Directions in Reporting Center-Specific Results

Jon J. Snyder, PhD, MS



The 12th Joint Annual Congress of the American Society of Transplant Surgeons and The American Society of Transplantation

Jon J. Snyder, PhD
Senior Epidemiologist
Scientific Registry of Transplant Recipients, Minneapolis, MN, USA

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

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

Questions about the PSRs...

Why does the SRTR produce PSRs?

What came out of the recent PSR Consensus Conference?

What are some recent developments in the PSRs?

What can we expect in the future?

Q: Why does the SRTR Produce PSRs? A: The Final Rule

"Make available to the public timely and accurate programspecific information on the performance of transplant programs. This shall include ... risk-adjusted probabilities of receiving a transplant or dying while awaiting a transplant, risk-adjusted graft and patient survival following the transplant, and risk-adjusted overall survival following listing ... These data shall include confidence intervals or other measures that provide information on the extent to which chance may influence transplant program-specific results."

OPTN Final Rule -Page 21- October 20, 1999

HRSA contract with the SRTR

- Produce PSRs no less than every 6 mo.
- Post-transplant:
 - risk-adjusted graft and patient survival
 - morbidity & functional impairment, etc.
- Waiting list probability of:
 - receiving a transplant
 - dying while waiting
 - being removed from the waiting list
- Living donor:
 - profiles (age, sex, ethnicities, comorbidities, etc.)
 - outcomes (death, re-hospitalization, etc.)

Consensus Conference on Transplant Program Quality and Surveillance

Arlington, VA February 13-15, 2012

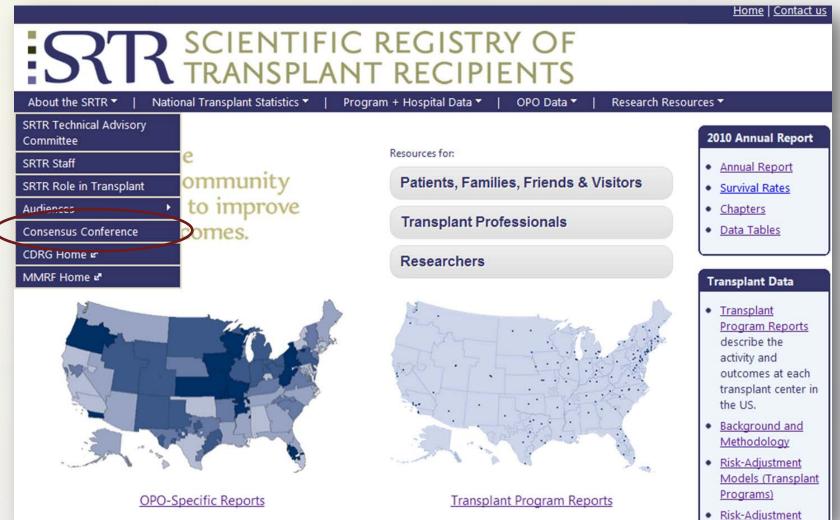


Key Questions

- What is the SRTR's mandate?
- Who uses PSRs and why?
- Are there unintended consequences?
- What can we learn from others?
- What statistical methods should we use?
- How should we adjust for risk?
- What outcomes should we use?
- What data should we collect?



PSR Consensus Conference Materials Available at www.srtr.org



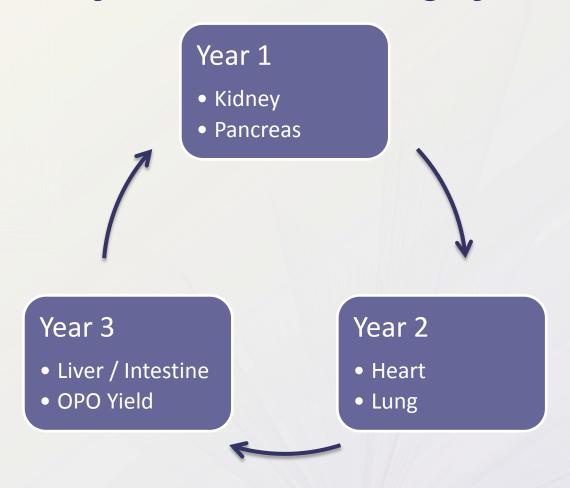


Highlighted Recommendations

- <u>I.1.</u> PSRs should be better suited to the needs of all users, particularly patients.
- I.2. Rather than refitting each model every 6 months, the time between revisions should be increased and used to more carefully review the models and data elements.
- <u>I.3.</u> The potential benefits of hierarchical and mixed effects methods should be studied.



Example of 3-year Model Building Cycle







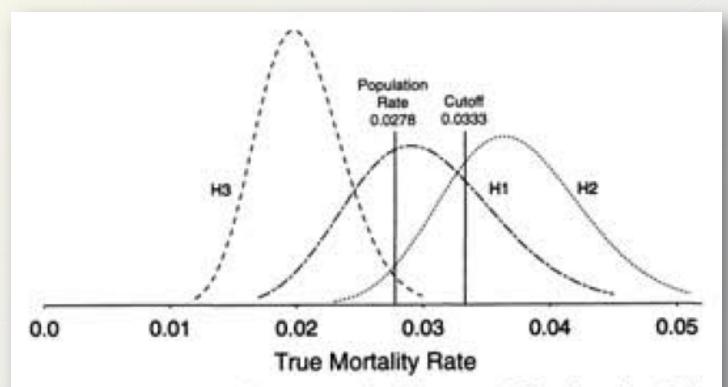


Figure 2. True mortality rate probability graphs for three hospitals (H1, H2, H3) in New York State (1). Vertical lines indicate the population rate and the chosen standard; curves represent the probability densities that determine the chance that the mortality rate at each hospital exceeded the 3.33% standard.



SRTR Action Following the Consensus Conference

Consensus Conference: 2/13 - 2/15

Reviewed the recommendations with the STAC on 2/23.

Developed a prioritized list of actions the SRTR will undertake in the coming year.

Constituting an STAC-PSR Subcommittee to oversee the SRTR's PSR development activities.



Consensus Conference Manuscript

Has been accepted for publication in AJT and is in press.

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Meeting Report

doi: 10.1111/j.1600-6143.2012.04130.x

Report of a Consensus Conference on Transplant Program Quality and Surveillance

B. L. Kasiske^{a,b,*}, M. A. McBride^c, D. L. Cornell^d,

R. S. Gaston^e, M. L. Henry^f, F. D. Irwin^g,

A. K. Israni^{a,b,h}, N. W. Metzlerⁱ, K. W. Murphy^j,

A. I. Reed^k, J. P. Roberts^l, N. Salkowski^b,

J. J. Snyder^{b,h} and S. C. Sweet^m

improvement. Additional statistical methods to assess outcomes at small-volume transplant programs should be developed. More data on waiting list risk and outcomes should be provided. Monitoring and reporting of short-term living donor outcomes should be enhanced. Overall, there was broad consensus that



What are some recent developments in the PSRs?

OPO Yield Models
Pancreas Transplant Outcomes Models



OPO Yield Monitoring

- Approved by UNOS Board of Directors on June 28, 2011.
- Flag if all 3 criteria are met.
- Flag for each individual organ as well as aggregate yield.

O per 100 – E per 100 donors < -10

O = Observed Yield

E = Expected Yield

O/E < 0.9

Two-sided p-value < 0.05



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
1/1/2009-12/31/10	1	1	1	1	2	0	6
7/1/2009-6/30/2011	2	3	1	0	2	0	8



OPO Yield Calculator Available to OPOs:

Questions in red are required fields. Donor Info Donor ID (6-character) Donor Hospital (6-character) Organ Recovered Outside the 48 Contiguous States* * Check if recovered in Hawaii, Alaska, Puerto Rico, U.S. Virgin Islands. Date of Birth month day year (yyyy) Date of Death Race Cause of Death Circumstance of Death Mechanism of Death	Clinical Information Donor Blood Type Height ft in OR cm Weight bs OR kg	Life Style Factors Cigarette Use (>20 pack-years) - Ever Yes AND Continued in Last 6 Months Yes Cocaine Use - Ever Yes AND Continued in Last 6 Months Yes Other Drug Use (non-IV) - Ever Yes Heavy (2+ drinks/day) Alcohol Use: Yes High-risk Donor (by CDC definition): Yes History of Diabetes Yes Insulin Dependence Yes History of Hypertension Yes History of Cancer Yes	Organs Actually Transplanted from this Donor Check which organs were actually transplanted from this donor: Heart Intestine Kidney I kidney I kidney Liver Lung I 1 or 2 lungs were transplanted Pancreas Total Organs Transplanted from this donor: ***This information is optional, but is necessary to compare the observed organ yield with the expected organ yield. If you do not enter the actual organs transplanted from this donor, you can enter the information later by saving the record and then manually entering the information on the "Archive" tab.
Expected or	Heart Intestine	Summary Reset Kidney Liver Lung	Pancreas



Monitoring Pancreas Transplant Outcomes

- MPSC and the Pancreas Transplantation Committee have been working with the SRTR on the development of models to evaluate pancreas transplant outcomes.
- In 2007, the Pancreas Review Subcommittee recommended having a combined SPK/PAK/PTA model to increase the statistical power of the model by increasing the number of events.
- In 2009, the subcommittee requested that the MPSC only use the 1 year patient survival model for evaluating pancreas programs and allow the committee to continue to work on the 1 year graft failure model in order to raise the index of concordance.



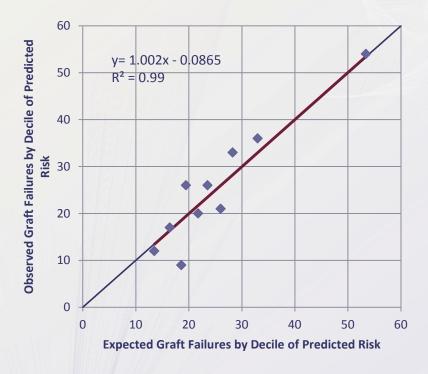
Comparison to other PSR outcomes models: C-statistics

Transplant Type	1-yr graft failure model	1-yr patient survival model
Kidney: Deceased Donor	0.659	0.706
Kidney: Living Donor	0.640	0.742
Liver: Deceased Donor	0.664	0.669
Liver: Living Donor	0.593	0.629
Heart	0.700	0.681
Lung	0.663	0.659
Proposed Pancreas Models		
Pancreas	0.654	0.682



Calibration: 1-year SPK Pancreas Graft Failure

Decile of Risk	N	Predicted Graft Failures	Observed Graft Failures
1	209	13.49	12
2	210	16.43	17
3	210	18.60	9
4	209	19.50	26
5	210	21.77	20
6	210	23.55	26
7	209	26.0	21
8	210	28.28	33
9	210	32.99	36
10	209	53.41	54



The Hosmer-Lemeshow test statistic (χ^2 = 10.83, p=0.21) indicated an overall good fit.



Pancreas Model Status

- Approved by Pancreas Committee on 3/14/2012.
- Approved by MPSC on 3/28/2012
- Currently programming the metrics into the SRTR's PSR development code.
- Working to provide a preview report of the combined pancreas metrics to pancreas programs shortly following this month's PSR release.
- MPSC may begin review of pancreas programs based on these results in January 2013.





PSR Conference Recommendation #1: Make the PSRs more user friendly.

- In December 2011, SRTR produced a beta version of a graphical PSR.
- Comments were sought and feedback received was largely positive.
- SRTR is producing a full graphical PSR to be release this month alongside the traditional tabular PSRs. Programs will have access to both.
- SRTR will continue to enhance this reporting format.



Current Summary Page

Program Summary

Center: Hennepin County Medical Center (MNHC)

Organ: KI: Kidney

Center Activity (07/01/2010-06/30/2011)	Center	Region	United States	Tables for More Information
Deceased donor transplants (n=number)	33	817	10,810	07C,08C,09C
Living donor transplants (n)	53	811	6,071	07L,08L,09L
On waitlist at start (n)	361	6,997	88,762	01,02,03
On waitlist at end (n)	375	7,596	93,159	01,02
Number of new patient registrations (n)	132	3,116	34,604	01,02

Waiting List Outcomes (07/01/2010-06/30/2011)				Tables for More Information
			Statistical Significance of	
	Observed	Expected	Difference	
Transplant rate among waitlist patients	0.21	0.16	Not Significantly Different (a)	03,04,05,06
Transplant rate (from deceased donors) among waitlist patients	0.09	0.12	Not Significantly Different (a)	03,04,05,06
Mortality rate while on waitlist	0.07	0.07	Not Significantly Different (a)	03,04

Post-transplant Outcomes (07/01/2008-12/31/2010)		1 Year		Tables for More Information
			Statistical Significance of	
	Observed	Expected	Difference	
Adult graft survival (based on 209 transplants) (%)	93.70	95.50	Not Significantly Different (a)	10
Adult patient survival (based on 183 transplants) (%)	95.10	97.96	Statistically Lower (b)	11
Pediatric graft survival (%)	NA	NA	NA	10
Pediatric patient survival (%)	NA	NA	NA	11



Graphical Summary Page



Center Code: Transplant Program (Organ): Kidney Release Date: January 13, 2012 SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS Based on Data Available: October 31, 2011

SRTR Program-Specific Report Feedback?: SRTR@SRTR.org 1.877.970.SRTR (7787) http://www.srtr.org

A. Program Summary

Figure A1. Waiting list and transplant activity

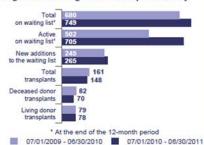


Table A1. Census of transplant recipients

Recipients	07/01/2009- 06/30/2010	07/01/2010- 06/30/2011	
Transplanted at this center	161	148	
Followed by this center*	2,174	2,185	
transplanted at this program	2,158	2,165	
transplanted elsewhere	16	20	

* Recipients followed are transplant recipients for whom the center has submitted a post-transplant follow-up form for a transplant that took place before the 12-month interval for

Figure A2. Transplant rates 07/01/2010 - 06/30/2011



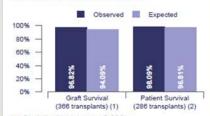
(1) Not significantly different (p=0.344) (2) Not significantly different (p=0.100)

Figure A3. Waiting list mortality rates 07/01/2010 - 06/30/2011



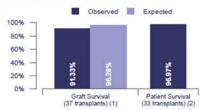
(1) Not significantly different (p=0.309)

Figure A4. First-year adult graft and patient survival: 07/01/2008 - 12/31/2010



(1) Statistically higher (p=0.026) (2) Not significantly different (p=0.246)

Figure A5. First-year pediatric graft and patient survival: 07/01/2008 - 12/31/2010



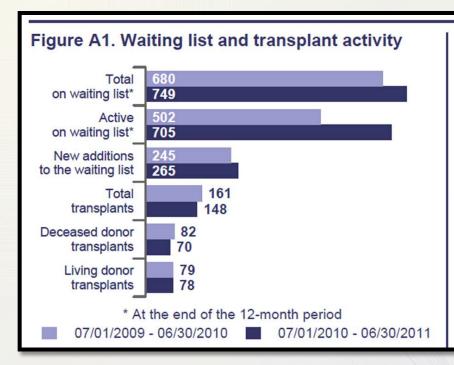
(1) Not significantly different (p=0.274)

(2) Expected patient survival was not estimated

The data reported here were prepared by the Scientific Registry of Transplant Recipients (SRTR) under contract with the Health Resources and Services Administration (HRSA).



Graphical Summary Page



07/01/2009-07/01/2010-Recipients 06/30/2010 06/30/2011 Transplanted at this center 161 148 Followed by this center* 2,174 2,185 2.158 2,165 ...transplanted at this program ...transplanted elsewhere 16 20

Table A1. Census of transplant recipients



^{*} Recipients followed are transplant recipients for whom the center has submitted a post-transplant follow-up form for a transplant that took place before the 12-month interval for each column.

Traditional Adult Graft Survival

	Graft Survival by Time since Transplant					
		This Center				
	1 Month	1 Year	3 Years	1 Month	1 Year	3 Years
ult (Age 18+)						
Transplants (n=number) ¹	209	209	203	39,063	39,063	38,602
Percent (%) of Grafts Surviving at End of P	eriod					
Observed at this Center ²	98.56	93.70	89.16	97.69	93.60	85.37
Expected, based on national experience ³	98.36	95.50	87.89			
Graft Failures During Follow-up Period						
Observed at this center	3	12	22	903	2,343	5,646
Expected, based on national experience 4	3.45	8.88	24.87	903	2,343	5,646
Ratio: Observed to Expected (O/E)	0.87	1.35	0.88	1.00	1.00	1.00
(95% Confidence Interval) 5	(0.18-2.54)	(0.70-2.36)	(0.55-1.34)			
P-value (2-sided), observed v. expected ⁶	0.999	0.370	0.654			
How does this center's survival compare to	Not Significantly	Not Significantly	Not Significantly			
what is expected for similar patients?	Different (a)	Different (a)	Different (a)			
Follow-up days reported by center (%) 7	100.0	98.3	98.2	99.9	97.6	95.8
Maximum Days of Follow-up (n)	30	365	1,095	30	365	1,095



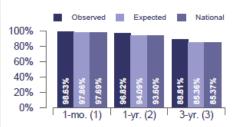


Center Code: Transplant Program (Organ): Kidney Release Date: January 13, 2012

SRTR Program-Specific Report Feedback?: SRTR@SRTR.org 1.877.970.SRTR (7787) http://www.srtr.org

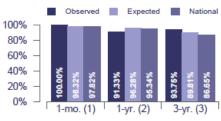
C. Transplant Metrics

Figure C1. Adult (18+) graft survival



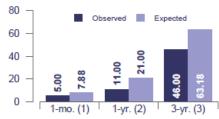
- (1) Based on 366 transplants performed 07/01/2008-12/31/2010
- (2) Based on 366 transplants performed 07/01/2008-12/31/2010 (3) Based on 411 transplants performed 01/01/2006-06/30/2008

Figure C2. Pediatric (<18) graft survival



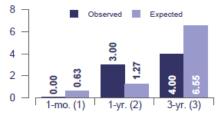
- (1) Based on 37 transplants performed 07/01/2008-12/31/2010 (2) Based on 37 transplants performed 07/01/2008-12/31/2010
- (3) Based on 64 transplants performed 01/01/2006-06/30/2008

Figure C3. Counts of observed and expected adult (18+) graft failures



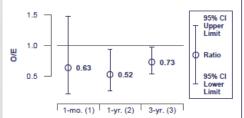
- (1) Based on 366 transplants performed 07/01/2008-12/31/2010
- (2) Based on 366 transplants performed 07/01/2008-12/31/2010 (3) Based on 411 transplants performed 01/01/2006-06/30/2008

Figure C4. Counts of observed and expected pediatric (<18) graft failures



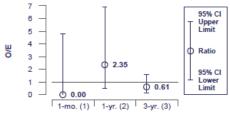
- (1) Based on 37 transplants performed 07/01/2008-12/31/2010
- (2) Based on 37 transplants performed 07/01/2008-12/31/2010 (3) Based on 64 transplants performed 01/01/2006-06/30/2008

Figure C5. Ratios of observed and expected adult (18+) graft failures



- (1) Not significantly different (p=0.405, 95% CI=[0.21, 1.48]) (2) Lower than expected (p=0.026, 95% CI=[0.26, 0.94])
- (3) Lower than expected (p=0.029, 95% CI=[0.53, 0.97])

Figure C6. Ratios of observed and expected pediatric (<18) graft failures

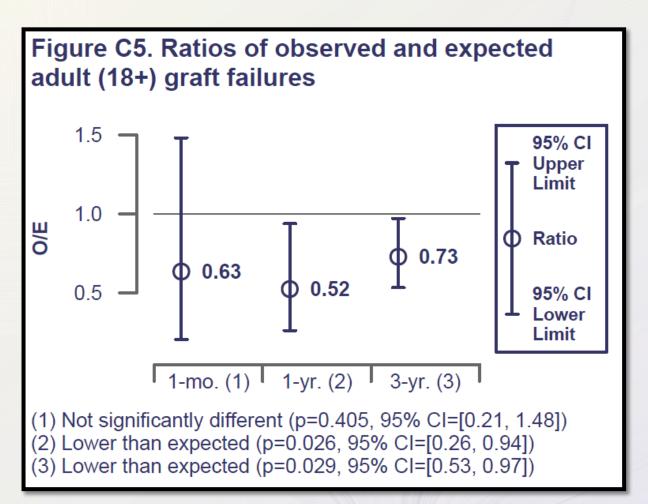


- (1) Not significantly different (p=0.999, 95% CI=[0.00, 4.77]) (2) Not significantly different (p=0.274, 95% CI=[0.49, 6.88])
- (3) Not significantly different (p=0.437, 95% CI=[0.17, 1.56])

The data reported here were prepared by the Scientific Registry of Transplant Recipients (SRTR) under contract with the Health Resources and Services Administration (HRSA).

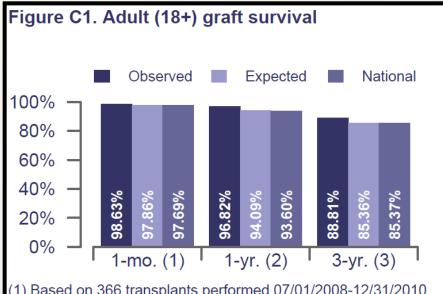


Traditional Adult Graft Survival





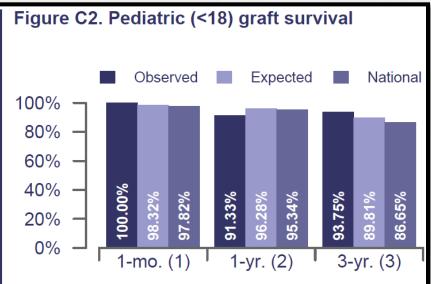
Traditional Adult Graft Survival





(2) Based on 366 transplants performed 07/01/2008-12/31/2010

(3) Based on 411 transplants performed 01/01/2006-06/30/2008



- (1) Based on 37 transplants performed 07/01/2008-12/31/2010
- (2) Based on 37 transplants performed 07/01/2008-12/31/2010
- (3) Based on 64 transplants performed 01/01/2006-06/30/2008



In the spirit of CQI, SRTR plans a process of improvement for the PSRs.

Feedback Welcome & **Encouraged:** srtr@srtr.org Presentation & Design Methodologies Communication



Directions in Reporting Center-Specific Results

Jon J. Snyder, PhD, MS Director of Operations, SRTR

