Live Kidney Donor Risk: Big Data and the New Calculators

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Director, Epidemiology Research Group in Organ Transplantation
Johns Hopkins University
"The only remaining problem was the ethical decision concerning the removal of a healthy organ from a normal person for the benefit of someone else. For the first time in medical history a normal healthy person was to be subjected to a major surgical operation not for his own benefit."

Joseph Murray, Nobel Lecture, 12/8/90
1965

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Questions We Want to Answer

• *Baseline risk*
  (risk individual will have if *doesn't* donate)

• *Absolute risk*
  (total risk individual faces if donates)

• *Attributable risk*
  (extra risk individual faces if *does* donate)

• By race, age, sex, BMI, insurance, SES, etc?
Questions We Can Answer

• *Baseline risk*
  Risk in “healthy non-donors”

• *Absolute risk*
  Risk in donors

• *Attributable risk*
  Difference between above two
Studying ESRD

• Rare event
  – Require thousands of donors to see one event
  – Require tens of thousands to estimate the risk with any degree of confidence, for any subgroups
  – Require a non-self-reported source
    (Most centers lose touch with donors)
  – Require national representation
    (Low-volume centers, various demographics)
Ibahim/Matas NEJM 2009

- 3698 living donors single center 1963-2007; 99% Caucasian
- ESRD ascertainment through donor followup
- 11 cases of ESRD (1.8 per 10,000 person-years); 3 were non-Caucasian
- All donors with ESRD were biologically related to recipient
Mjoen et al, Kidney Int 2014

• 1901 living kidney donors 1963-2007 (single center performing all donations in Norway)
• 368 marginal donors excluded (hypertension, BMI>30, eGFR<70, macroalbuminuria, age>70)
• Followup through 2010
• Controls: Norwegian cohort enrolled 1984-87; included only self-reported health as "good" or "excellent"; excluded obese, SBP>140, DM, cardiovascular disease
Mjoen et al, Kidney Int 2014

- Nine cases of ESRD in LD (3.0 per 10,000 py); all biologically related to recipient

<table>
<thead>
<tr>
<th>Kidney donation</th>
<th>11.38 (4.37–29.63, ( P &lt; 0.001 ))</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inclusion year</td>
<td>0.90 (0.82–0.99, ( P = 0.03 ))</td>
</tr>
<tr>
<td>Age, years</td>
<td>1.02 (0.99–1.05, ( P = 0.13 ))</td>
</tr>
<tr>
<td>Male</td>
<td>0.90 (0.43–1.88, ( P = 0.77 ))</td>
</tr>
<tr>
<td>Systolic BP</td>
<td>1.01 (1.00–1.06, ( P = 0.03 ))</td>
</tr>
<tr>
<td>Smoking</td>
<td>1.19 (0.51–2.76, ( P = 0.68 ))</td>
</tr>
<tr>
<td>BMI</td>
<td>1.13 (0.96–1.32, ( P = 0.14 ))</td>
</tr>
</tbody>
</table>
OPTN Live Donor Registry

• Every single live donor in the US since 1988
• Currently N>112,000
• Advantages: massive, unbiased
• Disadvantages:
  – Incomplete, limited-term outcome capture
  – But… SSN captured since 1994 – linkage
• Medicare (CMS)
• Social Security (SSDMF)
NHANES-III

- Interviews, physical examination, and laboratory tests of 20,024 adults and 13,000 children administered by medical personnel
- Very detailed initial visits
- Can identify “healthy non-donors”
- Cross-sectional: no follow-up (except linkage)
- Medicare (CMS)
- Social Security (SSDMF)
Live Kidney Donors: Mortality

- Size (N=80,347 -- previous study was 3700 donors: Ibrahim NEJM)
  - Powered for narrow confidence interval
  - Powered for subgroup estimates
- Generalizability (all U.S. centers represented, not just large-volume academic centers)
- Diversity (previous study was 98% Caucasian, national cohort was 27% non-Caucasian)

Segev, JAMA, 2010
<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Subgroup</th>
<th>90-day Mortality Rate</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td></td>
<td>3.1 (2.0-4.6) per 10,000</td>
<td></td>
</tr>
<tr>
<td>Age (years)</td>
<td>18-39</td>
<td>3.0 (1.6-5.3)</td>
<td>0.5</td>
</tr>
<tr>
<td></td>
<td>40-49</td>
<td>3.7 (1.7-7.0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>50-59</td>
<td>1.5 (0.2-5.4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;=60</td>
<td>6.6 (0.8-23.9)**</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>Men</td>
<td>5.1 (3.0-8.2)</td>
<td>0.007</td>
</tr>
<tr>
<td></td>
<td>Women</td>
<td>1.7 (0.7-3.4)</td>
<td></td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td>Caucasian</td>
<td>2.6 (1.4-4.2)</td>
<td>0.04</td>
</tr>
<tr>
<td></td>
<td>African American</td>
<td>7.6 (3.3-15.0)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hispanic</td>
<td>2.0 (0.2-7.3)</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>No</td>
<td>1.3 (0.4-3.4)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td></td>
<td>Yes</td>
<td>36.7 (4.4-132.6)**</td>
<td></td>
</tr>
</tbody>
</table>

Segev, JAMA, 2010

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Matched Controls
Live Donors

Segev, JAMA, 2010
Live Kidney Donors: ESRD

- Size (N=96,217)
  - Powered for narrow confidence interval
  - Powered for subgroup estimates
- Generalizability (all U.S. centers)
- Racial Diversity
- Proper comparison group
  - All previous studies had compared with “general population”
p=0.2

Muzaale/Segev, JAMA, 2014
Trend $p=0.9$
At 15 years post-donation
Donors: 30.8 per 10,000 [95% CI 24.3-38.5]
Healthy Nondonors: 3.9 per 10,000 [0.8-8.9]
Muzaale/Segev, JAMA, 2014
Attributable Risk

• “Extra risk” at 15y post-donation
  – Black:
    • $74.7 \ [47.8-105.8] - 23.9 \ [1.6-62.4] = 50.8 \text{ per 10,000}$
  – Hispanic:
    • $32.6 \ [17.9-59.1] - 6.7 \ [0.0-15.0] = 25.9 \text{ per 10,000}$
  – White:
    • $22.7 \ [15.6-30.1]$

Muzaale/Segev, JAMA, 2014
Questions We Want to Answer

• *Baseline risk*  
  (risk individual will have if doesn't donate)

• *Absolute risk*  
  (total risk individual faces if donates)

• *Attributable risk*  
  (extra risk individual faces if does donate)

• By race, age, sex, BMI, insurance, SES, etc?
Bigger Data
Kidney-Failure Risk Projection for the Living Kidney-Donor Candidate

CKD Prognosis Consortium

Grams et al, NEJM, 2016
- ACR 4 mg/g
- SBP 120 mmHg
- No diabetes
- No hypertension meds
- Non-smoker
- BMI 26

<table>
<thead>
<tr>
<th>Age</th>
<th>Base-case eGFR</th>
</tr>
</thead>
<tbody>
<tr>
<td>20</td>
<td>114</td>
</tr>
<tr>
<td>30</td>
<td>106</td>
</tr>
<tr>
<td>40</td>
<td>98</td>
</tr>
<tr>
<td>50</td>
<td>90</td>
</tr>
<tr>
<td>60</td>
<td>82</td>
</tr>
<tr>
<td>70</td>
<td>74</td>
</tr>
<tr>
<td>80</td>
<td>66</td>
</tr>
</tbody>
</table>
A 15-Year Projected Incidence of ESRD

- Black men
- Black women
- White men
- White women

Incidence (%)

Age (yr)
B  Lifetime Projected Incidence of ESRD

- Black men
- Black women
- White men
- White women

Incidence (%) vs. Age (yr)

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Base Case

![Bar charts showing lifetime incidence by age and gender for Black Men, Black Women, White Men, and White Women.](image)

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<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Hazard Ratio (95% CI)</th>
<th>β±SE</th>
<th>Population Cohort</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>NHANES</td>
</tr>
<tr>
<td>eGFR per decrease of 15 mL/min/1.73 m²</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt;60 mL/min/1.73 m²</td>
<td>6.61 (4.87–8.96)</td>
<td>1.89±0.16</td>
<td>12.82</td>
</tr>
<tr>
<td>60–89 mL/min/1.73 m²</td>
<td>1.63 (1.53–1.74)</td>
<td>0.49±0.03</td>
<td>1.05</td>
</tr>
<tr>
<td>90–119 mL/min/1.73 m²</td>
<td>1.02 (0.85–1.23)</td>
<td>0.02±0.09</td>
<td>0.83</td>
</tr>
<tr>
<td>≥120 mL/min/1.73 m²</td>
<td>0.79 (0.56–1.10)</td>
<td>−0.24±0.17</td>
<td>1.18</td>
</tr>
<tr>
<td>Systolic blood pressure, per increase of 20 mm Hg</td>
<td>1.42 (1.27–1.58)</td>
<td>0.35±0.06</td>
<td>2.90</td>
</tr>
<tr>
<td>Antihypertensive drug use</td>
<td>1.35 (1.01–1.82)</td>
<td>0.30±0.15</td>
<td>0.31</td>
</tr>
<tr>
<td>Noninsulin-dependent diabetes mellitus</td>
<td>3.01 (1.91–4.74)</td>
<td>1.10±0.23</td>
<td>0.77</td>
</tr>
<tr>
<td>Body-mass index, per 5-point increase</td>
<td></td>
<td></td>
<td>0.98</td>
</tr>
<tr>
<td>≤30</td>
<td>(0.81–1.17)</td>
<td></td>
<td>(1.11–5.21)</td>
</tr>
<tr>
<td>&gt;30</td>
<td>1.16 (1.04–1.29)</td>
<td>0.15±0.05</td>
<td>0.95</td>
</tr>
<tr>
<td></td>
<td>(0.40–2.24)</td>
<td></td>
<td>(0.95–1.79)</td>
</tr>
<tr>
<td>Smoking status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Former smoker</td>
<td>1.45 (1.23–1.71)</td>
<td>0.37±0.08</td>
<td>1.98</td>
</tr>
<tr>
<td>Current smoker</td>
<td>1.76 (1.29–2.41)</td>
<td>0.57±0.16</td>
<td>4.44</td>
</tr>
<tr>
<td>Urinary albumin-to-creatinine ratio, per increase of 10x</td>
<td>2.94 (0.99–8.75)</td>
<td>1.08±0.56</td>
<td>5.48</td>
</tr>
<tr>
<td></td>
<td>(2.37–12.71)</td>
<td></td>
<td>(1.26–2.56)</td>
</tr>
</tbody>
</table>
EgFR

Black Men

Black Women

White Men

White Women

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NIDDM

Black Men

Black Women

White Men

White Women

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Millions of healthy/CKD patients
120,000+ actual donors

### ESRD Risk Tool for Kidney Donor Candidates

#### Projected Incidence of End-Stage Renal Disease:

<table>
<thead>
<tr>
<th></th>
<th>Pre-Donation 15-Year*</th>
<th>Pre-Donation Lifetime*</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.04%</td>
<td></td>
<td>0.30%</td>
</tr>
<tr>
<td>Post-Donation 15-Year**</td>
<td></td>
<td>Post-Donation Lifetime**</td>
</tr>
<tr>
<td>?</td>
<td></td>
<td>?</td>
</tr>
</tbody>
</table>

*blue: < 1%, green: 1-2%, yellow: 2-3%, orange: 3-5%, red: >5%*

The pre-donation risks represent projections if a person does not donate a kidney. Details about estimating post-donation risk are provided below.

#### Patient Characteristics:

- **Age (18-89yrs)**: 40
- **Gender**: Female
- **Race (White or Black)**: White
- **eGFR (mL/min/1.73m²)**: 90
- **Systolic Blood Pressure (mmHg)**: 120
- **Hypertension Medication**: No Medication
- **BMI (kg/m²)**: 25
- **Non-Insulin Dependent Diabetes**: No Diabetes
- **Urine Albumin to Creatinine (mg/g)**: click on units to change between mg/g and mg/mmol
- **Smoking History**: Non-Smoker

*transplantmodels.com/esrdrisk*
Dialysis-to-Listing

Donors

Nondonors

p<0.001

Months

0  24  48  72  96  120  144

0.0  0.2  0.4  0.6  0.8  1.0

99  32  17  10  3  2  2
495 195 103 37 16 8 1

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Transplant-to-Graft Failure

Donors

Nondonors

p=0.7

# at Risk

<table>
<thead>
<tr>
<th></th>
<th>Donors</th>
<th>Nondonors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>54</td>
<td>270</td>
</tr>
<tr>
<td>24</td>
<td>46</td>
<td>220</td>
</tr>
<tr>
<td>48</td>
<td>28</td>
<td>151</td>
</tr>
<tr>
<td>72</td>
<td>15</td>
<td>84</td>
</tr>
<tr>
<td>96</td>
<td>7</td>
<td>50</td>
</tr>
<tr>
<td>120</td>
<td>2</td>
<td>19</td>
</tr>
<tr>
<td>144</td>
<td>1</td>
<td>8</td>
</tr>
</tbody>
</table>

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Death–Censored Graft Loss, %

Donor Developed ESRD
Donor Did Not Develop ESRD

p < .001

Years

0  5  10  15  20

# at Risk

257   164   88   30   15
955   739  500  228  107

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## Live Donor KDPI

<table>
<thead>
<tr>
<th>Donor characteristic</th>
<th>aHR</th>
</tr>
</thead>
<tbody>
<tr>
<td>LD: Age per year (over age 50)</td>
<td>1.02</td>
</tr>
<tr>
<td>LD: eGFR (per 10 units)</td>
<td>0.58</td>
</tr>
<tr>
<td>LD: BMI (per 10 units)</td>
<td>1.01</td>
</tr>
<tr>
<td>LD: Male donor to male recipient</td>
<td>0.75</td>
</tr>
<tr>
<td>LD: Black race</td>
<td>1.15</td>
</tr>
<tr>
<td>LD: ABO incompatible</td>
<td>1.03</td>
</tr>
<tr>
<td>LD: History of cigarette use</td>
<td>1.09</td>
</tr>
<tr>
<td>LD: Unrelated to recipient</td>
<td>0.84</td>
</tr>
<tr>
<td>LD: # HLA-B mismatches</td>
<td>1.03</td>
</tr>
<tr>
<td>LD: # HLA-DR mismatches</td>
<td>1.04</td>
</tr>
</tbody>
</table>

Adjusted for recipient characteristics. All coefficients p<0.05
Distribution of LKDPI

![Histogram of LKDPI distribution with two lines: LD KDPI and DD KDPI.](chart)
Conclusions

• Donor risk of death is very low (3:10,000) and there is no attributable risk beyond the operation at up to 12 years
• Donor risk of ESRD is very low (30:10,000) and there is attributable risk, which varies
• Baseline lifetime risk has be estimated from huge CKD populations
• Working on absolute/attributable lifetime risk
Implications

• We currently allow individuals to donate who have a very wide range of ESRD risk
• We currently decline potential donors who have conditions associated with a very wide range of ESRD risk
• We currently accept donors who have much higher risks than donors who we decline
• A new acceptable risk paradigm is coming
CKD-Prognosis Consortium

General Population Cohorts

Aichi
Hiroshi Yatsuya
Kentaro Yamashita
Hideaki Toyoshima
Koji Tamakoshi

AKDN:
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Brenda Hemmelgarn
Matthew James
Tanvir C Turin

ARIC:
Josef Coresh
Kunihiro Matsushita
Morgan Grams
Yingying Sang

AusDiab:
Robert C Atkins
Kevan R Polkinghorne
Steven Chadban

Beaver Dam:
Anoop Shankar
Ronald Klein
Barbara KE Klein
Kristine E Lee

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Fang Wang
Luxia Zhang
Li Zuo

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Nish Chaturvedi

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Heiko Müller
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Massimo Cirillo

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Hans Hillege

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Elizabeth Barrett-Connor
Jaclyn Bergstrom

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Suzanne Judd
William M McClellan

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Jaeseong Jo
Yejin Mok
Eunmi Choi

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Sung-Feng Wen
Chwen-Keng Tsao
Min-Kuang Tsai

ULSAM:
Johan Årnlöv
Lars Lannfelt
Anders Larsson

Ibaraki:

KSHS:

Torino:

Beaver Dam:

KSHS:

NHANES III:

ULSAM:

Beaver Dam:

KSHS:

NHANES III:

ULSAM:
High Risk Cohorts

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- Mark Woodward
- John Chalmers
- Stephen MacMahon
- Hisatomi Arima

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- Brenda Hemmelgarn
- Aminu Bello
- Matthew James

**CARE:**
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- Frank Sacks
- Gary Curhan

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- Joseph A Vassalotti
- Suying Li
- Shu-Cheng Chen

**KP Hawaii:**
- Brian J Lee

**MRFIT:**
- Areef Ishani
- James Neaton

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- Tim Kenealy
- Simon Moyes
- John Collins
- Paul Drury

**Pima Indian:**
- Robert G Nelson
- William C Knowler

**ZODIAC:**
- Henk J Bilo
- Hanneke Joosten
- Nanne Kleefstra
- Klaas H Groenier
- Iefke Drion

**AASK:**
- Jackson Wright
- Lawrence Appel
- Tom Greene
- Brad C Astor

**British Columbia CKD:**
- Adeera Levin
- Ogjenka Djurdjev

**CCF:**
- Sankar Navaneethan
- Joseph Nally
- Jesse Schold

**CRIB:**
- David C Wheeler
- Martin J Landray
- Jonathan N Townend
- Jonathan Emberson

**GCKD:**
- Kai-Uwe Eckardt
- Anna Kottgen
- Florian Kronenberg
- Stephanie Tilze

**Geisinger:**
- Robert Perkins
- H Les Kirchner

**GLOMMS 1:**
- Corri Black
- Angharad Marks
- Nicholas Fluck
- Gordon Prescott

**Gonryo CKD:**
- Sadayoshi Ito
- Mariko Miyazaki
- Masaaki Nakayama
- Gen Yamada

**KP Northwest:**
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- Eric S Johnson
- Micah L Thorp
- Jessica Weinstein

**MASTERPLAN:**
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- Peter J Blankestijn
- Arjan D van Zuijlen

**MDRD:**
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- Andrew S Levey
- Lesley Inker
- Vandana Menon

**MMKD:**
- Florian Kronenberg
- Barbara Kollerits
- Eberhard Ritz

**NephroTest:**
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- M. Metzger
- JP Haymann
- P Houllier
- M. Flamant

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- Barry Brenner
- Dick de Zeeuw

**SRR-CKD:**
- Marie Evans
- Maria Stendahl

**STENO CKD:**
- Peter Rossing
- Hans-Henrik Parving

---

CKD Prognosis Consortium

High Risk Cohorts

NZDCS: C Raina Elley, Tim Kenealy, Simon Moyes, John Collins, Paul Drury

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KP Northwest: David H Smith, Eric S Johnson, Micah L Thorp, Jessica Weinstein

MASTERPLAN: Jack F Wetzel, Peter J Blankestijn, Arjan D van Zuijlen

MDRD: Mark Sarnak, Andrew S Levey, Lesley Inker, Vandana Menon

MMKD: Florian Kronenberg, Barbara Kollerits, Eberhard Ritz

NephroTest: Marc Froissart, Benedicte Stengel, M. Metzger, JP Haymann, P Houllier, M. Flamant

RENAAL: Hiddo J Lambers Heerspink, Barry Brenner, Dick de Zeeuw

SRR-CKD: Marie Evans, Maria Stendahl

STENO CKD: Peter Rossing, Hans-Henrik Parving

---

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- Morgan Grams, MD PhD
  Nephrology Faculty; K08
- Christine Durand, MD
  ID Faculty; R01 Pending
- Rebecca Craig-Schapiro, MD
  Surgery Resident
- Jackie Garonzik-Wang, MD PhD
  Surgery Resident; PhD Graduate (KL2)
- Elizabeth King, MD
  Surgery Resident; PhD Student (F32)
- Babak Orandi, MD PhD MSc
  Surgery Resident; PhD Graduate (F32)
- Kyle Van Arendonk, MD PhD
  Surgery Resident; PhD Graduate (KL2)

Epidemiology/Biostatistics
- Allan Massie, PhD
  Epidemiology Faculty (K01 pending)
- Mara McAdams-DeMarco, PhD
  Epidemiology Faculty
- Tanja Purnell, PhD
  Epidemiology Faculty
- Abi Muzzaile, MD, MHS
  Epidemiology Postdoc
- Megan Salter, PhD
  Epidemiology Postdoc (T32)
- Andrew Law, ScM
  Epidemiology Staff
- Xun Luo, MD ScM
  Analytical Staff
- Israel Olorunda, MBBS MPH
  Analytical Staff
- Anna Poon, MHS MS
  Analytical Staff

Research Assistants

Full-Time:
- Jennifer Alejo
  Amanda Brennan
  Ryan Brown
  Cassandra Delp
  Erika Jones
  Komal Kumar
  Katie Marks

Part-Time:
- Lindsay Adam
  Saad Anjum
  Kate Appel
  Olivia Berman
  Seal-Bin Han
  Diana Cantu-Reyna
  Maurice Dunn
  Laura Grau
  Teal Harrison
  Sara Hawa
  Billy Kim

Medicine/Surgery
- Ravi Vardhan, PhD
  Biostatistics: Coinvestigator
- Lucy Meoni, ScM
  Biostatistics: Coinvestigator
- Josep Coresh, MD PhD
  Epidemiology: Coinvestigator
- Linda Kao, PhD
  Epidemiology: Coinvestigator
- Lauren Nicholas, PhD
  Health Policy: Coinvestigator
- Andrew Cameron, MD PhD
  Surgery: Collaborator
- Niraj Desai MD
  Surgery: Collaborator
- Bob Montgomery, MD PhD
  Surgery: Collaborator
- Nabil Dagher, MD
  Surgery: Mentee
- Elliott Haut, MD PhD
  Surgery: Mentee (KL2; PCORI)
- Kim Steele, MD PhD
  Surgery: Mentee (K23)
- Diane Schwartz, MD
  Surgery: Mentee
- Aliaksei Pustavoitau, MD
  Anesthesiology: Mentee (R03 pending)

Medical/Graduate Students
- Natasha Gupta
  Medical Student (Doris Duke)
- Lauren Kucirka, ScM
  MD/PhD Student (F30)
- Young Mee Choi
  Epidemiology; MPH Student

Computational Science
- Sommer Gentry, PhD
  Computer Science Faculty (HRSA)
- Eric Chow, MHS
  Decision Process Programmer/Analyst
- Corey Wickliffe, MHS
  Geographic Systems Analyst

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