Membership & Professional Standards Committee Overview

July 2010 – June 2011





### MPSC Projects 2010-2011 As approved by the Board

 OPO Performance Metrics – Completion of publication of initial model, dissemination to broader community improvement, use by MPSC for OPO evaluation [Board approved 6/28/11]

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 [Board approved 6/28/11]





# **MPSC Projects 2010-2011 (2)**

 Develop criteria for Directors of Liver Transplant Anesthesiology [Board approved 6/28/11]

Develop and consider use of pre-transplant program performance metrics for flagging [in development]

Modify bylaws related to flagging methodology [in development]





# **MPSC Projects 2010-2011 (3)**

- Revise bylaws to better define "transplant hospital" and "transplant program" [in discussion]
- Develop qualification criteria for Pediatric Organ Transplant Program approval [in discussion]
- Develop and implement Intestinal Transplant Program requirements in conjunction with the Liver and Intestinal Transplantation Committee [in development]





# **MPSC Projects 2010-2011 (4)**

 Review bylaws pertaining to program certification, and key personnel for currency and relevance [To be addressed during Phase 2 of the bylaws rewrite].

Create a pathway for kidney transplant programs to qualify with a primary kidney physician that has completed a transplant nephrology research fellowship. [To be addressed during Phase 2 of the bylaws rewrite]





# **Subcommittees & Work Groups**

- Work Group CPM
- Joint Work Group OPO Performance Metrics
- Joint Subcommittee (MPSC, LDC, LI/INT, Peds) formed to review LD donor surgeon requirements for currency
- Various center specific work groups.





# Committee Activity June 2010 to 2011

- Due Process Proceedings:
- 13 Interviews
- **Application Related:**
- 317 key personnel change applications approved (TXC, Lab, OPO).
- 2 new institutional transplant centers approved.
- 14 new programs (including LD components)
- 3 new hospital based labs
- 2 new business members





## **Review of LD Adverse Events**

Policy 12.8.4 Mandatory Reporting of Living Donor Adverse Outcomes to OPTN Initiated on July 1, 2006

As of 6/09/2011

Total Living Donor Kidney Cases Registered 56

- 44 deaths (6 deaths assoc with surgery, 3 suicide)
- **8** listed for transplant (3 tpl, 3 still listed, 2 no longer listed)
- 2 placed on dialysis, recovered kidney function
- 2 medical intervention to repair kidney after 5+ years

Total Living Donor LiverCases Registered7

- **5** death (2 assoc with surgery, 1 suicide)
- 2 listed for transplant (both transplanted)





# MPSC Policy Compliance Subcommittee (PCSC) Activities





## Total # of Referrals from PCSC to MPSC July 2010-June 2011

Source of referrals	Total
Survey and desk review results	317
Patient safety reporting system	22
Member complaints	10
Member self-referral	19
Allocation issues	4
Peer visits	2
Failure to report Hep + vessel use	1
Data submission	1
Other	2
Total	379



![](_page_9_Picture_3.jpeg)

## MPSC Actions on PCSC Referrals July 2010 – June 2011

Request to Secretary to take action	
under Final Rule	1
Member Not in Good Standing	1
Probation	0
Reprimand	5
Warning	12
Uncontested Violation	56
Follow-up review	145
Self-Assessments	38
No Further Action/Release	118
<b>PTN</b>	

# OPO peer visits completed July 2010 – June 2011

DEQ and Membership staff assisted a total of 5 peer visits to OPOs over the past 12 month where issues required review of both policy requirements as well as operations and quality.

This is a new process that has worked well in identifying opportunities for improvement.

![](_page_11_Picture_3.jpeg)

![](_page_11_Picture_4.jpeg)

# TRANSPLANT CENTERS The top violations resulting in MPSC action (June 2010-May 2011) involved:

- Verification and documentation of UNOS donor ID prior to transplant.
- Processes related to required patient notification of a center's action to list or delist.
- Absent or inadequate attempts to inform patients of options to list with multiple centers.

![](_page_12_Picture_4.jpeg)

![](_page_12_Picture_5.jpeg)

# TRANSPLANT CENTERS (2) Top violations resulting in MPSC action (June 2010-May 2011) involved:

- Absent or inadequate documentation showing that candidates have met criteria for accruing wait time.
- Removal of candidates from all wait lists within 24 hours of transplant or death.
- Submission of follow-up forms within 14 days notification of recipient death or graft failure.

![](_page_13_Picture_4.jpeg)

![](_page_13_Picture_5.jpeg)

### OPOs and HISTO LABS Top violations resulting in MPSC action (June 2010-May 2011) involved:

- Packaging and labeling errors involving organ and tissue typing materials
- DonorNet errors in entering laboratory values/or in miscalculating lab values
- Improper reporting of DonorNet data and donor information resulting in incorrect match runs
- Errors in laboratory reporting of histocompatibility results to OPOs, or incorrectly reporting data analysis into UNet.

![](_page_14_Picture_5.jpeg)

![](_page_14_Picture_6.jpeg)

# Performance Analysis & Improvement Subcommittee (PAIS) Activities

![](_page_15_Picture_1.jpeg)

![](_page_15_Picture_2.jpeg)

## **PAIS: Year in Review**

- Jul 2010: 131 reviews: 110 programs for outcomes, 21 programs for inactivity
- Dec 2010: 124 reviews: 106 programs for outcomes, 18 programs for inactivity
- Mar 2011: 143 reviews: 124 programs for outcomes, 18 programs for inactivity, 1 potential Category I review

Peer Visits Conducted

5 outcomes related (including 2 expedited reviews)

3 potential Category I investigations
OPTN

![](_page_16_Picture_7.jpeg)

# **New Performance Review Initiatives**

### OPO Performance Metrics

- Distributed for public comment, separate Board action item
- Modified Flagging Methodology
  - Review of existing outcome triggers and proposed new thresholds
- Pre-Transplant Performance Metrics
  - Develop metrics to trigger review for pretransplant performance

![](_page_17_Picture_7.jpeg)

![](_page_17_Picture_8.jpeg)

# **Modified Flagging Methodology**

- Review of existing outcome triggers and proposed new thresholds
  - Intent is to capture more "medium" sized programs
- Status: Evaluate if flagging methodology should be modified
  - Use in conjunction with existing flags?
  - Use with a hybrid of existing small volume flagging methodology?
- Study of metric to be conducted by PAIS 2011-2012
  OPTN

![](_page_18_Picture_7.jpeg)

# **Inactive Waitlist Focus Group**

- Review of existing bylaw requirements for patient notification of waitlist inactivation, cessation of portion of program
  - Intent to facilitate Member compliance by making it easier to understand the requirement and also making improvements to the reports

![](_page_19_Picture_3.jpeg)

![](_page_19_Picture_4.jpeg)

# **CPM Working Group Update**

![](_page_20_Picture_1.jpeg)

![](_page_20_Picture_2.jpeg)

### **Background & Motivation**

- GAO Report (2008) on oversight of transplant programs emphasized 3 severe, high profile cases of waitlist mismanagement.
- An OPTN site survey led to discovery of one of these issues.
- However, the existing (approved) OPTN / MPSC performance metrics were unable to detect the other two problems.

![](_page_21_Picture_4.jpeg)

![](_page_21_Picture_5.jpeg)

### **Current MPSC Performance Metrics**

### 1) Functional inactivity

- Zero transplants within the past 3 months triggers functional inactivity flag for Liver, Kidney programs
- Time window differs per organ type

### 2) Survival outcomes

- Graft and patient survival (1-year post transplant, 2.5 year cohort)
- Observed versus expected graft failures (or patient deaths)
- Flag if
  - O/E > 1.5
    - P-Value < 0.05 (one-sided)

### **OPTN**

O-E > 3

![](_page_22_Picture_12.jpeg)

### **Existing Performance Metrics were Insufficient...**

![](_page_23_Figure_1.jpeg)

#### Functional Activity

This program was performing just enough transplants to avoid functional activity flagging.

#### Survival Outcomes

This program's posttransplant survival metrics were better than expected, never approaching the flagging threshold.

![](_page_23_Figure_6.jpeg)

### **Risk-Adjusted, Pre-transplant Metrics (SRTR)**

### Waitlist mortality rates

- Observed vs. Expected deaths on the waitlist
- Adjusted for candidate age, ethnicity, gender, primary diagnosis, ABO, time on the waiting list, and medical urgency status (LI).

#### Transplant rates

- Observed vs. Expected transplants
- Adjusted for candidate ABO, age, previous transplant, medical status (LI), peak PRA (KI), and time on the waiting list, using a Cox model.

### Acceptance rates (organ and offer-based)

- Observed vs. Expected accepts
- Adjusted for donor & candidate covariates such as age, COD, serum creatinine, candidate diagnosis. Also adjusted for size of waitlist.
- Excludes all "marginal" or hard-to-place organs.

![](_page_24_Picture_11.jpeg)

![](_page_24_Picture_12.jpeg)

### **Pre-transplant Metrics for a High Profile Program**

![](_page_25_Figure_1.jpeg)

#### Waitlist Mortality Rates

Waitlist mortality was higher than expected during the trouble period, though not quite statistically significant.

#### Transplant & Acc Rates

Transplant rates were extremely low (p<0.05), as were (crude) organ acceptance rates.

![](_page_25_Figure_6.jpeg)

## What is the CPM?

- CPM = Composite Pre-transplant Metric
- Combines SRTR's risk-adjusted <u>mortality rates</u>, <u>transplant rates</u>, and <u>acceptance rates</u> into a single measure.
- An "aggregate, pre-transplant O/E ratio"
  - CPM > 1 Worse than expected
  - CPM = 1 Neutral value, equals national experience
  - CPM < 1 Better than expected
- Initially just for liver and kidney programs

![](_page_26_Picture_8.jpeg)

![](_page_26_Picture_9.jpeg)

# **Overarching Goal of CPM**

- To identify opportunities for process improvement in waitlist management
  - Detect outlier (liver or kidney) programs that may be severely under serving their waitlisted patients
  - Identify best practice programs
  - A tool to aid MPSC/PAIS decision-making

![](_page_27_Picture_5.jpeg)

![](_page_27_Picture_6.jpeg)

### Using the CPM...

CPM Distribution Among Kidney Programs

(Based on July 1, 2008 - June 30, 2009 Data)

![](_page_28_Figure_3.jpeg)

The CPM was developed to identify programs that *may* have waitlist management issues that warrant further investigation – not as a definitive indication that a problem actually exists.

![](_page_28_Picture_5.jpeg)

![](_page_28_Picture_6.jpeg)

### Retrospective CPM Distribution Reveals High Profile Program to be an Outlier During Troubled Period

![](_page_29_Figure_1.jpeg)

![](_page_29_Picture_2.jpeg)

OPTN

## **CPM Summary**

- Pre-transplant metrics are needed to provide a more complete picture of program performance.
- The CPM is a tool designed to help identify potential problems and best practices in W/L management.
- The MPSC is studying the merits of this approach as a potential complement to posttransplant outcomes and other means of performance monitoring.

![](_page_30_Picture_4.jpeg)

![](_page_30_Picture_5.jpeg)

### **CPM Working Group Activities**

- Group has been meeting since late 2009 to explore various aspects of CPM:
  - Effect of geography
  - Effect of program size
  - Pediatric vs. adult programs
  - Differences in kidney vs. liver programs
  - Correlation with existing flagging measures

![](_page_31_Picture_7.jpeg)

![](_page_31_Picture_8.jpeg)

### **CPM Working Group Activities**

### Awareness campaign for CPM / pre-tx metrics:

- ATC (oral presentation) May 2011
- Transplant Management Forum (poster) April 2011
- Upcoming UNOS e-Newsletter & Update articles
- Frequently asked questions (FAQ) document
- Upcoming 12-month study/evaluation project for CPM.
  - Survey focused on pre-transplant processes & performance, to be sent to sample of kidney and liver programs
  - Results should help further evaluate the utility of the CPM, and where to set flagging threshold(s)

![](_page_32_Picture_9.jpeg)

![](_page_32_Picture_10.jpeg)

### **CPM Implementation Timeline**

- Release new bylaws for public comment (Fall 2012)
- 2. Present proposal to BOD (June 2013 ?)
- 3. Incorporate CPM and pre-tx metric flagging into bylaws and MPSC process (pending Board approval, notice, programming)

![](_page_33_Picture_4.jpeg)

![](_page_33_Picture_5.jpeg)

# Proposal to include Qualifications for Director of Liver Transplant Anesthesia in the Bylaws

UNOS Bylaws, Appendix B, Attachment 1 (Designated Transplant Program Criteria), Section XIII (Transplant Programs), subsection D,3 (Liver Transplantation).

# Sponsored by the MPSC

![](_page_34_Picture_3.jpeg)

![](_page_34_Picture_4.jpeg)

# **Objective**

This proposal would require liver transplant programs to designate a Director of liver transplant anesthesia with expertise in the area of peri-operative care of liver transplant patients who could serve as an advisor to other members of the team.

### The new bylaw language will:

- Designate the appropriate board certification for the position.
- Describe certain administrative and clinical responsibilities that should be handled by the Director; and
- Suggest minimum qualifications needed for the position.

![](_page_35_Picture_6.jpeg)

![](_page_35_Picture_7.jpeg)
#### **Background - Collaborative Approach**

- Started in 1999 with inquiry from the American Society of Anesthesiology (ASA).
- Referred to MPSC and the LI & IN TX Committee
- OPTN/UNOS recommended ASA form Ad Hoc advisory Committee on LI TX Anesthesiology to formulate proposal
- Anesthesiologist added to MPSC.
- Input received from Anesthesiologists on program application forms (in use now)
- ASA presented proposed requirements to MPSC
- MPSC Work Group refined the proposal with input from ASA and ASTS representatives.





#### **Background - Collaborative Approach (2)**

- Proposal based on peer reviewed papers demonstrating that liver transplant programs have better outcomes when they utilize an anesthesiologist experienced in liver transplantation.
- Univ. of Wisconsin study\* suggests dedicated anesthesia team -
  - Reduces the need for blood transfusions & mechanical ventilation during & after surgery
  - decreases patient time spent in OR, ICU, Hospital

\* <u>Liver Transpl.</u> 2009 May;15(5):460-5.





## **Summary of Proposal**

#### Required Elements

- Submit name of the director and evidence that shows that they have expertise in the area of peri-operative care of liver transplant patients and can serve as an advisor to other members of the team; and
- Document certification by the American Board of Anesthesiology or its foreign equivalent.

#### Recommended Elements

- Administrative Responsibilities
- Clinical Responsibilities
- Qualifications





#### Implementation

- Does <u>not</u> require additional data collection in UNet<sup>sm</sup> as currently proposed.
- LI programs will be asked to verify info currently on file for Directors of LI TX Anesthesiology.
- New program applications already contain relevant Director questions.





# **Public Comment Tally**

Public·Comment·Response·Tally								
Туре	Response- Total	In·Favor	In·Favor·as· Amended	Opposed	No-Comment			
Individual·Comments	37	28 (75.68%)	NA	5·(14.51%)	4·(10%)			
<b>Regional</b> ·Comments	11	10 (90.9%)	1.(9.1%)	0	0			
Committee Comments	13	5.(38.4%)	1.(7%)	1.(7%)	<mark>6·(47.6%)</mark>			





## **Summary of Comments**

Am. Board of Anesthesiology does not accept any type of foreign training for board certification.

- Barrier to new programs, small programs, & Pediatric programs.
- Will become Key Personnel with associated responsibilities.
- Need more clinical data to show benefit.





#### Resolution

\*\* 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.





Proposal to Modify the Requirements for Transplant Hospitals that Perform Living Donor Kidney Recoveries

Bylaws, Appendix B, Attachment I, Designated Transplant Program Criteria, Section XIII. Transplant Programs.

Sponsored by the MPSC





# **Objective**

Align the bylaws pertaining to surgeons who perform living donor kidney recoveries with current practice.





# Background

- 2004 Board approved initial LD program bylaws
- 2005 Began program approval for LD Liver
- 6/06 Federal Register notice giving OPTN authority over living donation transplants
- 9/07 Board approved new bylaws providing guidelines for LD evaluation & consent
- 2008 Began approval process for KI programs performing LD transplants.
- 2009 Formed MPSC Joint Work Group to review bylaws for currency





#### Open versus Laparoscopic Recoveries for Living Donor Kidney Transplants, by Year, 2000-2008

	Procedure-Type¤						
•¤	Missing¤		Open¤		Laparoscopic¤		Total¤
	N¤	%¤	N¤	%¤	N¤	%¤	N¤
<ul> <li>Date-Organ-Recovered¤</li> </ul>							
2000¤	18¤	0.3¤	2,804¤	51.0¤	2,677¤	48.7¤	5,499¤
2001¤	31¤	0.5¤	2,343¤	38.8¤	3,668¤	60.7¤	6,042¤
2002¤	24¤	0.4¤	1,868¤	29.9¤	4,348¤	69.7¤	6,240¤
2003¤	35¤	0.5¤	1,529¤	23.6¤	4,909¤	75.8¤	6,473¤
2004¤	122¤	1.8¤	1,171¤	17.6¤	5,354¤	80.5¤	6,647¤
2005¤	71¤	1.1¤	953¤	14.5¤	5,547¤	81.1¤	6,571¤
2006¤	3¤	0.0¤	754¤	11.7¤	5,679¤	88.2¤	6,436¤
2007¤	6¤	0.1¤	574¤	9.5¤	5,462¤	90.4¤	6,042¤
■2008¤	2¤	0.0¤	451¤	7.6¤	5,517¤	92.4¤	5,970¤
Total¤	312¤	0.6¤	12,447¤	22.3¤	43,161¤	77.2¤	55,920¤

**OPTN** 



## **Summary of Proposed Changes**

This proposal will align the requirements with current practice. The need for a LDK transplant [recovery] program to qualify an open donor nephrectomy surgeon in addition to a laparoscopy surgeon will be eliminated. The laparoscopy surgeon will be considered qualified to perform both LDK recovery procedures.





#### **Proposed Changes (2)**

The <u>current</u> laparoscopic expertise requirement states that the surgeon must act as <u>either</u> primary surgeon or first assistant on at least fifteen (15) laparoscopic nephrectomies within the prior 5-year period.

The <u>proposed</u> amendment will further require that seven (7) of the fifteen (15) procedures must be performed just as a primary surgeon.





# **Proposed Changes (3)**

- Amend requirement to allow surgeon qualifying for open LDK procedure to meet the ten (10) required open donor nephrectomies without having to be done within the most recent 5 yr period (current)
- Remove language requiring the availability of both open & lap qualified surgeons when performing a laparoscopic nephrectomy. Mandatory conversion coverage no longer applicable. OPTN



#### **Proposed Changes (4)**

This proposal <u>adds</u> language that specifies that the donor procedure log included with LDK applications for primary surgeons must identify the type of procedure as open or laparoscopic.





#### Implementation

- The current proposal should not require any changes to the current Membership Database or its associated reports. Changes can be accommodated until Chrysalis is finished.
- OMB approved application forms will need to be modified.
- Hospitals should review the qualifications of the listed primary surgeons, and the coverage plans.





## **Public Comment Tally**

Public·Comment·Response·Tally								
Туре	Response- Total	In·Favor	In·Favor·as· Amended	Opposed	No-Comment			
Individual·Comments	25	16 (64%)	0	9 <mark>·(</mark> 36%)	0			
Regional·Comments	11	10 (90.9%)	0	1.(9.1%)	0			
Committee Comments	6	6.(100%)	0	0	15			





#### **Summary of Comments**

- Experience with deceased donor kidney recovery is not comparable to experience with living donor open nephrectomy.
- Use term "minimally invasive" rather than laparoscopic.
- Increase number of procedures required.
- Need to address kidney paired donation.
- Change "transplants" to "recoveries" and "hospital" to "recovery hospital"





### Resolution

\*\*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.





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

OPTN & UNOS Bylaws, Appendix B, Section I (Organ Procurement Organizations)

Sponsored by the MPSC & OPO Committee





## **Objective**

The MPSC recommends implementing 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.





### Background

- Joint work group began developing metrics with the SRTR in 2008.
  - OPTN/UNOS Board of Directors Initiative
- Extensive discussions regarding model covariates
- 2 AOPO presentations and an OPTN sponsored educational forum convened in 2010





#### **Background cont.**

The MPSC will use the model to identify OPOs for organ specific yield as well as aggregate performance

Predicts the number of organs that would have been recovered and transplanted if the OPO performed at the level of the national average for donors with similar characteristics.





- Overall Organs Transplanted Model (up to 8 organs per donor)
  - Ordinal Logistic Regression model
    - Adjusts for <u>donor</u> factors that impact yield
    - Observed (Actual) vs. Expected format
    - Statistical significance based on a 2-sided pvalue





#### Organ specific yield models

- Ordinal Logistic Regression model
  - Kidney
- Logistic Regression model
  - Liver
  - Heart
  - Pancreas
- Lung (expected number of organs from donors that had at least one lung
   OPTN transplanted)



## Assessment of Organ Yield Models

- C-statistic measures the accuracy of model predictions
  - Clinically useful c-statistic is > 0.7
- Overall model c-statistic=0.83
- Organ-specific models c-statistics range from 0.78 – 0.90





#### Outputs

- Number of donors
- Observed number of organs transplanted
- Expected number of organs transplanted
  - Based on the case mix of the donors recovered and what would be expected based on the US experience
- Observed/Expected
  - Absolute ratio of observed organs transplanted to expected organs transplanted
    - O/E = 1.10 this OPO transplants 10%

**OPTN** more organs than would be expected NOS **THE** 

- Outputs continued
  - Two sided p-value
    - Measure of statistical significance p<0.05 considered significant
  - Observed Yield per 100 Donors
    - The number of organs transplanted per 100 donors The number of donors the OPOs recover varies
  - Expected Yield per 100 Donors
- The number of organs that would be expected to be transplanted from this OPO per 100 donors recovered

#### Outputs continued

- Expected Observed per 100 Donors
  - How many more or fewer organs does this OPO transplant than would be expected based on their case mix (per 100 donors)
    - E per 100 O per 100 = 25
      - This OPO transplanted 25 fewer organs per 100 donor than would be expected
      - In 25% of their donors they transplanted 1 fewer organ than would have been expected





### **Clinical Significance**

Is the statistically significant difference actually clinically significant?

- How large of a difference warrants MPSC intervention?
- What thresholds should be set for determining clinical significance?





#### **Performance Measures**

3 potential performance measures were considered:

- Absolute ratio of observed to expected organs transplanted: O/E
- Difference in observed and expected organs transplanted per 100 donors: E per 100 – O per 100
- Absolute difference in organs transplanted E O
  - Irrespective of number of donors





### **Clinical Significance Thresholds**

#### 3 potential performance measures

- 1) Absolute ratio of observed to expected: O/E
  - A \_\_\_\_% difference in the observed number of organs transplanted compared to the expected number raises to the level of concern by the MPSC. (is it 5%? 10%?, \_\_\_%?)
  - Choice: 10%
  - Translates to an O/E ratio of 0.90 indicates 10% below expected is cause for concern





#### **Clinical Significance Thresholds**

#### 3 potential performance measures

- 2) Difference in organs transplanted per 100 donors: Expected per 100 – Observed per 100
  - An OPO that is getting 1 fewer organ from \_\_\_% of their donors is a concern for the MPSC. (is it 10%? 20%? 25%? \_\_\_%?)
  - Choice: 10%
  - E per 100 O per 100 > 10





## **Clinical Significance Thresholds**

#### 3 potential performance measures

- 3) Absolute difference in organs transplanted: Expected - Observed
  - What is the actual difference in organs (regardless of the number of donors procured by the OPO)
  - OPO yield may be significantly below expected: what difference is clinically relevant?
  - Choice: Not chosen





## Flagging Methodology

- The MPSC will use clinical relevance in addition to statistical significance triggers to identify OPOs for further inquiry.
  - Flagging is a method to begin dialogue, not intended to be punitive

The same flagging methodology will be used for both the organ specific and the aggregate models





## **Flagging Methodology**

- 2 year cohort, advanced every 6 months
   P-Value < 0.05 statistical significance threshold
- Ratio of observed to expected yield < 0.90 (O/E < 0.9)</p>
- Difference of more than 10 between expected and observed organs transplanted per 100 donors

 Based on either the overall model or any of the organ-specific models
 OPTN


# **Flagging Results**

- Based on time period: 2008-2009
- Overall Model
  - 4 OPOs "flagged"
- Organ Specific Models
  - Kidney 1 OPO (not already flagged)
  - Liver 1 OPO (already flagged)
  - Heart 2 OPOs (already flagged)
  - Lung 1 OPO (already flagged)
  - Pancreas 4 OPOs (2 already flagged)





## **Implementation & Monitoring**

 MPSC, through the Performance Analysis & Improvement Subcommittee (PAIS), will begin using the metric to identify OPOs that meet the flagging threshold

 Will follow similar processes in use for monitoring transplant program performance.





## An OPO Is Flagged, Now What?

#### Once an OPO is flagged, the MPSC will send a survey of inquiry

 Personnel, Board composition and involvement, DSA & geographic factors, allocation and practice patterns, collaboration with hospitals, internal reviews





#### An OPO Is Flagged, Now What? continued

PAIS may request additional information throughout the course of the review, including:

- Submission of protocols
- Participation in an informal discussion to interact directly with the PAIS
- Participation in peer visit





# An OPO Is Flagged, Now What?

If the OPO fails to demonstrate a plan for performance improvement or is recalcitrant in responding to inquiries/requests, the PAIS may recommend the MPSC consider taking an adverse action.





### **MPSC Review of Metric**

The MPSC will review the effectiveness of the flagging methodology annually.

Will consider modifications to the model and/or process of review based on:

- Changes in practice patterns
- If new data are collected
- Feedback from OPOs identified for review





### **Public Comment Feedback**

Recurring themes in PC feedback:

- 1. Performance influenced by factors outside of the OPOs control.
- 2. Additional factors should be included in the model.
- 3. Does not address geography, flight, weather issues.
- 4. Does not measure donor potential, consent or conversion rates.

5. Impact to OPOs that pursue marginal donors
OPTN

#### **Public Comment Feedback-II**

#### Recurring themes continued:

- 6. Relies on unverified, self reported data with no standard definitions.
- 7. Should be piloted or studied prior to implementation.
- 8. Cost of new oversight.
- 9. SRTR Tool availability at implementation.

10. Use of model for purposes other than improvement.





#### **Post Public Comment Modifications**

On April 29, 2011, the MPSC voted (16-0-0) to amend the modifications to the Bylaws distributed for public comment January – March 2011.

 Corrected 1 flagging criterion to read: <u>More than 10 fewer organs transplanted than</u> <u>expected (Observed organs transplanted</u> <u>per 100 donors-Expected organs</u> <u>transplanted per 100 donors < -10</u>)





#### **MPSC Recommendation**

The MPSC recommended that the SRTR review the models for additional modifications to the analysis (not the flagging methodology) to identify potential enhancements/improvements.





#### **Proposed Resolution:**

\*\* RESOLVED, that the 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



