

Would transplanting kidneys currently being discarded in the US place programs at risk for regulatory review?

Jon J. Snyder, PhD

Director of Transplant Epidemiology
Scientific Registry of Transplant Recipients
Minneapolis Medical Research Foundation
Minneapolis, Minnesota, USA

Disclosures

Jon J. Snyder, PhD
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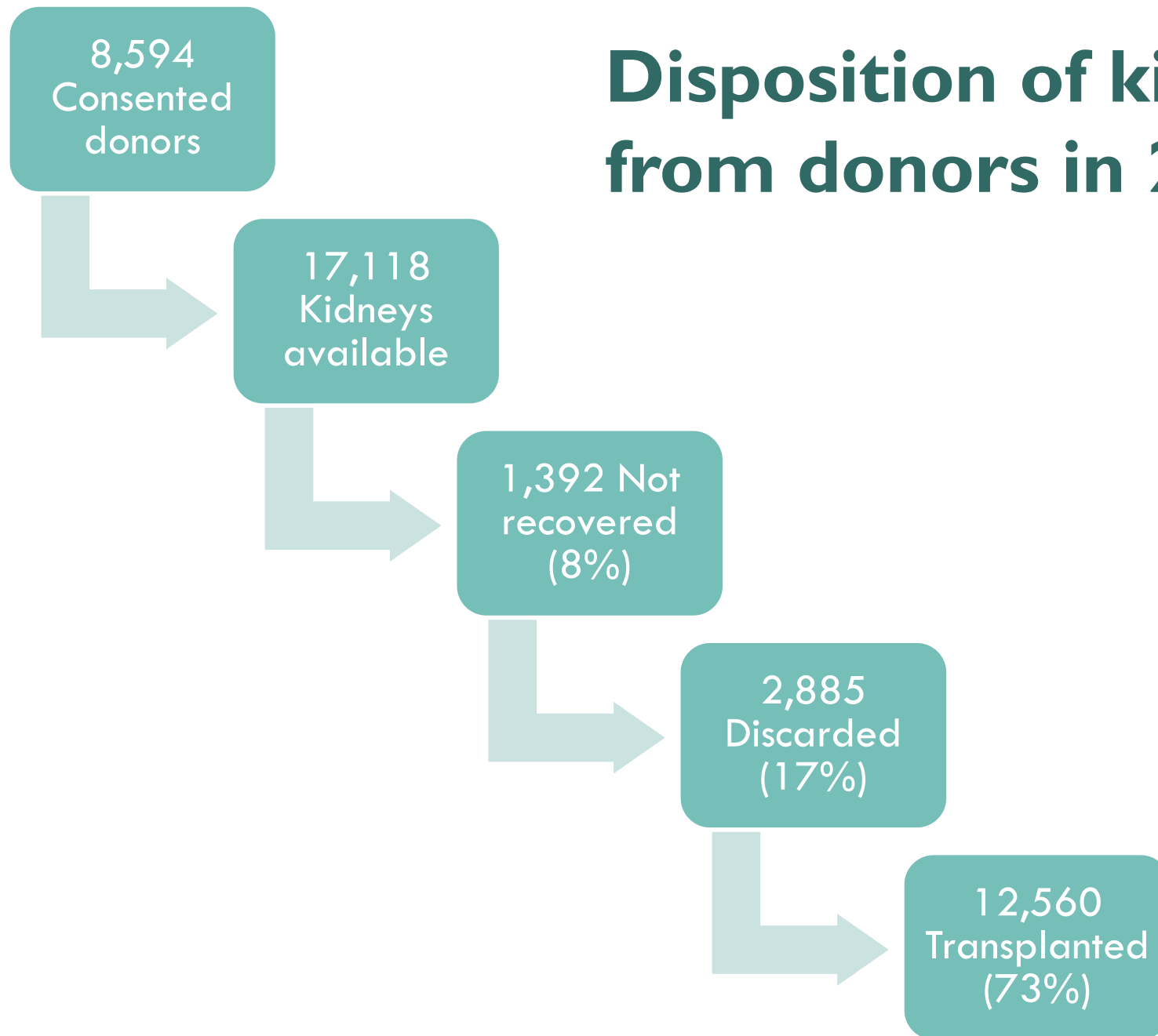
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Disposition of kidneys from donors in 2014



8,594
Consented
donors

17,118
Kidneys
available

1,392 Not
recovered
(8%)

2,885
Discarded
(17%)

12,560
Transplanted
(73%)

Reasons for non-recovery:

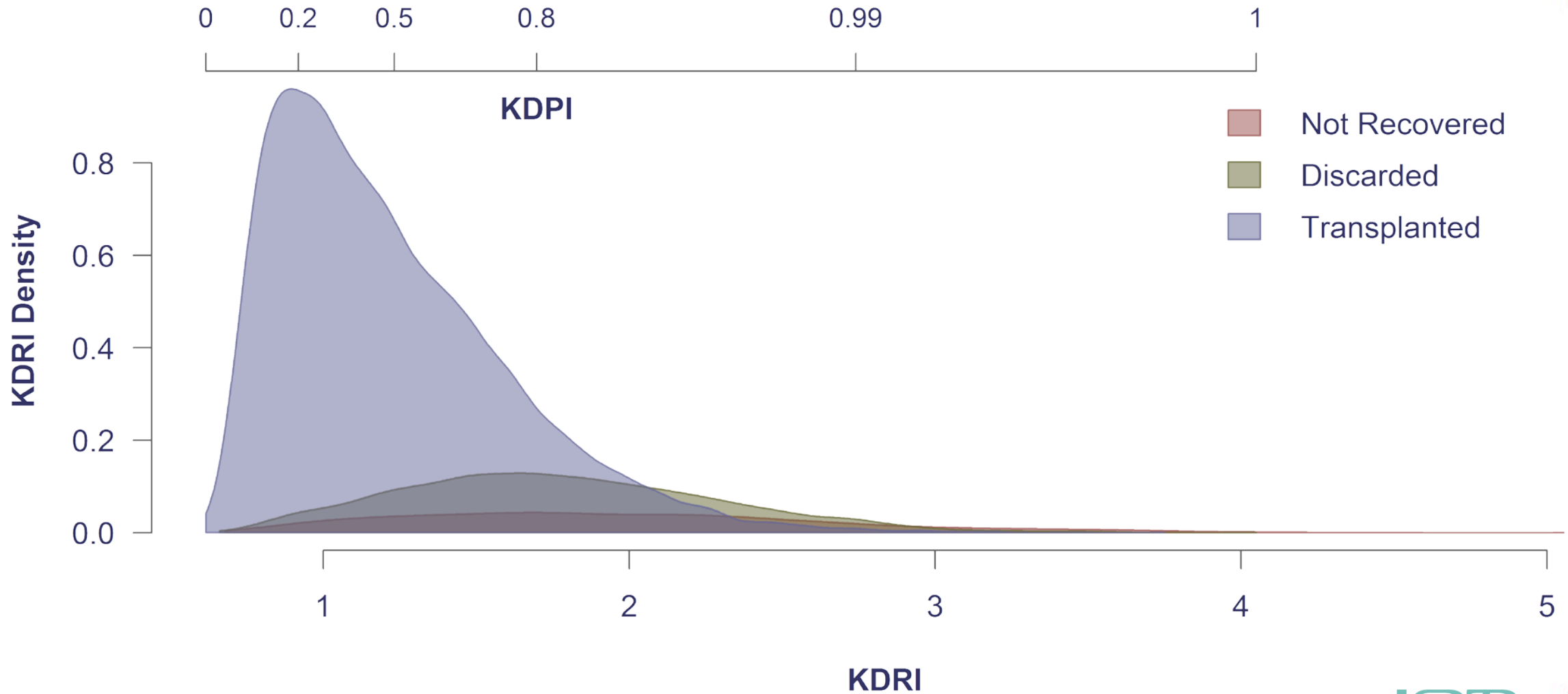
1. Poor organ function (552 kidneys: 40%)
2. No recipient located (271 kidneys: 19%)

Reasons for discard:

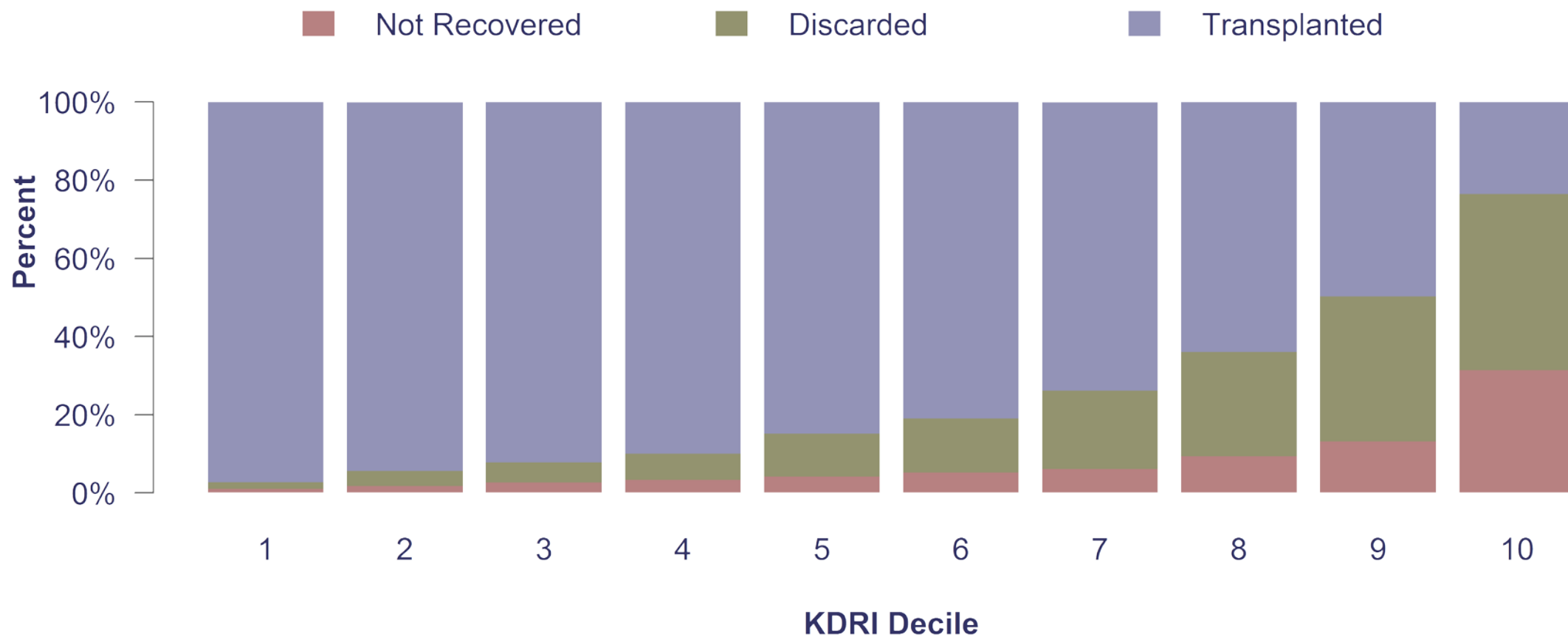
1. Biopsy findings (972 kidneys: 34%)
2. No recipient located (843 kidneys: 29%)

Disposition of kidneys from donors in 2014

KDRI distribution for not recovered, discarded, and transplanted kidneys



Disposition by KDRI



Factors included in the current deceased donor kidney risk adjustment models

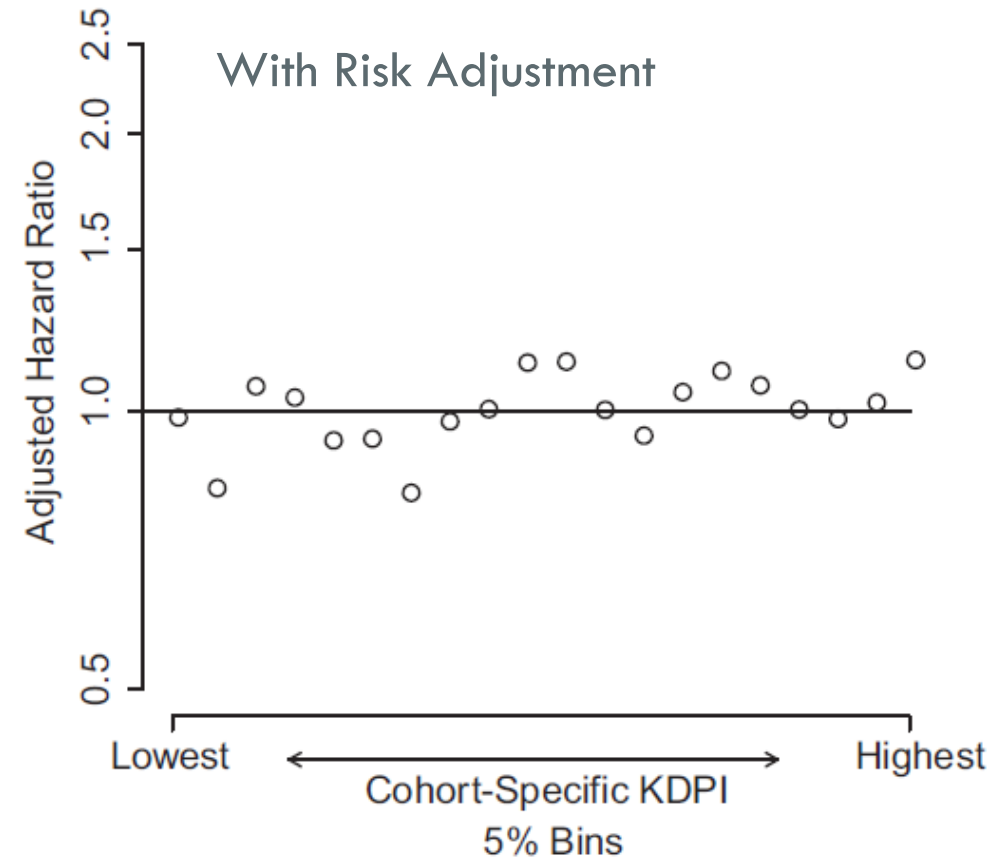
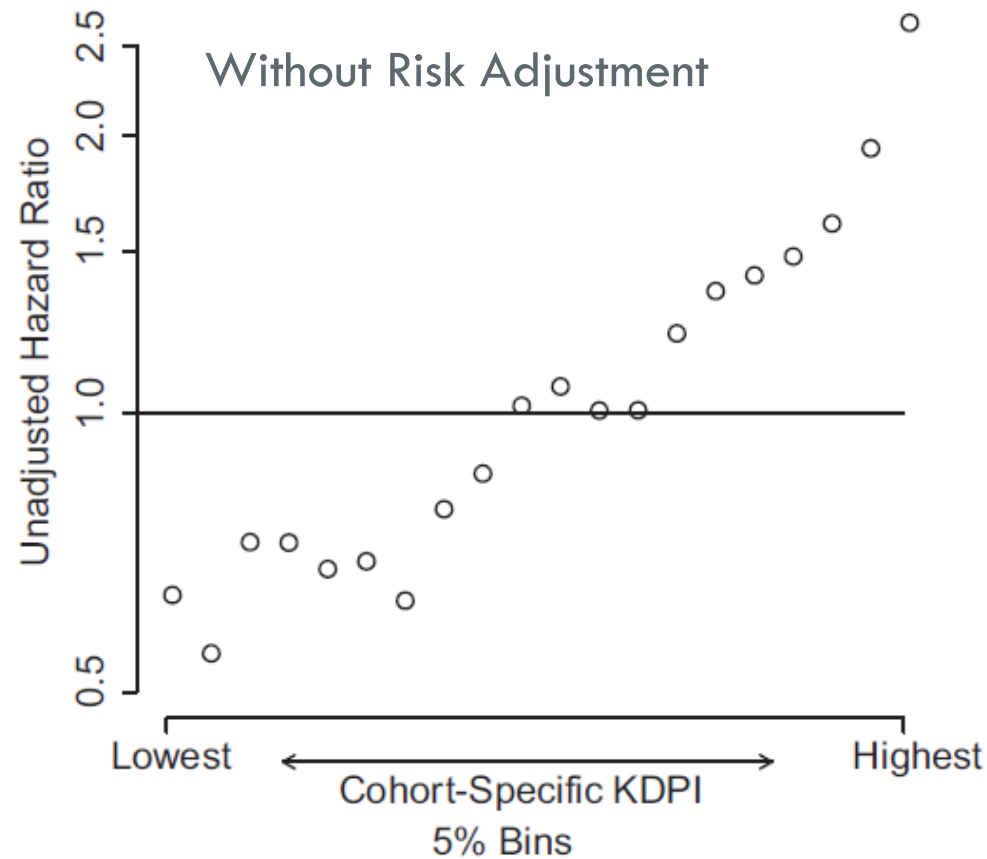
Candidate/Recipient Factors:

- Any previous malignancy
- Diabetes
- Ethnicity
- Highest education level
- Race
- Symptomatic peripheral vascular disease
- Total serum albumin (g/dL)
- Age at transplant (years)
- BMI (kg/m², calculated from height and weight)
- HBV core antibody
- HCV serostatus
- HIV serostatus
- Most recent CPRA (%)
- Previous solid organ transplant
- Primary diagnosis
- Primary source of payment
- Procedure type
- Total cold ischemia time (hours)
- Total ESRD time at transplant (days)

Donor Factors

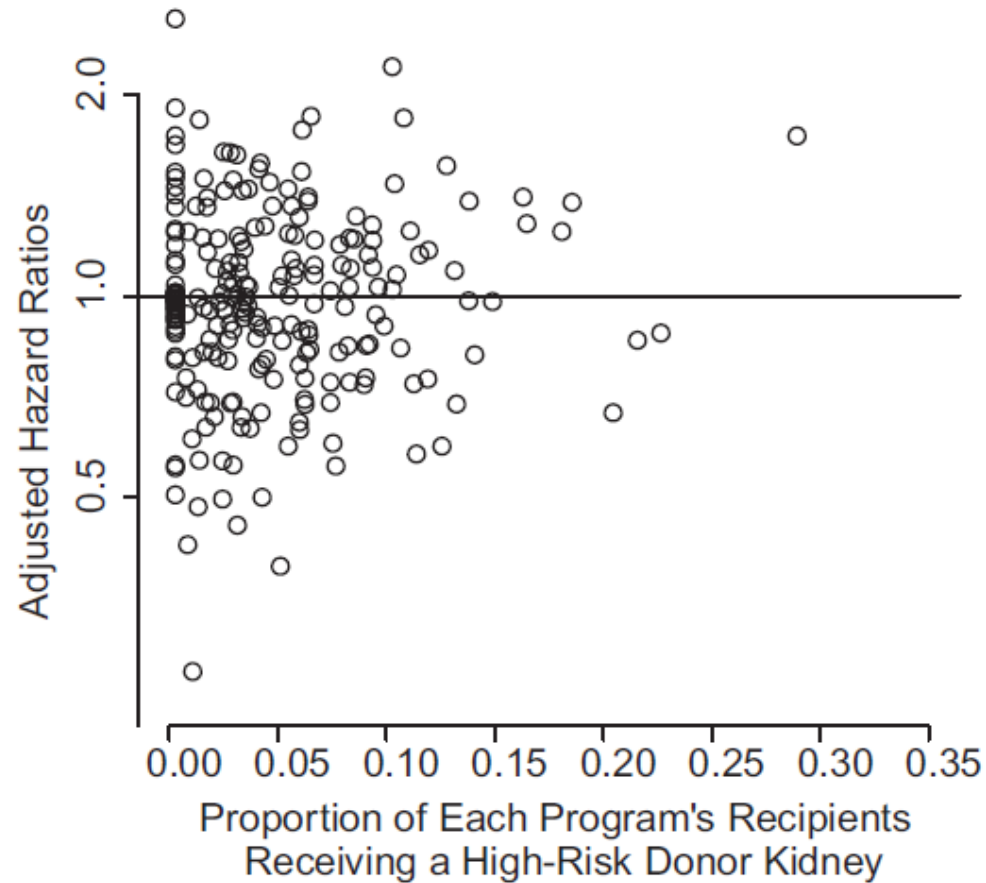
- ABO blood group
- Age (years)
- Anti-HBV
- Anti-HCV
- Arginine vasopressin
- BMI (kg/m², calculated from height and weight)
- BUN (mg/dL)
- Cigarette use (> 20 pack years) ever
- Clinical infection of the lung (confirmed or unconfirmed)
- Diuretics
- Drug-treated systemic hypertension
- eGFR (mL/min/1.72m², calculated from SCr, age, sex, race)
- Ethnicity
- Sex
- Hematocrit (%)
- History of cancer
- Kidney donor risk index (KDRI, calculated*)
- Local vs. regional/national share
- Neonatal donor (age < 7 days)
- Pumped
- Serum creatinine (g/dL)
- T4
- Tattoos
- Vasodilators
- Was this donor recovered under DCD protocol?
- HLA A mismatches (calculated)
- HLA DR mismatches (calculated)

How good is the model at adjusting for donor risk?



Snyder JJ, Salkowski N, Wey A, et. al., Effects of High-Risk Kidneys on Scientific Registry of Transplant Recipients Program Quality Reports. Am J Transplant, 2016. In Press.

Do programs with high percentages of high-risk donors have worse outcomes evaluations?



Snyder JJ, Salkowski N, Wey A, et. al., Effects of High-Risk Kidneys on Scientific Registry of Transplant Recipients Program Quality Reports. Am J Transplant, 2016. In Press.

How would a carve-out of high risk kidneys change current evaluations?

Population Evaluated	Programs Flagged by MPSC
All transplants (standard PSR methodology)	30
Low-risk* donor transplants alone	31
All transplants + (low- or high-risk donor alone)	30
All transplants + low-risk donor transplants alone	25

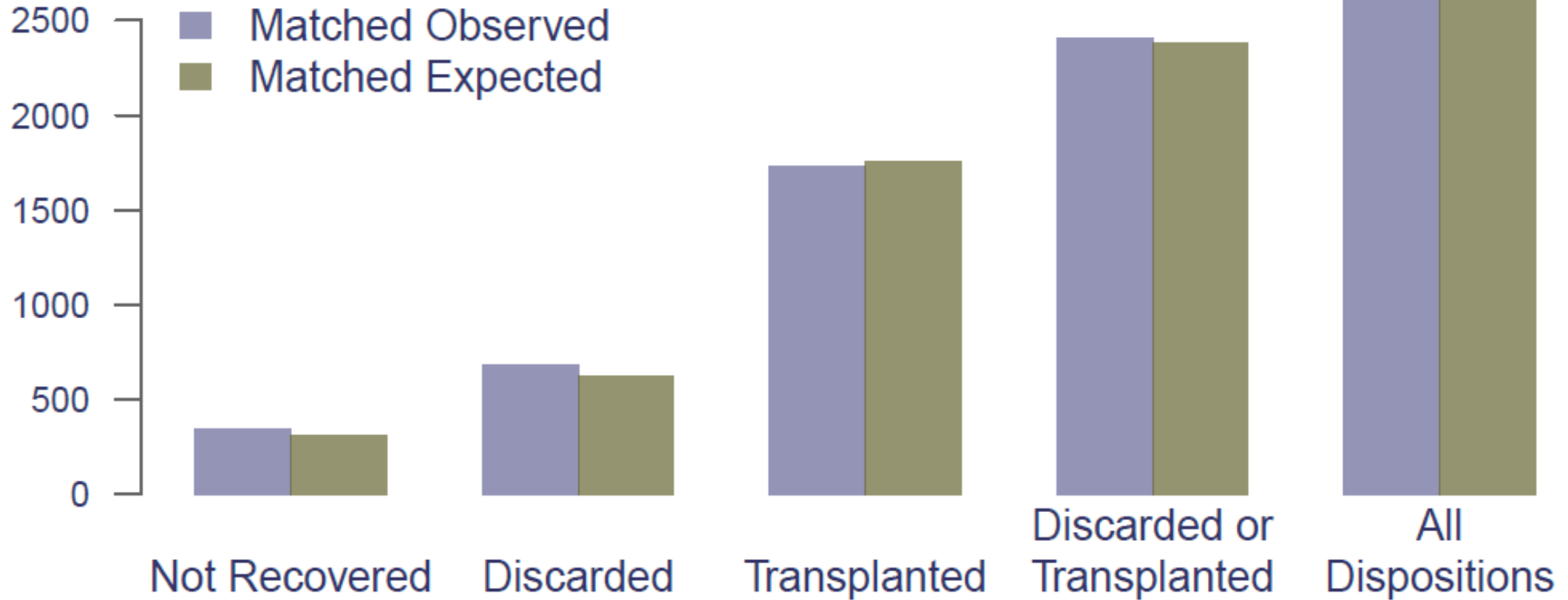
*Low risk = KDPI <85%; high risk = KDPI ≥85%

What if kidneys currently discarded or not recovered were transplanted?

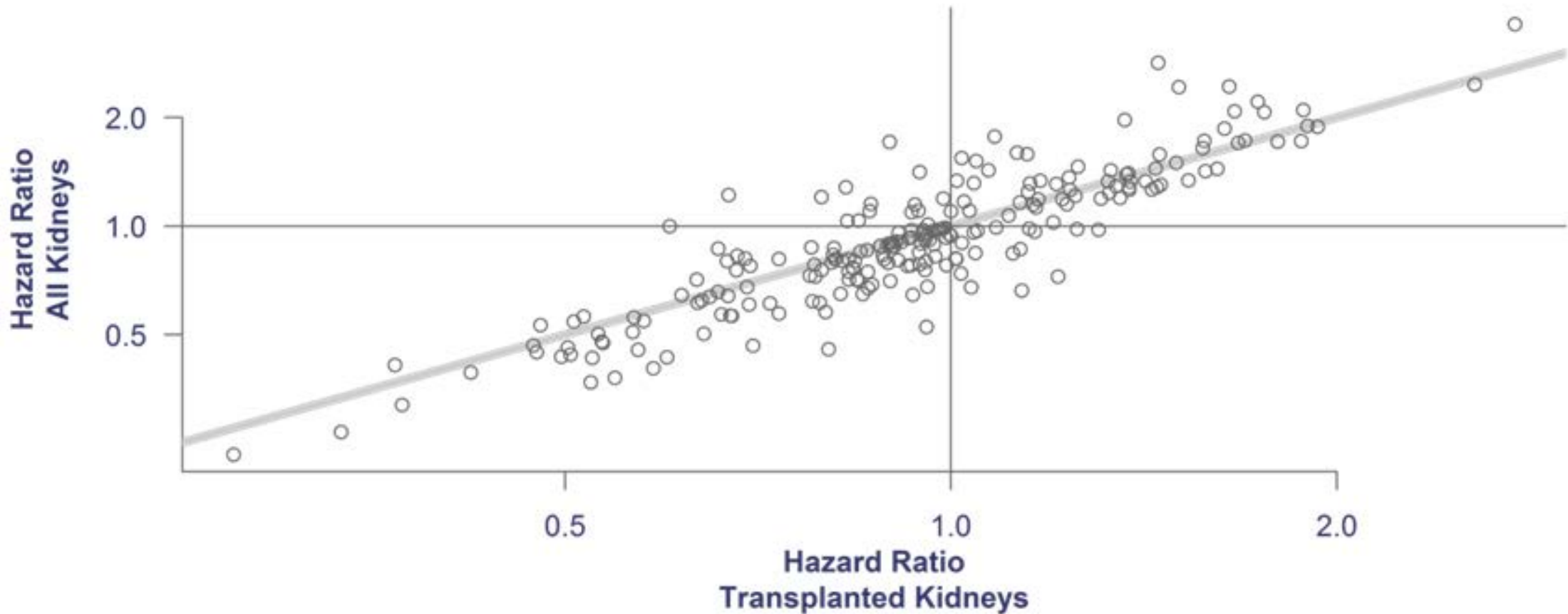
- Matching analysis population: donors from January 1, 2012–June 30, 2014.
- 3,090 not recovered kidneys and 6,726 discarded kidneys matched to transplanted kidneys by KDPI and donor age.
- Outcome of hypothetical transplant assumed to be the same as the matched transplant.
- Programs were allocated discarded/not-recovered kidneys in 1 of 2 ways:
 - Proportional to the program's historic use of high-risk kidneys.
 - Proportional to the program's total number of transplants performed.

Matching analysis:

If not recovered or discarded kidneys were used, observed and expected continue to align well.



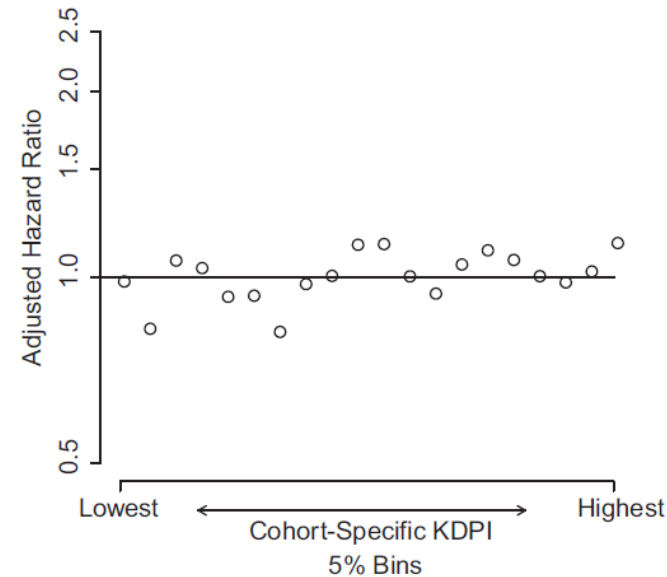
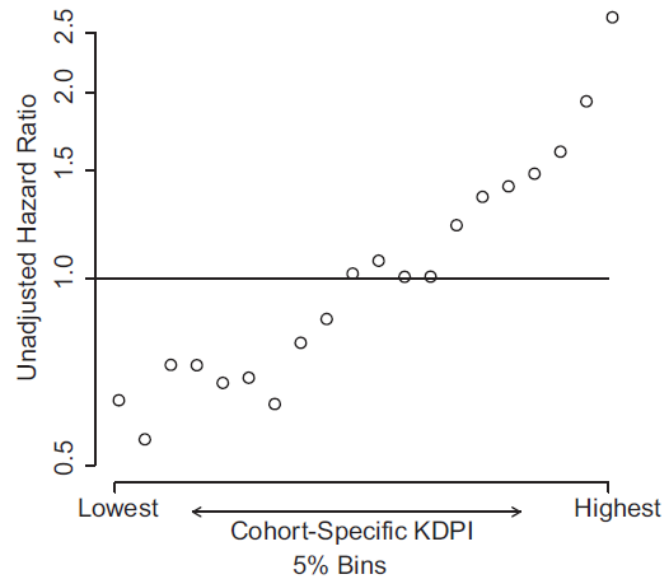
Correlation among program evaluations with and without the hypothetical transplants: 0.98



Common Questions:

Question: Risk adjustment models have poor discrimination, i.e., low C statistics. Doesn't this call into question the ability to judge programs?

- Discrimination assesses how well the models can distinguish two patients. Model calibration describes how well the models predict absolute risk, which is fairly robust. Models are used to provide aggregate program evaluations based on expected outcomes (calibration) for all patients at the program, not to distinguish any two patients (discrimination).



Common Questions:

Question: What about important risk factors that are not included in the risk adjustment models?

- SRTR supports all efforts to collect necessary risk factors to better calibrate risk adjustment models. Cornfield's Theorem allows one to assess potential bias introduced by unmeasured risk factors. For example, if a risk factor exists that confers an additional 25% increased risk (and isn't correlated with factors already in the model), and 10% of your recipients have it, and no other programs in the country perform any of these transplants, program hazard ratios may be biased by 0.02, i.e., from 1.00 to 1.02.

Summary:

- This analysis demonstrates a few key findings:
 - Discarded and non-recovered kidneys have KDPI largely within the range of kidneys that were transplanted.
 - Risk adjustment models are well calibrated for donor risk factors.
 - Carving out high-risk kidneys from evaluations has little effect on which programs are identified as underperforming.
 - Transplanting kidneys currently discarded would have little/no impact on program evaluations, under the assumption that they would be transplanted into similar candidates by programs that achieve similar outcomes. If this assumption is violated, the “KDPI” effect in the models will recalibrate to take this into account during each evaluation cycle.

Conclusions:

- Avoidance of risk based on measured and risk-adjusted factors, e.g., KDPI, is unwarranted.
- Important factors missed by current OPTN data collection should be collected to better calibrate the risk adjustment models and to assure care teams that appropriate medical care can be provided to patients without fear of impacting outcomes assessments.

Acknowledgments

Co-Authors:

Nicholas Salkowski, PhD

Bryn Thompson, MPH

Andrew Wey, PhD

Ajay Israni, MD, MS

Bertram Kasiske, MD, FACP

HRSA Division of Transplantation:

Monica Lin, PhD

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