



# **LONG-TERM RISK ASSESSMENT AND PREDICTION IN KIDNEY DONORS: THE NEW KDIGO GUIDELINES AND THE NEW CALCULATORS**

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<http://kdigo.org/home/guidelines/livingdonor/>

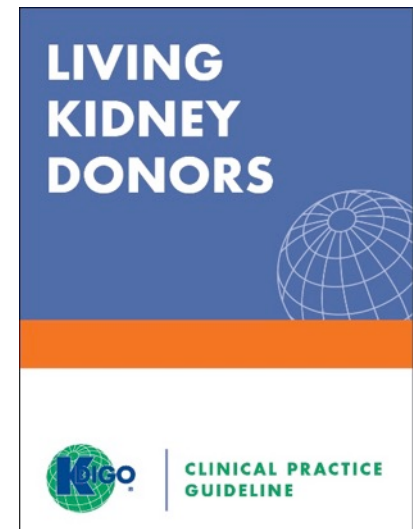
Summary of 16 prior guidelines in living kidney donation

New **2016** KDIGO living kidney donor guidelines

~ 130 pages, 18 chapters

Supported by evidence based review of published outcomes

Revised with community comments



# JOSEPH MURRAY, NOBEL LECTURE, 12/8/90

"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."

# INDIVIDUALIZED RISK PREDICTION

- Typically, risk factors are considered **in isolation**.
- Transplant centers lack empirical evidence on **overall** ESRD risk associated with combinations of risk factors. Need a tool to estimate the risk of ESRD from multiple health characteristics.

# QUESTIONS WE WANT TO ANSWER

*Absolute risk*

(total risk individual faces after donation)

= *Baseline risk*

(risk individual will have if doesn't donate)

+ *Attributable risk*

(extra risk individual faces if does donate)

By race, age, sex, BMI, insurance, SES, etc?

# STUDYING DEATH/ESRD IN KIDNEY DONORS

- 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)

# OPTN LIVE DONOR REGISTRY

- Every live donor in the US since 1988
- Currently N>120,000
- Advantages: massive, unbiased
- Disadvantages:
  - Incomplete, limited-term outcome capture
  - But... SSN captured since 1994 – linkage
- Medicare (CMS)
- Social Security (SSDMF)



# NHANES III

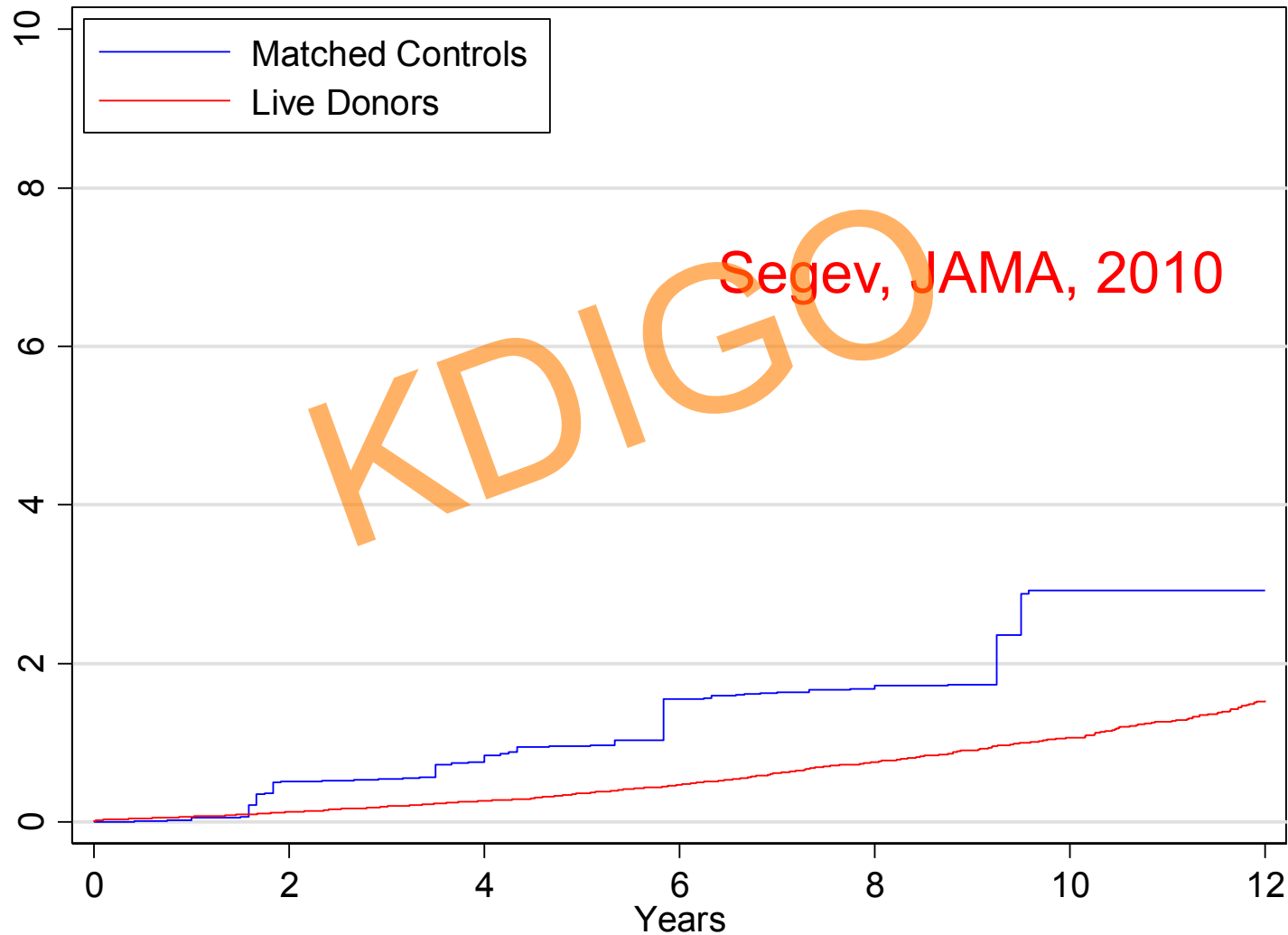
- Interviews, physical examination, and laboratory tests of 20,024 adults and 13,000 children administered by medical personnel
- Very detailed initial visits
- Can identify “healthy non-donors”
- Cross-sectional: no follow-up (except **linkage**)
- **Medicare (CMS)**
- **Social Security (SSDMF)**

# PERIOPERATIVE MORTALITY

Characteristic	Subgroup	90-day Mortality Rate	P-value
<b>Overall</b>		3.1 (2.0-4.6) per 10,000	
<b>Age (years)</b>	18-39	3.0 (1.6-5.3)	0.5
	40-49	3.7 (1.7-7.0)	
	50-59	1.5 (0.2-5.4)	
	>=60	6.6 (0.8-23.9)**	
<b>Sex</b>	Men	5.1 (3.0-8.2)	0.007
	Women	1.7 (0.7-3.4)	
<b>Race/Ethnicity</b>	Caucasian	2.6 (1.4-4.2)	0.04
	African American	7.6 (3.3-15.0)	
	Hispanic	2.0 (0.2-7.3)	

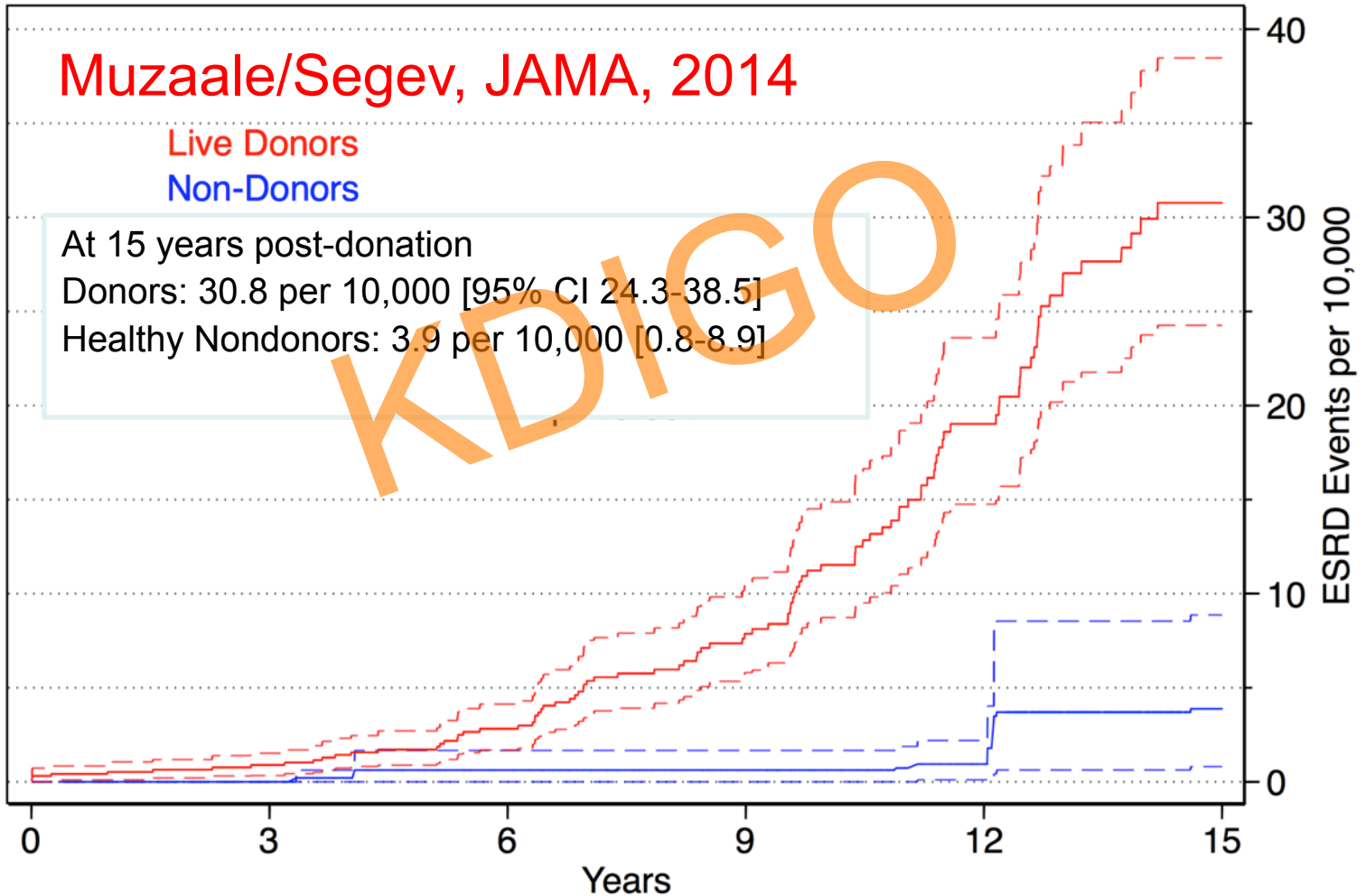
Segev, JAMA, 2010

# MORTALITY VERSUS HEALTHY NON-DONORS



Segev, JAMA, 2010

# ESRD VERSUS HEALTHY NON-DONORS



# INDIVIDUALIZED RISK PREDICTION

- Typically, risk factors are considered **in isolation**.
- Transplant centers lack empirical evidence on **overall** ESRD risk associated with combinations of risk factors. Need a tool to estimate the risk of ESRD from multiple health characteristics.
- Data from donors is insufficient for lifetime risk estimation – even N=120,000 is not enough for individualized risk prediction given rarity of ESRD events

# CKD-PROGNOSIS CONSORTIUM

## Resources

- Collaborative random effects meta-analysis (7 general population cohort studies; subset - low-risk only)
- Relative risks from meta-analysis calibrated to the age, sex, and race-specific incidence of ESRD in the US low-risk population using NHANES, USRDS, & US Census data
- Predictors: Age, race, sex, eGFR, albuminuria, BMI, hypertension, diabetes
- Outcome: ESRD



# CKD-Prognosis Consortium

## General Population Cohorts

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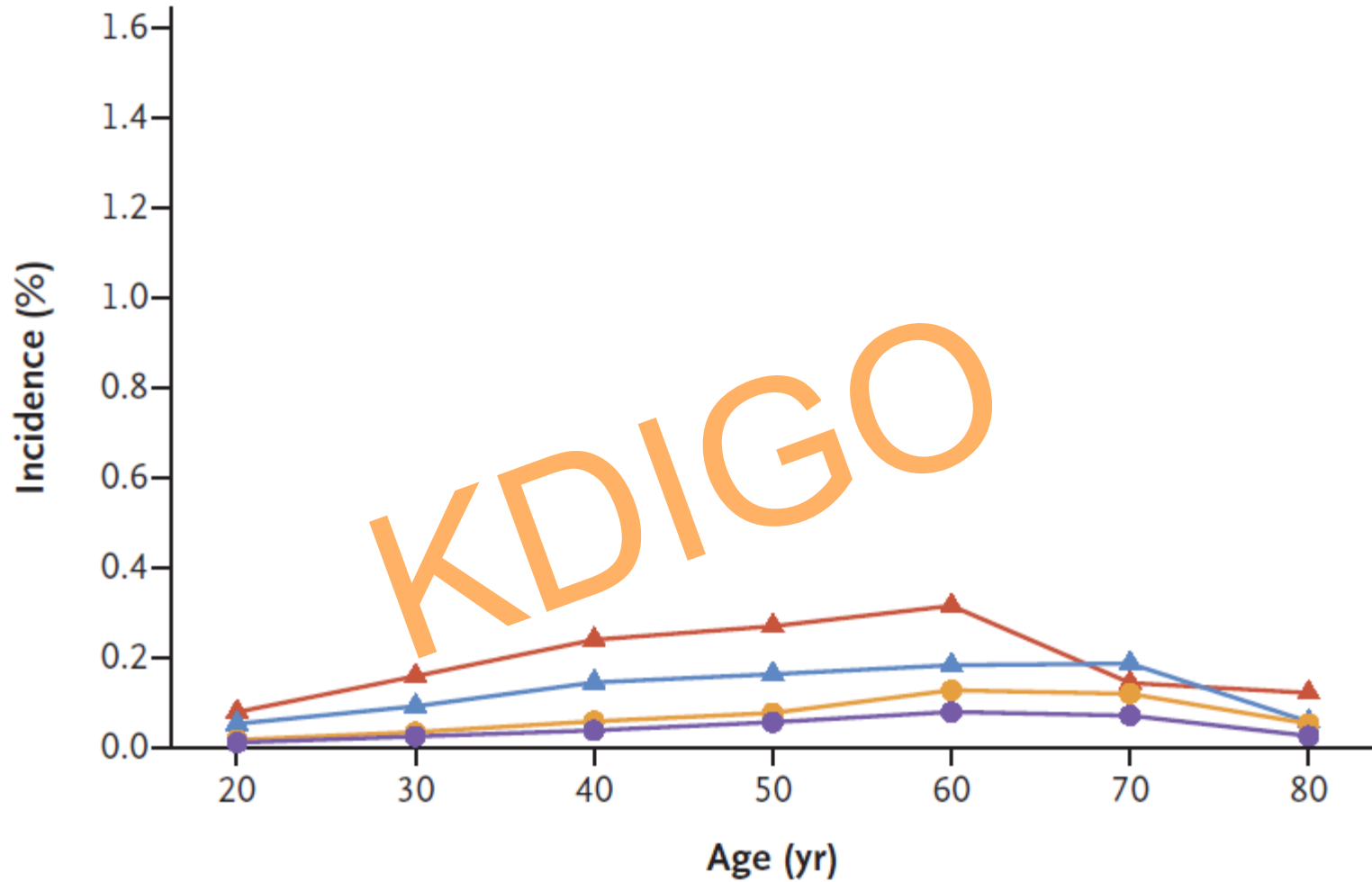
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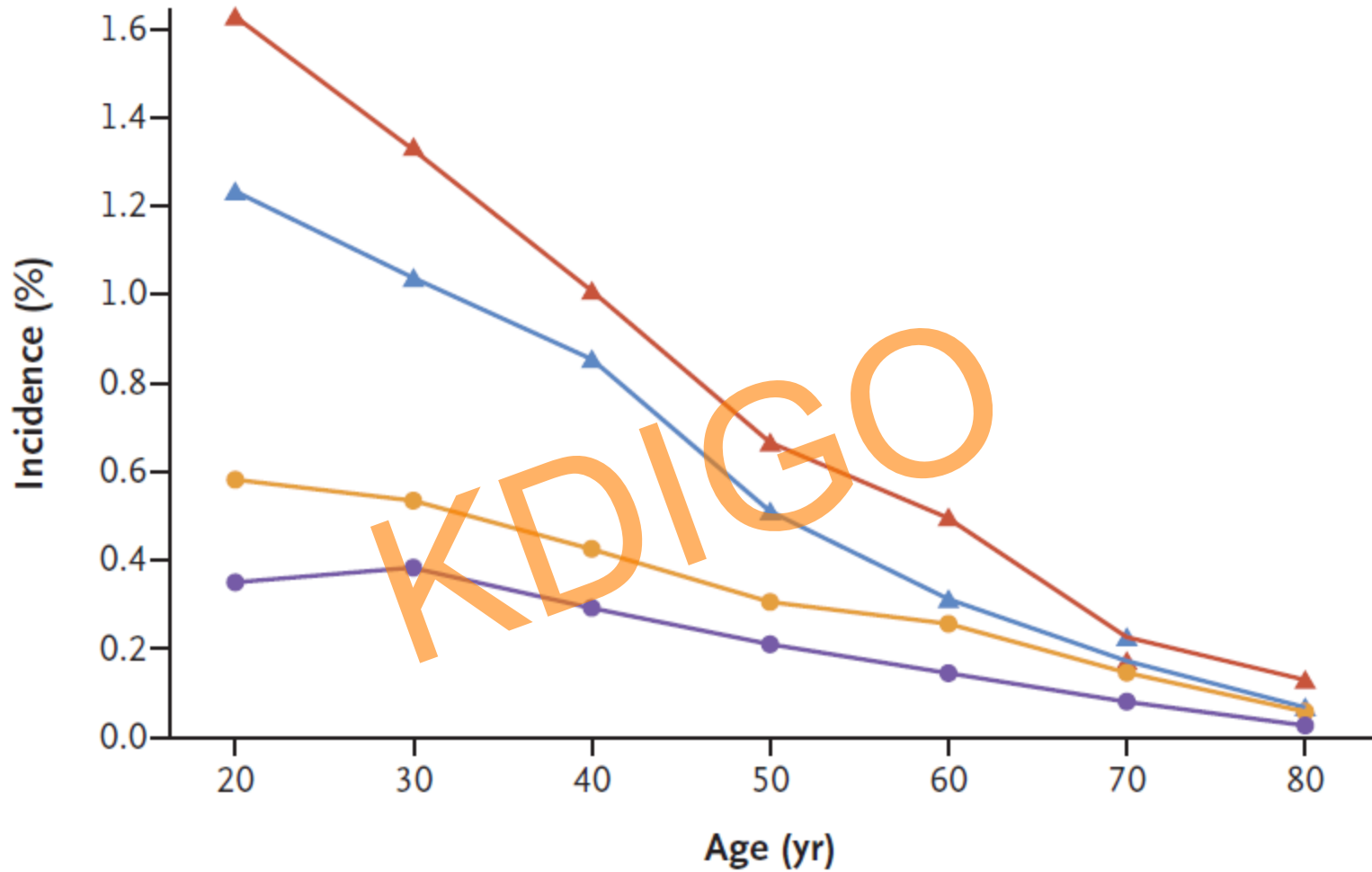
# A 15-Year Projected Incidence of ESRD



ME Grams, et al. *N Engl J Med.* 2016; 374:411

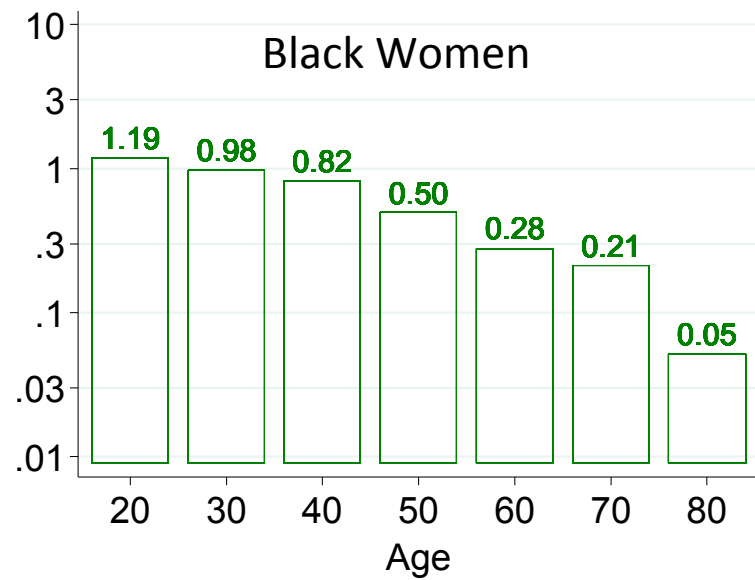
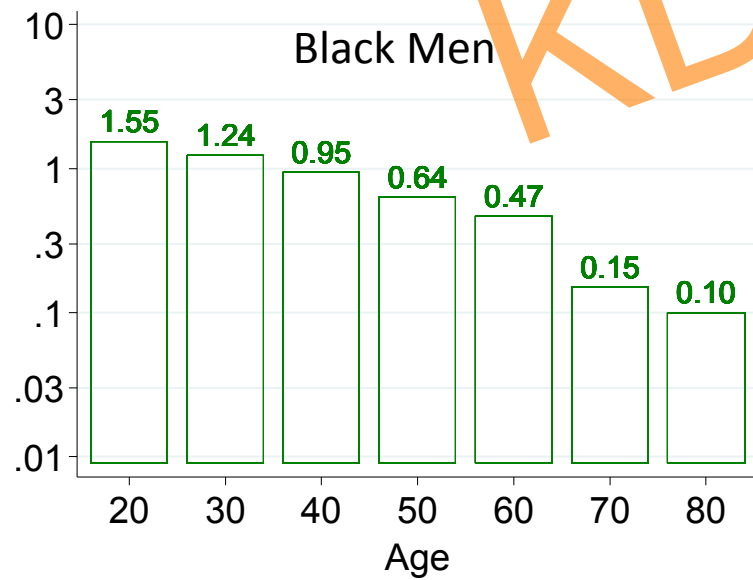
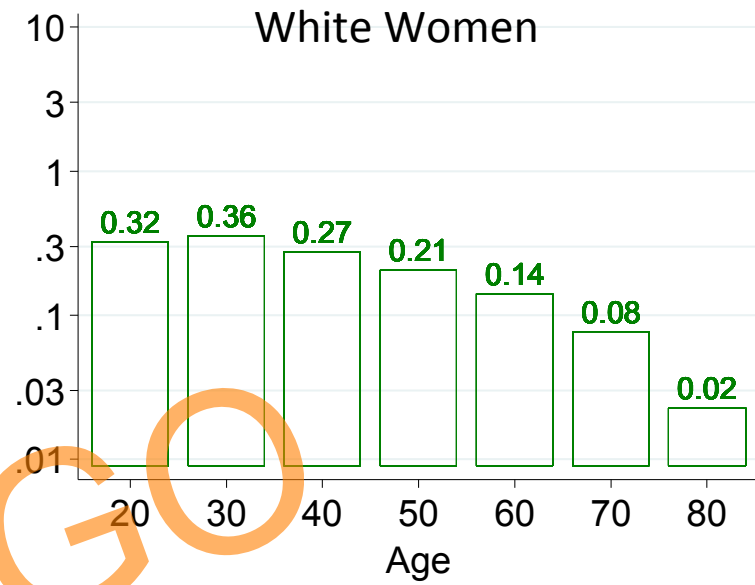
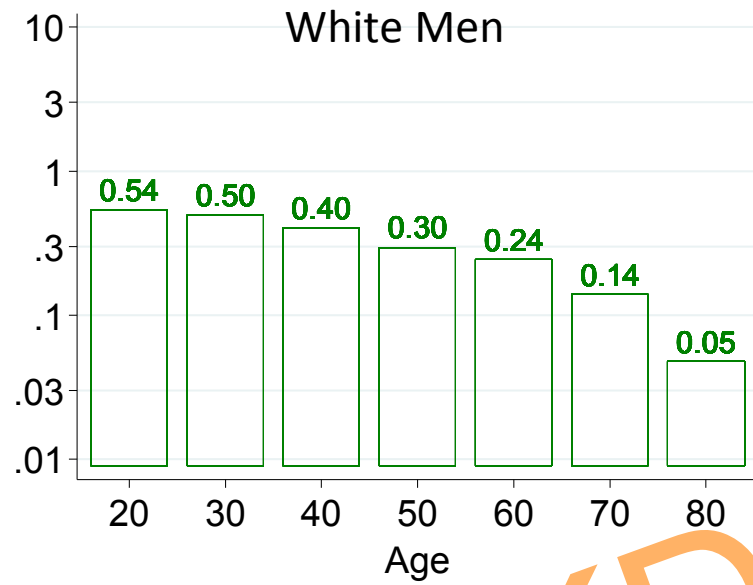


## B Lifetime Projected Incidence of ESRD

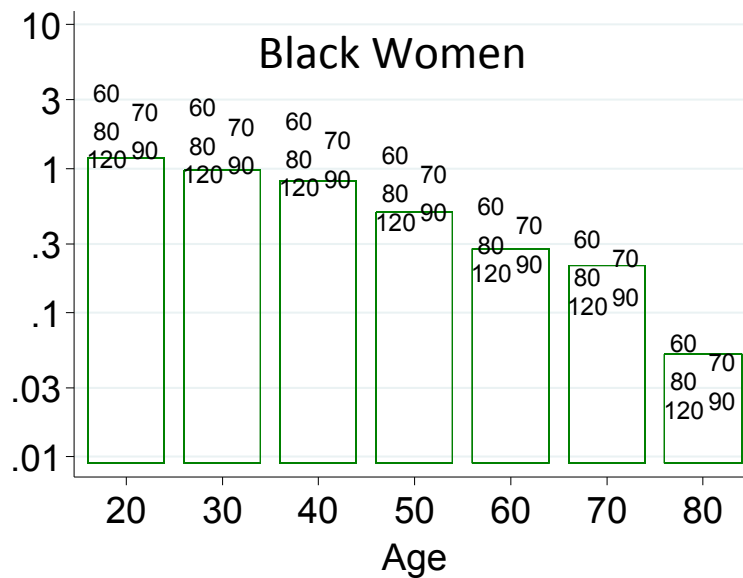
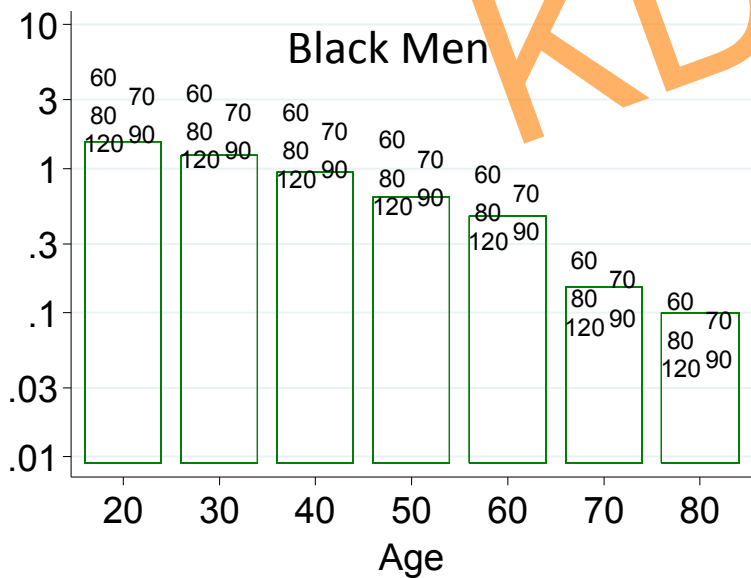
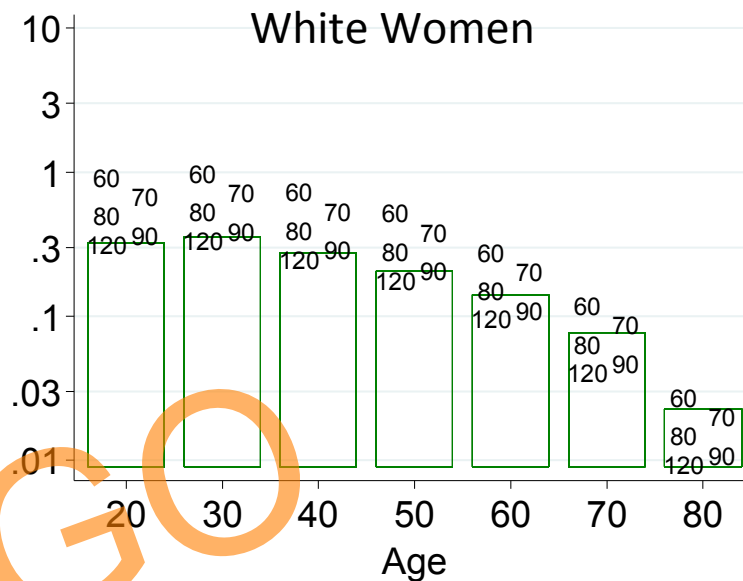
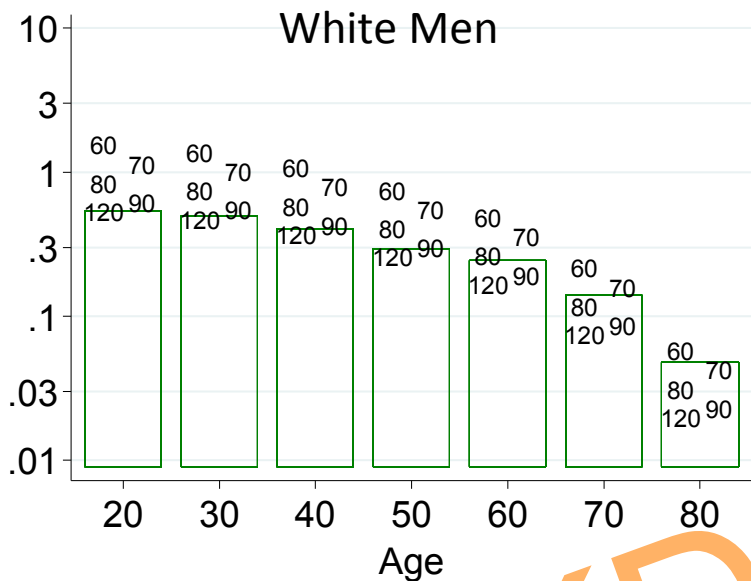


ME Grams, et al. *N Engl J Med.* 2016; 374:411

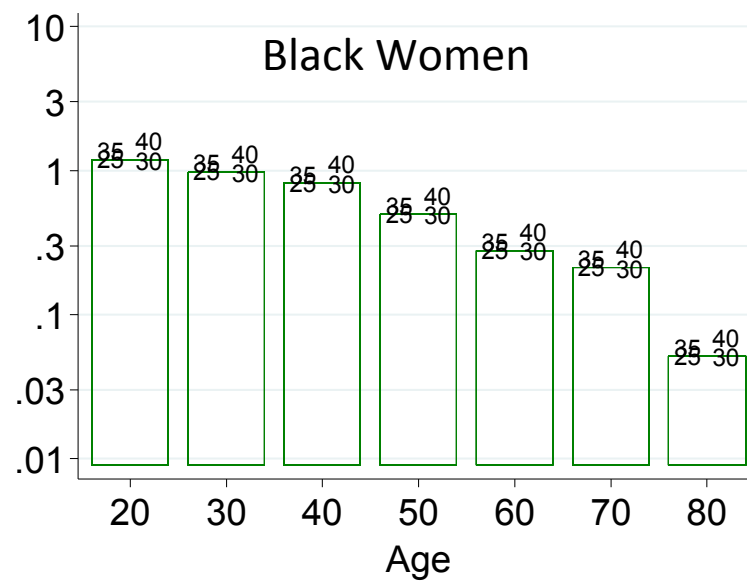
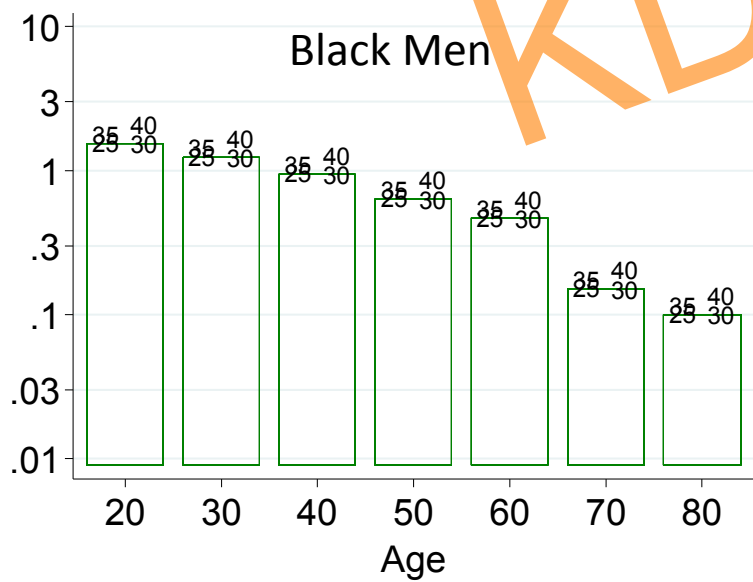
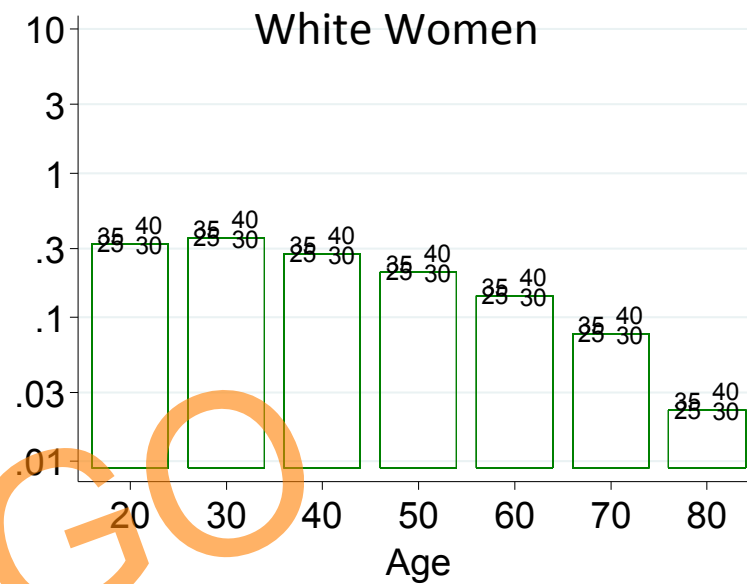
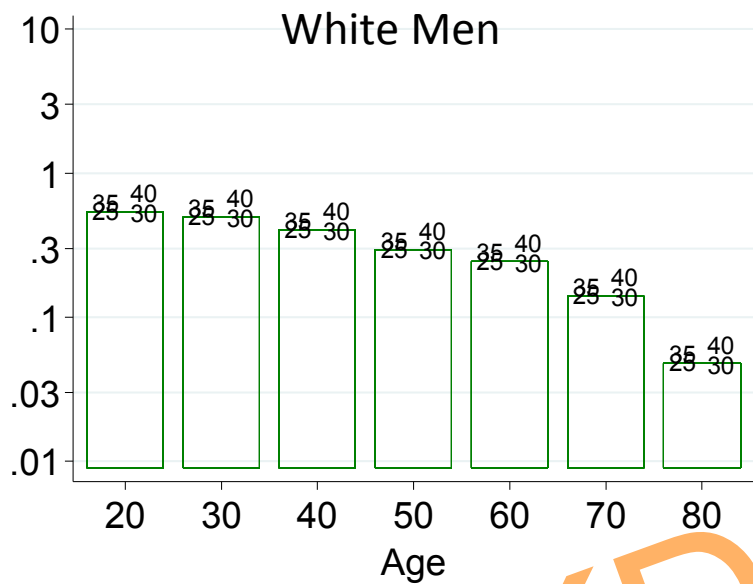
Figure 1: Base-case, age varying eGFR and ACR=4



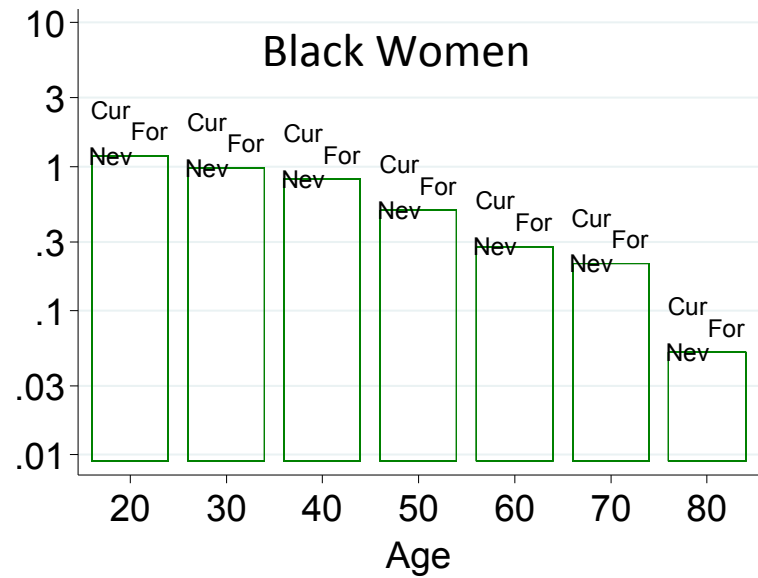
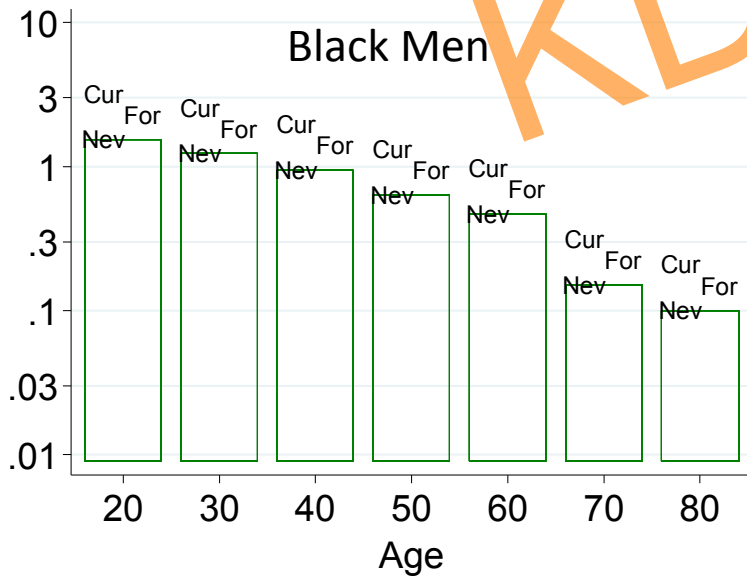
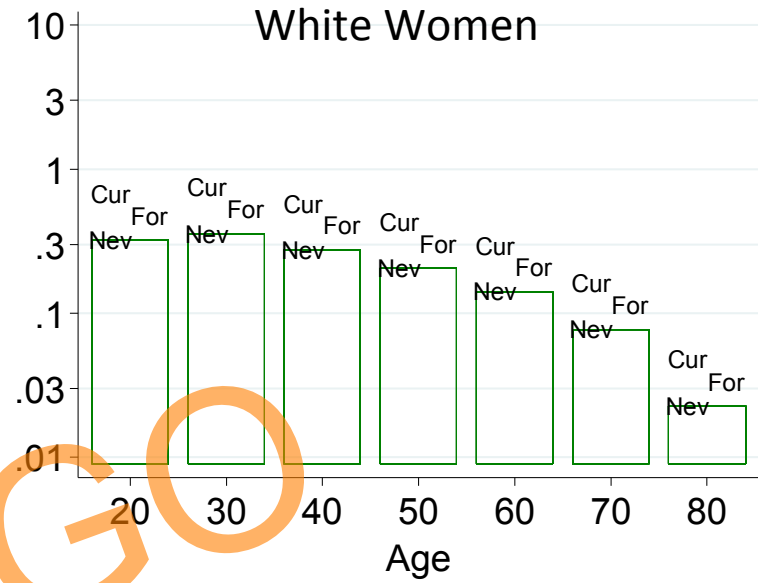
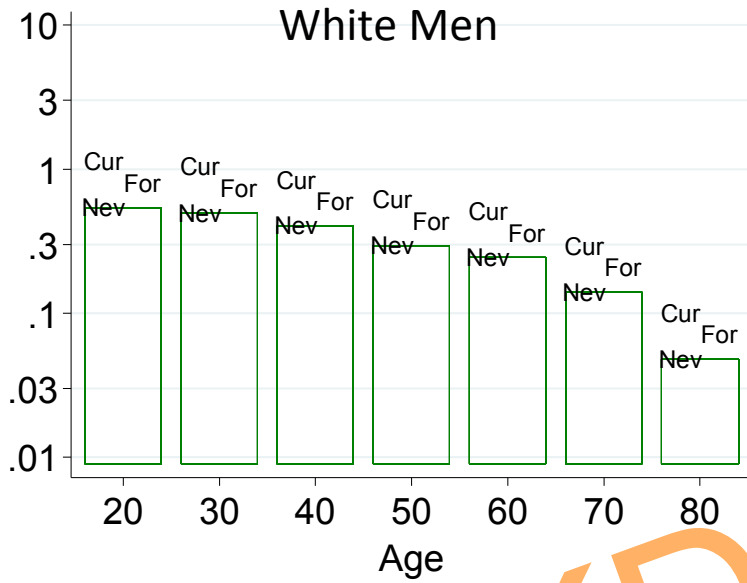
# Figure 2: eGFR



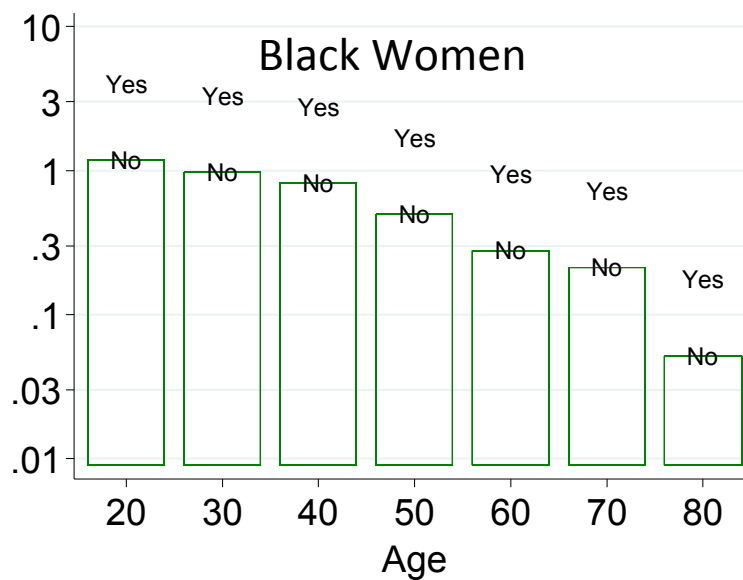
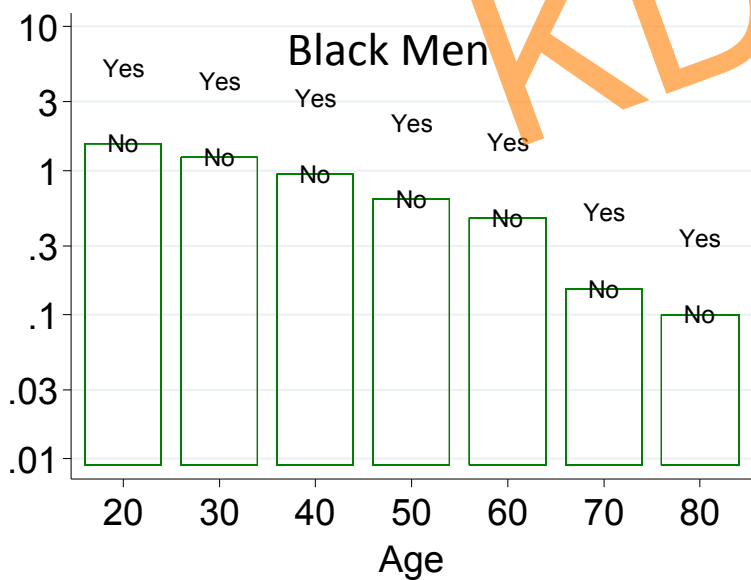
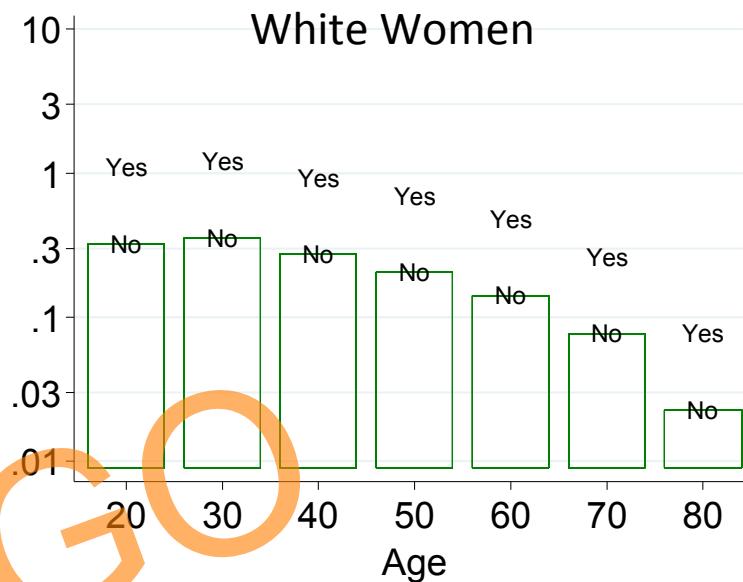
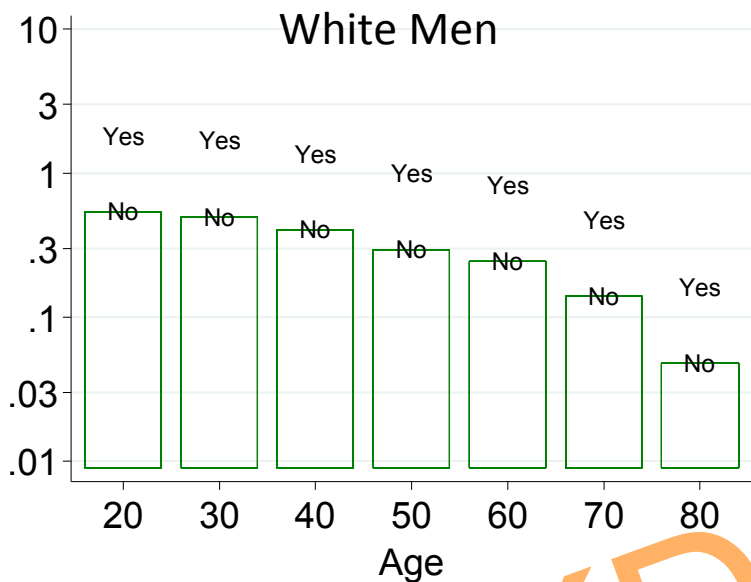
# Figure 2: BMI



# Figure 2: Smoking



# eFigure 1: Non-insulin dependent DM



# RISK PREDICTION: DONORS

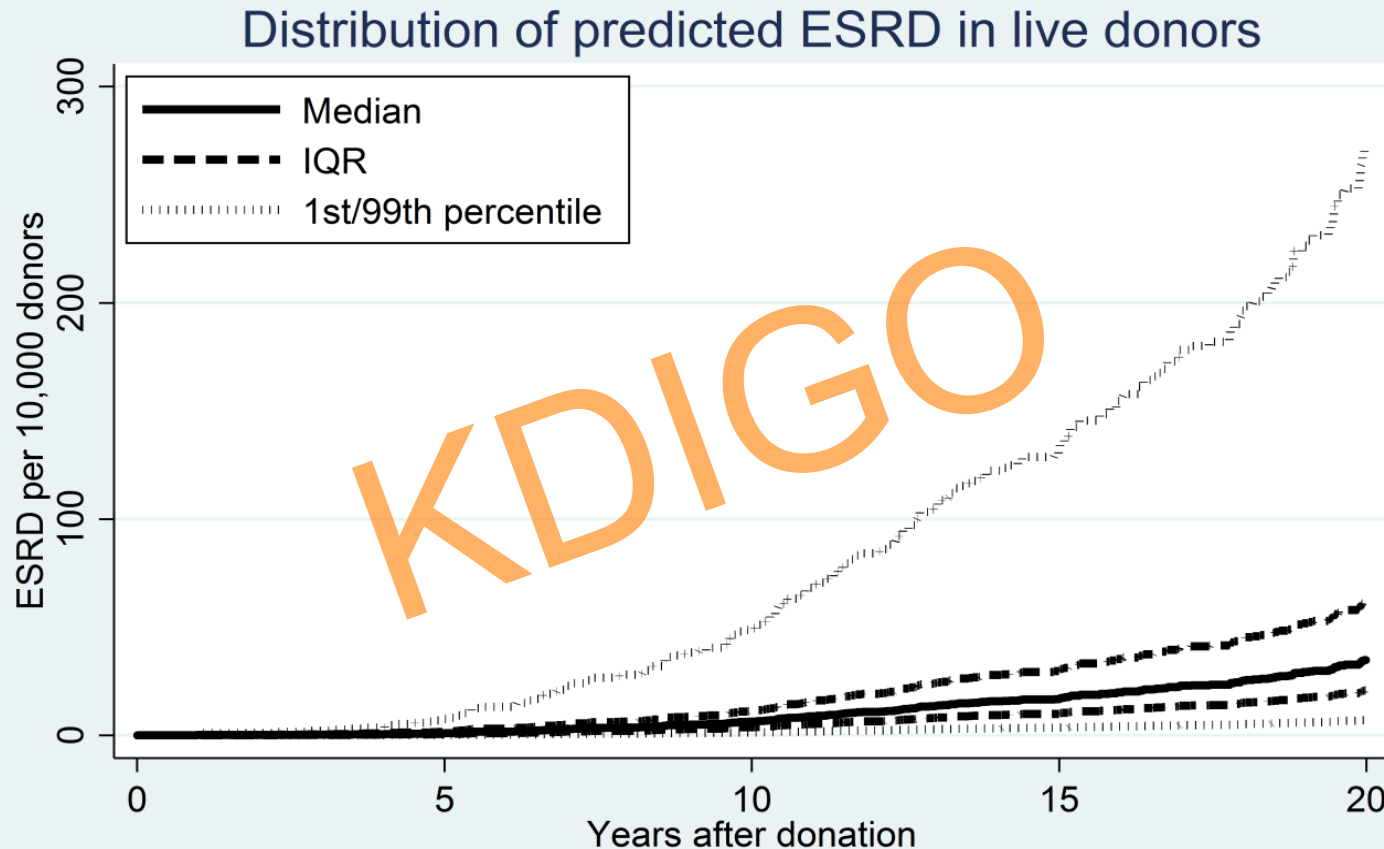
Characteristic	No ESRD	ESRD
<b>N</b>	127,923	285
<b>Median (IQR) year of donation</b>	2004 (1998-2009)	1995 (1991-1999)
<b>Median (IQR) age at donation</b>	40 (31-48)	38 (30-49)
<b>Median (IQR) BMI at donation</b>	26.6 (23.7-29.7)	28.9 (24.3-31.1)
<b>% Male</b>	40.9%	61.4%
<b>% African-American</b>	12.6%	36.1%
<b>% biologically unrelated</b>	31.9%	10.0%



# RISK PREDICTION: DONORS

Characteristic	Hazard ratio	p
Male sex (at age 40)	1.49 1.91 2.44	<0.001
AA race (at age 40)	2.66 3.05 4.11	<0.001
Age per 10y: non-AA, male	1.35 1.58 1.85	<0.001
Age per 10y: non-AA, female	0.98 1.22 1.52	0.07
Age per 10y: AA	0.63 0.79 0.98	0.03
BMI per 5 units	1.23 1.59 2.06	<0.001
Biologically unrelated	0.43 0.64 0.96	0.03

# RISK PREDICTION: DONORS



Predicted ESRD risk is calculated for each individual.  
50% of predicted survival curves fall between the dashed lines,  
but a few individuals have substantially higher predicted 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 big data-driven risk paradigm is here

# TRANSPLANTMODELS.COM/ESRDRISK

## Projected Incidence of End-Stage Renal Disease:

<b>0.04%</b> Pre-Donation 15-Year*	<b>0.30%</b> Pre-Donation Lifetime*
?	?
Post-Donation 15-Year**	Post-Donation Lifetime**

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:

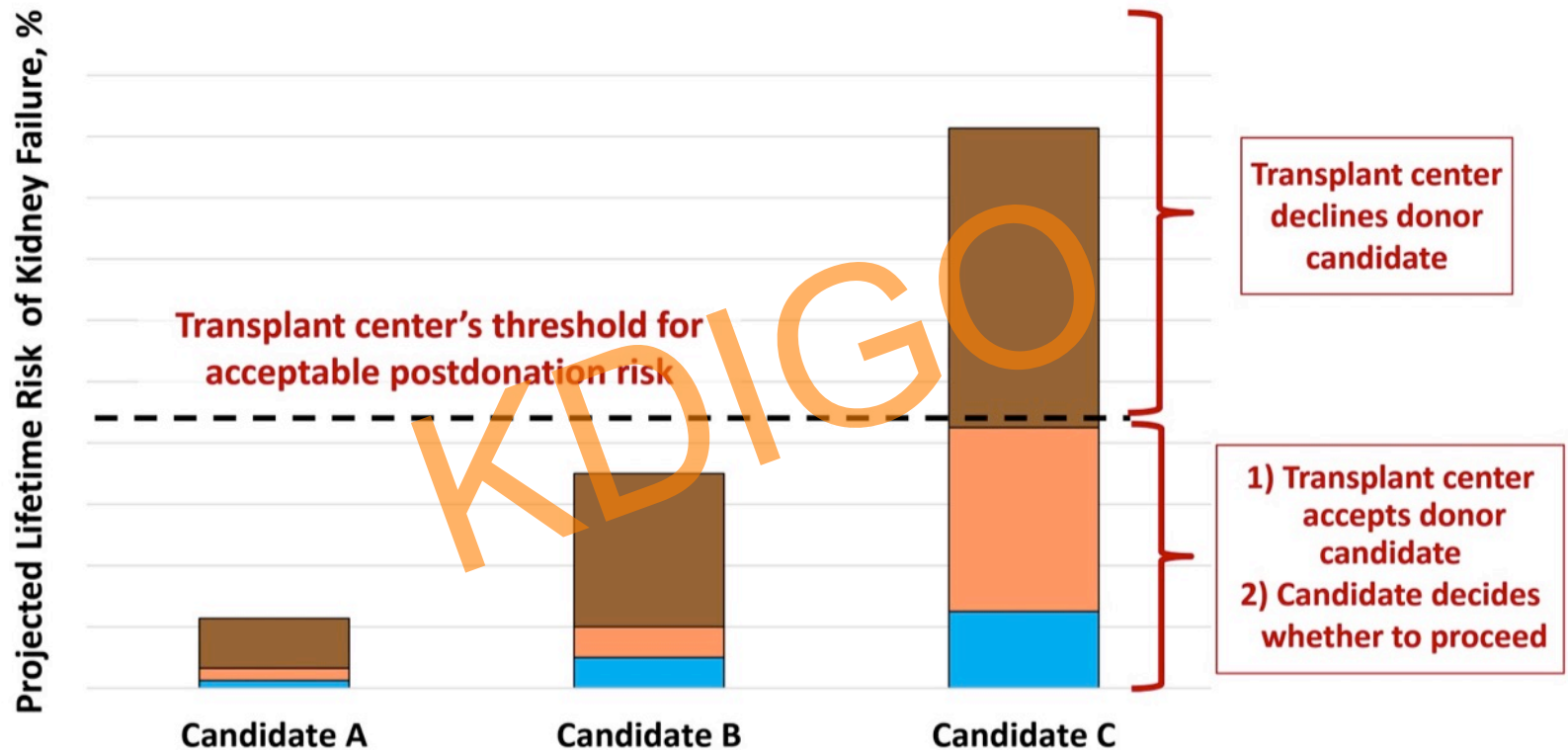
Age (18-80yrs)	40
Gender	Female
Race (White or Black)	White
eGFR (mL/min/1.73m <sup>2</sup> )	90
Systolic Blood Pressure (mmHg)	120
Hypertension Medication	No Medication
BMI (kg/m <sup>2</sup> )	25
Non-Insulin Dependent Diabetes	No Diabetes
Urine Albumin to Creatinine (mg/g) <small>click on units to change between mg/g and mg/mmol</small>	4
Smoking History	Non-Smoker



# EVALUATING DONOR RISK EQUITABLY

- Establish the risk your program is willing to accept, e.g. lifetime risk of ESRD <5%
- Estimate individual pre-donation ESRD risk based on age, gender, race/ethnicity, eGFR, systolic BP, antihypertensive meds, BMI, NIDDM, ACR, smoking (use risk calculator)
- Multiply pre-donation risk times the estimated attributable risk from donation, e.g. 5-10-fold (this is a big assumption)

# ACCEPTABLE RISK FRAMEWORK



- Demographic-related risk in the absence of donation (age, sex, and race)
- Aggregate risk related to clinical characteristics in the absence of donation (e.g. GFR, blood pressure, BMI, smoking)
- Donation-attributable risk (may vary by demographic and clinical characteristics)

# LIVE DONOR KDPI CALCULATOR

Donor characteristic		aHR	
LD: Age per year (over age 50)	1.02	<b>1.02</b>	1.03
LD: eGFR (per 10 units)	0.58	<b>0.70</b>	0.83
LD: BMI (per 10 units)	1.01	<b>1.09</b>	1.16
LD: Male donor to male recipient	0.75	<b>0.81</b>	0.87
LD: Black race	1.15	<b>1.25</b>	1.37
LD: ABO incompatible	1.03	<b>1.27</b>	1.58
LD: History of cigarette use	1.09	<b>1.16</b>	1.23
LD: Unrelated to recipient	0.84	<b>0.90</b>	0.97
LD: # HLA-B mismatches	1.03	<b>1.08</b>	1.14
LD: # HLA-DR mismatches	1.04	<b>1.09</b>	1.15

# LIVE DONOR KDPI CALCULATOR

- 5.23**
- + 2.24** \* (age-50) if age>50
  - 0.37** \* eGFR
  - + 0.89** \* BMI
  - 22.20** if don/recip both male
  - + 23.47** if African-American
  - + 25.04** if ABO incompatible
  - + 15.03** if donor history of cigarette
  - 10.51** if unrelated
  - + 8.34** \* (# HLA-B mismatches)
  - + 8.77** \* (# HLA-DR mismatches)





# LIVE DONOR KDPI CALCULATOR

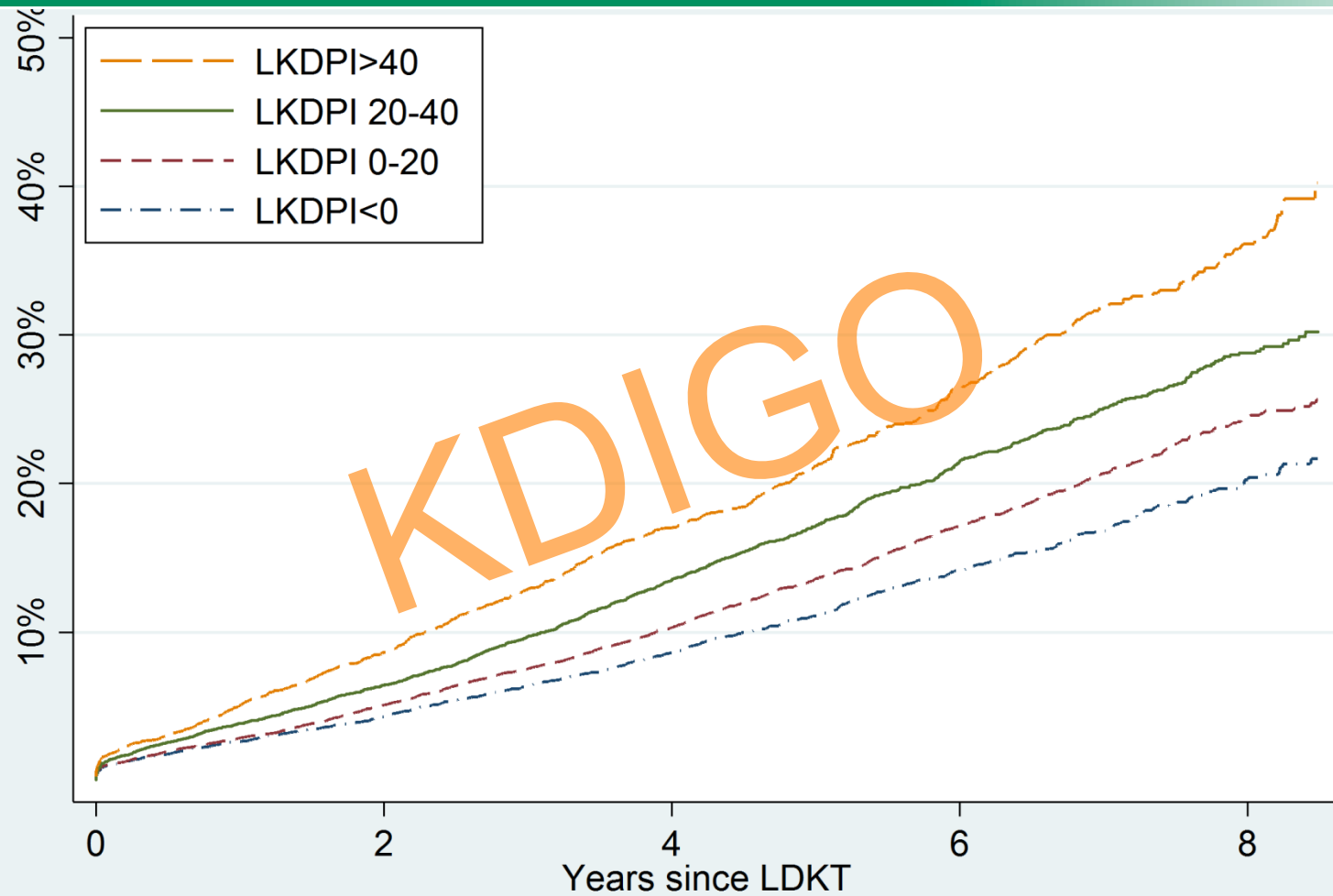
Example: 43-year-old nonsmoking non-AA F, eGFR 95, BMI 24

<b>5.23</b>		<b>5.23</b>	
<b>+ 2.24</b>	* (age-50) if age>50	<b>+ 2.24</b>	* 0
<b>- 0.37</b>	* eGFR	<b>- 0.37</b>	* 95
<b>+ 0.89</b>	* BMI	<b>+ 0.89</b>	* 24
<b>- 22.20</b>	if don/recip both male	<b>- 0</b>	
<b>+ 23.47</b>	if African-American	<b>+ 0</b>	
<b>+ 25.04</b>	if ABO incompatible	<b>+ 0</b>	
<b>+ 15.03</b>	if donor history of cigarette	<b>+ 0</b>	
<b>- 10.51</b>	if unrelated	<b>- 0</b>	
<b>+ 8.34</b>	* (# HLA-B mismatches)	<b>+ 8.30</b>	* 1
<b>+ 8.77</b>	* (# HLA-DR mismatches)	<b>+ 8.77</b>	* 1

**LKDPI = 8.4**



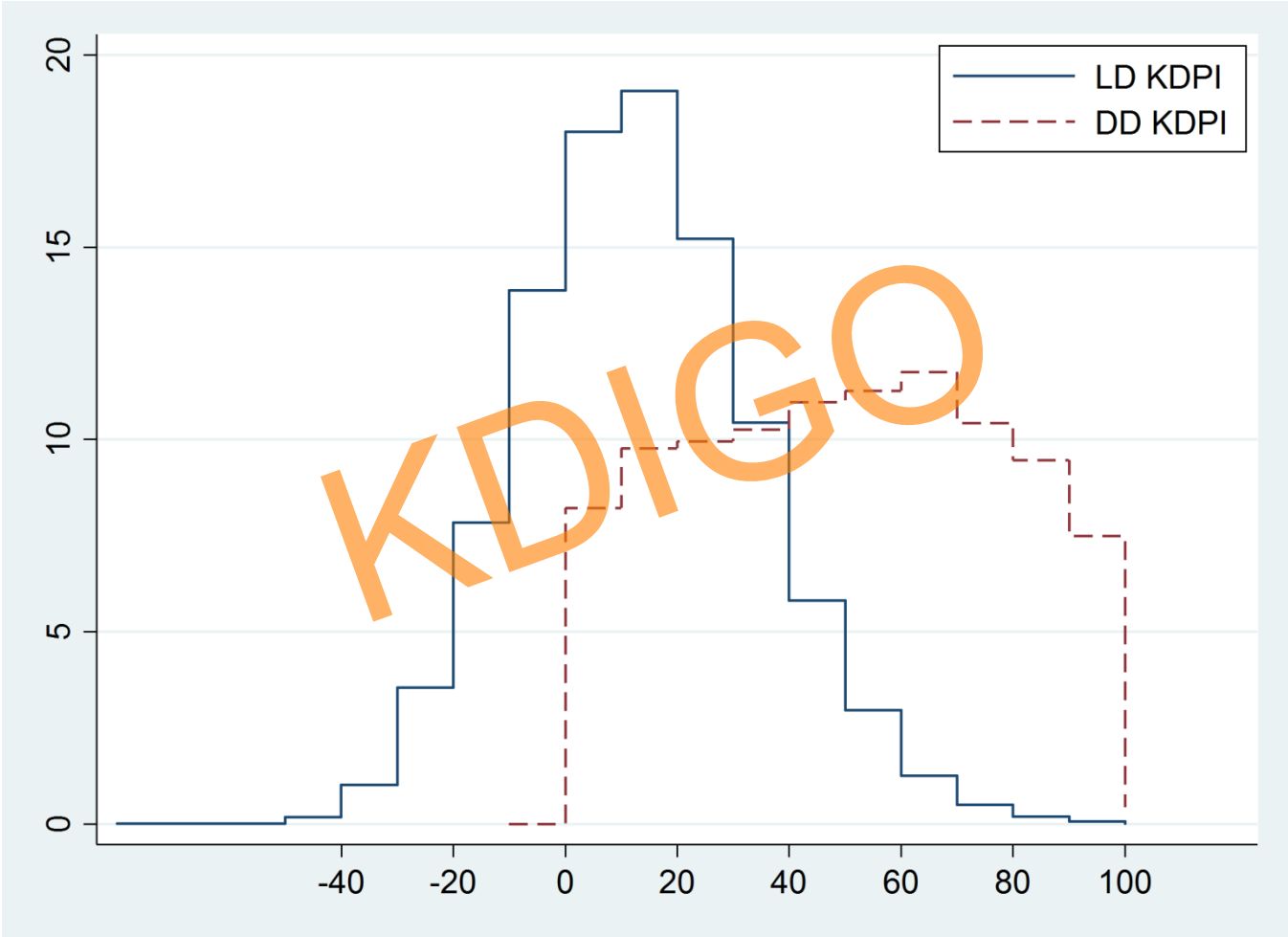
# CUMULATIVE GRAFT LOSS BY LKDPI



KDIGO



# DISTRIBUTION OF LKDPI





Age (18-80 yrs)	20	60
Gender	Male	Male
Race (White or Black)	White	White
eGFR (mL/min/1.73m <sup>2</sup> )	90	90
Systolic Blood Pressure (mm Hg)	120	120
Hypertension Medication	No	No
BMI (kg/m <sup>2</sup> )	25	25
Non-Insulin Dependent Diabetes	No	No
ACR (mg/g)	4	4
Smoking History	No	No

Age (18-80 yrs)	20	60
Gender	Male	Male
Race (White or Black)	White	White
eGFR (mL/min/1.73m <sup>2</sup> )	90	90
Systolic Blood Pressure (mm Hg)	120	120
Hypertension Medication	No	No
BMI (kg/m <sup>2</sup> )	25	25
Non-Insulin Dependent Diabetes	No	No
ACR (mg/g)	4	4
Smoking History	No	No

Pre-donation 15-y risk	0.02%	0.10%
Pre-donation lifetime risk	0.60%	0.20%
Post-donation lifetime risk (x5)???	3.00%	1.00%

Age (18-80 yrs)	20	60
Gender	Male	Male
Race (White or Black)	White	White
eGFR (mL/min/1.73m <sup>2</sup> )	90	90
Systolic Blood Pressure (mm Hg)	120	120
Hypertension Medication	No	No
BMI (kg/m <sup>2</sup> )	29	29
Non-Insulin Dependent Diabetes	No	No
ACR (mg/g)	10	10
Smoking History	Current	Current
Pre-donation 15-y risk	0.05%	0.26%
Pre-donation lifetime risk	1.60%	0.52%
Post-donation lifetime risk (x5)???	8.00%	2.50%

# DONOR HYPERTENSION

“Patients with a BP 140/90 by ABPM are generally not acceptable as donors.”

“Some patients with easily controlled hypertension who meet other defined criteria (e.g., 50 years of age, GFR 80 ml/min, and urinary albumin excretion 30 mg/day) may represent a low-risk group for development of kidney disease after donation and may be acceptable as kidney donors.

-Amsterdam Forum, *Transplantation* 2005;79: S53

“We suggest well-controlled primary hypertension, as assessed by ambulatory blood pressure <130/85 mmHg, under treatment with maximum two anti-hypertensive drugs (diuretics included) is not considered a contra-indication to living kidney donation. (2C)”

-ERBP, *Nephrol Dial Transplant* 2015; 30: 1790



Age (18-80 yrs)	45	45
Gender	Male	Male
Race (White or Black)	White	White
eGFR (mL/min/1.73m <sup>2</sup> )	90	90
Systolic Blood Pressure (mm Hg)	120	150
Hypertension Medication	No	No
BMI (kg/m <sup>2</sup> )	25	25
Non-Insulin Dependent Diabetes	No	No
ACR (mg/g)	10	10
Smoking History	No	No

Pre-donation 15-y risk	0.11%	0.18%
Pre-donation lifetime risk	0.42%	0.71%
Post-donation lifetime risk (x5)???	2.10%	3.55%

Age (18-80 yrs)	45	45
Gender	Male	Male
Race (White or Black)	White	White
eGFR (mL/min/1.73m <sup>2</sup> )	90	90
Systolic Blood Pressure (mm Hg)	120	150
Hypertension Medication	No	Yes
BMI (kg/m <sup>2</sup> )	25	25
Non-Insulin Dependent Diabetes	No	No
ACR (mg/g)	10	10
Smoking History	No	No

Pre-donation 15-y risk	<b>0.11%</b>	<b>0.24%</b>
Pre-donation lifetime risk	<b>0.42%</b>	<b>0.96%</b>
Post-donation lifetime risk (x5)???	<b>2.10%</b>	<b>4.80%</b>

Age (18-80 yrs)	45	45
Gender	Male	Male
Race (White or Black)	Black	Black
eGFR (mL/min/1.73m <sup>2</sup> )	90	90
Systolic Blood Pressure (mm Hg)	120	150
Hypertension Medication	No	No
BMI (kg/m <sup>2</sup> )	25	25
Non-Insulin Dependent Diabetes	No	No
ACR (mg/g)	10	10
Smoking History	No	No

Pre-donation 15-y risk	0.42%	0.71%
Pre-donation lifetime risk	1.03%	1.73%
Post-donation lifetime risk (x5)???	4.12%	8.65%

# DONOR KIDNEY FUNCTION

“GFR 80 ml/minute or 2 SDs below normal (based on age, gender, and BSA corrected to 1.73/m<sup>2</sup>) generally preclude donation.”

-Amsterdam Forum, *Transplantation* 2005;79: S53

Age (18-80 yrs)	25	65
Gender	Female	Female
Race (White or Black)	White	White
eGFR (mL/min/1.73m <sup>2</sup> )	70	70
Systolic Blood Pressure (mm Hg)	120	120
Hypertension Medication	No	No
BMI (kg/m <sup>2</sup> )	25	25
Non-Insulin Dependent Diabetes	No	No
ACR (mg/g)	10	10
Smoking History	No	No

Pre-donation 15-y risk	0.07%	0.11%
Pre-donation lifetime risk	1.04%	0.13%
Post-donation lifetime risk (x5)???	5.20%	0.65%

# DONOR BMI

“Patients with a BMI  $35 \text{ kg/m}^2$  should be discouraged from donating, especially when other comorbid conditions are present.”

-Amsterdam Forum, *Transplantation* 2005;79: S53

“We recommend that patients with a body mass index  $>30 \text{ kg/m}^2$  reduce weight before transplantation..”

-ERBP, *Nephrol Dial Transplant* 2015; 30: 1790

Age (18-80 yrs)	45	45
Gender	Female	Female
Race (White or Black)	White	White
eGFR (mL/min/1.73m <sup>2</sup> )	90	90
Systolic Blood Pressure (mm Hg)	120	145
Hypertension Medication	No	No
BMI (kg/m <sup>2</sup> )	35	35
Non-Insulin Dependent Diabetes	No	No
ACR (mg/g)	10	10
Smoking History	No	No

Pre-donation 15-y risk	0.09%	0.14%
Pre-donation lifetime risk	0.33%	0.51%
Post-donation lifetime risk (x5)???	1.65%	2.55%

# DONOR ALBUMINURIA

“...microalbuminuria determination may be a more reliable marker of renal disease, but its value as an international standard of evaluation for kidney donors has not been determined.”

-Amsterdam Forum, *Transplantation* 2005;79: S53

“We suggest considering persistent (more than three measurements with 3 months interval) moderate albuminuria (30–300 mg/24 h) a high risk for donation.”

-ERBP. *Nephrol Dial Transplant* 2015: 30: 1790



Age (18-80 yrs)	45	45
Gender	Female	Female
Race (White or Black)	White	White
eGFR (mL/min/1.73m <sup>2</sup> )	90	90
Systolic Blood Pressure (mm Hg)	120	120
Hypertension Medication	No	No
BMI (kg/m <sup>2</sup> )	25	25
Non-Insulin Dependent Diabetes	No	No
ACR (mg/g)	10	160
Smoking History	No	No

Pre-donation 15-y risk	0.08%	0.29%
Pre-donation lifetime risk	0.29%	1.05%
Post-donation lifetime risk (x5)???	1.55%	5.25%

