### Limitations of the Program-Specific Reports?

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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.

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

### **Limitations of the PSRs???**

# No Too Many Limitations!! Limitations!!



### **Limitations of the PSRs???**

# Let's not throw the baby out with the bath water.



### **Current limitations...**

#### Currency

• PSR cohorts are too old to yield meaningful data

#### Risk adjustment

• Can we build better models?

#### Lack of clarity

• Too confusing? Can we build better reports?

Unintended Adverse Consequences

• Payer contracting



## **Limitations to Report Currency**

- PSRs contain outcomes data on a recent 2.5-year cohort of transplant recipients.
  - July 2012 reports
    - 1-year outcomes: 1/1/2009 6/30/2011... 1 to 3.5 years old!
    - 3-year outcomes: 7/1/2006 12/31/2008... 3.5 to 6 years old!
- Programs have indicated that a more real-time assessment of performance would be helpful.



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Meeting Report

doi: 10.1111/j.1600-6143.2012.04130.x

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Key words: Program-specific reports, OPTN, SRTR

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**<u>I.4.</u>** Provide transplant centers with tools like the cumulative sum (CUSUM) technique and tools to perform subgroup analysis to facilitate Quality Assessment and Performance Improvement.



# CUSUM: Coming to Transplant Programs in July 2013





### Draft CUSUM Recipient Survival Reports: Selecting the Time Period

Sliders on the bottom of the figure can limit the view to a specific time period

EXAMPLE DRAFT REPORT

[250 Simulated Recipients] Kidney: Adult 1-Year Deceased Donor Graft Survival CUSUM Report

Kidney: Adult 1-Year Deceased Donor Graft Survival O - E CUSUM Plot



R version 2.15.1 (2012-06-22) • googleVis-0.2.16 • Google Terms of Use • Data Policy

### **Draft CUSUM Recipient Survival Reports: Selecting the Time Period**

#### • Zoom options at the top of the figure can select time frames

#### EXAMPLE DRAFT REPORT

[250 Simulated Recipients] Kidney: Adult 1-Year Deceased Donor Graft Survival CUSUM Report

Kidney: Adult 1-Year Deceased Donor Graft Survival O - E CUSUM Plot



Data: cusum.plot.data • Chart ID: AnnotatedTimeLinelD1c9078125711 R version 2.15.1 (2012-06-22) • googleVis-0.2.16 • Google Terms of Use • Data Policy

### Draft CUSUM Recipient Survival Reports: Data Table

• HTML data table of covariates and recipients included can by copied into a spreadsheet and used for data quality reviews

Recipient ID	Transplant Date	Graft Failure Date	Cold Ischemia Time	Donor Kidney: Pumped	Donor History of Diabetes	Donor History of Hypertension	Donoation after Circulatory Death (DCD)	Donor Age	Organ Shipped Outside Recovery DSA	Expanded Criteria Dnoor (ECD)	Donor Race/Ethnicity	Donor Creatinine	Donor/Recipient Weight Ratio	Donor COD CVA/Stroke	A/B/DR Mismatches	DR Mismatches	Previous Solid Organ Transplant	Recipient Age at Transplant	Recipient Body Mass Index	Recipient Diagnosis	Recipient Hepatitis C Serology	Peak PRA/CPRA	Time on Renal Replacement Therapy	Recipient Insurance Coverage	Recipient Race/Ethnicity	Recipient Sex
X105368	2008-05-01		10.000	Pumped	No	Yes	Not DCD		Not Shipped	ECD	White	1.100	0.980	Not Cerebrovascular/Stroke	Not Zero	2.000	No	71	29.239	Polycystic Kidney Disease	Not Positive	86	0.044	Public	White	Female
X845443	2008-05-08		12.500	Not Pumped	No	Yes	Not DCD	50	Not Shipped	ECD	White	1.100	0.989	Cerebrovascular/Stroke	Not Zero	2.000	No	56	27.836	Hypertensive Nephrosclerosis	Not Positive	59	5.090	Private	Black	Female
X802772	2008-05-09		18.150	Pumped	No	No	DCD	47	Not Shipped	SCD	White	0.800	0.884	Not Cerebrovascular/Stroke	Not Zero	1.000	No	55		Diabetes	Not Positive	7	3.926	Private	Black	Male
X256600	2008-05-14		14.100	Pumped	No	Yes	Not DCD	24	Not Shipped	SCD	White	1.800	0.870	Not Cerebrovascular/Stroke	Not Zero	2.000	No	49	29.530	Hypertensive Nephrosclerosis	Not Positive	10	3.611	Public	Black	Male
X925948	2008-05-16		12.550	Pumped	No	No	DCD	47	Not Shipped	SCD	White	0.600		Not Cerebrovascular/Stroke		2.000	No	55	25.764	Glomerular Diseases	Not Positive	0	7.162	Public	White	Male
X196916	2008-05-23		17.920	Pumped	No	No	DCD	30	Not Shipped	SCD	White	1.000		Not Cerebrovascular/Stroke		1.000	No	27	19.215	Glomerular Diseases	Not Positive	0	5.183	Public	Multi-Racial, Other, Unknown, or Missing	Female
X823139	2008-05-25		27.110	Not Pumped	Yes	Yes	Not DCD	43	Shipped	SCD	White	0.500		Not Cerebrovascular/Stroke	Zero	0.000	Yes	37		Glomerular Diseases	Not Positive	94	16.498	Private	White	Female
X815157	2008-05-26		24.000	Pumped	No	No	Not DCD	57	Not Shipped	SCD	White	1.400	0.861	Cerebrovascular/Stroke	Not Zero	1.000	No	32	26.581	Hypertensive Nephrosclerosis	Not Positive	83	13.697	Public	White	Male
X844372	2008-05-26		9.120	Pumped	No	Yes	Not DCD	63	Not Shipped	ECD	White	1.300	1.652	Not Cerebrovascular/Stroke	Not Zero	2.000	No	69	24.017	Glomerular Diseases	Not Positive	19	2.724	Public	White	Female
X382848	2008-05-30		2.800	Not Pumped	No	No	Not DCD	24	Not Shipped	SCD	White	1.100		Not Cerebrovascular/Stroke		1.000	No	67	32.420	Other or Missing (Includes Tubular, Congenital)	Not Positive	81		Other or Missing	White	Female
X430976	2008-06-02			Not Pumped		No	Not DCD	4	Not Shipped	SCD	Hispanic/Latino	0.500	0.288	Not Cerebrovascular/Stroke	Not Zero	1.000	No	55	23.129	Other or Missing (Includes Tubular, Congenital)	Not Positive	82	8.162	Private	White	Female
X113152	2008-06-12		25.000	Not Pumped	No	No	Not DCD	40	Shipped	SCD	Hispanic/Latino	1.200	0.815	Cerebrovascular/Stroke	Zero	0.000	Yes	50	27.977	Diabetes	Not Positive	80	7.617	Public	White	Male
X542950	2008-06-16			Pumped		No	DCD	21	Not Shipped	SCD	White	0.600	0.523	Not Cerebrovascular/Stroke	Not Zero	2.000	Yes	39	35.983	Hypertensive Nephrosclerosis	Not Positive	75	15.630	Private	White	Male
X242809	2008-06-18			Not Pumped	No	No	Not DCD	1	Not Shipped	SCD	Black	0.500	0.212	Not Cerebrovascular/Stroke	Not Zero	1.000	No	40	22.750	Hypertensive Nephrosclerosis	Not Positive	96	4.799	Public	Asian	Female
X561810	2008-06-23	2009- 05-04	21.900	Pumped	No	No	Not DCD	44	Not Shipped	SCD	White	0.700	0.619	Not Cerebrovascular/Stroke	Not Zero	1.000	Yes	48		Hypertensive Nephrosclerosis	Not Positive	60	19.984	Public	Black	Male
X109534	2008-07-03		27.500	Pumped	No	No	Not DCD	55	Shipped	ECD	White	2.400		Cerebrovascular/Stroke	Not Zero	2.000	No	63		Other or Missing (Includes Tubular, Congenital)	Not Positive	65	3.069	Public	Black	Male
X493932	2008-07-03		16.000	Not Pumped	No	No	Not DCD	44	Not Shipped	SCD	Hispanic/Latino	1.300	0.771	Cerebrovascular/Stroke	Not Zero	2.000	No	54	31.011	Glomerular Diseases	Not Positive	0	4.868	Public	White	Male

Kidney: Adult 1-Year Deceased Donor Transplant Recipients Included in CUSUM

### **Example: Two-Sided CUSUM with Indication of Potential Problem**





### **Example One-Sided CUSUM with Trigger**





## **Risk Adjustment: Can we build better models?**

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Key words: Program-specific reports, OPTN, SRTR

Abbreviations: ACD, Adult Cardiac Surgery Database;



# **Risk Adjustment: Can we build better models?**

<u>I.2.</u> 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.



## **3-year Model Building Cycle**





### Detailed Model-Building Schedule: Note STAC-PSR Subcommittee will Review Throughout





# **Update on Kidney Model Rebuild Progress**

- Available variable documentation and process developed.
- OPTN Kidney Committee Subgroup tasked with reviewing the list of variables; Committee feedback received; Suggestions for additional data elements solicited.
- Model-building underway.

#### Candidate Weight (kg)

Non-Extreme Data Summary: Deceased Donor Transplants



Figure 13: Summary of Candidate Weight (kg) with extreme values treated categorically.



Figure 14: Proportional hazards regression fit of Candidate Weight (kg) for 1-year graft failure with exteme values treated categorically.



#### **Pros and Cons of Adding New Data elements**

Burdening Programs

Building the Best Risk with Additional Data Adjustment Models Collection Cons Pros Cons Pros Cons Pros



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# **Risk Adjustment: Can we build better models?**

# <u>I.3.</u> The potential benefits of hierarchical and mixed effects methods should be studied.



# Use of hierarchical models with (Bayesian) suggested performance criteria



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.

Christiansen CL, Morris CN. Ann Intern Med. 1997;127:764.



## The COPSS Report: January 27, 2012

#### STATISTICAL ISSUES IN ASSESSING HOSPITAL PERFORMANCE

Commissioned by the Committee of Presidents of Statistical Societies

The COPSS-CMS White Paper Committee:

Arlene S. Ash, PhD; Stephen E. Fienberg, PhD; Thomas A. Louis, PhD Sharon-Lise T. Normand, PhD; Thérèse A. Stukel, PhD; Jessica Utts, PhD

> Original report submitted to CMS on November 28, 2011 Revised on January 27, 2012



# What questions are answered by the different approaches?

Current: Is a particular center performing **as expected**?

- Produces a Yes/No Decision
- p-value shows how extreme the program's performance would be if the program truly had expected performance.

**Bayesian:** What is the **probability** that a particular center is **underperforming**?

- Produces a probability that the program's true mortality rate exceeds a given standard.
- Produces a probability distribution for center performance.



# **Bayesian Statistics in a Nutshell**

- Employs the Use of a "Prior Belief"
  - For example, we believe that all transplant programs are performing about average (Mean HR = 1, Variance = 0.5).
- The data observed must be able to overwhelm this prior belief... a lot of data (large centers) makes it easier to overwhelm our prior belief.
- Results in a "Posterior" probability distribution... gives the probability that a program is "underperforming" based on the available data.



### **Bayesian Balancing Act:**



### **PSR Output Comparison: Large Center "A"**

#### **Current Output:**

Number of Transplants:	299
<b>Observed 1-Year Patient Deat</b>	hs: <b>13</b>
Expected 1-Year Patient Deat	hs: <b>6.97</b>
O/E Ratio:	1.87
95% Confidence Interval:	(0.99, 3.19)
Two-sided p-value:	0.052

#### **Bayesian Output:**



**Center Hazard Ratio (HR)** 

### **PSR Output Comparison: Small Center "B"**

#### **Current Output:**

Number of Transplants:6Observed 1-Year Patient Deaths:1Expected 1-Year Patient Deaths:0.18O/E Ratio:5.4295% Confidence Interval:(0.14, 30.20)Two-sided p-value:0.337

#### **Bayesian Output:**



**Center Hazard Ratio (HR)** 

### Handling of Missing Data...

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### Handling of Missing Data...

I.7. SRTR should substitute missing data with values that are least favorable to the center, thus encouraging centers to accurately record data, and should consider including the timeliness and completeness of data submission as a quality indicator.



#### **Improvement in Clarity**

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### **Improvement in Clarity**

# I.1. PSRs should be better suited to the needs of all users, particularly patients.





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

#### C. Transplant Metrics



(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 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 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])



(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 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 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, 1.58])

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



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









### **OPO-Specific Reports, beta-release**



Arkansas Regional Organ Recovery Agency OPO Code: AROR Release Date: July 12, 2012 Based on Data Available: April 30, 2012

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

#### A. Description of the Donation Service Area (DSA) Served by AROR

#### Figure A1. Donation Service Area of AROR



Indicates the location of OPO headquarters

Figure A2. Counties Served



Table A3. Transplant Programs* within This DSA								
Hospital Name (Code)	HR IN	KI	LI LU PA					
Arkansas Children's Hospital (ARCH)	Х	Х						
Baptist Medical Center (ARBH)	Х	Х						
UAMS Medical Center (ARUA)		Х	X					

\*Performed at least one transplant of that type from 1/1/2011 to 12/31/2011.

Arkansas Regional Organ Recovery Agency OPO Code: AROR

Release Date: July 12, 2012 SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS Based on Data Available: April 30, 2012

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

#### B. Population Density, Death, and Donations

#### Figure B1. Population Density (Per Square Mile)\*



Land area of this DSA: 44.074.2 This ranks 26th among the 58 DSAs (1st is the highest).

< 13 13 - 34 34 - 67 67 - 186 > 186

\*US Census Bureau, 2011 projected population/2010 land area

#### Figure B2. Death Rate (Per 1000 Population)\*



#### Figure B3. Deaths (Per 1000 Square Miles)\*

38



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## **Kidneys Transplanted from this OPO, 2012**



Indicates the location of OPO headquarter



### **Unintended Consequences**

- Original intent was:
  - To provide consumers with quality information
  - To provide HRSA and the OPTN with data to support quality assurance and quality improvement efforts
- Third party payers use the SRTR data to make decisions on contracting.



### **Unintended Consequences**

- SRTR cannot control how others use/interpret the data.
- SRTR can control how clear we are about our assessments and our level of certainty!
- We are currently working with our SRTR Technical Advisory Committee (STAC) to consider ways to display program performance in better ways.



## **Using AHRQ's "Best Practices" as a Guide**





# **Conclusions**

