The Good, The Bad, The Needs: Current Prediction Methods Used in Program Specific Reports

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SRTR
SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Disclosures

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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.

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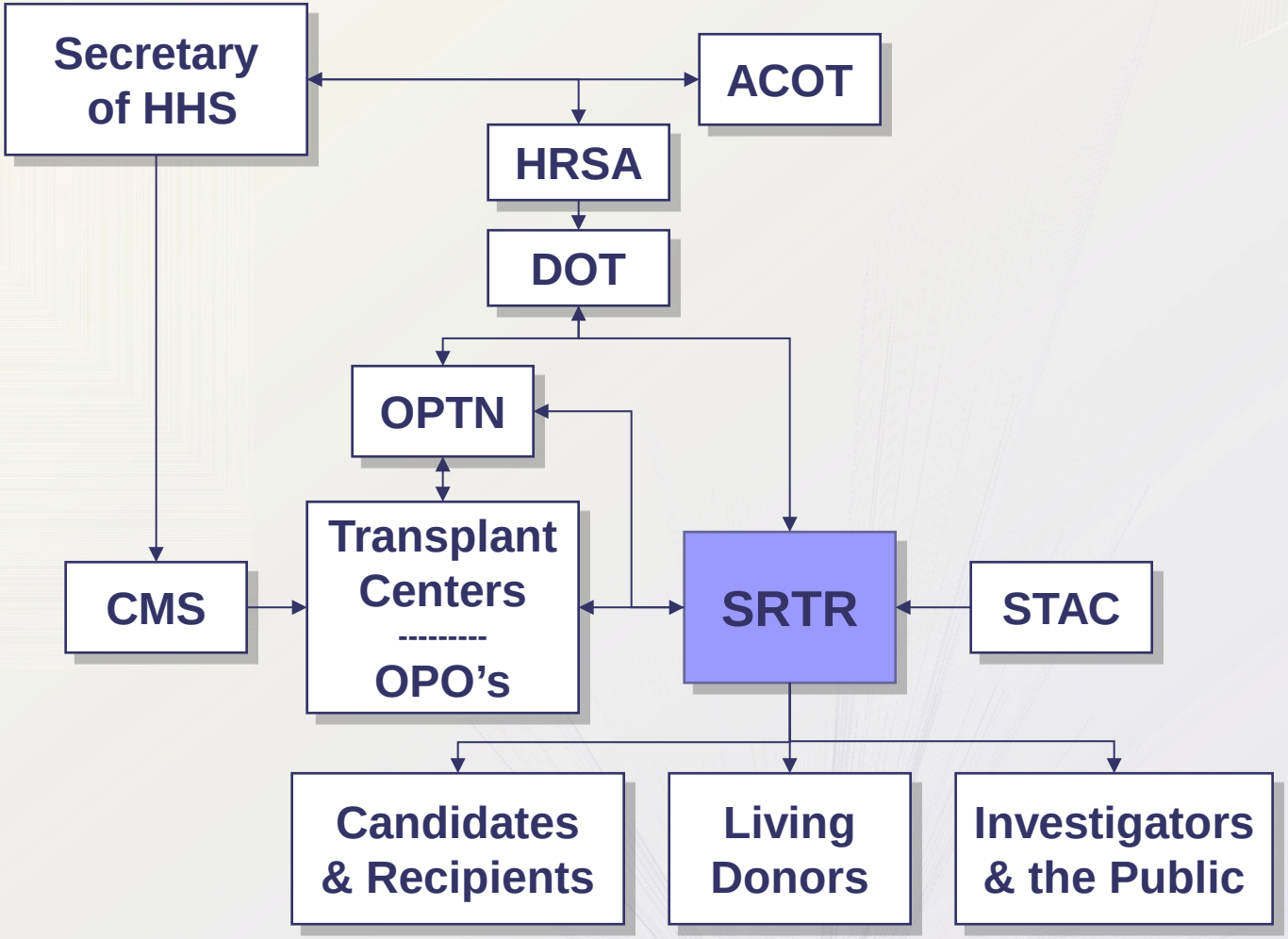
SRTR SCIENTIFIC REGISTRY OF TRANSPLANT RECIPIENTS

Outline

- Role of Scientific Registry of Transplant Recipients (SRTR) in quality improvement
- Prediction methods: High risk donors, recipients & patient survival
- Future directions & limitations

Role of the SRTR in Organ Transplantation



SRTR Activities as per Final Rule Reporting Requirements

…data shall include the following measures of inter-transplant program variation:

- risk-adjusted total life-years pre- and post-transplant,
- risk-adjusted patient and graft survival rates …
- risk-adjusted waiting time, and
- risk-adjusted transplantation rates,
- …as well as data regarding patients…who were inappropriately kept off a waiting list or retained on a waiting list.
  - » Final Rule implemented in 2000

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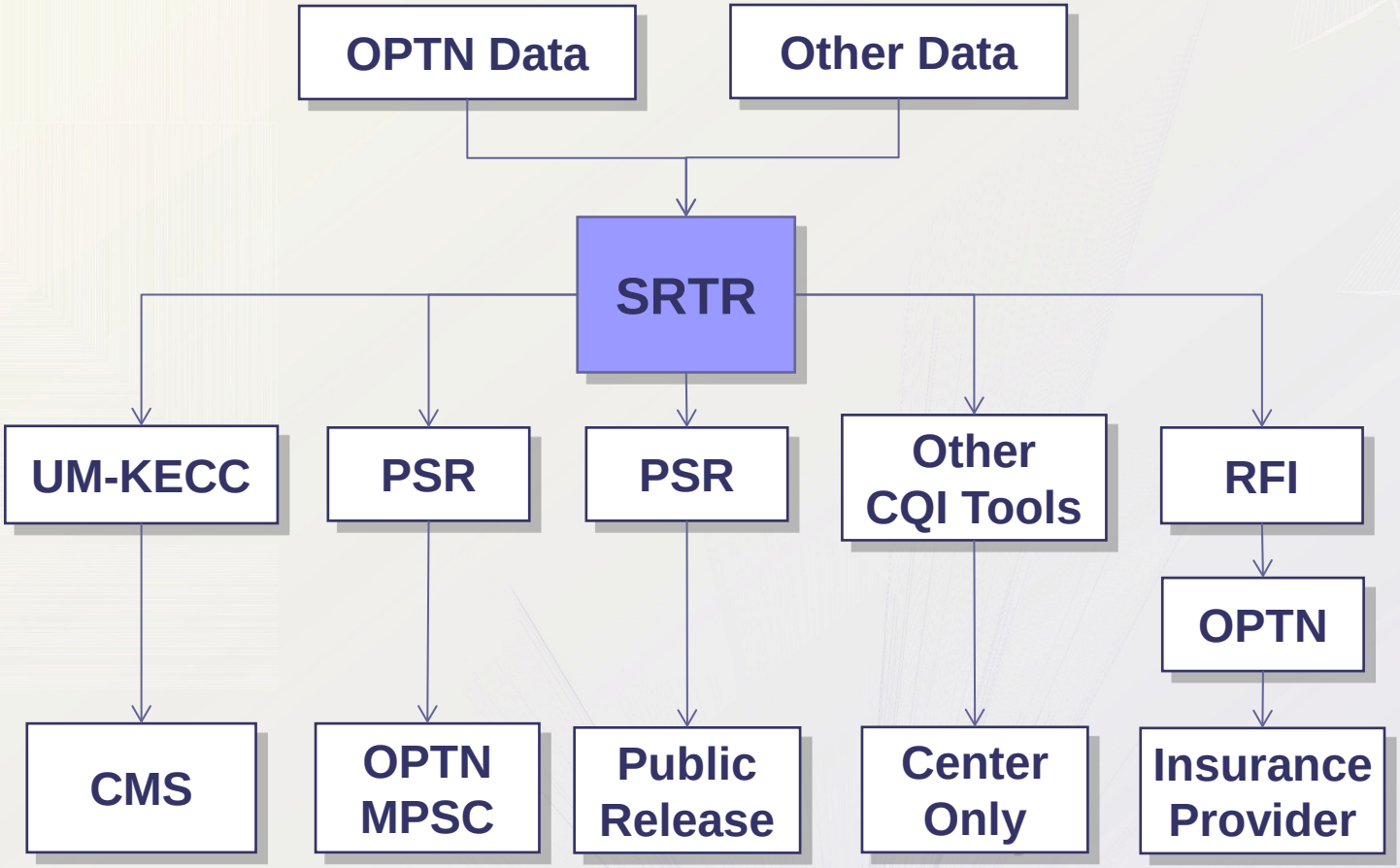
Role of the SRTR in Quality Improvement



Recommendations from the Consensus Conference on Transplant Program Quality and Surveillance

Arlington, VA
February 13-15, 2012

American Journal of Transplantation
Wiley Periodicals Inc.

doi: 10.1111/j.1600-6143.2012.04130.x

Meeting Report

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. Metzler[i], 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]

Outline

- Role of Scientific Registry of Transplant Recipients (SRTR) in quality improvement
- Prediction methods: High risk donors, recipients & patient survival
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American Journal of Transplantation 2012; 12: 1988–1996
Wiley Periodicals Inc.

doi: 10.1111/j.1600-6143.2012.04130.x

Meeting Report

Report of a Consensus Conference on Transplant Program Quality and Surveillance

II.2. Identify centers that manage high-risk patients and donors well

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be enhanced. Overall, there was broad consensus that substantial improvement in reporting outcomes of transplant programs in the United States could and should be made in a cost-effective manner.

Key words: Program-specific reports, OPTN, SRTR

Abbreviations: ACD, Adult Cardiac Surgery Database;

Recommendations (continued)

- PSR results are adjusted for donor and recipient factors known to adversely affect outcomes.
- Nevertheless, widespread belief persists that a program will be at risk if it accepts donors and recipients who are high-risk.
- Some have suggested that high-risk transplants be removed from PSRs.
- Therefore, we examined the relationship between donor and recipient risk and PSR outcomes.

Methods

- Included all 199 kidney transplant programs in the US that performed both low- and high-risk adult deceased donor transplants 1/1/2011-6/30/13.
- We defined high-risk donors by a KDPI ≥85%.
- We defined combined donor and recipient high-risk based on risk for graft failure and mortality ≥85%-tile.

Methods (continued)

- Observed and expected event counts were converted to estimated hazard ratios using new Bayesian methodology adopted by SRTR in 2014.
- Programs meeting the new MPSC review criteria were identified as those with:

    1. The probability that the HR is >1.2 is >75%, or
    2. The probability that the HR is >2.5 is >10%.

Components of Previous PSR Kidney Graft Failure Model

Donor	Recipient
Age*	Age
Race	Race
Cold ischemia time	Sex
DCD	BMI
ECD*	CPRA
Cause of death*	Primary Diagnosis
Terminal serum creatinine*	ESRD Time
HLA mismatches	HCV
History of diabetes mellitus	Insurance
History of hypertension	Previous solid organ transplant
Donor/Recipient weight ratio	
Local vs. shipped	
Pumped	

*ECD components

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Components of the New PSR Kidney Graft Failure Model

Donor	Recipient
Age*	Age
Ethnicity*	Ethnicity
BMI*	Cold ischemia time
ABO Group	BMI
KDPI*	CPRA
DCD*	Primary Diagnosis
Terminal serum creatinine*	Total ESRD Time
Terminal eGFR*	HIV serostatus
Drug-Treated Systemic hypertension*	History of drug-treated COPD
HLA A Mismatches	History of malignancy
HLA DR Mismatches	History of symptomatic PVD
Local vs. Shipped	Insurance
History of Cancer	Pre-transplant transfusions
Anti-Hepatitis B core antibody	En bloc, L or R kidney
Arginine vasopressin	Total serum albumin at listing
BUN	
Cigarette use	
Clinical infection of the lung	
Diuretics	
Thyroid function (free T4)	

*KDPI components

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KDPI Components in the New PSR

Donor parameter	Transplant parameter
Age*	HLA-B mismatch
African American*	HLA-DR mismatch*
Serum creatinine*	Cold ischemia time*
Hypertensive*	En bloc transplant
Diabetic	Double kidney transplant
COD CVA	
Height*	
Weight*	
DCD*	
HCV positive	

*In new PSR model

Rao, et al. *Transplantation* 2009; 88:231

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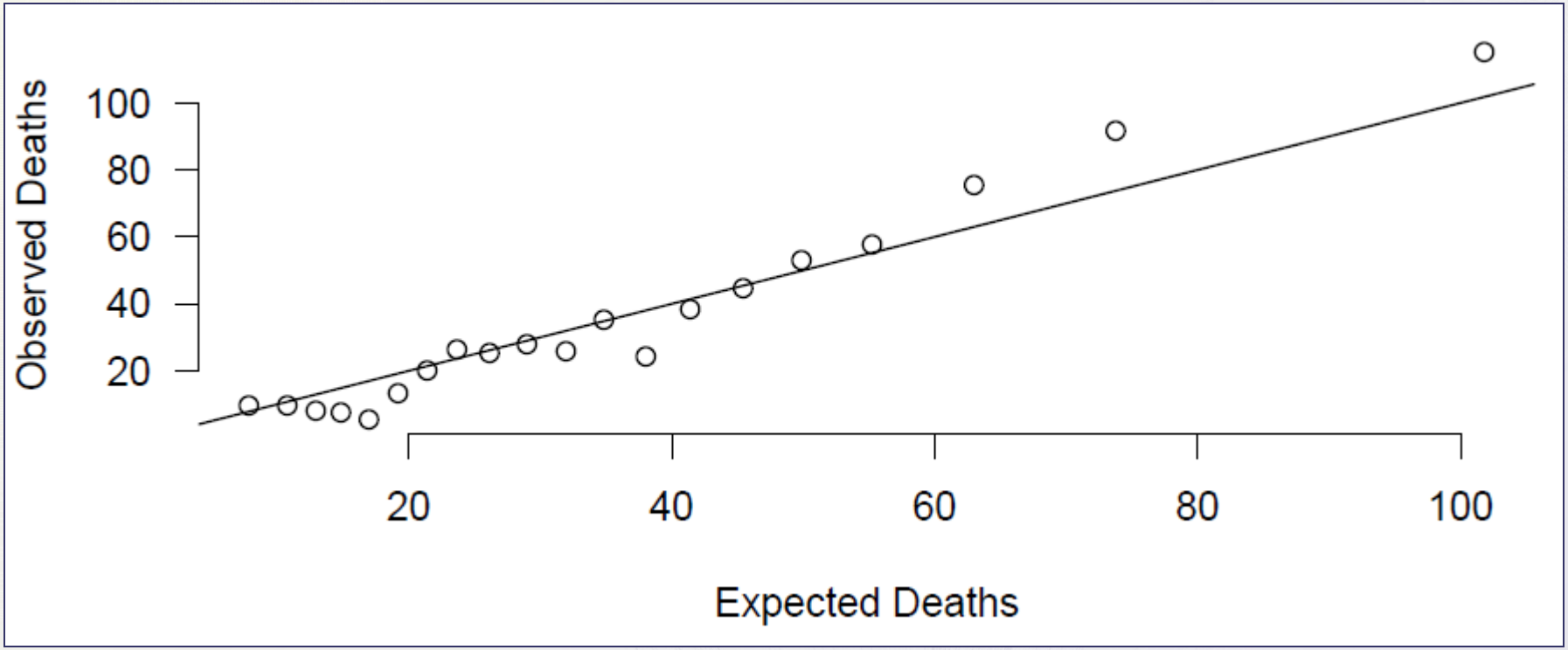
Adult, Deceased Donor, Kidney Patient Survival



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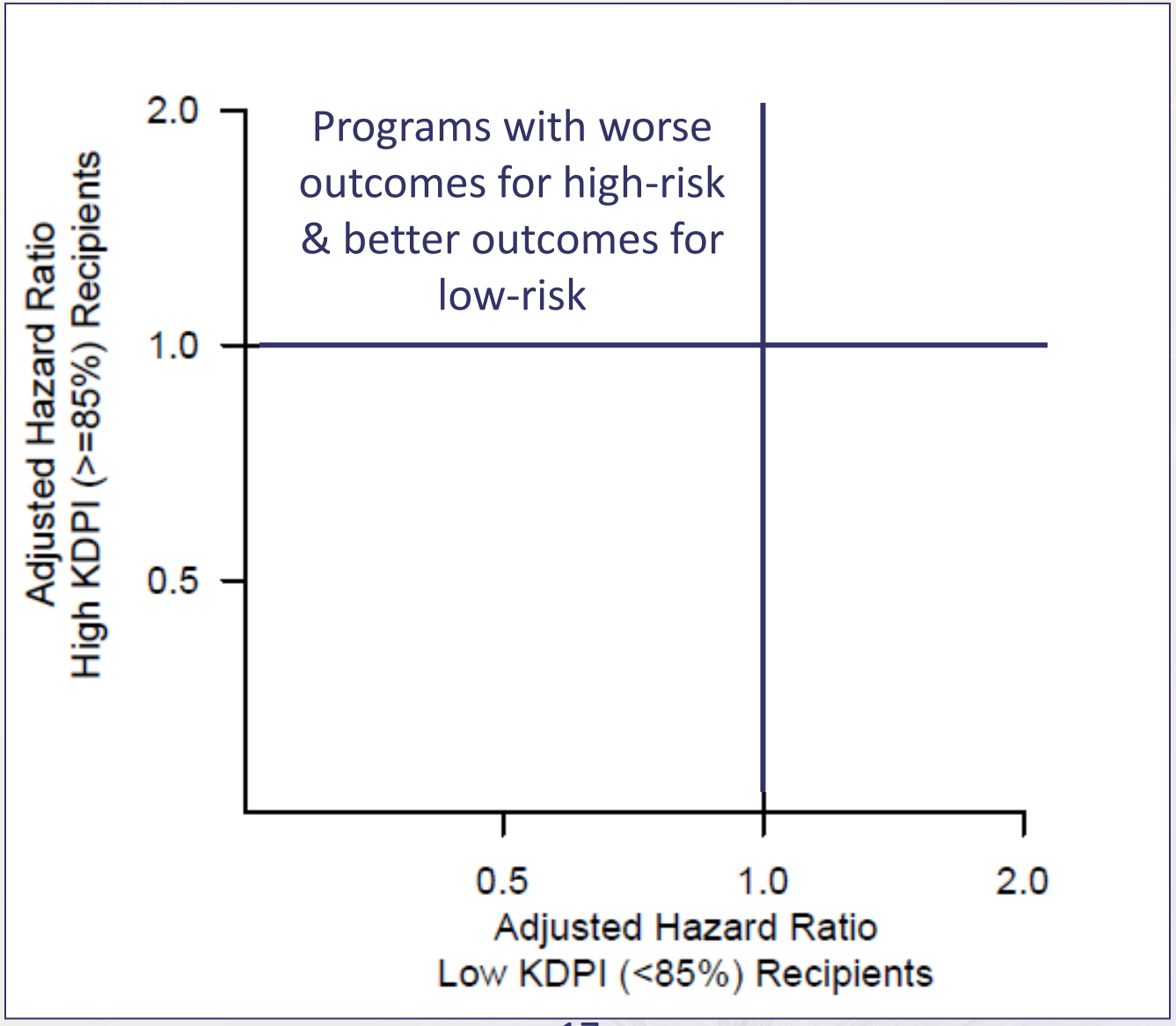
Adult, Deceased Donor, Kidney Patient Survival



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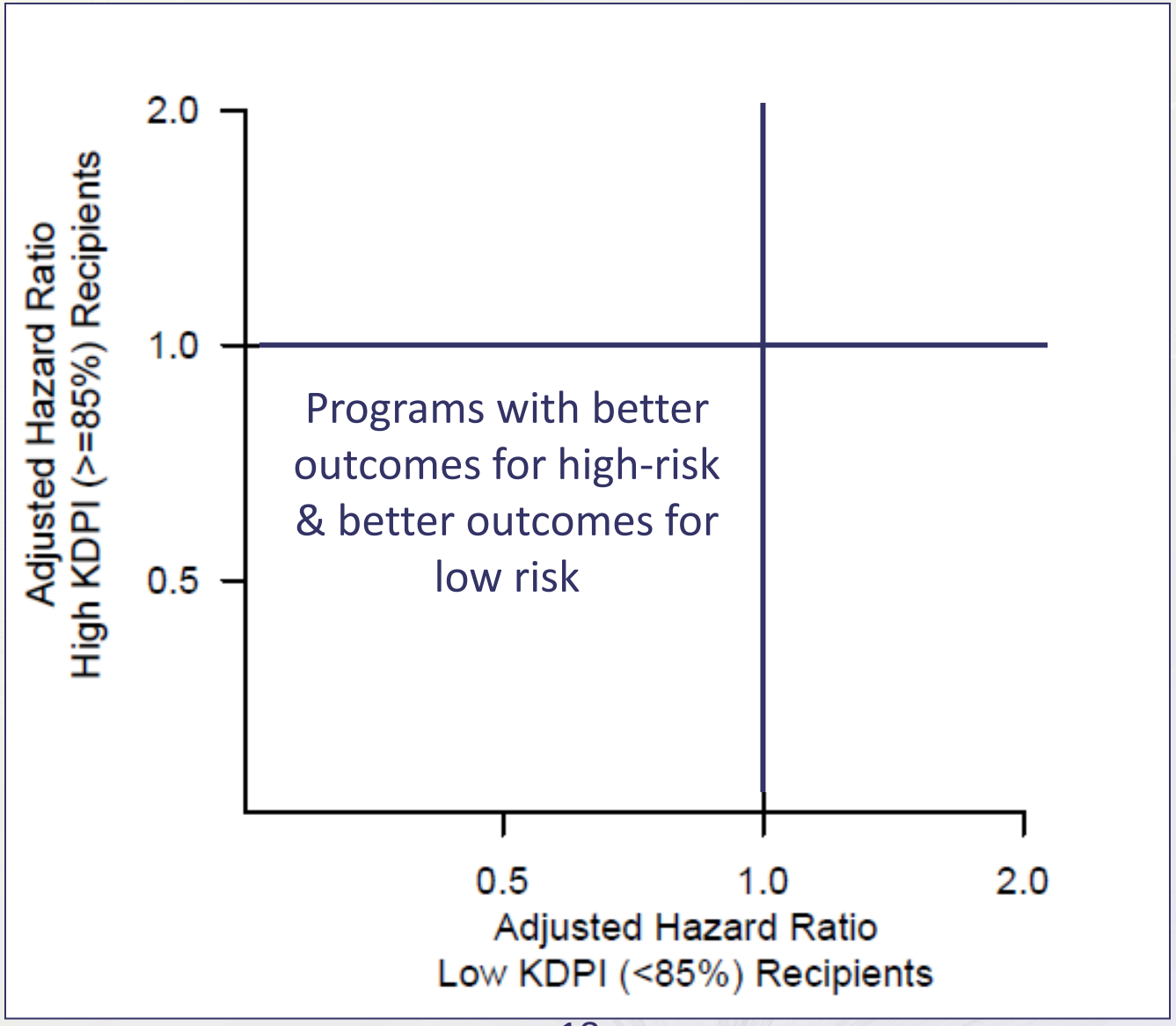

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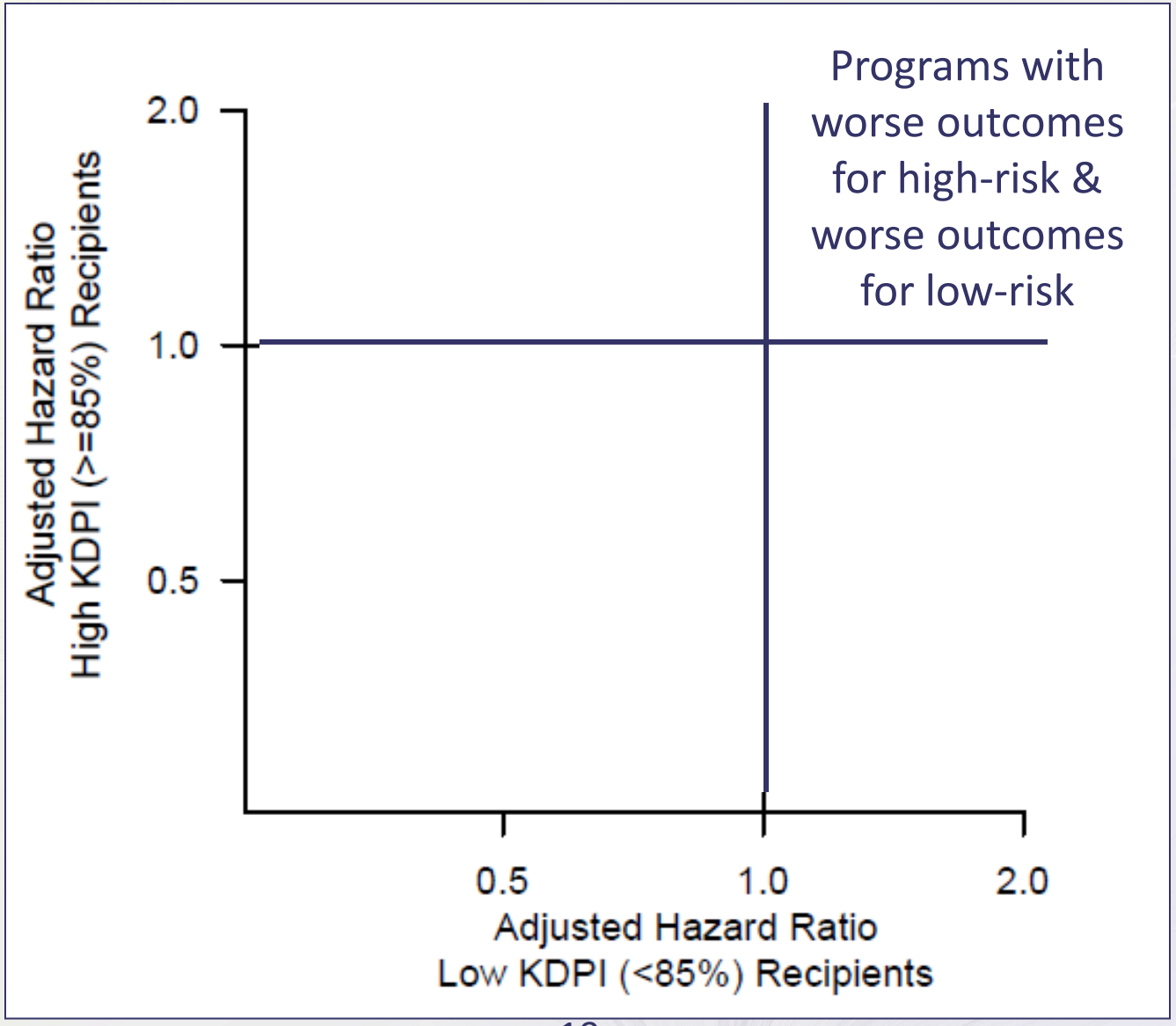
Adult, Deceased Donor, Kidney Patient Survival



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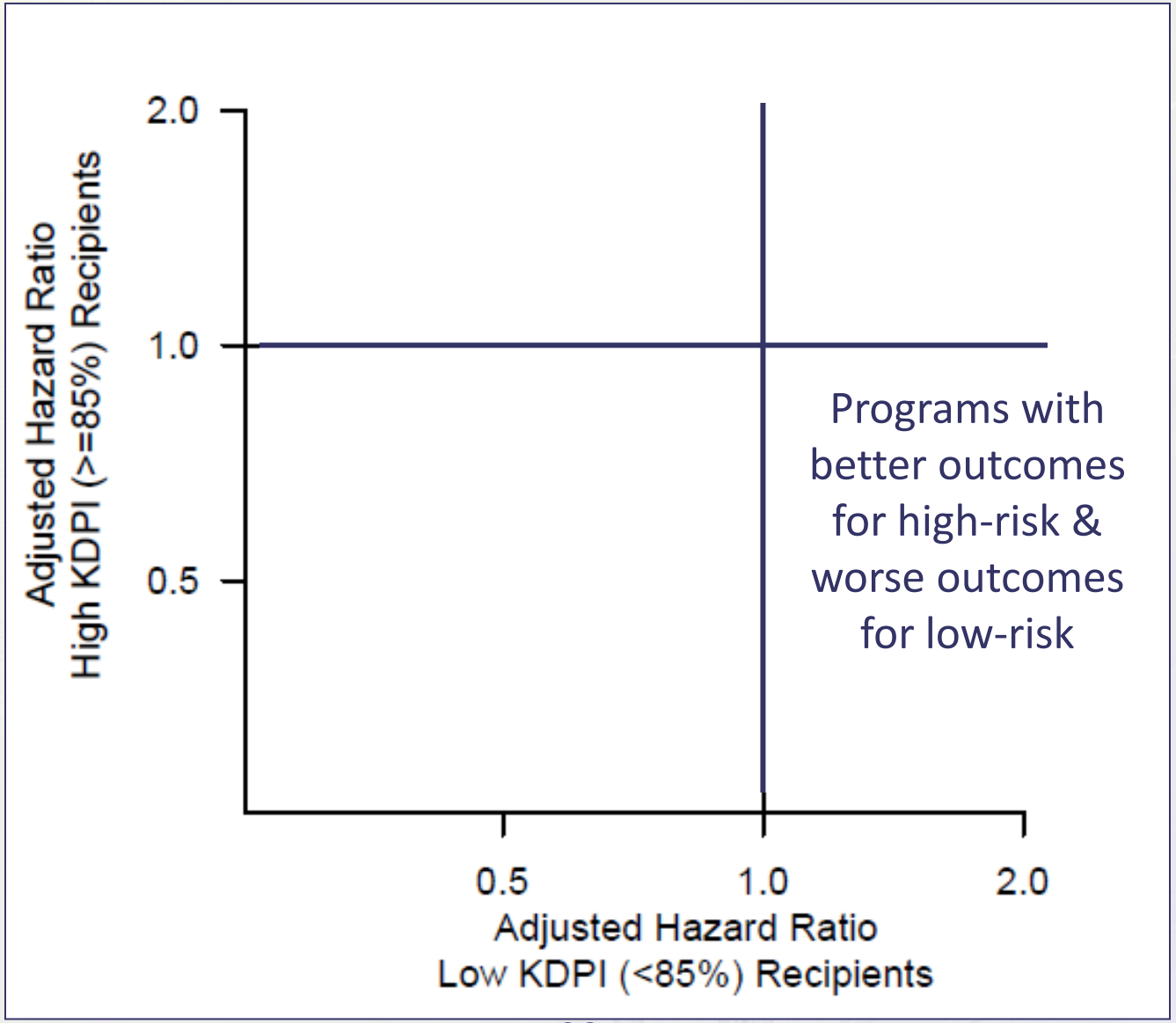
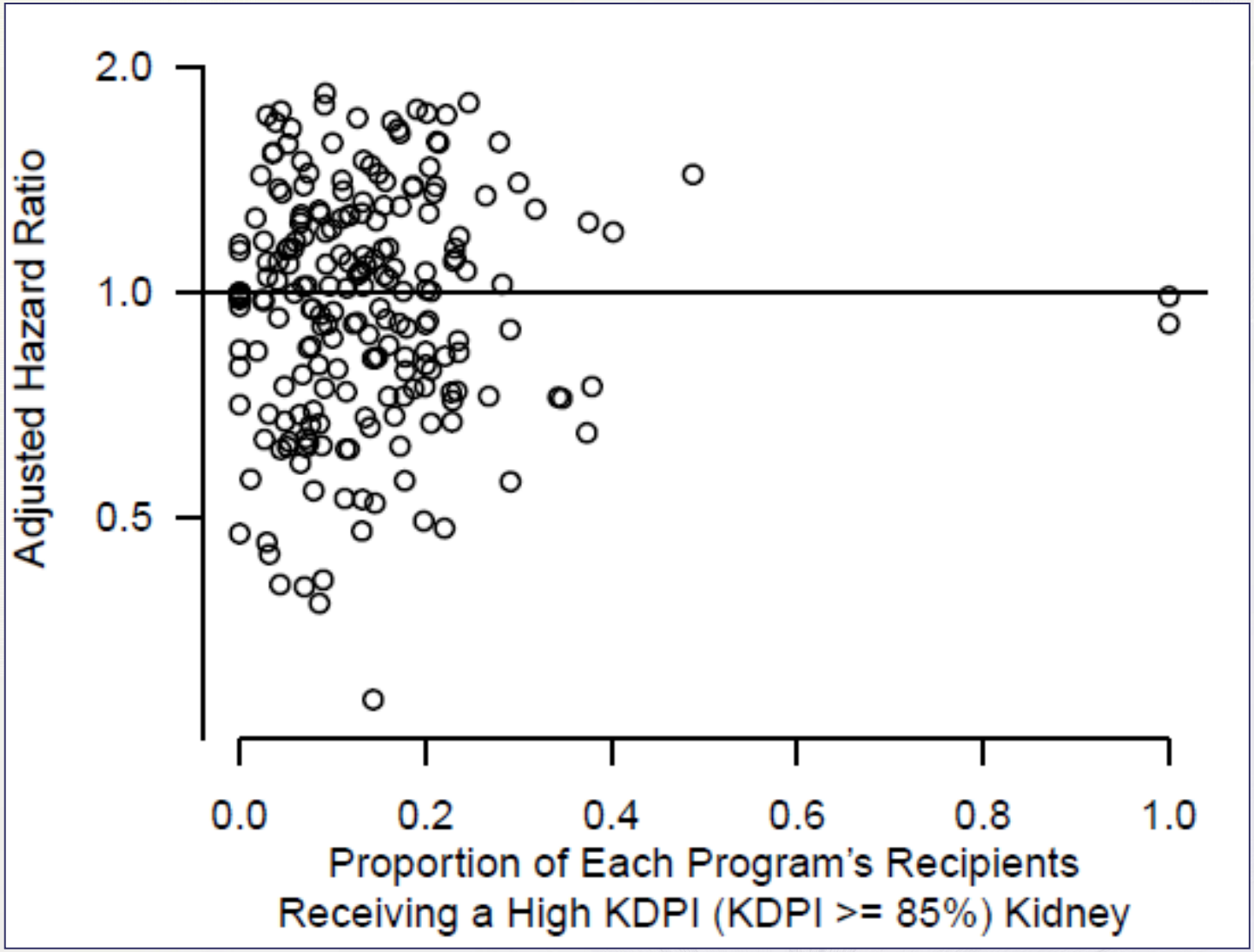
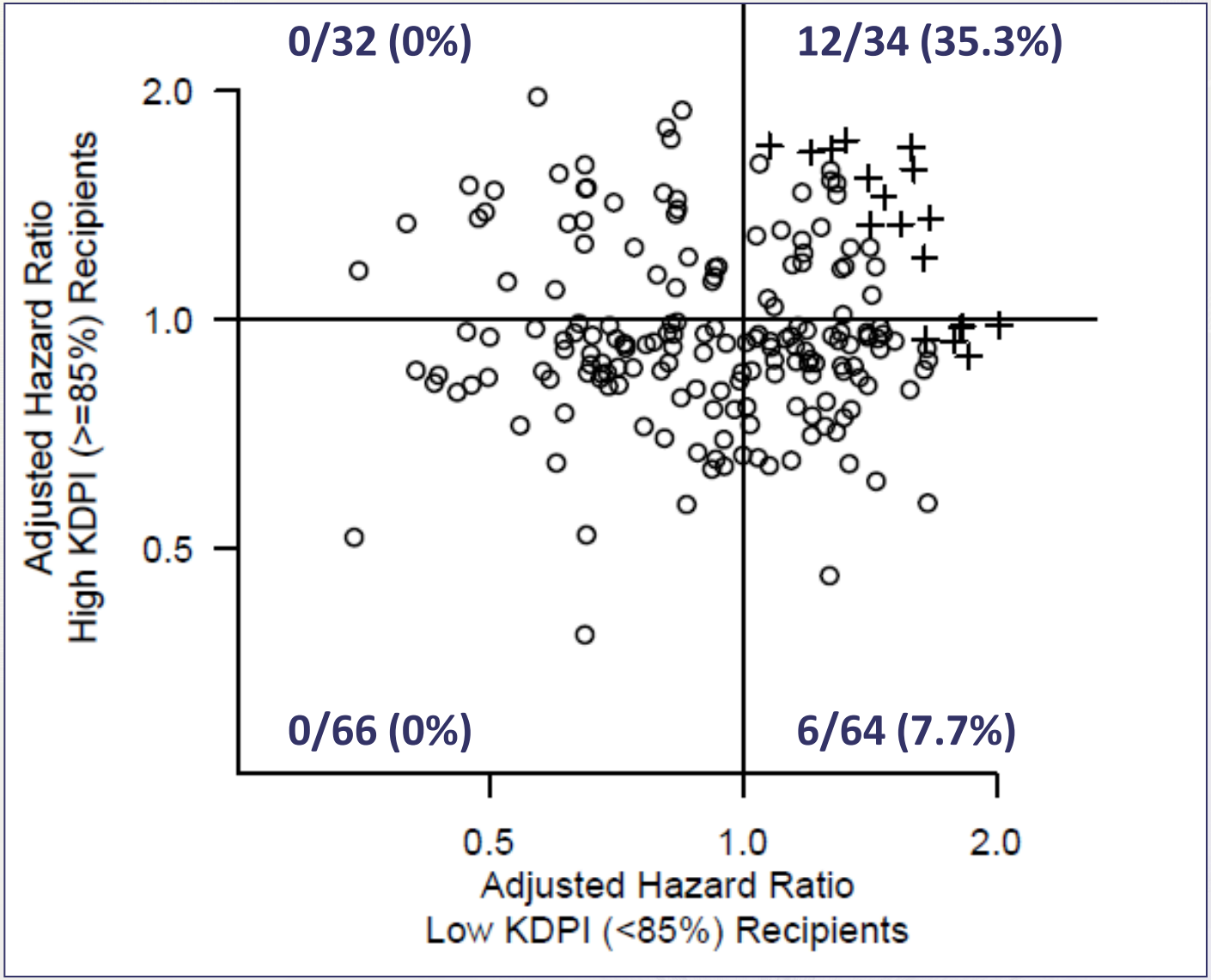


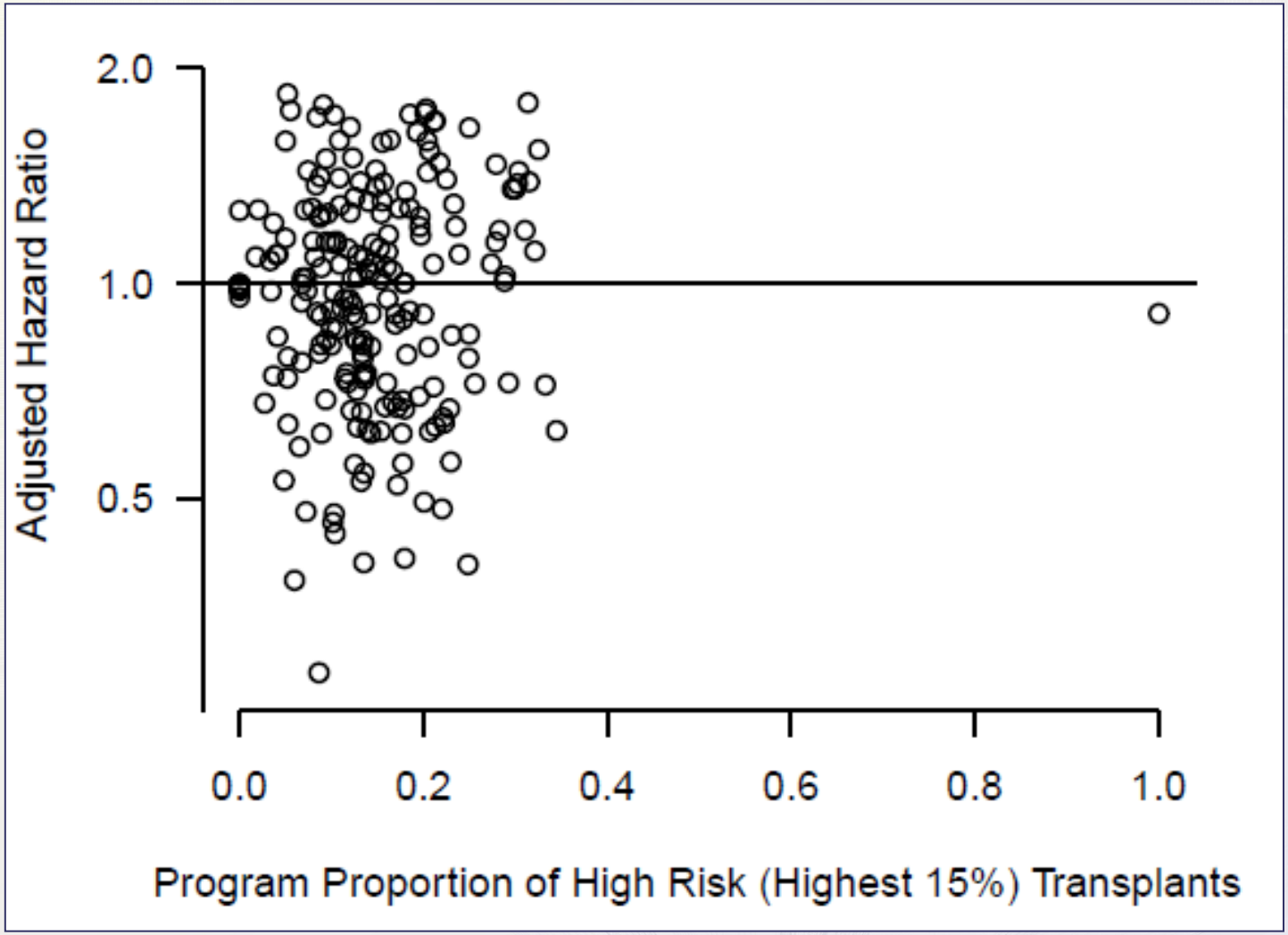
Adult, Deceased Donor, Kidney Patient Survival



Adult, Deceased Donor, Kidney Patient Survival



Adult, Deceased Donor, Kidney Patient Survival



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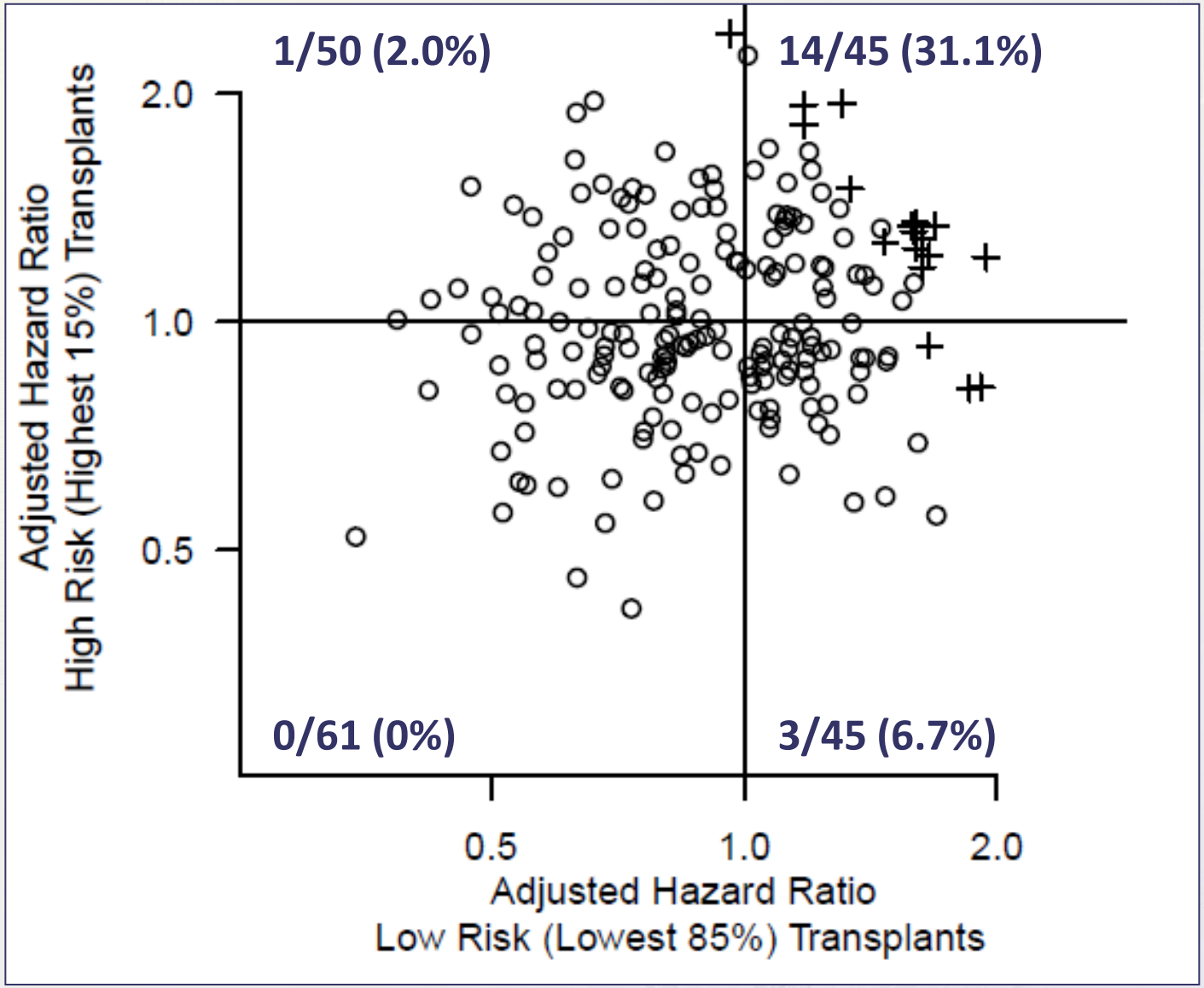
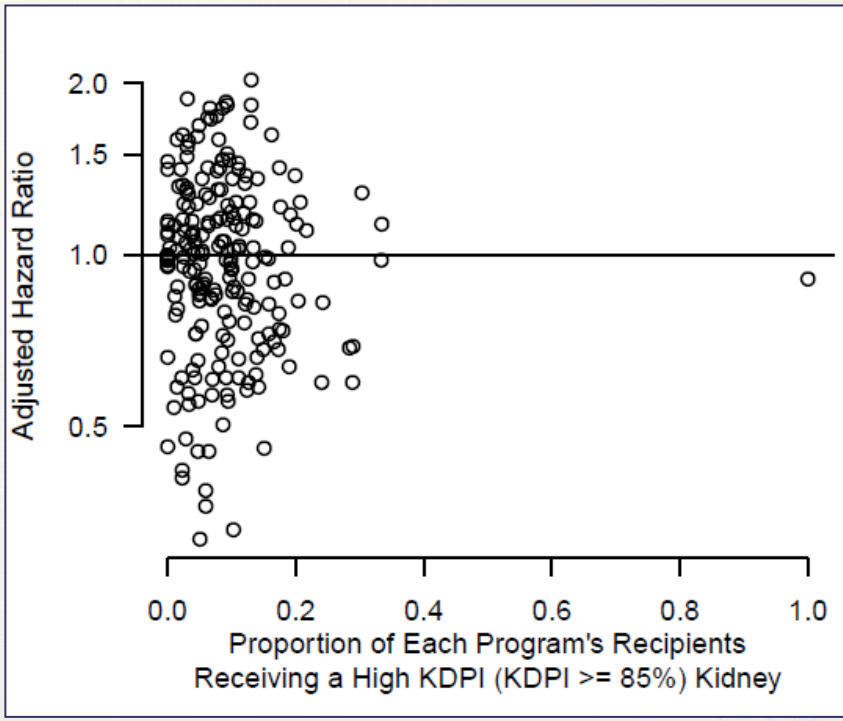
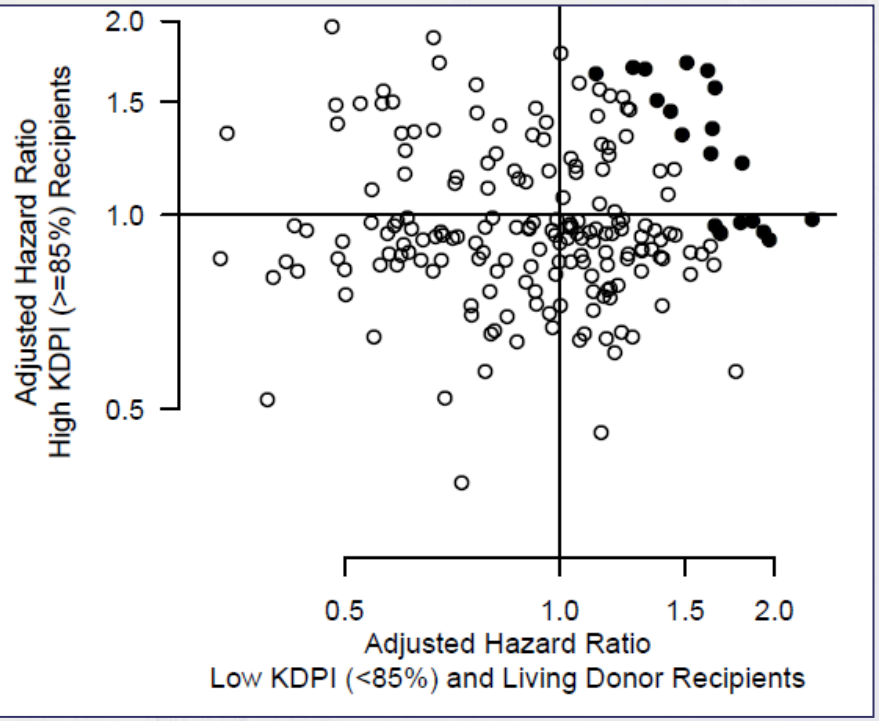
Adult, Deceased Donor, Kidney Patient Survival



Adult, Deceased Donor, Kidney Patient Survival (Including Living Donor Transplants)





Conclusions

- The PSR models are doing a reasonably good job of adjusting for donor and recipient risk.
- Accepting high-risk donors and recipients does not reduce risk-adjusted PSR outcomes and does not increase the likelihood of identification for regulatory oversight.
- Avoiding high-risk donors and recipients is a flawed strategy that will not improve PSR outcomes.

- Snyder, et al., The Effects of High-Risk Donors and Recipients on SRTR Program Specific Outcomes, ATC 2015, Sunday, Room 118-C, 2:27pm

Conclusions (continued)

- Removing from PSRs the transplants that are high-risk per current OPTN data is neither necessary nor feasible.
- Such a strategy would reduce the statistical power of the PSR models and would penalize programs that do well with high-risk donors and patients.
- Whether unmeasured risk affects outcomes warrants further study.

OPTN/UNOS Ad Hoc Committee on Program-Specific Reports
Report to the Board of Directors
June 24-25, 2013
Richmond, VA

John R. Lake, MD, Chair

OPTN/UNOS Ad Hoc Committee on PSRs

Committee	Role	Support Staff	Org.
John R. Lake	Chairman	Christopher McLaughlin	HRSA
Sandy Feng	Member	Monica Lin	HRSA
Tom Gonwa	Member	Bertram L. Kasiske	SRTR
Ken Andreoni	Member	Jon Snyder	SRTR
Larry Hunsicker	Member	Nicholas Salkowski	SRTR
Robert Merion	Member	David Zaun	SRTR
Jennifer Milton	Member	Tabitha Leighton	SRTR
Ron Potts	Member	John Roberts	UNOS Pres.
Thomas Hamilton	Member (CMS)	Jacqueline O'Keefe	UNOS
Karen Tritz	Member (CMS)	Erick Edwards	UNOS
		Robert Hunter	UNOS
		David Kappus	UNOS

Possible PSR exclusion: Questions

a. How is a protocol agreed upon as being acceptable for exclusion?
b. Does a protocol need to have scientific merit?
c. Who decides?
d. Does there need to be some type of DSMB and stop rules?
e. Is there a need for a consent process, who approves the consent?
f. Is there a limitation to the size of the center that can participate?
g. Is there a limitation on the number of patients (% of population) that can be entered in by a center?
h. How can “gaming” be avoided?

Possible PSR exclusion: Conclusions

- There would need to be a “true” research protocol, e.g. a government-registered clinical trial.
- The MPSC would need to determine whether the experimental protocol qualified for exclusion.
- PSRs would start with the total cohort, but patients in research protocols would be excluded.
- Centers would choose whether to exclude patients.
- Data forms would collect information from the experimental protocols at the time of transplant.

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doi: 10.1111/j.1600-6143.2012.04130.x

Meeting Report

Report of a Consensus Conference on Transplant Program Quality and Surveillance

III.3. Consider reporting transplant program risk tolerance.

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[b]Scientific Registry of Transplant Recipients, Minneapolis Medical Research Foundation, Minneapolis, Minnesota
[c]United Network for Organ Sharing, Richmond, Virginia
[d]LifeQuest, Gainesville, Florida

substantial improvement in reporting outcomes of transplant programs in the United States could and should be made in a cost-effective manner.

Key words: Program-specific reports, OPTN, SRTR

Abbreviations: ACD, Adult Cardiac Surgery Database; CABG, coronary artery bypass grafting; CIBMTR®

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doi: 10.1111/j.1600-6143.2012.04130.x

Meeting Report

Report of a Consensus Conference on Transplant Program Quality and Surveillance

IV.5. Use OPTN policy development process for adding new data elements.

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[a]Department of Medicine, Hennepin County Medical Center, University of Minnesota, Minneapolis, Minnesota
[b]Scientific Registry of Transplant Recipients, Minneapolis Medical Research Foundation, Minneapolis, Minnesota
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Meeting Report

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II.3. Collect more reliable organ-specific data on coronary heart disease (e.g. revascularizations), peripheral vascular disease (e.g. revascularizations and amputations),diabetes mellitus, ZIP code socioeconomic status, donor risk and ventricular assist devices.

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OPTN/HRSA Proposal – Overview of Data Advisory Committee (DAC) Charge/Functions

- The DAC will seek broad input in developing a long term vision for the OPTN/SRTR data including:
  - process for the identification of OPTN data,
  - methods of collection (Electronic Medical Records),
  - types of products to be supported
- Advise the OPTN BOD on collecting data
  - pertinent to the operation of the OPTN & SRTR
  - further the state-of-the-art in SOT including
  - continuous quality and patient safety improvements

Data Advisory Committee (DAC) Members

- Charles Alexander, RN, MSN,MBA (chair)
- Joseph Kim, MD, FRCPC (vice chair)
- Yael Coppleson
- Sandy Feng, MD, PhD
- Alexandra Glazier, JD, MPH
- Richard Hasz, Jr, MFS
- Ian Jamieson, MBA, MHA
- Maryl Johnson, MD
- Alan Leichtman, MD
- Robert Merion, MD
- Mike Peterson, PhD
- Jesse Schold, PhD, MStat, MEd
- James Wynn, MD
- Stuart Sweet, MD, PhD

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Nicholas Salkowski, SRTR
Bertram L. Kasiske, SRTR
Jesse D. Schold, Cleveland Clinic

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