Supplement

Analysis Key: Lifetime Risks of Kidney Donation

Bryce Kiberd, Karthik K Tennankore

Department of Medicine, Dalhousie University, Halifax, Nova Scotia Canada

Address of Correspondence.

Bryce Kiberd

5082 Dickson Building, Queen Elizabeth II HSC-VG site, 5280 University Avenue, Halifax, Nova Scotia, B3H 1V8. Bryce.kiberd@nshealth.ca, tele 902-473-5160, FAX 902-473-2675.

The following gives insights into model and additional findings in table and figure format.

1. Model Inputs
2. Transition Rates/Probabilities
3. Added Analyses and Observations
4. Risk in Perspective
5. Additional References
6. Added Figures

1.Model Inputs

The model uses 2009 US vital statistics to calculate overall life expectancies in the model. Since the model includes disease states with higher relative mortality rates, normal health states are adjusted downward by a coefficient (MRadj) that varies by race and sex. CDC/National Center for Health Statistics http://www.cdc.gov/nchs/data/dvs/LEWK3_2009.pdf

eTable, 1, 2, 3 and 4 show the relative risks of progression, mortality and quality of life scaling for the health states. References for most of these can be found in Kiberd BA. Estimating the long term impact of kidney donation on life expectancy and end stage renal disease. Transplant Res. 2013; 2: 2.

eTable 1. Relative Mortality Risks for Disease States

State	Mortality
Normal	1.0
Hypertension	1.2
Diabetes Mellitus (DM) alone	1.8
Proteinuria (CKD 1-2)	1.8
Low GFR (CKD stage 3+)	1.3
DM/Proteinuria	2.2
DM/CKD	2.8
DM/CKD/Proteinuria	3.3
CKD/Proteinuria	2.8

Relative risk for CKD used in the base case analysis was 1.3. The true risk in subjects with CKD stage 3+ likely about 1.5 taking into account that there is a distribution of stages within CKD 3+ of 3A, 3B, 4, and 5 non-dialysis, each with progressively higher mortality risk. The lower risk was used given the prevailing opinion that low GFR associated with donation is not associated with the same increase in all cause mortality. We did explore higher average relative risks and an age related risk i.e. higher in younger (1.7 <age 65) and lower in older (1.2 if age >65) however this did not change the conclusions much and does not take into effect different weighting of 3a, 3b, 4 and 5 in the different age populations (Mortality Risk Stratification in CKD. JASN 2006;17:846). Since the majority of patients with low GFR states and late onset DM have hypertension we assumed this in the model. (United States Renal Data System. 2016 USRDS annual data report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2016. Colosia AD, Palencia R, Khan S. Prevalence of hypertension and obesity in patients with type 2 diabetes mellitus in observational studies: a systematic literature review. Diabetes, Metabolic Syndrome and Obesity: Targets and Therapy. 2013;6:327-338.

eTable 2. Progression to ESRD for Disease States

State	Progression N→CKD	Progression CKD→ESRD
No DM/HTN/Proteinuria	1.0	1.0
Proteinuria	1.2	4
Hypertension (y/n)	1.1	1.4
Diabetes Mellitus	2	2.8
Hypertension/Proteinuria	1.2	4
DM/Proteinuria	2	5.2

eTable 3. Quality of Life Adjustments

State	Utility
No Diabetes mellitus/Hypertension/Proteinuria	1.0
Proteinuria	1.0
Hypertension	0.98
Diabetes Mellitus	0.9
CKD	0.95
CKD/diabetes mellitus/proteinuria	0.85
ESRD (combination dialysis/transplant)	0.8
Death	0

eTable 4. Risk factors for Smoking, obesity and family history of disease.

CKD progression	White Male	White Female	Black Male	Black Female
BMI 30-35	1.16	1.16	1.16	1.16
Smoke	1.76	1.76	1.76	1.76
Biologic	1.225	1.225	1.225	1.225
Non-biologic	0.54	0.54	0.54	0.54
Mortality	White Male	White Female	Black Male	Black Female
BMI 30-35	1.25	1.25	1.34	1.24
Smoke	2	2	2	2

CKD progression risks for obesity and smoking were taken from Grams ME, Sang Y, Levey AS, Matsushita K, Ballew S, Chang AR, et al. Kidney-Failure Risk Projection for the Living Kidney-Donor Candidate. N Engl J Med 2016;374:411-21.

Mortality risks for obesity (white race) were taken from 'The Global BMI Obesity Collaboration'. Body-mass index and all cause mortality: individual-participant-data meta-analysis of 239 prospective studies in four continents. Lancet 2016;388:776-86. Mortality risks for obesity 30-35 BMI for black race were taken from Cohen SS, Park Y, Signorello et al Plos One 2014;9:e111980.

Risk for smoking were roughly estimated at 2.0. Mehta N, Preston S. Continued Increases in the Relative Risk of Death From Smoking. American Journal of Public Health. 2012;102):2181-2186. doi:10.2105/AJPH.2011.300489 shows increases in relative risks of 3.2 for men and 2.53 for women. These risks take into account all deaths (including CKD and ESRD). Since we included a relatively high risk of progression to CKD and ESRD using the higher risks associated with smoking and the increased risk of ESRD would be excessive, we therefore used a lower mortality relative risk associated with smoking. In addition the model could not run if high mortality risks (>2) associated with smoking were used as this resulted in death rates >1 in older recipients with diabetes mellitus and proteinuria or ESRD. Smokers who are potential donors (no proteinuria etc) may be a biased sample of all smokers who either smoke less or are more resistant to disease and may have less associated mortality.

The increased risk associated from biologic relations ship was calculated from Muzaale AD, Massie AB, Wang MC, Montgomery RA, McBride MA, Wainright JL, Segev DL. Risk of end-stage renal disease following live kidney donation. JAMA. 2014;311(6):579-86. We back calculated the elevated risk from knowing the percentage of non- biologic and biologic and their relative absolute rates of ESRD. Since the risk applies to both donors and non-donors these risks were applied accordingly. The increased risk for diabetes mellitus was based on starting all patients in the isolated diabetes mellitus health state rather than normal.

2. Transition Rates/Probabilities

Transition rates for the model were empirically derived through an iterative process to match population observed cumulative risks for the various health states. Rates were converted to probabilities. eTable 5 shows the life years and cumulative risks of ESRD, DM, and CKD3+ for 20 year olds. eFigure 1 shows the cumulative risks modeled for ESRD and CKD. eTable 6 –eTable 9 are model details to show how well calibrated the ESRD event rates were, the uncertainty examined and the multiplier used for each of the analyses. The GFR multiplier was less for the non-donors (lower rate of developing CKD in the non-donors compared to the unselected general population) and higher for the selected population who donated (NephGFR). In the sensitivity analysis in the ideal cases the 0.4 for diabetes mellitus means that the rate of developing diabetes was 40% of the rate in the general population.

eTable 5. Baseline Model 20 year old Subjects

	White Male		White Female		Black Male		Black Female	
Life Time	Observed	Model	Observed	Model	Observed	Model	Observed	Model
Life years	57.1	57.1	61.7	61.76	52.5	52.47	58.6	58.58
CKD 3+	54.4	54.5	65.7	65.2	53.0	53.0	64.3	64.6
Diabetes Mellitus %	37.2	37.2	33.7	33.8	44.8	44.7	55.2	55.16
ESRD %	3.4	3.41	2.3	2.33	8.7	8.69	7.9	7.91

e Table 6. White Male Age 40
File: Pop CKD age 20 WM Version2016update
White Males [MRadj=0.631; GFR=0.6 non-donor; GFR =1.41 post donation]
[Sensitivity Analysis: Ideal DM 0.4, Proteinuria 0.4, GFR 0.41 non-d, 0.963 post]

	NEJM	Model
15 yr Cum% ESRD, Average non-donor	0.067% (0.03, 0.08)	0.067% (0.03, 0.08)
LT Cum%, Average non-donor Ideal donor []	0.43% [0.43%] (0.19, 0.58)	1.118% [0.436%] (0.185, 0.584)
LT Cum%, donor	ND	4.97%

BaseCase 95% CI 15 year cum risk 0.067% (0.03, 0.08) NephGFR =0.6 (0.4, 0.66)
Ideal 95% CI Lifetime cum risk 0.436% (0.185, 0.584) NephGFR =0.41 (0.26, 0.48)

Age 20 NephGFR Ideal non-donor 0.51; donor 1.20
Age 60. NephGFR Ideal non-donor 0.375; donor 0.881

See eFigure 2 and 3 for cumulative incidences of ERSD in cohorts for average and ideal donors and non-donors.

eTable7. White female Age 40

File: Pop CKD age 20 WF Version2016update

White Females [MRadj=0.54; GFR=0.53 low risk; GFR =1.0 low risk post donation]

[Sensitivity Analysis: Ideal DM 0.4, Proteinuria 0.4, GFR 0.452 non-d, 0.853 post]

	NEJM	Model
15 yr Cum% ESRD, Average non-donor	0.045% (0.02, 0.06)	0.044% (0.02, 0.06)
LT Cum%,Average non-donor Ideal donor []	0.21% [0.21] (0.13, 0.47)	0.535% [0.209] (0.133, 0.469)
LT Cum%, Average donor	ND	1.67%

BaseCase 95% CI 15 year cum risk 0.045% (0.02, 0.06) NephGFR =0.53 (0.355, 0.62)

Ideal 95% CI Lifetime cum risk 0.21% (0.133, 0.469) NephGFR =0.452 (0.3, 0.585)

Age 20 NephGFR Ideal non-donor 0.415; donor 0.783

Age 60. NephGFR Ideal non-donor 0.41 ; donor 0.774

See eFigure 2 and 3 for cumulative incidences of ESRD in cohorts for average and ideal donors and non-donors

eTable 8. Black Male Age 40

File: Pop CKD age 20 BM Version2016update
Black males [MRadj=0.615; GFR=0.337 low risk; GFR =0.84 low risk post donation]

	NEJM	Model
15 yr Cum% ESRD, Average non-donor. 95% CI	0.21% (0.12, 0.33)	0.21% (0.123, 0.331)
LT Cum%, Average non-donor Ideal donor []	1.00% [1.02%] (0.49, 1.37)	1.257% [1.02%] (0.487, 1.374)
LT Cum%, Average donor	ND	5.902%

Sensitivity Analysis: Ideal DM 0.53, Proteinuria 0.53
BaseCase 95% CI 15 year cum risk 0.21% (0.123, 0.331) NephGFR =0.337 (0.25, 0.435)
Ideal 95% CI Lifetime cum risk 1.02% (0.487, 1.374) NephGFR =0.337 (0.225, 0.3975)

Ideal DM 0.57, Proteinuria 0.57
Age 20 NephGFR Ideal non-donor 0.39; donor 0.97
Age 60. NephGFR Ideal non-donor 0.339; donor 0.844

See eFigure 2 and 3 for cumulative incidences of ERSD in cohorts for average and ideal donors and non-donors

eTable 9. Black Female Age 40

File: Pop CKD age 20 BF Version2016update

Black Females [MRadj=0.567; GFR=0.345 low risk; GFR =0.805 post donation]

Sensitivity Analysis: Ideal DM 0.49, Proteinuria 0.49

	NEJM	Model
15 yr Cum% ESRD, Average non-donor 95% CI	0.12% (0.06, 023)	0.12% (0.062, 0.229)
LT Cum%, Average donor	ND	4.898%
LT Cum%, Ideal donor (95% CI)	0.85% (0.37, 1.35)	0.851% (0.371, 1.354)

BaseCase 95% CI 15 year cum risk 0.1157% (0.062, 0.229) NephGFR =0.345 (0.225, 0.3975)

Ideal 95% CI Lifetime cum risk 0.851% (0.371, 1.354) NephGFR =0.345 (0.22, 0.447)

Age 20 NephGFR Ideal non-donor 0.382; donor 0.891

Age 60. NephGFR Ideal non-donor 0.27; donor 0.63

See eFigure 2 and 3 for cumulative incidences of ERSD in cohorts for average and ideal donors and non-donors

3. Added Analyses and Observations

eTables 10-12 show added analyses and model information.

eTable 10. Time Spent in Health States in the Cohorts

	White Male		White Female		Black Male		Black Female	
	Non-D	Donor	Non-D	Donor	Non-D	Donor	Non-D	Donor
ESRD yrs	0.048	0.211	0.024	0.075	0.073	0.346	0.066	0.285
Isolated CKD yrs	2.299	4.040	3.088	4.720	1.303	2.440	1.665	2.974
Total CKD yrs	4.010	6.635	5.146	7.555	2.618	4.568	4.164	6.827
ESRD/CKD	1.2%	3.1%	0.47%	0.99%	2.8%	7.6%	1.6%	4.2%

Since it is observed that more death occurs from the CKD state, we examined different mortality risks. It is possible that isolated CKD (i.e. excluding CKD with diabetes or proteinuria) associated with removing a kidney is different from a CKD as a result of disease. Lower mortality rates were modeled. Since it is not possible to determine which CKD is from donation and which is from later disease, we used a weighted average. For instance for a white male 2.299 years are spent with isolated CKD (CKD no proteinuria or diabetes) whereas post donation 3.285 years are spent with isolated CKD. Assuming no increase in mortality in 0.986 years (3.285-2.299) and 1.7 in 2.299 years leaves a weighted average of 1.49 hazard ratio post donation. The hazard ratios were 1.455, 1.337, and 1.308 for white females, black males, and black females respectively. The results are shown in eTable 11. We also showed the impact of higher relative risks as in the general population (eTable 11). eTable 12 shows the impact of lower CKD hazard rates both non-donors and donors. Only a small decrease in the relative outcomes between donor and non-donor were observed. We assumed that low GFR CKD associated with proteinuria or diabetes mellitus would progress in the general population and donors at the same rate. In a white male donation would increase the time with these CKD states (with diabetes, proteinuria or both) from 1.53 years to 2.25 years.

eTable 11. Sensitivity Analysis: Effect of Higher and Lower Relative Risk of Mortality on Loss of Life Years with Donation

Lost Life Years	White Male	White Female	Black Male	Black Female
Lower CKD Mortality Risk*	-0.55	-0.32	-0.68	-0.72
Baseline	-0.77	-0.53	-0.84	-0.88
Higher CKD Mortality Risk**	-0.96	-0.73	-0.99	-1.02

* Assuming No Increase in Mortality Rate in the Proportion of Isolated Low Glomerular Filtration Rate CKD Associated with Donation

**Assuming General Population Mortality Risk with isolated CKD (HR 1.7)

eTable 12. Sensitivity Analysis: Variation of Isolated CKD Associated Mortality Relative Risks on Loss of QALYs in Current 40 year old Donors

CKD Mortality Ratio	White Male	White Female	Black Male	Black Female
1.1	-0.243 (1.11%)	-0.151 (0.64%)	-0.285 (1.39%)	-0.263 (1.18%)
1.3 (base case)	-0.272 (1.24%)	-0.177 (0.76%)	-0.308 (1.51%)	-0.283 (1.28%)
1.5	-0.298 (1.36%)	-0.199 (0.86%)	-0.329 (1.61%)	-0.300 (1.35%)
1.7	-0.321 (1.47%)	-0.219 (0.95%)	-0.340 (1.66%)	-0.315 (1.43%)

eTable 13. Sensitivity Analysis: Effect of Discount Rate on Percent of Remaining QALYs Lost from Donation

Discount Rate	White Male	White Female	Black Male	Black Female
3%	-1.24%	-0.76%	-1.51%	-1.28%
5%	-0.82%	-0.47%	-1.03%	-0.82%
7%	-0.54%	-0.30%	-0.71%	-0.62%

The model also allows risk to be interpreted from the potential donor's perspective. A person donating to a spouse or child may have greater quality of life by improving the duration and quality of life for a sick loved one now rather than worrying about a complication that could arise to their own health at a later time. We explored this concept using higher discount rates (rates of time preference), where current life was valued greater than later life. Higher discount rates were associated with proportionately smaller reductions in remaining QALYs lost from donation (eTable 13).

We examined uncertainty in the estimate for progression to ESRD for obesity using the published 95% Confidence interval point for the estimate of 1.16 (1.04, 1.29) from Grams ME, Sang Y, Levey AS, Matsushita K, Ballew S, Chang AR, et al. Kidney-Failure Risk Projection for the Living Kidney-Donor Candidate. N Engl J Med 2016;374:411-21. The variance in this one way sensitivity analysis is small. For example in a 40 year otherwise ideal obese white male the loss for life years was 0.545 (0.508, 0.590).

Obesity was examined in ideal donors. Ideal donors were felt to have rates of diabetes mellitus and proteinuria that were between 40% and 50% that of the general population (eTables 6-9). If obesity was associated with the same or higher rates of proteinuria and diabetes mellitus as in the general population (see review Isbel N, Nephrology (Carlton, Vic) CARI guidelines, 01 Apr 2010, 15 Suppl 1:S121-32) then the rates of ESRD would be higher in non-donors and the added risk of ESRD would be even higher with donation. For example, in obese 40 year old black females with low future rates of diabetes mellitus and proteinuria, the Grams calculator and our analysis project lifetime cumulative ESRD to be about 1% in non-donors. Our study projects donors to have an added lifetime cumulative ESRD of 3.3% with donation. However if higher subsequent rates of diabetes mellitus and proteinuria are associated with obesity then the lifetime ESRD risk may be 1.8% (versus 1%) in non-donors and the added risk would be 5.5% (versus 3.3%) with donation. The net loss of life years from donation increases from -0.758 to -1.0 years, after taking into account higher rates of diabetes mellitus and proteinuria.

We examined uncertainty in the estimate for progression to ESRD for smoking using the published 95% Confidence interval point for the estimate of 1.76 (1.29, 2.41) from Grams ME, Sang Y, Levey AS, Matsushita K, Ballew S, Chang AR, et al. Kidney-Failure Risk Projection for the Living Kidney-Donor Candidate. N Engl J Med 2016;374:411-21. For a 40 year otherwise ideal smoking white male the loss for life years was 0.496 (0.378, 0.663).

4. Risk in Perspective

eTable 14. Other Risks

	White Male	White Female	Black Male	Black Female
Loss of Life From Colorectal Cancer	-0.287 yr	-0.264 yr	-0.338 yr	-0.32 yr
Years smoked from age 40 Loss of life smoking	5 -0.766	6 -0.803	5 -1.25	6 -1.054

Donating a Liver: Live liver donation is reported to have a perioperative death rate of 1.7 deaths per 1000 operations, but no long term consequences. An immediate loss of life of 1.7 in 1000 persons without long term consequences is equivalent to 0.067 life years lost in the average 40 year old white male non-donor in this model. A recent document suggests that the range be 1 to 10 per 1000 depending on the lobe retrieved. In comparison, live kidney donation is much lower at 3.1 in 10,000. This would be equivalent to 0.011 years lost in average age white male donor. Therefore despite a higher post operative mortality with partial live liver donation, kidney donation results in more loss of life when adding in the long term impact (assuming no long term consequences of partial live liver donation).

Colorectal cancer: We wanted to examine the impact of a similar age (and remaining life years) potential kidney donor cohort that was screened for colorectal cancer compared to no screening, but this would require many assumptions. Reduction in death from this cancer over time is well demonstrated. This could be from a combination of better treatment and screening. Life time remaining years lost from colorectal cancer in baseline cohorts were calculated using cancer specific mortality rates from the SEER registry by 5 year age, sex and race and by a method similar to eliminating ESRD in the model above. This would assume that these cohorts were at average population risk for colorectal cancer. A formal quality adjusted analysis was not performed, but current calculations (eTable 14) would suggest donating a kidney may be greater than dying of colorectal cancer given current screening and treatments. A recent study calculating the benefits of screening and found that screening saved 244 to 270 years of life per 1000 people screened or 0.244 to 0.27 years of life saved from screening depending on the method used. The difference between their calculations are ours is small and lower, likely reflecting that cancer deaths are not completely eliminated with screening.

Smoking: Smoking is associated with significant increases in mortality. For unexplained reasons the relative mortality risks for smokers compared to non-smokers has increased over the last few decade. In

this analysis (eTable14) we examine the number of years smoking that would result in an equivalent loss of life as live kidney donation. As above we did not discount or apply a quality of life scales. We also assume that the risk would return to baseline with cessation. Only 5 to 6 years of smoking were associated with as much life lost as donating a kidney. In the model we used a lower risk of all-cause mortality since we included smoking effects to increase CKD and ESRD (see above).

V. Additional References

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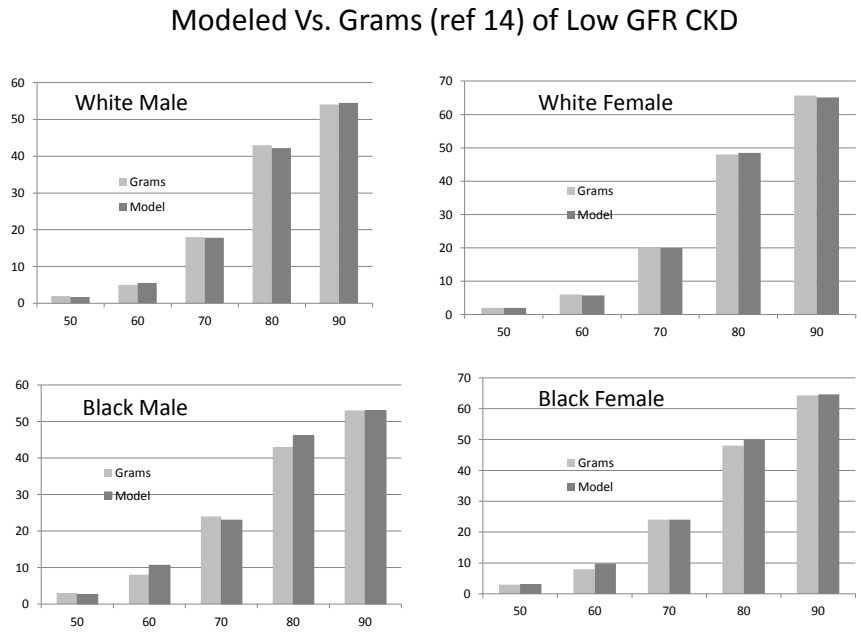
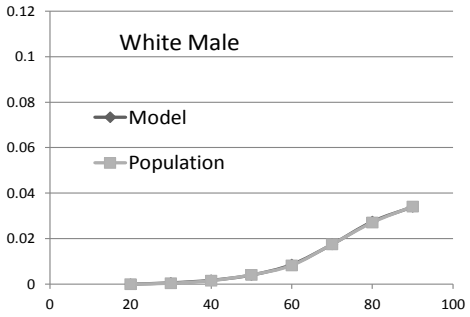
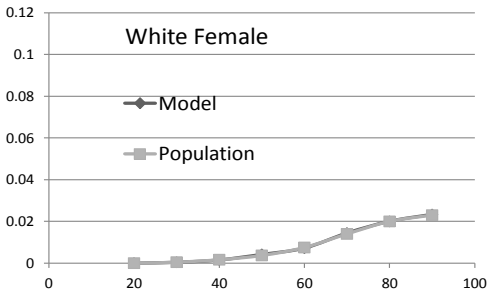
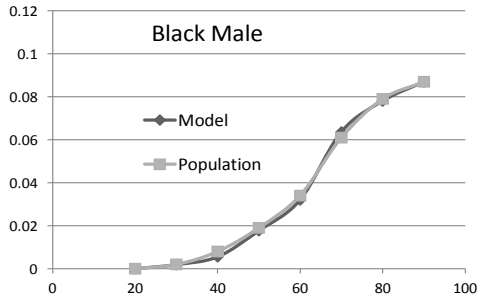
eFigure 1. Performance of CKD and ESRD of Model Versus Reference (1)

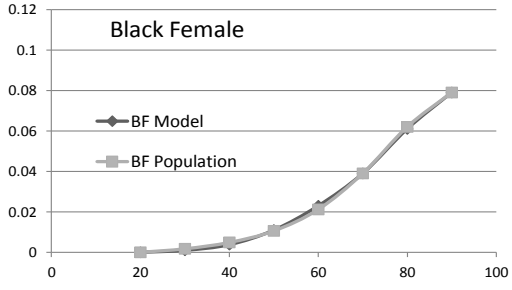


Modeled Vs. Population of ESRD

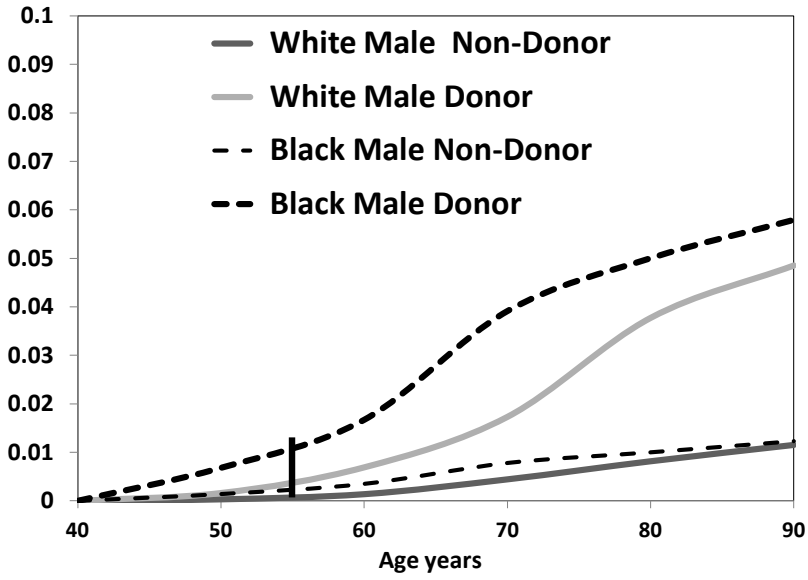




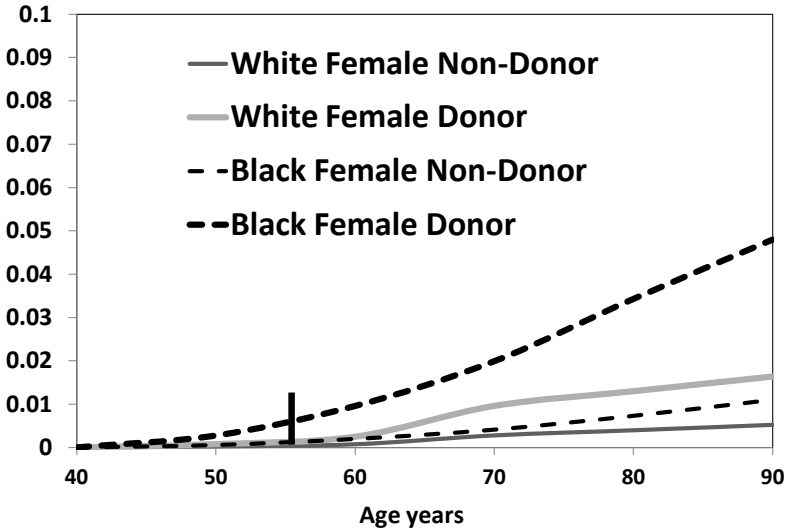




eFigure 2A. Cumulative ESRD Risk in Average Male Donors Versus Non-Donors

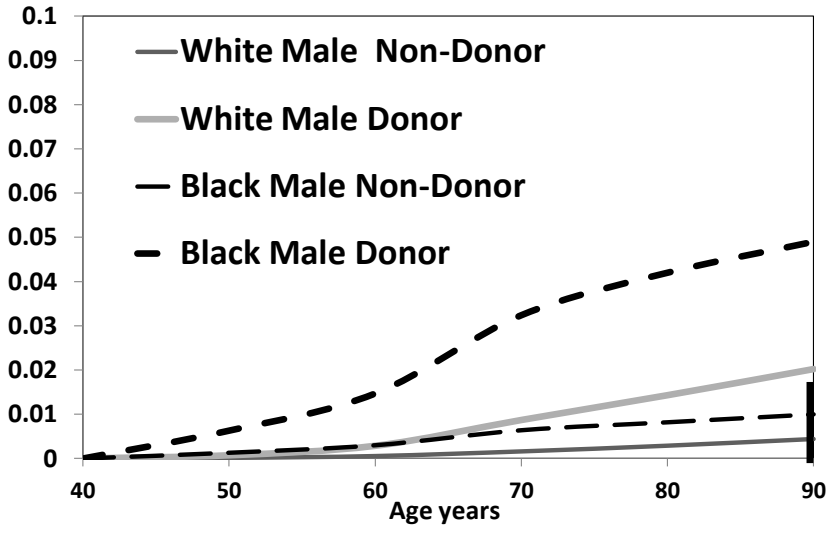


eFigure 2B. Cumulative ESRD Risk in Average Female Donors Versus Non-Donors

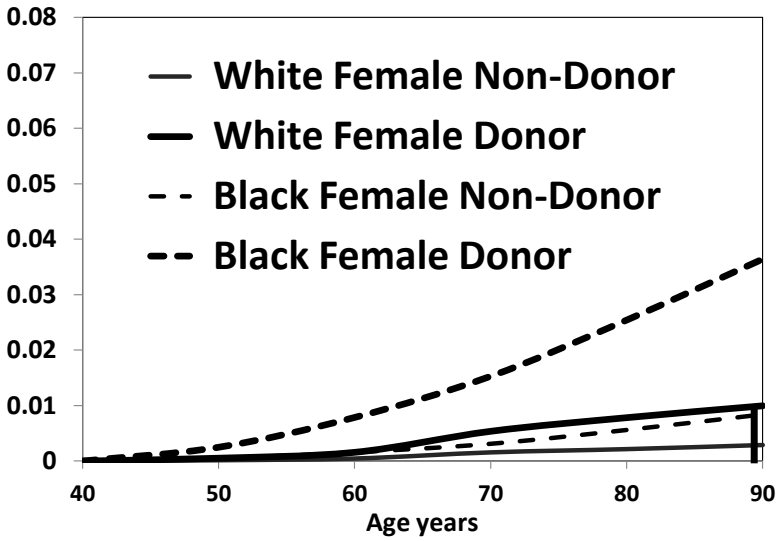


Legend. The cumulative risk of ESRD in current black and white males (2A) and black and white females (2B). The horizontal line at age 55 intersects the curves at the 15 year ESRD cumulative percent for actual donors and a theoretical cohort of matched non-donors from the published source. Cumulative risk curves after 15 years are generated by the model in both donors and non-donors.

eFigure 3A. Sensitivity Analysis: Cumulative ESRD Risk in Ideal 40 year old Male Donors Versus Non-Donors



eFigure 3B. Sensitivity Analysis: Cumulative ESRD Risk in Ideal Female Donors Versus Non-Donors



Legend. The cumulative risk of ESRD in ideal black and white males (3A), and black and white females (3B). The horizontal line at age 90 intersects the curves at the ESRD cumulative percent for a theoretical cohort of ideal non-donors from the published source. Cumulative risks curves then generated by the model for donors based higher relative risks empirically derived from observed risk in current donors.