023
OPO4		1	0.2336	0.1698	1.8930	0.1689
OPO5		1	-0.1901	0.0682	7.7733	0.0053
OPO6		1	0.0227	0.1354	0.0282	0.8667
OPO7		1	-0.2074	0.1258	2.7192	0.0991
OPO8		1	0.1252	0.2215	0.3195	0.5719
OPO9		1	0.3638	0.1337	7.4052	0.0065
OPO10		1	0.2386	0.1355	3.0980	0.0784
OPO11		1	0.3745	0.1214	9.5235	0.0020
OPO12		1	-0.2867	0.1128	6.4557	0.0111
OPO13		1	-0.1698	0.0977	3.0170	0.0824
OPO14		1	-0.0772	0.0818	0.8902	0.3454
OPO15		1	0.0597	0.2483	0.0578	0.8100
OPO16		1	0.0567	0.1892	0.0899	0.7643
OPO17		1	0.3731	0.0846	19.4433	<.0001
OPO18		1	-0.4578	0.1057	18.7556	<.0001
OPO19		1	-0.3813	0.1216	9.8270	0.0017
OPO20		1	-0.1704	0.1091	2.4403	0.1183
OPO21		1	0.4888	0.0992	24.2934	<.0001
OPO22		1	0.2106	0.1194	3.1105	0.0778
OPO23		1	0.1267	0.0777	2.6597	0.1029
OPO24		1	0.1468	0.1087	1.8243	0.1768
OPO25		1	-0.3126	0.1049	8.8737	0.0029
OPO26		1	-0.0973	0.1533	0.4030	0.5256
OPO27		1	-0.1884	0.0930	4.1028	0.0428
OPO28		1	-0.0628	0.1475	0.1814	0.6702
OPO29		1	-0.1406	0.0952	2.1815	0.1397
OPO30		1	0.2123	0.2105	1.0167	0.3133

Table 3. Kidney Ordinal Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.856.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
OPO31	1	0.3117	0.1093	8.1318	0.0043
OPO32	1	-0.3048	0.2069	2.1702	0.1407
OPO33	1	-0.2380	0.1773	1.8025	0.1794
OPO34	1	0.0896	0.1861	0.2316	0.6303
OPO35	1	-0.0257	0.1875	0.0188	0.8910
OPO36	1	-0.00726	0.0786	0.0085	0.9264
OPO37	1	0.1031	0.1925	0.2869	0.5922
OPO38	1	-0.2388	0.1182	4.0827	0.0433
OPO39	1	0.7853	0.2332	11.3390	0.0008
OPO40	1	-0.1702	0.1300	1.7150	0.1903
OPO41	1	-0.6212	0.1826	11.5764	0.0007
OPO42	1	0.0174	0.1449	0.0143	0.9047
OPO43	1	0.1008	0.1549	0.4233	0.5153
OPO44	1	0.4536	0.0727	38.9643	<.0001
OPO45	1	-0.4381	0.0887	24.3904	<.0001
OPO46	1	0.0969	0.4952	0.0383	0.8449
OPO47	1	-0.4624	0.0972	22.6097	<.0001
OPO48	1	-0.4078	0.0874	21.7605	<.0001
OPO49	1	-0.1172	0.1602	0.5355	0.4643
OPO50	1	-0.1515	0.0773	3.8427	0.0500
OPO51	1	-0.2066	0.1274	2.6308	0.1048
OPO52	1	-0.1767	0.0895	3.8959	0.0484
OPO53	1	-0.0310	0.1574	0.0388	0.8438
OPO54	1	0.4147	0.1205	11.8444	0.0006
OPO55	1	0.1164	0.1196	0.9471	0.3305
OPO56	1	-0.1334	0.1445	0.8525	0.3559
OPO57	1	0.6855	0.1304	27.6355	<.0001
Organs recovered outside US	1	-0.5773	0.5121	1.2706	0.2596
Donor age	1	0.1132	0.00394	824.5893	<.0001
Age_spline25	1	-0.1672	0.00716	544.3762	<.0001
Age_spline43	1	0.0179	0.00767	5.4517	0.0195
Age_spline55	1	-0.0914	0.00717	162.5415	<.0001

Table 3. Kidney Ordinal Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.856.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Male	1	0.2507	0.0316	63.0006	<.0001
Blood type A (vs O)	1	-0.0732	0.0319	5.2480	0.0220
Blood type AB (vs O)	1	-0.3864	0.1074	12.9400	0.0003
Blood type B (vs O)	1	0.0427	0.0484	0.7769	0.3781
COD anoxia (vs Stroke)	1	-0.0235	0.0880	0.0716	0.7891
COD head trauma (vs Stroke)	1	-0.1504	0.0899	2.7999	0.0943
COD other (vs Stroke)	1	-0.4211	0.0977	18.5716	<.0001
Circ. of death MVA (vs Natural causes)	1	0.3621	0.0779	21.6154	<.0001
Circ. of death Suicide (vs Natural causes)	1	0.2488	0.1033	5.7998	0.0160
Circ. of death Homicide (vs Natural causes)	1	0.2466	0.1098	5.0420	0.0247
Circ. of death Other (vs Natural causes)	1	0.0936	0.0446	4.4006	0.0359
Mech. of death Blunt injury	1	0.2477	0.0888	7.7764	0.0053
Mech. of death GSW (vs Stroke)	1	0.3754	0.1262	8.8494	0.0029
Mech. of death Cardio (vs Stroke)	1	0.00783	0.0878	0.0079	0.9290
Mech. of death Asphyx (vs Stroke)	1	0.2693	0.1347	3.9993	0.0455
Mech. of death Drug (vs Stroke)	1	0.1107	0.1218	0.8262	0.3634
Mech. of death Other (vs Stroke)	1	-0.0685	0.0867	0.6234	0.4298
Clinical infection source: Blood (vs No infection)	1	-0.0570	0.0601	0.8994	0.3429
Clinical infection source: Lung (vs No infection)	1	0.1119	0.0374	8.9409	0.0028
Clinical infection source: Urine (vs No infection)	1	-0.0312	0.0551	0.3211	0.5709
Clinical infection source: Other (vs No infection)	1	0.1632	0.0626	6.7981	0.0091
Cigarette use	1	-0.1115	0.0344	10.4931	0.0012
Cocaine use	1	-0.0825	0.0498	2.7486	0.0973

Table 3. Kidney Ordinal Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.856.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Heavy alcohol use	1	0.1817	0.0429	17.9491	<.0001
Meets CDC high risk guidelines	1	-0.5121	0.0591	74.9887	<.0001
History of diabetes	1	-0.4918	0.0530	86.1032	<.0001
Insulin dependence	1	-0.6177	0.0824	56.1834	<.0001
History of hypertension	1	-0.6041	0.0356	288.5690	<.0001
History of cancer	1	-0.6958	0.0853	66.4838	<.0001
DCD	1	-0.7670	0.0504	231.1837	<.0001
Cardiac arrest after brain death	1	0.0464	0.0633	0.5381	0.4632
Hepatitis B Core Antibody Positive	1	-0.4005	0.0586	46.7359	<.0001
Hepatitis C Antibody Positive	1	-2.1729	0.0672	1045.9277	<.0001
Creatinine	1	-0.9657	0.0174	3085.2279	<.0001
Creatinine missing	1	-2.5579	0.3225	62.9000	<.0001
Year 2006 (vs 2007)	1	0.0908	0.0420	4.6805	0.0305
Year 2008 (vs 2007)	1	0.0389	0.0416	0.8734	0.3500
Year 2009 (vs 2007)	1	0.0183	0.0418	0.1917	0.6615

Table 4. Heart Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.841.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-1.9101	0.2160	78.1707	<.0001
OPO1	1	0.4334	0.1481	8.5636	0.0034
OPO2	1	0.1072	0.1132	0.8980	0.3433
OPO3	1	0.4191	0.0814	26.5296	<.0001
OPO4	1	-0.2169	0.1731	1.5709	0.2101
OPO5	1	0.1820	0.0678	7.2013	0.0073
OPO6	1	-0.0118	0.1333	0.0078	0.9296
OPO7	1	0.0701	0.1175	0.3565	0.5505
OPO8	1	0.5630	0.1972	8.1522	0.0043
OPO9	1	0.00487	0.1376	0.0013	0.9718
OPO10	1	-0.1565	0.1321	1.4039	0.2361
OPO11	1	0.2384	0.1137	4.3997	0.0359
OPO12	1	-0.3643	0.1246	8.5491	0.0035
OPO13	1	-0.3015	0.1076	7.8536	0.0051
OPO14	1	0.0364	0.0866	0.1764	0.6745
OPO15	1	-1.9859	0.4381	20.5477	<.0001
OPO16	1	0.6125	0.1703	12.9347	0.0003
OPO17	1	0.3936	0.0851	21.4077	<.0001
OPO18	1	0.2325	0.1071	4.7107	0.0300
OPO19	1	0.0530	0.1299	0.1666	0.6832
OPO20	1	-0.3306	0.1111	8.8554	0.0029
OPO21	1	0.2574	0.0912	7.9617	0.0048
OPO22	1	0.5157	0.1192	18.7187	<.0001
OPO23	1	0.3103	0.0793	15.3244	<.0001
OPO24	1	0.5851	0.1005	33.8936	<.0001
OPO25	1	-0.1908	0.1079	3.1229	0.0772
OPO26	1	-0.2890	0.1575	3.3676	0.0665
OPO27	1	0.1375	0.0903	2.3191	0.1278
OPO28	1	0.1546	0.1414	1.1947	0.2744
OPO29	1	0.3273	0.0956	11.7274	0.0006
OPO30	1	-0.2466	0.1954	1.5928	0.2069

Table 4. Heart Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.841.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
OPO31	1	0.1267	0.1110	1.3023	0.2538
OPO32	1	-0.4364	0.2119	4.2438	0.0394
OPO33	1	-0.00087	0.1807	0.0000	0.9962
OPO34	1	-0.1102	0.2188	0.2537	0.6145
OPO35	1	-0.1938	0.2215	0.7655	0.3816
OPO36	1	0.3224	0.0869	13.7659	0.0002
OPO37	1	-0.0962	0.2090	0.2117	0.6455
OPO38	1	0.5006	0.1267	15.6016	<.0001
OPO39	1	-0.2385	0.1750	1.8577	0.1729
OPO40	1	0.3372	0.1320	6.5275	0.0106
OPO41	1	-0.3930	0.1964	4.0019	0.0454
OPO42	1	-0.2280	0.1446	2.4860	0.1149
OPO43	1	-0.1489	0.1339	1.2369	0.2661
OPO44	1	0.0129	0.0730	0.0311	0.8600
OPO45	1	0.0444	0.1058	0.1764	0.6745
OPO46	1	-0.1882	0.4535	0.1722	0.6782
OPO47	1	0.3866	0.1050	13.5539	0.0002
OPO48	1	0.3549	0.0887	16.0079	<.0001
OPO49	1	-0.3374	0.1772	3.6248	0.0569
OPO50	1	-0.0497	0.0781	0.4048	0.5246
OPO51	1	-0.2609	0.1224	4.5448	0.0330
OPO52	1	0.2764	0.0898	9.4737	0.0021
OPO53	1	-0.2714	0.1389	3.8167	0.0507
OPO54	1	-0.0863	0.1189	0.5269	0.4679
OPO55	1	-0.1180	0.1067	1.2225	0.2689
OPO56	1	0.3412	0.1464	5.4284	0.0198
OPO57	1	-0.5329	0.1340	15.8259	<.0001
Organs recovered outside US	1	-0.4320	0.4677	0.8532	0.3557
Donor age	1	-0.0291	0.00371	61.5648	<.0001
Age_spline25	1	0.00368	0.00579	0.4032	0.5254
Age_spline43	1	-0.0775	0.00820	89.2567	<.0001
Age_spline55	1	-0.1411	0.0218	41.9483	<.0001

Table 4. Heart Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.841.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Male	1	0.4072	0.0332	150.5293	<.0001
Black (vs White)	1	0.0198	0.0455	0.1903	0.6627
Hispanic (vs White)	1	0.1062	0.0473	5.0271	0.0250
Other race (vs White)	1	-0.0726	0.0956	0.5771	0.4474
Blood type A (vs O)	1	-0.2851	0.0324	77.3015	<.0001
Blood type AB (vs O)	1	-1.3633	0.1382	97.2462	<.0001
Blood type B (vs O)	1	-0.3991	0.0490	66.3422	<.0001
COD anoxia (vs Stroke)	1	-0.0609	0.0961	0.4014	0.5264
COD head trauma (vs Stroke)	1	0.4365	0.0780	31.3081	<.0001
COD other (vs Stroke)	1	-0.0323	0.1045	0.0954	0.7575
Mech. of death Blunt injury	1	-0.0592	0.0759	0.6086	0.4353
Mech. of death GSW (vs Stroke)	1	0.1978	0.0831	5.6587	0.0174
Mech. of death Cardio (vs Stroke)	1	-0.6171	0.1030	35.9123	<.0001
Mech. of death Asphyx (vs Stroke)	1	-0.0927	0.1215	0.5818	0.4456
Mech. of death Drug (vs Stroke)	1	0.0777	0.1158	0.4498	0.5024
Mech. of death Other (vs Stroke)	1	-0.0708	0.0919	0.5948	0.4406
BMI	1	0.0758	0.0116	42.7324	<.0001
BMI_spline22	1	0.0196	0.0248	0.6254	0.4290
BMI_spline25	1	-0.0784	0.0281	7.7998	0.0052
BMI_spline30	1	-0.0259	0.0183	2.0021	0.1571
BMI missing	1	2.0035	0.2647	57.2835	<.0001
Clinical infection source: Blood (vs No infection)	1	-0.1639	0.0637	6.6260	0.0100
Clinical infection source: Lung (vs No infection)	1	0.2888	0.0367	62.0022	<.0001
Clinical infection source: Urine (vs No infection)	1	-0.0597	0.0624	0.9164	0.3384
Clinical infection source: Other (vs No infection)	1	0.0412	0.0657	0.3941	0.5301
Cigarette use	1	-0.2433	0.0412	34.7996	<.0001

Table 4. Heart Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.841.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Cocaine use within the last 6 months	1	-0.2253	0.0625	13.0023	0.0003
Other drug use	1	-0.0625	0.0365	2.9402	0.0864
Meets CDC high risk guidelines	1	-0.5121	0.0591	74.9887	<.0001
History of diabetes	1	-0.7349	0.0802	83.9028	<.0001
History of hypertension	1	-0.5227	0.0465	126.2477	<.0001
Cardiac arrest after brain death	1	-0.1531	0.0631	5.8849	0.0153
PO2 on FiO2	1	0.00230	0.000105	480.7992	<.0001
PO2 on FiO2 missing	1	-0.2145	0.0965	4.9402	0.0262
Hepatitis B Core Antibody Positive	1	-0.7715	0.0904	72.8826	<.0001
Creatinine	1	-0.1041	0.0134	60.0897	<.0001
Creatinine missing	1	-0.5978	0.4220	2.0071	0.1566
Year 2006 (vs Year 2007)	1	-0.00474	0.0419	0.0128	0.9100
Year 2008 (vs Year 2007)	1	0.0335	0.0421	0.6303	0.4272
Year 2009 (vs Year 2007)	1	0.0541	0.0424	1.6285	0.2019

Table 5. Liver Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.784.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	0.3473	0.2421	2.0575	0.1515
OPO1	1	0.2415	0.1803	1.7939	0.1805
OPO2	1	0.1094	0.1247	0.7701	0.3802
OPO3	1	0.0978	0.0886	1.2185	0.2696
OPO4	1	-0.4269	0.1543	7.6558	0.0057
OPO5	1	-0.4140	0.0665	38.7892	<.0001
OPO6	1	-0.2373	0.1266	3.5153	0.0608
OPO7	1	-0.0104	0.1302	0.0063	0.9366
OPO8	1	-0.0102	0.2147	0.0022	0.9622
OPO9	1	-0.2123	0.1190	3.1826	0.0744
OPO10	1	0.1065	0.1380	0.5954	0.4404
OPO11	1	0.1127	0.1223	0.8498	0.3566
OPO12	1	0.6478	0.1337	23.4728	<.0001
OPO13	1	0.1323	0.1091	1.4690	0.2255
OPO14	1	0.2233	0.0949	5.5299	0.0187
OPO15	1	-0.8216	0.2147	14.6456	0.0001
OPO16	1	0.2307	0.1941	1.4135	0.2345
OPO17	1	0.1220	0.0839	2.1162	0.1457
OPO18	1	-0.1381	0.1148	1.4466	0.2291
OPO19	1	0.3302	0.1447	5.2112	0.0224
OPO20	1	0.5311	0.1334	15.8468	<.0001
OPO21	1	-0.0740	0.0903	0.6716	0.4125
OPO22	1	0.2155	0.1216	3.1431	0.0762
OPO23	1	-0.3368	0.0741	20.6473	<.0001
OPO24	1	0.3805	0.1160	10.7530	0.0010
OPO25	1	0.3419	0.1187	8.2950	0.0040
OPO26	1	-0.6716	0.1420	22.3767	<.0001
OPO27	1	0.1682	0.0963	3.0482	0.0808
OPO28	1	0.1265	0.1588	0.6343	0.4258
OPO29	1	-0.3050	0.0959	10.1156	0.0015
OPO30	1	0.5894	0.2316	6.4794	0.0109

Table 5. Liver Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.784.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
OPO31	1	-0.2080	0.1013	4.2191	0.0400
OPO32	1	0.0115	0.2037	0.0032	0.9550
OPO33	1	-0.3554	0.1715	4.2925	0.0383
OPO34	1	-0.1505	0.1802	0.6977	0.4035
OPO35	1	0.2871	0.1947	2.1738	0.1404
OPO36	1	-0.1128	0.0768	2.1575	0.1419
OPO37	1	0.0513	0.1863	0.0759	0.7829
OPO38	1	0.1661	0.1330	1.5591	0.2118
OPO39	1	-0.2834	0.1794	2.4948	0.1142
OPO40	1	-0.2349	0.1289	3.3226	0.0683
OPO41	1	-0.0997	0.2071	0.2317	0.6302
OPO42	1	-0.4098	0.1374	8.8946	0.0029
OPO43	1	-0.1004	0.1421	0.4991	0.4799
OPO44	1	-0.5470	0.0655	69.7505	<.0001
OPO45	1	-0.2978	0.0868	11.7655	0.0006
OPO46	1	0.0515	0.1337	0.1483	0.7002
OPO47	1	0.2970	0.1164	6.5136	0.0107
OPO48	1	0.1337	0.1000	1.7887	0.1811
OPO49	1	0.1903	0.1811	1.1048	0.2932
OPO50	1	-0.4944	0.0743	44.2712	<.0001
OPO51	1	0.9353	0.1761	28.1964	<.0001
OPO52	1	0.2910	0.0982	8.7776	0.0030
OPO53	1	0.1870	0.1557	1.4423	0.2298
OPO54	1	-0.2309	0.1136	4.1313	0.0421
OPO55	1	-0.3553	0.1108	10.2762	0.0013
OPO56	1	0.3336	0.1516	4.8412	0.0278
OPO57	1	0.2939	0.1148	6.5505	0.0105
Donor age	1	0.0237	0.00457	26.9135	<.0001
Age_spline25	1	-0.0665	0.00727	83.5329	<.0001
Age_spline43	1	0.0218	0.00739	8.6632	0.0032
Age_spline55	1	0.000283	0.00694	0.0017	0.9674
Black	1	0.3284	0.0480	46.7897	<.0001

Table 5. Liver Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.784.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Hispanic	1	-0.3140	0.0504	38.8229	<.0001
Other race	1	-0.0447	0.0882	0.2573	0.6120
Blood type A ( vs O)	1	-0.0420	0.0326	1.6609	0.1975
Blood type AB (vs O)	1	-0.6183	0.1068	33.5025	<.0001
Blood type B (vs O)	1	-0.2155	0.0479	20.2650	<.0001
COD anoxia (vs Stroke)	1	-0.1427	0.0447	10.1783	0.0014
COD head trauma (vs Stroke)	1	-0.0448	0.0562	0.6345	0.4257
COD other (vs Stroke)	1	-0.3612	0.0840	18.4948	<.0001
Circ. of death MVA (vs Natural causes)	1	0.2512	0.0720	12.1694	0.0005
Circ. of death Suicide (vs Natural causes)	1	0.2528	0.0788	10.2876	0.0013
Circ. of death Homicide (vs Natural causes)	1	0.2616	0.0964	7.3575	0.0067
Circ. of death Other (vs Natural causes)	1	-0.0180	0.0440	0.1675	0.6824
BMI	1	0.0768	0.0131	34.2475	<.0001
BMI spline22	1	-0.1173	0.0276	18.0597	<.0001
BMI spline25	1	-0.0308	0.0289	1.1380	0.2861
BMI spline30	1	0.00290	0.0166	0.0305	0.8613
BMI missing	1	-0.2227	0.2810	0.6279	0.4281
Clinical infection source: Blood (vs No infection)	1	0.0527	0.0605	0.7583	0.3839
Clinical infection source: Lung (vs No infection)	1	0.0883	0.0378	5.4632	0.0194
Clinical infection source: Urine (vs No infection)	1	-0.0340	0.0555	0.3749	0.5404
Clinical infection source: Other (vs No infection)	1	-0.1771	0.0608	8.4751	0.0036
Cigarette use	1	0.0689	0.0355	3.7666	0.0523
Cocaine use within the last 6 months	1	0.1504	0.0689	4.7719	0.0289
Drug use	1	0.1194	0.0403	8.7947	0.0030
Heavy alcohol use	1	-0.8208	0.0401	418.6052	<.0001
Meets CDC high risk guidelines	1	0.1354	0.0624	4.7083	0.0300

Table 5. Liver Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.784.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
History of diabetes	1	-0.3714	0.0534	48.4570	<.0001
Insulin dependence	1	0.2373	0.0800	8.7913	0.0030
DCD	1	-3.1573	0.2365	178.1880	<.0001
DCD (controlled)	1	0.9631	0.2383	16.3263	<.0001
Cardiac arrest after brain death	1	-0.1518	0.0623	5.9347	0.0148
PO2 on FiO2	1	0.00109	0.000122	80.6481	<.0001
PO2 on FiO2 missing	1	0.0399	0.0792	0.2541	0.6142
Hepatitis B Core Antibody Positive	1	-0.2223	0.0608	13.3681	0.0003
Hepatitis C Antibody Positive	1	-1.4726	0.0675	475.7061	<.0001
Year 2006 (vs 2007)	1	0.1161	0.0426	7.4292	0.0064
Year 2008 (vs 2007)	1	-0.00857	0.0418	0.0421	0.8375
Year 2009 (vs 2007)	1	0.0132	0.0422	0.0987	0.7535

Table 6. Pancreas Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.904.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Intercept	1	-3.4022	0.2600	171.2506	<.0001
OPO1	1	-1.0283	0.2122	23.4749	<.0001
OPO2	1	0.6996	0.1316	28.2628	<.0001
OPO3	1	0.1014	0.1014	0.9993	0.3175
OPO4	1	-0.1790	0.2206	0.6587	0.4170
OPO5	1	-0.2529	0.0862	8.6017	0.0034
OPO6	1	-0.1218	0.1725	0.4989	0.4800
OPO7	1	-0.0905	0.1447	0.3907	0.5319
OPO8	1	-0.3583	0.2678	1.7904	0.1809
OPO9	1	0.7888	0.1578	24.9743	<.0001
OPO10	1	0.1754	0.1599	1.2027	0.2728
OPO11	1	0.5439	0.1344	16.3747	<.0001
OPO12	1	-0.3309	0.1601	4.2736	0.0387
OPO13	1	-0.2435	0.1294	3.5389	0.0599
OPO14	1	-0.2932	0.1098	7.1281	0.0076
OPO15	1	0.4920	0.3094	2.5283	0.1118
OPO16	1	0.0577	0.2162	0.0712	0.7896
OPO17	1	1.1282	0.1005	126.1024	<.0001
OPO18	1	1.1080	0.1257	77.7376	<.0001
OPO19	1	-0.3869	0.1613	5.7525	0.0165
OPO20	1	0.1217	0.1296	0.8813	0.3479
OPO21	1	0.1273	0.1181	1.1606	0.2813
OPO22	1	0.6161	0.1537	16.0739	<.0001
OPO23	1	0.1659	0.1044	2.5287	0.1118
OPO24	1	0.5994	0.1252	22.9196	<.0001
OPO25	1	-0.7642	0.1489	26.3356	<.0001
OPO26	1	-0.1296	0.1834	0.4994	0.4797
OPO27	1	-0.0200	0.1157	0.0300	0.8625
OPO28	1	0.2289	0.1690	1.8338	0.1757
OPO29	1	0.1989	0.1209	2.7049	0.1000
OPO30	1	0.7348	0.2214	11.0195	0.0009

Table 6. Pancreas Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.904.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
OPO31	1	0.00919	0.1351	0.0046	0.9458
OPO32	1	-0.9266	0.2928	10.0181	0.0016
OPO33	1	-1.3823	0.2907	22.6090	<.0001
OPO34	1	0.5943	0.2579	5.3113	0.0212
OPO35	1	-0.00976	0.2913	0.0011	0.9733
OPO36	1	0.0619	0.1158	0.2858	0.5929
OPO37	1	-0.4575	0.2910	2.4711	0.1160
OPO38	1	0.5726	0.1568	13.3251	0.0003
OPO39	1	0.4427	0.2031	4.7521	0.0293
OPO40	1	1.6352	0.1565	109.2339	<.0001
OPO41	1	0.4422	0.2187	4.0885	0.0432
OPO42	1	-1.2246	0.2130	33.0644	<.0001
OPO43	1	-0.0620	0.1693	0.1340	0.7144
OPO44	1	-0.3349	0.1014	10.9141	0.0010
OPO45	1	-0.4502	0.1547	8.4716	0.0036
OPO46	1	-1.3858	0.5919	5.4810	0.0192
OPO47	1	-0.3184	0.1396	5.1989	0.0226
OPO48	1	-0.0816	0.1100	0.5500	0.4583
OPO49	1	-0.4954	0.2203	5.0564	0.0245
OPO50	1	-0.6926	0.1062	42.5110	<.0001
OPO51	1	-0.9722	0.1797	29.2558	<.0001
OPO52	1	-0.2999	0.1123	7.1276	0.0076
OPO53	1	-0.1688	0.1763	0.9167	0.3383
OPO54	1	-0.6197	0.1618	14.6695	0.0001
OPO55	1	0.0661	0.1305	0.2564	0.6126
OPO56	1	0.6632	0.1840	12.9900	0.0003
OPO57	1	2.2288	0.1432	242.2014	<.0001
Organs recovered outside US	1	0.1610	0.5979	0.0725	0.7878
Donor age	1	0.0492	0.00435	128.3577	<.0001
Age_spline25	1	-0.1348	0.00715	355.3983	<.0001
Age_spline43	1	-0.1276	0.0153	69.7370	<.0001

Table 6. Pancreas Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.904.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
Age_spline55	1	-0.3915	0.1482	6.9798	0.0082
Black (vs White)	1	0.0817	0.0583	1.9678	0.1607
Hispanic (vs White)	1	-0.3485	0.0603	33.3882	<.0001
Other race (vs White)	1	-0.1115	0.1185	0.8855	0.3467
Blood type A (vs O)	1	-0.2178	0.0412	27.9033	<.0001
Blood type AB (vs O)	1	-1.1688	0.1721	46.1392	<.0001
Blood type B (vs O)	1	-0.3983	0.0629	40.0820	<.0001
COD anoxia (vs Stroke)	1	-0.3174	0.1309	5.8830	0.0153
COD head trauma (vs Stroke)	1	0.0966	0.1099	0.7721	0.3796
COD other (vs Stroke)	1	-0.3615	0.1445	6.2608	0.0123
Circ. of death MVA (vs Natural causes)	1	0.0290	0.0934	0.0964	0.7562
Circ. of death Suicide (vs Natural causes)	1	0.2134	0.1130	3.5697	0.0588
Circ. of death Homicide (vs Natural causes)	1	0.2330	0.1137	4.1996	0.0404
Circ. of death Other (vs Natural causes)	1	0.0819	0.0708	1.3377	0.2474
Mech. of death Blunt injury	1	-0.1120	0.0937	1.4271	0.2322
Mech. of death GSW (vs Stroke)	1	0.1593	0.1215	1.7179	0.1900
Mech. of death Cardio (vs Stroke)	1	-0.3461	0.1399	6.1160	0.0134
Mech. of death Asphyx (vs Stroke)	1	-0.0484	0.1633	0.0880	0.7667
Mech. of death Drug (vs Stroke)	1	-0.3730	0.1583	5.5527	0.0185
Mech. of death Other (vs Stroke)	1	-0.2516	0.1214	4.2973	0.0382
BMI	1	0.1446	0.0135	114.4288	<.0001
BMI_spline22	1	-0.2646	0.0293	81.6544	<.0001
BMI_spline25	1	-0.0224	0.0362	0.3825	0.5363
BMI_spline30	1	-0.0586	0.0325	3.2441	0.0717

Table 6. Pancreas Binary Logistic Regression Model for OTPD. Based on donors for whom at least one organ was procured for the purpose of transplantation from January 1, 2006 - December 31, 2009. Model c-statistic = 0.904.

Parameter	DF	Estimate	Standard Error	Wald Chi-Square	Pr > ChiSq
BMI missing	1	2.4099	0.3178	57.5116	<.0001
Cocaine use	1	-0.2370	0.0624	14.4059	0.0001
Heavy alcohol use	1	-0.5362	0.0654	67.2554	<.0001
Meets CDC high risk guidelines	1	-0.7854	0.0735	114.2323	<.0001
History of hypertension	1	-0.5783	0.0755	58.7207	<.0001
History of cancer	1	-0.5814	0.2016	8.3143	0.0039
DCD	1	-2.1367	0.1020	438.7877	<.0001
PO2 on FiO2	1	0.00151	0.000128	139.4888	<.0001
PO2 on FiO2 missing	1	0.1670	0.1256	1.7674	0.1837
Hepatitis B Core Antibody Positive	1	-1.2738	0.1635	60.6985	<.0001
Creatinine	1	-0.4729	0.0283	279.0535	<.0001
Creatinine missing	1	-1.2108	0.5747	4.4386	0.0351
Year 2006 (vs Year 2007)	1	0.0435	0.0526	0.6825	0.4087
Year 2008 (vs Year 2007)	1	0.0453	0.0536	0.7157	0.3976
Year 2009 (vs Year 2007)	1	0.0228	0.0542	0.1763	0.6745