

Monitoring Performance of
Organ Procurement
Organization in the United
States: Observed and
Expected Donor Yield

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I have no financial relationships to disclose within the past 12 months relevant to my presentation

AND

My presentation does not include discussion of off-label or investigational use

I do not intend to reference unlabeled/unapproved uses of drugs or products in my presentation.



Background

- The OPTN Board of Directors approved monitoring the performance of organ procurement organizations (OPOs) in the US in June 2011
- Performance will be assessed biannually by the Scientific Registry of Transplant Recipients (SRTR)
- Since board approval, SRTR has been working to refine the initial models developed during the policy development phase (Messersmith et. al., Am J Transplantation 2011)

Estimating Expected Organ Yield

- The donor characteristics within each OPO must be taken into account in order to adjust the likelihood that a particular donor will yield an organ for transplant.
- The SRTR developed risk adjustment models to estimate expected organ yield for each donor from whom at least one organ was procured for transplant.
- The models predict how many organs would have been recovered and transplanted if the OPO performed at the level of the national average for donors with similar characteristic

Factors Included in the Risk Adjustment Models

Factor	Heart	Intestine	Kidney	Liver	Lung	Pancreas
Age	Y		Y	Y	Y	Y
BMI	Y			Y	Y	Y
Gender	Y		Y		Y	
Race/Ethnicity	Y			Y	Y	Y
Blood Type	Y		Y	Y	Y	Y
Cause of Death	Y		Y	Y	Y	Y
Circumstances of Death			Y	Y	Y	Y
Mechanism of Death	Y		Y		Y	Y
Clinical Infection Present	Y		Y	Y	Y	
Cigarette Use	Y		Y	Y	Y	

Factors Included in the Risk Adjustment Models

Factor	Heart	Intestine	Kidney	Liver	Lung	Pancreas
Cocaine Use	Y		Y	Y	Y	Y
Other Drug Use	Y			Y	Y	
Heavy Alcohol Consumption			Y	Y		Y
CDC High Risk Donor	Y		Y	Y	Y	Y
History of Diabetes	Y	Y*	Y	Y		Y*
Insulin Dependence		Y*	Y	Y	Y	Y*
History of Hypertension	Y		Y			Y
History of Cancer			Y		Y	Y
DCD	Y*	Y*	Y	Y	Y	Y
If DCD, Controlled?				Y		

*Indicates a conditional exclusion (transplant of this organ type is rare in donors meeting these criteria); donors meeting any of these criteria had expected organ-specific yield estimated as the national probability of yield for donors meeting these criteria.

Factors Included in the Risk Adjustment Models

Factor	Heart	Intestine	Kidney	Liver	Lung	Pancreas
Cardiac Arrest After Brain Death	Y		Y	Y	Y	
Lung pO2 terminal value	Y			Y	Y	Y
Hepatitis B Surface Antigen	Y*	Y*	Y*	Y*	Y*	Y*
Hepatitis B Core Antibody	Y		Y	Y	Y	Y
Hepatitis C Antibody	Y*		Y	Y	Y*	Y*
Serum Creatinine	Y		Y		Y	Y
Organ Recovered Outside the Contiguous 48 States?	Y		Y	Y	Y	Y

*Indicates a conditional exclusion (transplant of this organ type is rare in donors meeting these criteria); donors meeting any of these criteria had expected organ-specific yield estimated as the national probability of yield for donors meeting these criteria.

OPOs will be Evaluated on Individual Organ Yield as Well as Aggregate Yield

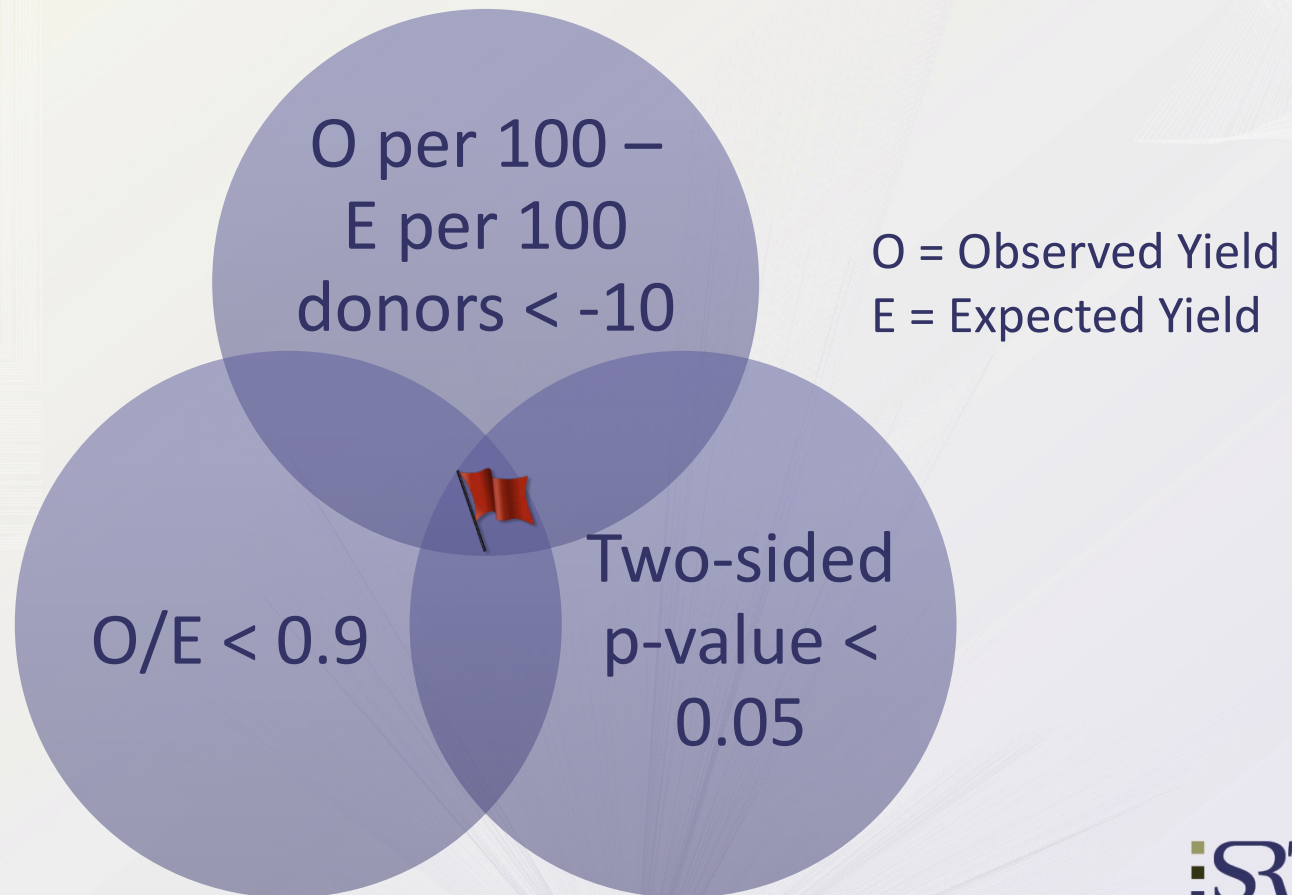
- Observed and expected yield for individual organs and aggregate yield will be evaluated:
 - Heart
 - Intestine (included in aggregate yield, but not evaluated individually).
 - Kidney (0, 1, or 2)
 - Liver
 - Lung (0 vs. >0)
 - Pancreas
 - Aggregate yield (0-7, sum of individual organ yields)

Review Criteria

- OPO performance will be assessed in 2-year cohorts, and an OPO will be reviewed if:
 - Observed yield is more than 10% lower than expected yield ($O/E < 0.9$)
 - Observed per 100 donors is more than 10 less than expected per 100 donors ($O \text{ per } 100 - E \text{ per } 100 < -10$),
AND
 - Observed is statistically significantly different from expected (2-sided $p < 0.05$)

OPO Flagging Algorithm

- Flag if all 3 criteria are met.
- Flag for each individual organ as well as aggregate yield.



How many OPO's may be flagged each review cycle? Historical Analyses:

Review Period	Heart	Kidney	Liver	Lung	Pancreas	Aggregate	Total OPOs meeting review criteria
7/1/2007-6/30/2009	2	1	1	0	2	1	6
1/1/2008-12/31/2009	1	1	2	0	3	1	7
7/1/2008-6/30/2010	1	1	1	1	1	1	5
1/1/2009-12/31/2010	1	1	1	1	2	0	6
7/1/2009-6/30/2011	2	3	1	0	2	0	8
1/1/2010-12/31/2011	2	2	0	0	2	0	6

Review Summary

- In these historical cohorts, 9%-14% of 58 OPOs met the review criteria each cycle
- This is similar to the percentage of transplant programs meeting review criteria (approximately 10% of heart, lung, liver, and kidney programs in the July 2011 review cycle)
- These results demonstrate the volume of OPOs that may be subjected to performance review as OPTN initiates monitoring

Monitoring Performance of OPOs

Questions and Answers

