Index of Supplements for: A Cost-Benefit Analysis of Government Compensation of Kidney Donors

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Supplement 1: Important Footnotes for the Main Text

 Monetary Value of a Quality-Adjusted Life Year: One of the best reviews of estimates of the value of a quality-adjusted life year (QALY) was done by Hirth et al. (Ref. 11). The authors estimated the value of a QALY that was implied by 42 estimates of the value of a life. These estimates were classified by study method: human capital (HK), contingent valuation (CV), revealed preference/job risk (RP-JR) and revealed preference/non-occupational safety (RP-S). Median values by study method were \$24,777 (HK estimates), \$93,402 (RP-S estimates), \$161,305 (CV estimates), and \$428,286 (RP-JR estimates).

The medians of the first and fourth study methods seem implausibly low and high, respectively, so they were disregarded. The medians of the middle two methods averaged \$127,353 -- but that was in 1997 dollars. The value of a QALY has increased since then for two reasons: (a) the U.S. standard of living has risen, so society is willing to pay more in real terms for a year of human life; and (b) inflation. Per capita nominal GDP combines both of these factors, and that rose by a factor of 1.734 from 1997-2Q to 2014-2Q (= \$54,429/\$31,385). So the value of a QALY in 2014 was:

\$127,353 X 1.734 = \$220,830

which conservatively rounded down to one significant figure is \$200,000. (A sensitivity analysis using \$100,000 and \$300,000 per QALY is shown in Item 2 of Supplement 8.)

An earlier synthesis of the literature by Tolley et al. (Ref. 13) concluded that a range of \$70,000 to \$175,000 per life year was reasonable. And

since per capita nominal GDP has roughly doubled since then, the range in 2015 would be \$140,000 to \$350,000 with a \$245,000 midpoint.

Furthermore, Huang et al. (Ref. 3, p. 23) say: ". . . more recent studies of the value of health improvements have suggested thresholds of \$100,000 to \$400,000 per life year gained, with midpoint estimates most often around \$200,000."

- Quality of Life: Whiting (Ref. 12) says, "... The value of 0 is attached to death and 1 to "perfect health", although the health state being measured is assigned a value in between (e.g., life on dialysis has been valued in a range between 0.45 and 0.60 by different investigators, although life with a kidney transplant has been measured in a range between 0.65 and 0.85." In keeping with our practice of using midpoints of ranges, we assume the quality of life is 0.52 on dialysis and 0.75 after a transplant. These numbers are very close to the average of the estimates reported by Laupacis et al. (Ref. 14), Zenios et al. (Ref. 23), Russell et al. (Ref. 15), and Hornberger et al. (Ref. 16) -- (0.54 on dialysis and 0.74 after transplant).
- 3. Second and Third Transplants: About 14% of current transplant recipients obtain a second transplant, perhaps after spending some time back on dialysis. But we will disregard this consideration in our analysis of the current situation case since a sensitivity analysis indicates it would have little effect on our results. For example, the net welfare gain for society from transplantation at the current time is \$20.9 billion per year if these second transplants are taken into account and \$19.8 billion per year if they are not (see row 6 of left column of Table 4). Moreover, to offset this slight bias, the number of transplant recipients at the present time was conservatively assumed to be 17,500 per year.

4. Number of Patients on the Kidney Transplant Wait List: This count changes day to day as patients receive kidneys, die, or move in and out of active status as their health or other circumstances change. Moreover, there are at least four organizations that estimate the number of patients on the wait list: The Organ Procurement and Transplantation Network (OPTN), the United States Renal Data System (USRDS), the Scientific Registry of Transplant Recipients (SRTR), and the Department of Health and Human Services (HHS). Consequently, there is considerable variation in estimates of the number of patients on the wait list.

This analysis uses wait list statistics from the USRDS (Ref. 7), projected ahead to 2015 based on the 5-year prior trend. However, estimates by other organization are almost universally higher. Consistent with our general approach, we have used the conservative lower estimate

5. Government and Private Insurance: Currently Medicaid and private insurance pay for a substantial portion of the ESRD costs, and not just for patient obligations. Private insurance for example is the primary insurer for at least 15 percent of the ESRD patients (see Supplement 5), and private insurers most likely pay more than Medicare for the same procedure. This special set aside (called "Medicare Secondary Insurance") is probably more common in transplantation than in dialysis because potential transplant patients tend to be younger and employed, and thus have access to employer group health insurance. However, there is a substantial likelihood that that this form of insurance will become less common under the Affordable Care Act as more patients are moved from private employer group health insurance to policies procured on the Web [see Tanriover et al. (Ref. 17)]. The resulting lower reimbursements will put added financial pressures on transplant and dialysis centers [Cook and Krawiec (Ref. 20), DaVita (Ref. 24), Englesbe et al. (Ref. 18)].

- The estimated half-lives of waitlist dialysis patients may seem long, but dialysis patients on the wait list are in substantially better health than dialysis patients not on the waitlist. This has been noted by others, such as Wolfe, McCullough et al. (Ref. 19).
- 7. Living and Deceased Donors: This analysis is based on estimates of the half-lives of (a) kidney transplant recipients and grafts, and (b) dialysis patients on the waiting list. Supplement 9 provides a discussion of deceased donor (DD) and living donor (LD) grafts and shows that DD grafts, even at a maximum possible retrieval rate, will be insufficient for the level of transplantation needed to eliminate the waiting list [see Becker and Elias (Ref. 5), Cook and Krawiec (Ref. 20)]. Kidneys from living donors will also be needed. At the current time, LD transplants clearly have better outcomes than DD transplants. But an important finding of this study is that, with a ready supply of transplant kidneys available, the difference in outcomes between LD and DD grafts may be small or non-existent. As shown in Supplement 12, not being on dialysis for 4 or 5 years waiting for a transplant kidney will result in a much healthier and younger patient at the time of transplant. And these two facts will greatly improve the outcome of DD transplants. In fact the empirical calculations, based on the work by Wolfe, McCullough et al. (Ref. 19), suggest that outcomes may be slightly better with DD than with LD grafts. (Our analysis took the conservative route and used the lower LD estimates). Muzaale et al. (Ref. 21) show that black race, sex, and age are correlated with donor ESRD. Future research should focus on the difference in outcomes among living donor groups. The findings of this analysis, which show the difference between DD and LD grafts approaching zero, is consistent with prior research on the pre-transplant treatment of ESRD.

- 8. Inflation: In this analysis, cost figures do not include future inflation, and they are discounted using a <u>real</u> interest rate of 3%. If we had instead assumed inflation of 2% per year, that would have boosted the <u>nominal</u> interest rate to 5% (because nominal interest rates tend to rise with inflation). And if we discounted costs that were rising at 2% per year by a nominal interest rate of 5%, the two would cancel out, and we would wind up with the same discounted present value. On the other hand, if we had assumed medical care would rise <u>faster</u> than overall inflation, that would increase <u>both</u> future <u>benefits</u> and <u>costs</u>, partially cancelling each other out. To the extent that benefits exceeded costs, that would just increase the net benefits from the government compensating kidney donors. So by disregarding this consideration we are being conservative.
- 9. The Level of Compensation: What level of government compensation of donors would be sufficient to induce people to donate enough kidneys to eliminate the existing kidney waiting list and keep it from returning? The only serious attempt to answer this question was made by Nobel Prize-winning economist Gary Becker and co-author Julio Elias [Ref. 5]. They concluded that compensation of \$15,000 per kidney would be sufficient. The pool of potential donors is huge all of the healthy adults in this country. And we only need an additional 18,000 transplant kidneys per year to meet the "steady-state" demand for kidney transplants of 35,000 per year in 2020.

[According to the OPTN/SRTR 2012 Annual Data Report, about 31,000 patients (adults and children) were added to the kidney transplant waiting list in 2012, but only about 17,000 kidney transplants were performed. We estimate that if the number of kidney transplants were increased to about 43,000 per year, that would be sufficient to eliminate the 94,000-patient waiting list in five years. Thereafter, in steady state, it would take

only about 35,000 kidney transplants a year to meet demand (extrapolating 2012 additions to the waiting list out to 2020). (Along with other analysts, we disregard the more than 400,000 other patients on dialysis who do not now qualify for the kidney transplant waiting list, an unknown percentage of whom might benefit from a transplant if an ample supply of donated kidneys were available).]

To be very conservative, we have proposed a level of government compensation of living donors that is triple Becker and Elias's \$15,000 estimate, i.e., \$45,000 per kidney. But even if the actual required compensation turns out to be some multiple of this, it is still trivial compared to the benefits of transplantation – the value of a longer and healthier life for the recipient and the savings on dialysis costs. (See Item 1 in Supplement 8 for a sensitivity analysis of changing the level of government compensation.)

It might be noted that Iran is a real world example of the efficacy of compensating kidney donors to eliminate the waiting list for transplant kidneys. Iran is the only country in the world that allows kidney donors to be compensated above their expenses, and, consequently, it is the only country in the world that does not have a waiting list for transplant kidneys. (Ghods, Ref. 26, Mahdavi-Mazdeh Ref. 27)

 A Lower Level of Compensation for Deceased Donors: We propose that the government <u>initially</u> compensate <u>living</u> donors \$45,000 -- but compensate the estates of <u>deceased</u> donors by only \$10,000. These numbers are based on several considerations.

One very practical reason for compensating deceased as well as living donors is that a large administrative apparatus currently exists to acquire kidneys from both groups -- the organ procurement organizations for deceased donors and the transplant centers for living donors. Hence, it would be prudent to make any changes in the relative importance of these two establishments only gradually.

A second practical reason for compensating deceased donors as well as living donors is to avoid a backlash from the next of kin of the deceased. If the latter become aware that the government is paying compensation of \$45,000 for kidneys from living donors, but nothing for almost identical kidneys from deceased donors, they may be upset enough to refuse to donate the kidneys of the deceased. This would be especially true if, as argued in item 7 of Supplement 1, government compensation of donors causes the gap in quality between kidneys from living and deceased donors to diminish sharply.

But the compensation received by deceased donors should be considerably less than that received by deceased donors because living donors incur substantial expenses that deceased donors do not. These include travel and lodging for medical evaluation and surgery, lost wages and the cost of hiring household help while recuperating, and the longterm risk of illness, disability, and death. Furthermore, we are already obtaining a high percentage of the potential kidneys from deceased donors, so the prospects for gaining additional kidneys are limited. [SRTR reports that in 2012 the donation rate for eligible kidney donors was 67 percent (Ref. 8, page 169)]. Also, if the level of compensation for the kidneys of deceased donors rises too high, it may give rise to a whole new set of complications with unintended consequences, such as creating perverse incentives for the next of kin to cease life support.

Some have expressed concern that a few potential living donors might be so desperate for cash that they might impulsively sell their kidney. To forestall this possibility, we suggest compensating living donors in a delayed form. There are many potential payment strategies. One would be to place the payment into a fund that would compensate the donor over time, either with cash or payments in kind (such as the premiums for health insurance). The Medicare ESRD program could provide overall management of the process, with another entity, such as the transplant center, being responsible for donor evaluation and follow-up, as is done today.

In any event, we are discussing here only the <u>initial</u> level of government compensation. In the long run, the amount of compensation paid to living and deceased donors will be strongly influenced by the forces of supply and demand. The level of compensation will have to be high enough to induce sufficient donations to end the kidney shortage and eliminate the waiting list, thus ending the suffering and premature deaths of a large number of patients on dialysis. If it becomes clear with experience that there is a greater demand by patients and their surgeons for kidneys from one source than the other, the government would likely increase the relative price of the more desirable kidneys. But this is the type of question that can only be resolved by experience after the program has been adopted (or perhaps by experimental trials beforehand).

Whatever the amount of compensation actually paid to each group of donors, it will not significantly affect our cost-benefit analysis because donor compensation is so small relative to the other magnitudes involved. In our analysis, we have made the most conservative assumption that the government will pay \$45,000 for all transplant kidneys.

11. **Insurance Policy for Living Donor:** The compensation package offered by the government to potential living donors would include an insurance

policy to cover the possibility that a living kidney donor might suffer adverse health consequences from donating a kidney, including disability and death. But since these adverse consequences occur in only a very small percentage of cases, the cost of such insurance would be small and could easily be incorporated in the \$45,000 compensation. It should be noted that these risks already exist for living donors under the present system, and there is no clear path to financial assistance.

It also might be noted that the probability of any particular living donor suffering adverse health consequences would be less under a system where the government compensates kidney donors than under the current system because the government and transplant centers would have more choice of donors. Currently, transplant programs and donors balance donor risk and recipient need, and may accept increased donor risk because of a shortage of donor organs. In any event, compensation of donors offers the possibility of obtaining donors who have fewer predisposing conditions than is currently the case.

12. Administrative Costs of the Program: Perhaps surprisingly to noneconomists, having the government compensate the estate of <u>deceased</u> kidney donors would likely <u>decrease</u>, not increase, the <u>other</u> administrative costs associated with procuring a kidney. At the present time, the Organ Procurement Organizations charge about \$50,000 to deliver a kidney from a deceased donor to a transplant center. This charge covers all the expenses of providing the kidney, including the efforts to persuade people to donate their kidneys when they die and persuade their next of kin to donate the kidney for free. If the OPOs were able to directly compensate the estate of the donor, they could save the expenses of trying to persuade people to donate the kidney for free. Therefore, compensating the estate of deceased donors would almost certainly cause the <u>other</u> administrative expenses to fall on a per kidney basis. Indeed, every business knows that paying suppliers for inputs is much more cost effective than asking that the inputs be donated. That is what UNOS, the Organ Procurement Organizations, and the transplant centers do for all of their other inputs. If donations were really a low cost way of obtaining inputs, all of these groups would do it to obtain their other inputs as well. They do not do so. [This analysis is based on arguments made by economists Becker and Elias (Ref. 5, p. 12) and Beard, Kaserman, and Osterkamp (Ref. 4, p. 90).]

With regard to <u>living</u> donors, the costs per kidney of the transplant centers would probably decline slightly because of economies of scale in testing and removing the donated kidneys.

October 13, 2015

Supplement 2: Detailed Calculations of Costs and Benefits

This supplement expands on the text in the body of the paper to provide details about how the numbers in Tables 2-4 were calculated.

Costs and Benefits at the Current Time When Compensating Donors Is Prohibited

Beginning with the current situation when compensating donors is legally prohibited, the top two rows of the left column of Table S2-2 show the increase in life expectancy that kidney transplant recipients currently enjoy, compared to patients who remain on dialysis on the transplant waiting list. A typical kidney transplant recipient can expect to live an additional 19.3 years, but if they remain on dialysis, they can expect to live only 12.3 years. (Note dialysis patients on the transplant waiting list are healthier and hence have longer life expectancies than dialysis patients who are not on the waiting list.)

Assuming the quality of life of a dialysis patient is 0.52 before a transplant and 0.75 afterward, the <u>gain</u> in quality-adjusted life years for the typical kidney transplant recipient is 0.75 times the life expectancy after receiving a transplant minus 0.52 times the life expectancy if they had remained on dialysis. At the current time, the half-life of a kidney transplant graft is 12.6 years (see third row of the left column of Table S2-2, and Table S12-1 in Supplement 12). So for those 12.6 years, the quality of life of a typical transplant recipient improves from 0.52 to 0.75. But it falls back to 0.52 when the patient returns to dialysis for the remaining 6.7 years of their expected life of 19.3 years. So the increase in the quality-adjusted life years as a result of the transplant is $\{(0.75 \times 12.6) + [0.52 \times (19.3 - 12.6)]\}$ -- minus (0.52 $\times 12.3$) years if they had remained on dialysis. The result is 6.5 QALYs (as shown in the fourth row of the left column of Table S2-2.

But each of these three components must be discounted back to the present using discount factors that are specific to each term. For example, the first product occurs over the first 12.6 years, and the discount factor is 0.83 [= $1/(1.03)^{(12.6/2)}$] since the average QALY will be gained in (12.6/2) years. The second product occurs over the period from 12.6 years to 19.3 years after the transplant, and the discount factor is 0.62 {= 1/ [(1.03)^{((12.6 + 19.3)/2)]}. And the third product occurs over the first 12.3 years, and the discount factor is 0.83. Adding up these three terms yields a gain of 4.7 discounted quality-adjusted life years as a result of the transplant (fifth row of the left column of Table S2-2). And valuing each of these 4.7 years at \$200,000 produces a lifetime welfare gain of \$937,000 per kidney recipient (top row of the left column of Table S2-3). It is well known that kidney recipients benefit greatly from receiving a transplant, and this puts a credible monetary value on it.

A second benefit of kidney transplants is the savings from no longer requiring dialysis and other medical treatments, which cost about \$121,000 per patient year and would have continued for the 12.3-year expected life of a dialysis patient. The product of those two numbers is multiplied by 0.83 to discount back to the present the stream of costs that would have accrued over the 12.3 years. But, as seen above, the half-life of a kidney transplant is only 12.6 years, after which a typical kidney transplant recipient has to return to dialysis for their remaining 6.7 years of life. Therefore they incur a dialysis cost of 6.7 years times \$121,000 over the period from 12.6 years to 19.3 years after the transplant, and the discount factor would be 0.62. Consequently, the lifetime net savings from temporarily stopping dialysis would be \$735,000 [= (12.3 X \$121,000 X 0.83) – (6.7 X \$121,000 X 0.62)] (row 2 of the left column of Table S2-3).

Turning to the other side of the ledger, the cost of the transplant itself (i.e., payments at the time of the transplant to all parties except the kidney donor) is about \$145,000 (row 3 of the left column of Table S2-3). And compensation to

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kidney donors is zero because it is currently legally prohibited (row 4 of left column of Table S2-3).

Medical costs following a transplant are about \$32,000 per year for the 12.6year expected life of the kidney graft, plus an additional \$88,000 when the graft of the typical patient fails in 12.6 years. Thus, the lifetime total costs are $395,000 [= (12.6 \times 32,000 \times 0.83) + (888,000 \times 0.69)]$, as shown in the fifth row of the left column of Table S2-3.

The net welfare gain for society over the lifetime of a kidney recipient (row 6 of the left column of Table S2-3) is just the net of the rows above it, or \$1,132,000 [= \$937,000 + \$735,000 - \$145,000 - \$0 - \$395,000].

The bottom row of the left column of Table S2-3 shows taxpayer savings over the lifetime of the kidney recipient. Since taxpayers currently bear about 75 percent of the cost of both dialysis and kidney transplants, taxpayers would reap 75 percent of the benefits from patients stopping dialysis after receiving a transplant. Specifically, taxpayer savings are equal to 75 percent of the savings from stopping dialysis -- minus: (a) the cost of the transplant, (b) compensation to donors (when allowed), and (c) medical costs after the transplant. This comes to \$146,000 per kidney recipient [= 0.75 X (\$735,000 - \$145,000 - \$0 - \$395,000)].

Increase	e in Discounted Qual Compared to F	ity-Adjusted Life Years from Re Remaining on Dialysis on Waiti	eceiving a Transplant ng List
		No Donor Compensation (current situation)	If Donors are Compensated (steady state after first five years)
Expected Remaining	If Remain on Dialysis on Waiting List	12.3	15.0
Lifetime If (years) T	If Receive a Transplant	19.3	24.9
Half-Life of Transplant Kidney Graft		12.6	15.7
Increase in Quality-Adjusted Life Years from Receiving a Transplant (vs. remaining on dialysis on waiting list)*		(0.75 X 12.6) + [0.52 X (19.3 - 12.6)] - (0.52 X 12.3) = 6.5	(0.75 X 24.9) - (0.52 X 15.0) = 10.9
Increase in <u>Discounted</u> Quality- Adjusted Life Years from Receiving a Transplant (vs. remaining on dialysis on waiting list)		(0.75 X 12.6 X 0.83) + [0.52 X (19.3 - 12.6) X 0.62] - (0.52 X 12.3 X 0.83) = 4.7	(0.75 X 24.9 X 0.69) - (0.52 X 15.0 X 0.80) = 6.7

Table S2-2 (details of calculations in Table 2 of the text)

* In the current situation, when the graft fails in 12.6 years, 86% of the patients go back on dialysis. In the transition and steady-state cases, when the first graft fails, patients will be readily able to obtain a second graft.

Sources: U.S. Renal Data System, USRDS, 2013 Annual Data Report; Reference 7. Scientific Registry of Transplant Recipients, SRTR, 2012; Reference 8. Laupacis et al. (1996); Reference 14. Russell et al. (1992); Reference 15. Hirth et al. (2000); Reference 11.

Table S2-3 (details of calculations in Table 3 of the text)					
Present Value of Benefits and Costs Over a Kidney Recipient's Lifetime (per kidney recipient)					
	No Donor Compensation (current situation)	If Donors are Compensated (steady state after first five years)			
Benefits					
Welfare Gain for Kidney Recipient (over a lifetime)	4.7 X \$200,000 = \$937,000	6.7 X \$200,000 = \$1,335,000			
Savings from Stopping Dialysis (over a lifetime)	(12.3 X \$121,000 X 0.83) - (6.7 X \$121,000 X 0.62) = \$735,000	15.0 X \$121,000 X 0.80 = \$1,454,000			
Costs					
Cost of Transplant (everything at time of transplant except compensation to donors)	\$145,000	\$145,000 + (\$145,000 X 0.63) = \$236,000			
Compensation to Donors	\$0	\$45,000 + (\$45,000 X 0.63) = \$73,000			
Medical Costs After Transplant (including cost of kidney graft failure)	(12.6 X \$32,000 X 0.83) + (\$88,000 X 0.69) = \$395,000	(24.9 X \$32,000 X 0.69) + (\$88,000 X 0.63) = \$607,000			
Net Welfare Gain for Society per Kidney Recipient	(\$937,000 + \$735,000 - \$145,000 - \$0 - \$395,000) = \$1,132,000	(\$1,335,000 + \$1,454,000 - \$236,000 - \$73,000 - \$607,000) = \$1,873,000			
Taxpayer Savings per Kidney Recipient	0.75 X (\$735,000 - \$145,000 - \$0 - \$395,000) = \$146,000	0.75 X (\$1,454,000 - \$236,000 - \$73,000 - \$607,000) = \$403,000			

Source: see sources for Table 2

Table S2-4 (details of calculations in Table 4 of the text))						
Present Value of Benefits and Costs for All Kidney Recipients in a Given Year (per year)						
	No Donor Compensation	If Donors are Compensated (steady state after first five years)				
Benefits						
Welfare Gain for All Kidney Recipients in a Given Year	17,500 X \$937,000 = \$16.4B/yr	35,000 X \$1,335,000 = \$46.7B/yr				
Savings from Stopping Dialysis for All Kidney Recipients in a Given Year	17,500 X \$735,000 = \$12.9B/yr	35,000 X \$1,454,000 = \$50.9B/yr				
Costs						
Costs of Transplants for All Kidney Recipients in a Given Year (everything at time of transplant except compensation to donors)	17,500 X \$145,000 = \$2.5B/yr	35,000 X \$236,000 = \$8.3B/yr				
Compensation to Donors for All Kidney Recipients in a Given Year	0	35,000 X \$73,000 = \$2.6B/yr				
Medical Costs after Transplant for All Kidney Recipients in a Given Year (including cost of kidney graft failure)	17,500 X \$395,000 = \$6.9B/yr	35,000 X \$607,000 = \$21.2B/yr				
Net Welfare Gain for Society from All Transplant Recipients in a Given Year	17,500 X \$1,132,000 = \$19.8B/yr	35,000 X \$1,873,000 = \$65.6B/yr				
Taxpayer Savings from All Transplant Recipients in a Given Year	17,500 X \$146,000 = \$2.6B/yr	35,000 X \$403,000 = \$14.1B/yr				

Source: see sources for Table 2

Table S2-5 (This table explains how the benefit-cost ratios at the bottom of Table 4 in the text were calculated, but there is no Table 5 in the text)				
Increase in Welfare: Compensation of Doi (for all kidney recip	nors (Steady State) Minus Current Situation ients in a given year)			
Increase in:				
Welfare of Transplant Recipients	\$46.7B - \$16.4B = \$30.3B/yr			
Savings from Stopping Dialysis	\$50.9B - \$12.9B = \$38.0B/yr			
Cost of Transplants (everything except compensation to donors)	\$8.3B - \$2.5B = \$5.7B/yr			
Compensation to Donors	\$2.6B - \$0 = \$2.6B/yr			
Medical Costs after Transplants	\$21.2B - \$6.9B = \$14.3B/yr			
Net Welfare Gain for Society from All Transplant Recipients in a Given Year	\$65.6B - \$19.8B = \$45.8B/yr			
Taxpayer Savings from All Transplant Recipients in a Given Year	\$14.1B - \$2.6B = \$11.6B/yr			
Benefit/Cost Ratio for Society	(\$30.3B + \$38.0B) / (\$5.7B + \$2.6B + \$14.3B) = 3.0			
Benefit/Cost Ratio for Taxpayers	\$38.0B / (\$5.7B + \$2.6B + \$14.3B) = 1.7			

See sources for Table 2

October 13, 2015

Supplement 3: Compensating Kidney Donors Would be a Boon for the Poor

One of the major arguments – perhaps the major argument -- put forth by those who oppose compensating kidney donors is that poor people would be more likely to be living kidney donors than rich people. So rich people would wind up buying kidneys from poor people, thereby "exploiting" them. Hence, poor people would be worse off if kidney donors were compensated than they are under the present system.

The purpose of this supplement is to show that this conclusion is exactly backward: the present system, in which compensation of kidney donors is legally prohibited, has resulted in a huge shortage of transplant kidneys that seriously harms all transplant candidates, including the poor. In contrast, if the government compensated living kidney donors \$45,000 per kidney, it would greatly increase the availability of transplant kidneys, making all transplant candidates, including the poor, much better off. Indeed, the poor would enjoy the greatest net benefit because they would gain the \$1.33 million value of a longer and healthier life, but most of the costs of transplantation for the poor would be borne by the taxpayer through Medicare and Medicaid.

We can see this by going through Tables 2 and 3 step by step to isolate the effects on poor people of a government program to compensate kidney donors. Beginning with the right column of Table 2, the life expectancy of poor transplant recipients may be less than average because their health problems are usually more serious than average. But this would be true both before and after transplantation. And the crucial variable for our analysis is the <u>increase</u> in life expectancy as a result of a transplant, and there is no reason to think that would be different for a poor kidney recipient than for an average kidney recipient. So, too, for the <u>improvement</u> in quality of life as a result of a transplant. Therefore, we expect poor transplant recipients would gain the

same 6.7 discounted quality-adjusted life years as the average kidney recipient (shown in the fourth row of the right column of Table 2).

Continuing on to the top row of the right column of Table 3, the welfare gain for poor kidney recipients would be the same \$1.33 million as for the average recipient. (Some might be inclined to argue that the life of a poor patient is worth less than \$200,000 per year, but that is an extremely controversial position to which we do not subscribe. Moreover, in Item 2 of Supplement 8 we looked at two alternative monetary values of a quality-adjusted life year -- \$100,000 and \$300,000 -- and found there were still substantial net benefits for society and the kidney recipient at even the lower number.)

In row 2 of the right column of Table 3, the savings from a poor patient stopping dialysis would accrue to the taxpayer because the taxpayer is paying for most of these dialysis costs.

Similarly, in rows 3 and 4 of the right column of Table 3, the cost of a poor patient's transplant operation and the compensation paid to the kidney donor would be mostly borne by the taxpayer.

In row 5 of the right column of Table 3, medical care after the transplant would be the same \$607,000 for poor kidney recipients as for the average recipient. Although Medicare coverage for ESRD patients under 65 ends three years after a transplant, most poor ESRD patients have Medicaid coverage which does not cease three years after transplant. [At least 45 percent of patients who have Medicare as their primary insurance also have Medicaid coverage (see Table S5-3 in Supplement 5)]. In addition, younger transplant patients who lose the Medicare coverage that they have because they have ESRD, quite commonly obtain Medicare coverage because they are disabled. In fact, recent research suggests that the patients who have no Medicare coverage three years after transplant are not the poor [see Tanriover et al. (Ref. 17), and Leighton et al. (Ref. 32)]. Thus, poor people would have to pay little or none of these post-transplant costs.

The bottom line is poor kidney recipients would gain the \$1,330,000 benefit of a longer and healthier life that results from a transplant, but almost all of the costs would be picked up by the taxpayer. Thus, they would enjoy a net benefit of \$1,330,000 every time they become a transplant recipient. So the current prohibition on compensating kidney donors, which is supposedly intended to prevent the poor from being exploited, is in fact seriously harming the poor. And having the government compensate kidney donors would be an enormous boon for the poor. (See also "Exploitation" in Supplement 6.)

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Supplement 4: Comparisons of Matas & Schnitzler (AJT, 2003) with Held and McCormick et al. (AJT 2015, H&M et al.)

Table S	64-1: Comparison o	f Matas & Schnitzler	with Held and Mc	Cormick et al.		
Overview	Both papers focus on compensating kidney donors and estimating the benefits of increased transplantation vs. dialysis. Both report substantial benefits to the recipients of transplants and savings to the taxpayer. Held et al. find larger quantitative benefits; report more information at the level of the entire society; and provide quantitative estimates of the value of increased transplantation as a result of the government compensating kidney dopors					
Details	Items	Matas & Schnitzler (AJT, 2003)	Held and McCormick et al (AJT, 2015)	Comments		
Issues		(*****) = ****	(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
	Both papers focus on: kidney shortage; payment to donors; savings from transplantation vs. dialysis	Derive maximum payment to donors that is cost effective	Broader focus: value to recipient and society; ending wait list	M&S was path breaking; H&M et al. extend and update their work		
Methods	Time Period and Subjects	USRDS data from 1995-1999; living donors only; waitlist dialysis patients; two transplant centers;	USRDS reports 2013 & 2014; living and deceased donors and waitlist; also uses SRTR	H&M et al is current and projects out to 2020		
	Analysis Framework	Cost Effectiveness	Cost-Benefit & Cost Effectiveness			
	Both papers focus on QALYs and costs	Value QALYs at cost of a dialysis QALY	Value QALYs using value of a year of life	This is a major difference between the two papers		
	Statistical Tools	Markov & Cox Models	Cost-benefit calculations; binary measures; half-life (median)	Held et al. is more transparent		
	Interest Rate Used to Discount Cost and Outcomes	5 percent (presumably nominal i.e., allows for inflation) Continued Next Pa	3 percent real	QALYs should be discounted using a real interest rate		

Supplement 4 (continued)

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Table S4-1 Continued: Comparison of Matas & Schnitzler with Held and McCormick et al						
Details	lter	ms	Matas & Schnitzler (AJT, 2003)	Held and McCormick et al. (AJT, 2015)	Comments	
	Quality of	After Transplant	0.84	0.75	H&M et al. use wider	
	Life Assumptions	Receiving Dialysis	0.68	0.52	(consensus) spread between transplant and dialysis. They	
		After Transplant	8.9 years	12.9 years	also perform	
	Discounted Quality Adjusted Life Years	Receiving Dialysis	5.4 years in 1997	6.2 years in 2020	0.57 - 0.70; & 0.47 - 0.80; Item 2 Sup. 1; Item 3 Sup. 8.	
		Gain from Transplant	3.5 years	6.7 years in Steady State		
Validation	Selected metrics: patient & graft survival		No	Yes; compare selected half-lives to actual survival & SRTR published values	See Suppl. 12, Fig. S12-3; Table S12-3.	
	Taxpayer Savings per Kidney Recipient		\$94,579	\$403,000 in 2020	H&M et al. benefits are	
Results	Cost per QALY	From Transplant	Not readily available	\$49,000 in 2020	larger due to: (1) later time period; (2) lower discount rate; (3)	
		Receiving Dialysis	\$132,000 In 1997	\$186,000 in 2020	transplant outcomes are better	

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Supplement 5 Estimates of Transplant and Dialysis Costs

Shown in the upper half of Table S5-1 are reported statistics from the USRDS (Ref. 7) "Model 2" series both for 2011 (most recent) and projected to 2015. These statistics are based on an assignment of Medicare paid claims for a near census of Medicare Primary insured patients (497,000) to one of four mutually exclusive <u>event year cells</u> listed in the top of Table S5-1.

Shown in the lower half of the Table S5-1 are 2015 Medicare cost estimates after some rearrangements. To these Medicare cost estimates were added estimates of the patient obligations (PO) developed in Table S5-2 below. However, USRDS statistics do not include organ acquisition costs (OAC; personal communication from USRDS). Based on clinical experience, \$49,000 was assumed for OAC.

The adjustments of the USRDS statistics were primarily designed to produce two "event statistics" to be added to the two calendar year statistics. The two events were a transplant and a failed graft. In the case of a failed graft, the starting USRDS statistics were reduced by the costs of a half-year of dialysis and a half-year with a functioning graft. Similarly, in the case of a transplant, the starting statistics were also reduced by the costs of a half-year of dialysis and a half-year with a functioning graft, assuming the transplant occurred mid year. However, the transplant costs were increased by \$49,000 for OAC. Dialysis years were separately counted independent of "Transplant" and "Failed Graft" events.

Table S5-1: Medicare Plus Patient Obligations, Cost Per Patient Year and by Event Year						
Start with USRDS	l	JSRDS reports Med	licare Paid Clair	ns Data		
Model 2		In 4 Categories (cel	ls) for 497,000 p	oatients		
	Year on	Transplant Event	Year with	Failed Graft		
Categories	Dialysis	In Calendar	Functioning	In Calendar Voor		
	Пегару	i eai	Grait	Tear		
2011 USRDS	¢97.000	\$126,000	\$24,000	¢112.000		
Direct Quote	\$67,000	\$120,000	\$24,000	φ112,000		
1 rend (2006-		0.0.0//	0.7.0//			
2011)	3.6 %/yr.	2.2 %/yr.	3.7 %/yr.	5.7 % /yr.		
2015 Medicare	# 400.000	0 440.000	#00.000	\$110,000		
(USKUS) Projected Deced	\$100,000	\$140,000	\$28,000	\$140,000		
Projected Based						
on Trend		unt LICDDC Statist				
Adjust USRDS Statistics to Derive the Statistics Used in this Cost Benefit Analysis						
Adjustments None Year to Event None Year to E			Year to Event			
•		- 0.5 yr. of		- 0.5 yr. of		
Detailed		(dialysis +		(dialysis +		
Adjustments		functioning graft)		functioning		
-		+ OAC*		graft)		
Result	\$ / <u>Year</u>		\$ / <u>Year</u>	\$ / Graft		
(by year or event)	Dialysis	\$ / Transplant	Functioning	Rejection Event		
	Therapy	Event	Graft	-		
2015 (Cost)	\$100,000	\$125,000	\$28,000	\$76,000		
	Patier	nt Obligations as a 9	% of Medicare P	aid Claims**		
Adding Patient						
Obligations	+21% =	+16% =	+16% =	+16% =		
	-	Total Cost Includin	ng Patient Oblig	jations		
Results in Total	\$121,000/					
Cost 2015-2020	yr. on	\$145,000/	\$32,000/ yr. of	f \$88,000/ Graft		
	Dialysis	Transplant	Functioning	Rejection		
OAC: Organ Acquisition	Cost: Are not in	Event cluded in USRDS "Cos	Gran t" Reference Tables	Personal		
Communication from USRDS 4/28/15). Assumed OAC to be \$49,000 per organ. Source of cost statistics USRDS (Ref. 7) 2013 Reference Tables K10-K13, which use "Model 2". Year statistics are period measures as developed by USRDS. Event statistics are cost per event and are developed in this analysis. For example, in a transplant year, a patient was assumed to have 6 months of dialysis and 6						

months of functioning graft maintenance, plus a transplant event. ** See Supplement 12.

Patient Obligations (Co-Pays)

Shown in Table S5-2 are calculations of patient obligations (PO) based on USRDS data reported in "Model 1" fashion. These statistics differ slightly from the "Model 2" statistics used above in Table S5-1. (e.g., total dialysis spending is \$88,000 in Model 1 and \$89,000 in Model 2). Going from Model 2 to Model 1 Medicare reported statistics is not an easy process. "Model 1" reports spending in the categories of Medicare Part A, B, and D, while "Model 2" as reported in Table S5-1 above uses procedures and time periods to report spending. The calculations in Table S5-2 use PO rules applied to the various A, B, and D categories of Medicare spending. The Medicare patient obligation rules differ by the Medicare divisions, (A, B, D). For example patient obligations for Medicare Part B are 20 percent of the total of Medicare spending which algebraically is 25 percent of all outpatient paid claims with no stop loss provisions. Precise statistics on Medicare Part D co-pay are not readily available. We assumed that Medicare Part B rules for patient obligations would approximate those applicable to Part D (twenty-five percent of Medicare spending). Generally we included the typically low reported amounts of Part D spending in with Part B accounts. (Apparently immunosuppressive drugs are not part of Medicare Part D but rather are still in Part B Medicare. (Tanriover et. al. Ref. 17). We had to make a few assumptions about hospital inpatient stays which we based on a general reading of hospital stays per patient year as reported by USRDS, (Ref. 7).

Consider an example: Average Medicare part A paid claims for a dialysis patient in 2010 totaled \$30,000. Assuming 4 deductibles (the precise patient copay for Part A Medicare is a complicated notion that depends on number, timing and length of hospitalizations in a year) would say the patient obligations are \$4200 for the year (4 X \$1050) which is a PO and is 14 percent of total Medicare Part A spending for the year (\$4200/\$30,000).

As shown towards the bottom of Table S5-2, total patient obligations for dialysis patients are \$18,500 or 21 percent of Medicare paid claims; for transplant patients, \$5,400 or 16 percent of total Medicare paid claims. Taking a weighted

average across dialysis and transplant patients the patient obligations are 20 percent of Medicare paid claims amounts.

Taxpayer Share of ESRD Spending

Table S5-3 presents estimates of the fraction of Total ESRD costs (for dialysis and transplant patient) paid by the taxpayer. These estimates are generated by combining Medicare paid claims (M) with patient insurance coverage, which covers M as well as some fraction of PO. For example, ESRD patients with Medicare primary insurance are 78 percent of all ESRD patients in a given time period (row 1, left corner of Table S5-3). All these patients receive services costing Medicare at least 1.0 of M, i.e., they have Medicare primary insurance. Some receive more than 1.0M at taxpayer expense (e.g., Medicaid) from the government, but all 78 percent receive at least 1.0M).

Forty-five percent of these patients with Medicare Primary insurance have dual Medicare and <u>Medicaid</u> insurance (supported by a combination of federal and state taxes), which means that Medicaid pays for all the patient obligations. (See Table S5-2 for PO of 20 percent). Taxpayers pay for the entire Medicare and the Medicaid services (1.20M) for these patients. For the other 55 percent of Medicare primary insured patients, the taxpayer pays only 1.0M, i.e., no patient obligations. But the patient obligations are presumably paid by the patient or private insurance.

Across all Medicare Primary insured patients, the taxpayer pays an average of 1.09M [weighted average of 1.20M (45 percent with dual Medicare Medicaid insurance) and 1.00M (55 percent of patients that have Medicare without Medicaid)]. These patients are 78 percent of the total ESRD population (see Table S5-3 row 1, left column). So for the typical Medicare primary insured patient, the average amount paid by the taxpayer is 0.85M = (0.78 X 1.09), a combination of Medicare alone and joint coverage of Medicaid and Medicare.

Table S5-2: Calculating Patient Obligations (PO) as Percent of Medicare Paid Claims (M)					
	D	ialysis 2010	Í Trar	nsplant 2010	
Total Medicare (M)	Total	-	Total Paid	-	
(sum of lines below)	Paid	PO as % of M	Claims (M)	PO as %	
	Claims		\$33,000 for	of M	
	(M)		year		
	\$88,000				
	for year				
Medicare	Part A Ca	alculations: Rules PO	O = Deductible	s plus/ M	
Medicare Part A	\$30,000	Assume 4	\$16,000	Assume 1	
Inpatient		Deductibles of		Deductible of \$1050.	
		\$1050=\$4,200			
	<u> </u>		* 10.000		
Total Medicare Part A	\$30,000		\$16,000		
Total PO Part A		\$4.2K (14%)		\$1.1K (7%)	
Medicare Pa	art B Calcu	lations; Rules: Patie	ent Obligations	= 25% of M	
Part B, Outpatient*	\$31,000		\$3,000		
SKE Home Health	\$6 000	Patient	\$2 000	Patient obligations =	
Hospice*	ψ0,000	obligations =	<i>\\\\\\\\\\\\\</i>	25% OT \$17K	
Physician Supplier*	\$16.000	25% OT \$58K	\$9.000	- ¢1 2K	
Part D* (assume Part	\$5.000	- ¢14 5K	\$3,000	– 94.3N	
B PO rules apply)	<i>vvvvvvvvvvvvvv</i>	- \$14.5K	<i>↓0,000</i>		
Total Part B (+D)	\$58,000		\$17,000		
Total Part (A+B+D)	\$88,000		\$33,000		
Total PO (A+B+D)		\$18.5K		\$5.4K	
Patient Obligations as		21% for Dialysis		16% for Transplant	
% of Total Medicare		<u>2170101 Dialysis</u>			
Weighted Average	Averag	e of Dialysis and Tra	ansplant (weigl	nted by share of total	
of Dialysis and		Medica	re per patient)	=	
Transplant	(21% X 88/121) + (16% X 33/121) =				
	20% for All ESRD				
Sources: USKDS (Ref. /)	able Ka and	a iviedicare.Gov. K is 10	100. Patients are N	Part A in 2015 was	
\$1260 per benefit period. A	ssumed to b	be \$1050 in 2010. http://	www.medicare.go	v/your-medicare-	
costs/costs-at-a-glance/cos	sts-at-glance	.html. Part B Deductible	not included. Pat	ient premiums not	
included					

Medicare secondary (row 2 of Table S5-3) is the most troublesome cell for estimation. Fortunately for our analysis it only has a weight of 15%. Medicare Secondary ESRD patients typically are dialysis patients, but frequently transplant patients who have private insurance at the time of incidence. Such patients are considered Medicare secondary insurance patients because Medicare is the secondary insurer for the first 30 months, which under Medicare reimbursement rules make these patients highly desirable from both the government's view and the medical provider's view. For the first 30 months, private insurance is the first payer of the medical claims, and typically private insurance pays substantially more for the same services than Medicare would pay if they were primarily insured by Medicare. (See Englesbe et al. Ref. 18; Cook et al. Ref. 20; Fresenius, Ref. 25; DaVita, Ref. 24).

For this analysis of taxpayer paid share of ESRD costs, we have assumed that private insurance pays a third more than Medicare's Approved Charge, a conservative assumption. In theory, Medicare as secondary payer would be obligated to pay that part of the Medicare approved charge not covered by the private insurance, but typically private insurance pays in excess of the total Medicare approved charge including patient obligations. So Medicare has ruled that Medicare as secondary payer will pay nothing in these cases. Medical persons and institutions obtain higher payments for these services provided by private insurance, and Medicare typically does not pay anything, at least for the first 30 months following incidence. After the 30 months following incidence, Medicare becomes primary payer for patients who had private primary insurance (technically private employer group health insurance EGHI). If the patient is still eligible for EGHS at 30 months, the private insurance becomes secondary payer. And this is where we are unable to make definitive statements. Presumably these patients switch from Medicare secondary to Medicare primary insurance status. Another issue for this analysis is these Medicare secondary payer patients are somewhat more likely to be transplant recipients (younger with EGHI) than the typical ESRD patient, and they would also be facing the 36-month post-transplant loss of Medicare-ESRD insurance coverage. (It might be noted that it is common practice to suggest that these patients "lose drug coverage" when this policy is implemented. They lose drug coverage because they lose Medicare eligibility, but this has insurance implications well beyond drugs). The fact is we do not have reliable information on government expenditures for these patients. For example, recent research has shown transplant recipients less than 65 years of age who are in the post-transplant 36-month loss of Medicare-ESRD insurance status tend to be these private insured patients who are not poor and definitely have better survival than other transplant recipients (Leighton et al. Ref. 32).

The analysis reported in Table 5-3 calculates what each group (row) of insurance patients would cost, in total, as a fraction of Medicare paid claims (M) and what fraction is being paid by the taxpayer. On average, the total (private and public) payment across all patients is 1.26M. While one may at first think costs could not exceed 1.20M, recall the 15% (row 2 of Table S5-3) of patients who at incidence have private insurance whose insurance most likely pays substantially more than the Medicare-approved charge for all covered services. We have conservatively assumed that private insurance (EGHI) pays 33 percent more than Medicare Approved Charge.

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The last column of Table S5-3 calculates how much of each insurance row is paid by the taxpayer. And the bottom right cell shows the taxpayer pays approximately 79 percent of all ESRD costs in the U.S.

Some caveats: Veterans Affairs spending is not included, which is a very small fraction of the total. Patients treated in HMOs are not included here (Wetmore et al. Ref. 31). Neither of these caveats are large enough to change our bottom line significantly. However, the private insurance extra payment we assumed (33 percent over Medicare customary) is probably a conservative estimate of private spending premium. In addition, the proportion of Medicare primary insured patients who are dually covered by Medicare and Medicaid may be somewhat lower than reported in Table S5-3 (45 percent in this analysis). USRDS (Ref. 7) suggests it might be as low as 35 percent. This would change the bottom line estimate of 79 percent (Table S5-3 bottom right column) to 78 percent).

Consistent with our general practice of making conservative choices, i.e., estimates that produce lower net benefits from the government compensating kidney donors, we assume that the tax payer pays only 75 percent of total cost rather than the 79 percent shown in Table S5-3. This reduces our estimated taxpayer saving. It does not affect the other benefits and costs in the benefit-cost calculation.

Table S5-3: Taxpayers (Federal & State) Pay 79% of Total ESRD Costs, Including Patient Obligations (PO)							
Insurance at li as Reported b	ncidence y USRDS*		Total Cost Taxpayer Pays				
Insurance Source	Percent of ESRD Patients*	Medicaid	(including 20% PO) Per Patien	Per Patien	Weighted Average Across All ESRD or Types of Insurance		
Medicare Primary with 45% Dual Medicaid**	78%	45% of 78% paid copay by Medicaid= 0.45 X 0.2M = 0.09 M	1.20M (see Table S5-2)	1.20 X 0.45) + (1.0 X 0.55) = 1.09M	0.78 X 1.09M = 0.85M		
Private Primary & Medicare Secondary**	15%	0	1.60M***	0.38**** X 1.00M= 0.38M	0.15 X 0.38M = 0.06M		
Initially No Insurance (Assume Medicaid Ultimately)	7%	100% of 7% have Medicaid as Primary and Secondary. Medicaid pays copay for 7 % = 0.07 copay = 0.07x 0.2 M = 0.014M	1.20M	1.20M	0.07 X 1.20M = 0.08M		
Total	100%		1.26M		0.99M		
Bottom Line Approximate: Taxpayer pays 0.99M/1.26M = 79% of All ESRD Costs							
Federal and state taxpayers (TP). M is Average Medicare paid amount; *Insurance Source: USRDS 2013 (Ref. 7) Table C-3, K-4 approximate time period: 2009; ** Wetmore et. al. (Ref. 31). *** Assume private insurance pays 1.33 of Medicare Allowed Charges = 1.33 X 1.20). **** Assumes typical half-life of all ESRD is 48 months. Medicare is primary for 18 months = (48 -30). 18/48 = 0.38.							

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Supplement 6: Some Arguments Against Compensating Kidney Donors

The analysis in the main text focused on the most important costs and benefits associated with compensating kidney donors. It necessarily omitted many less important considerations, among which are several made by opponents of donor compensation, namely:

- The poor would be "exploited" because they would be most likely to sell their kidneys.
- Buying and selling organs is morally "repugnant".
- It would result in fewer donated kidneys.
- It would result in poorer quality kidneys.
- It would represent a "commodification" of the human body.

We could not find any estimates in the literature of the monetary value of these considerations. Nor do we know how to make such estimates ourselves. Indeed, we are not even sure what the terms "exploit", "repugnant", and "commodification" mean, or whether they are, on net, arguments for or against compensating kidney donors. We will discuss each in turn.

Exploitation: What does this term mean, especially when applied to kidneys from deceased donors? One plausible definition is that someone is paid less than the free-market value of the good they are selling. But that is exactly what the current prohibition against compensating kidney donors does. Donors are paid nothing for something that has a free market value of tens of thousands of dollars. Moreover, compensating kidney donors is precisely the remedy needed to end this exploitation. In addition, there are many poor people on the other side of the market, who suffer on dialysis and die because of a lack of transplant kidneys (see Supplement 3). It is particularly noteworthy that African Americans account for a disproportionate percentage of those needing transplant kidneys. Their incidence rate for end stage renal disease is more than three times that of

Caucasian Americans. Finally, when it comes to obtaining a kidney from a living donor, poor people are at a significant disadvantage. Most of their relatives and friends are also poor, and it is a greater hardship for them to incur the expenses and suffer the loss of income associated with donating a kidney. If we could somehow place a monetary value on these considerations, they would likely increase the net benefit from compensating kidney donors, not decrease it.

Repugnance: Similarly, while some people find the idea of buying and selling kidneys repugnant, many more likely find the premature deaths of five to ten thousand kidney patients each year and the suffering of about a hundred thousand more on dialysis to be even more repugnant. Again, if we could place a monetary value on feelings of repugnance, it would likely increase the net benefit from compensating kidney donors.

Reduced Quantity: Some argue that compensating kidney donors would so offend some donors that they would refuse to donate their kidneys at all, which would actually reduce the supply of kidneys. It is conceivable that this might happen for extremely low levels of compensation if the donors view such small amounts as an insult (just as it might happen in the current situation when people are offered nothing). But as the level of compensation rises, the quantity of kidneys supplied would almost surely increase, just as occurs in virtually all other markets. Certainly, the experience of Iran does not support this concern: providing compensation to living donors has been accompanied by increased, not decreased, donation levels, helping to eliminate the waiting list for kidney transplants. [See Beard et al. (Ref. 4, pp.177-182); Ahad et al. (Ref. 26); Mahdavi-Mazdeh (Ref. 27); Rana et al. (Ref. 28)].

Reduced Quality: Likewise, some argue that compensating donors will lead to a decrease in the quality of donated kidneys. But exactly the opposite is likely to be true. We know the current shortage of kidneys has led to the acceptance of lower quality kidneys (Extended Criteria Donors for example). Conversely, if the supply of kidneys increases and the shortage is reduced or eliminated, it will no

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longer be necessary to use these clearly inferior kidneys [see Beard et al. (Ref. 4), p. 187].

Commodification: Finally, some argue that compensating kidney donors will lead to body parts being bought and sold like commodities. But kidneys are already bought and sold. When a kidney is delivered to the operating room of a transplant recipient, it is not provided free. The patient is charged about \$50,000 (which may be passed on to an insurance company or the taxpayer) that reflects the costs of recovery, testing, and transporting the kidney. Indeed, everyone involved in the procurement process – doctors, nurses, hospitals -- are paid the going market rate for their services – everyone except the person who donates the kidney. Why is it considered "commodification" to compensate kidney donors, but not to compensate everyone else involved?

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Supplement 7: Conservative Assumptions

To the best of our knowledge, all of the assumptions and estimates made in this paper have either been neutral (i.e., the mid-point of a range of published estimates) or conservative (i.e., they tend to reduce the net benefits from compensating kidney donors). Among the latter are:

- When patients begin dialysis treatments, many stop working and collect Social Security disability. But in this analysis, we do not assume any savings to society from workers continuing to work and pay taxes and not collecting disability.
- 2. This analysis did not assume any reduction in the \$145,000 cost of transplants in response to compensating kidney donors \$45,000. However, as explained in Item 12 of Supplement 1, these other costs of procuring kidneys would almost certainly fall since the organ procurement organizations would save some of the money they now spend persuading people to donate kidneys.
- With a larger supply of kidneys, it would be easier to ensure the medical compatibility of donors and recipients. This would increase the number and the success rate of transplants, which would increase the benefits and lower the costs.
- 4. For simplicity, our analysis has focused on the net benefit for society going from our current situation to the steady-state situation. But in addition, even larger welfare gains and taxpayer savings would occur during the five-year transition period, during which the 94,000 patient waiting list would be eliminated. During this period, the net welfare gain to society would be a substantial \$73 million per year, and taxpayer savings would be \$15 million per year both greater than in the steady-state period because of the higher number of transplants needed to eliminate the waiting list. Furthermore, besides the 94,000 other dialysis

patients who did not qualify for the waiting list. With the greater availability of transplant kidneys, some of these patient will likely also receive transplants [see Schold, J.D., et al. 2008 (Ref. 10)]. Both of these considerations would increase the net benefit from the government compensating kidney donors beyond what we have estimated.

- 5. In this analysis, we have conservatively used the half-lives of patients as a proxy for <u>mean</u> life expectancies (the concept that would be most appropriate for estimating costs and benefits). But in survival distributions, half-lives are always less than means because the right tail of the distribution is very long, i.e., some people live a very long time. So this assumption results in smaller benefits from compensating kidney donors than would actually occur.
- 6. With regard to the increased donations from <u>deceased donors</u>, we have counted only the benefits from the use of their <u>kidneys</u>. But if the next of kin is willing to donate the kidneys of their loved ones in return for compensation, they will likely also be willing to donate <u>other</u> organs as well (heart, liver, lungs, pancreas). We have not included the benefits to the recipients of these other organs in this analysis.
- 7. With regard to the cost of ESRD care, we have used Medicare (Part A, B, and D) paid medical claims statistics (USRDS, Ref. 7. SRTR Ref. 8). These are the national costs cited by all studies. However, what is not reported in nearly all other studies is that all these Medicare costs have a patient obligation of approximately 20 percent of the total cost, i.e., the cost commonly reported are low by possibly 25 percent (see Supplement 5 above for more detail). Thus, our higher costs lower the net benefits from the government compensating kidney donors and is conservative.

How much of the patient obligations are collected is not readily available, but it should be noted:

- Providers of medical services to Medicare patients are obligated by law to make good faith efforts to collect these obligations;
- Substantial percentages of Medicare patients have supplemental insurance policies that cover at least in part patient co-pays (Englesbe et al. 2008. Ref. 18).
- Thirty-five to forty-five percent of Medicare ESRD patients are jointly eligible for Medicaid (federal medical assistance to the poor) (USRDS, 2013 Ref. 7, V2, pgs. 224-225). Medicaid is a source of public money (both state and federal) that funds patient obligations in the Medicaid Program (Supplement 5 has more detail).
- A review of filings by the two largest dialysis organizations (Fresenius Inc. Ref. 25, and DaVita Inc. Ref. 24) to the Security and Exchange Commission generally report bad debts of less than 3 percent of revenue, suggesting that most of the patient obligations are collected.

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Supplement 8: Sensitivity Analyses

In this supplement, we show how our major results would change if we varied three key inputs: (1) the amount of government compensation of kidney donors, (2) the monetary value of a discounted quality-adjusted life year (QALY), and (3) the quality of life before and after transplant.

1. Changing the Government Compensation of Kidney Donors

In the main text of the paper, we assumed the compensation to kidney donors needed to elicit a sufficient supply of kidneys to end the shortage and eliminate the waiting list would be \$45,000 per kidney. In this section we examine how our results might change if the necessary compensation turns out to be \$20,000 higher or lower than this amount.

Note in Table S8-1 that both the net welfare gain for society and taxpayer savings are little affected by the alternative levels of government compensation of donors. Both remain quite substantial, even with compensation of \$65,000 per kidney. Note also that donor compensation could be increased to \$375,000 per kidney before taxpayers would no longer save money by paying for kidney transplantation instead of dialysis. And compensation could be increased all the way to \$1,200,000 per kidney before society would no longer enjoy a net welfare gain from transplantation.

One of the most surprising results of this paper is how large the welfare gain for society and the savings for the taxpayer would be compared to the small cost of the government compensating kidney donors. Many people are concerned about details of the proposed government compensation program, but any likely changes in that program will have little effect on our major results.

Table S8- 1						
Sensitivity Analysis of Changing the Compensation of Kidney Donors (steady-state case)						
Compensation	\$25,000	\$45,000 (in paper)	\$65,000		\$375,000	\$1,200,000
Net Welfare Gain for Society per Transplant Recipient	\$1,906,000	\$1,873,000	\$1,841,000		\$1,336,000	\$0
Taxpayer Savings per Transplant Recipient	\$428,000	\$403,000	\$379,000		\$0	-\$1,007,000

2. Changing the Monetary Value of a Quality-Adjusted Life Year

We estimated in the main text of the paper that the value of a discounted quality-adjusted life year (QALY) was \$200,000. In this section, we investigate how our results would change if we instead assume values of \$100,000 and \$300,000.

Note in Table S8-2 that changing the value of a QALY just affects the net welfare gain for society; it does not affect the taxpayer savings. Note also that even for the value of a QALY at the lower end of the range (\$100,000), there is still a substantial net welfare gain for society per transplant recipient of \$1.2 million.

Table S8-2					
Sensitivity Analysis of Changing the Value of a Quality-Adjusted Life Year (steady-state case)					
Assumed Value of a Quality-Adjusted Life Year (QALY)	\$100,000	\$200,000 (in paper)	\$300,000		
Net Welfare Gain for Society per Transplant Recipient	\$1,205,000	\$1,873,000	\$2,541,000		
Taxpayer Savings per Transplant Recipient	\$403,000	\$403,000	\$403,000		

3. Changing the Quality of Life Before and After a Transplant

We also estimated in the main text of the paper that the quality of life before and after a transplant was 0.52 and 0.75, respectively. In this section, we examine how our results would change if we instead assume values of:

(a) 0.57 and 0.70, and

(b) 0.47 and 0.80.

Note in Table S8-3 that changing the quality of life before and after transplant just affects the net welfare gain for society. It does not affect taxpayer savings. Note also that even for the smallest differential between the quality of life before and after a transplant (i.e., 0.70 - 0.57 = 0.13), there is still a substantial net welfare gain for society per transplant recipient of \$1.6 million.

Table S8 -3					
Sensitivity Analysis of Changing the Quality of Life Before and After a Transplant (steady-state case)					
Quality of Life:		(in paper)			
After Transplant: <u>Before Transplant:</u> Difference:	0.70 <u>0.57</u> 0.13	0.75 <u>0.52</u> 0.23	0.80 <u>0.47</u> 0.33		
Net Welfare Gain for Society per Transplant Recipient	\$1,581,000	\$1,873,000	\$2,166,000		
Taxpayer Savings per Transplant Recipient	\$403,000	\$403,000	\$403,000		

4. Tornado Diagrams

Figure S8-1 shows how much the net welfare gain for society would change as the three inputs discussed above vary throughout their likely ranges (i.e., there is only a 10% probability the variable would be above this range and a 10% probability it would be below this range).

For instance, the top row shows that the net welfare gain for society would increase from \$1,205,000 to \$2,541,000 as the assumed value of a quality-adjusted life year (QALY) increases from \$100,000 to \$300,000. This assumes the other two variables are held constant at their expected levels (0.52 and 0.75 for the quality of life before and after a transplant, and \$45,000 for government compensation of donors).

Similarly, the second row shows the net welfare gain for society would increase from \$1,581,000 to \$2,166,000 as the quality of life before and after a transplant

varied from (0.57 - 0.70) to (0.47 - 0.80) -- again holding the other two inputs constant at their expected levels.

The third row shows the net welfare gain for society would increase from \$1,841,000 to \$1,906,000 as the government's compensation of kidney donors decreases from \$65,000 to \$25,000 – again holding the other two variable constant at their expected levels.

It is clear that the net welfare gain for society would vary: (a) most in response to likely changes in the value of a quality-adjusted life year; (b) second most in response to variations in the quality of life; and (c) least in response to changes in donor compensation.



Now turning to Figure S8-2, we see how taxpayer savings would vary as the same three inputs change. The top row shows taxpayer savings would increase from \$379,000 to \$428,000 as the required amount of government

compensation of donors <u>decreases</u> from \$65,000 to \$25,000 -- holding the other two variable constant at their expected levels.

Figure S8-2 also shows taxpayer savings would remain constant at \$403,000 as both (a) the quality of life, and (b) the monetary value of a QALY varied in their normal ranges. Clearly, taxpayer savings would vary most in response to the likely changes in the value of donor compensation. Indeed, it would not vary at all in response to changes in the quality of life and the monetary value of a QALY since those variables do not affect the costs of either dialysis or transplantation.



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Supplement 9: Living vs. Deceased Donors Under a Donor Compensation Program

Currently, the U.S. kidney transplantation program performs approximately 17,500 transplants per year with about 2/3 from deceased donors (DD) and 1/3 from living donors (LD). Both the total number and the distribution between DD and LD have been relatively constant over the last several years. Transplantation has been relying on, and will continue to rely on, DD organs for the foreseeable future.

As demonstrated in Supplement 12, DD transplants <u>currently</u> do not have as good an outcome as LD transplants, both for recipient and graft survival. However, one of the benefits of eliminating the kidney waiting list is that all transplants essentially become preemptive transplants, even with DD organs. This will lead to two changes that will go a long way toward eliminating the difference in outcomes between LD and DD kidneys. First, no waiting list for a transplant implies that patients will on average be 5 years younger when they receive their transplant. Second, patients will be in better health, not having to endure 4 or 5 years of dialysis therapy. As shown in Table S12-2 of Supplement 12, these two changes would increase the half-life of the recipient of DD kidneys by over 60 percent, and the half-life of the graft by over 30 percent. When combined with the improving secular trend observed in recent years in DD transplant outcomes (also shown in Table S12-1 of Supplement 12), the difference in outcomes between DD and LD transplants would be negligible.

A second consideration is the limited number of DD organs. Several sources (Hall et al. 2013, (Ref. 22); Beard et al. 2013 (Ref. 4); Cook and Krawiec; 2014 (Ref. 20) indicate that the maximum number of medically appropriate deceased donors is approximately 7,000 to 8,000 per year, which would imply a maximum of 14,000 to 16,000 DD kidneys available for transplantation. So even the

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maximum number of DD kidneys would not be sufficient to provide the required supply of kidneys needed to eliminate the waiting list in five years (about 43,000 per year) or to keep it from coming back again in steady state (about 35,000 per year as shown at the top of the right column of Table 4 in the main text). In addition, the definition of "medically qualified" is likely to expand as the supply of available kidneys grows, so the supply of DD kidneys would be quite insufficient even under the most ideal procurement program for DD kidneys.

If compensation of kidney donors were successfully implemented, it would most likely draw upon LD as well as DD kidneys. Simply put, there are not enough DD grafts available to eliminate the waitlist. Fortunately, the consequence of no waitlist is that the difference in outcomes between DD and LD grafts will be negligible. There is need for both DD and LD grafts. For proposed compensation of LD and DD see Supplement 1, items 9 and 10.

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Supplement 10: The Cost of a Quality-Adjusted Life Year: Dialysis vs. Transplantation

Much previous research on the cost of transplantation vs. dialysis has focused on comparing the cost effectiveness of the two treatments in terms of the cost per quality-adjusted life year (QALY). Our analysis provides those metrics as a side benefit. This is useful information, but it does not tell us whether either treatment provides a net benefit for society, or who wins and loses -- as does our cost-benefit analysis.

The Cost of a QALY from Dialysis: Consider the steady-state case. The discounted present value of the cost of dialysis is \$1,454,000 per kidney recipient (second row of right column of Table 3). For this cost, the dialysis patient obtains 15.0 additional years of life (top row of right column of Table 2). But if we adjust these years of life for the lower quality of life on dialysis, the patient obtains only 7.8 quality-adjusted life years (= 15.0×0.52). So the cost of QALY obtained from dialysis is $$186,000 = $1,454,000 / (15.0 \times 0.52)$]

The Cost of a QALY from Transplantation: Again considering the steady-state case, the discounted present value of the cost of transplantation is \$916,000 (sum of rows 3, 4, and 5 of the right column of Table 3). For this cost, the transplant recipient obtains 24.9 additional years of life (second row of right column of Table 2). But if we adjust these years of life for the quality of life after a transplant, it buys only 18.7 quality-adjusted life years (= 24.9 X 0.75). So the cost of a QALY obtained from transplantation is \$49,000 [= \$916,000 / (24.9 X 0.75)]. Note that the cost of QALY from transplantation is less than one-third the cost of a QALY from dialysis. Transplantation is clearly much less expensive than dialysis.

The Current Situation Case: The comparable numbers for the current situation case are:

The cost of QALY obtained from dialysis is \$115,000 [= \$735,000 / (12.3 X 0.52)].

The cost of a QALY obtained from transplantation is \$37,000 [= \$540,000 / (19.3 X 0.75)].

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Supplement 11:Capacity of US Kidney Transplant Centers

USRDS (Ref. 7, Reference Tables J5, J7) reports there were 327 Medicare certified Transplant Centers (or Transplant and Dialysis Centers) in 2012. A web site "National Kidney Center", run by Johns Hopkins University, reports only 274 kidney transplant centers

(http://www.nationalkidneycenter.org/treatment-options/transplant/find-atransplant-center/). The difference between the two, 53, most likely represents centers that did not perform any kidney transplants in 2012. USRDS also reports that the median number of transplant procedures per center performed in 2011 was 21. Since a total of 17,671 kidney transplants (both DD and LD) were performed in 2011 (USRDS, Ref. 7, Table E6), this implies the mean number of transplants per center was 59 (assuming a conservative estimate of 300 kidney transplant centers). A mean of 59 and a median of 21 indicates transplant activity is currently concentrated at a relatively few centers. Or put differently, there is considerable unused capacity at most U.S. transplant centers. A median of 21 transplants per year indicates that half the U.S. transplant centers perform less than 2 kidney transplants a month. So if the number of transplants were increased by a factor of four to 84 transplants a year per center, that would be 7 per month, or less than 2 transplants a week. The implication of these estimates is the U.S. transplant community does have substantial capacity to expand dramatically as would be required in both the transition phase (eliminating the current waiting list) and in the steady state. In the transition phase, it is assumed there would be an average of 43,000 transplants a year; in steady state, 35,000. Currently, the U.S. is performing approximately 17,500 kidney transplants a year.

Finally, There is the potential to expand transplantation at both large and small centers and that surgical experience suggests that a higher frequency of procedures offers the potential for better transplant outcomes.

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Supplement 12: Estimating Half-Lives of Dialysis Patients, Transplant Patients, and Kidney Grafts

A central part of the analysis of this paper is determining the difference in the lifetimes of patients who receive a kidney transplant compared to patients receiving dialysis therapy while on the waiting list. In addition, the lifetime of the kidney <u>graft</u> is also important. This analysis uses half-lives as a conservative proxy for expected lifetimes.

The data used in this analysis are from both the USRDS (Ref. 7) and the SRTR (Ref. 8). In this supplement, we both derive some estimates and reference the work of others. We consider both recipient and graft survival, and we distinguish between kidneys from living donors (LD) and deceased donors (DD). Graft half-lives have been published by SRTR (Ref. 8), but we estimate patient half-lives for this analysis. We adjust for trends over time in these variables. We also adjust for the effects of lower patient age at transplant, as well as fewer years on dialysis before transplant.

Table S12-1 is the bottom line of Supplement 12. This table is brought forward to provide the reader with the final product of the analyses of this supplement. It is followed by the four tables and three figures that support the arguments.

Shown in row 1 of Table S12-1 are estimated half-lives for patients (in 2005) and grafts (in 2010) for both LD and DD transplants. Also shown is the half-life of wait list patients in 2011.

These 2005-2011 estimates are projected forward to 2015, which is referred to as the "current period" in the main text. Three estimates in bold and underlined for 2015 provide the <u>"current situation" half-life estimates</u> for:

- o Dialysis patients on the wait list
- o Transplant patients, and
- o Graft survival

DD and LD transplant half-life estimates for both patient and graft are also provided and merged with the current distribution of living versus deceased donors (LD: 33%; DD 67%) to arrive at estimates for all (or total) transplants.

"Steady state" projections (bottom line of Table S12- 1), based on the 2015 estimates, are projected forward to adjust for trend from an earlier period. In addition, in the case of DD outcomes, estimates are adjusted for expected clinical changes of younger age at transplant and no dialysis treatment time pre-transplant.

The trend line effects, employed in Table S12-1, are depicted graphically in Figure S12-1 below. Note particularly the decreasing mortality for wait list dialysis patients. Steady state projections for patient and graft survival are the minimum of LD and DD projected values. The DD projected estimates (28.4 years patient, 16.1 years graft) reflect not only trend lines, but, as mentioned, the two changes of younger age and no dialysis pre-transplant, which results from no waiting list for DD organs under a donor compensation program. These DD half-life estimates, which are larger than the LD estimates, are not used in the analysis, given our general approach of using conservative estimates, i.e., we use the lower estimates for LD transplants in the text of the paper.

See Table S12-2, below, for the estimated effect of younger age and no dialysis pre transplant. See Supplement 9 above for a discussion of DD and LD transplants under a proposed program of donor compensation.

Of note is the <u>decreasing</u> mortality of dialysis patients (see Figure S12-1) starting in 2001 and continuing through 2011, which has been incorporated into

the estimates of Table S12-1. A decreasing mortality trend is also seen for waitlist patients, which means that the bar for improvement with a kidney transplant is being raised. The measure of improvement is the difference between waitlist and transplant survival, and as the baseline (current situation) waitlist survival improves, the difference (benefit of transplantation) decreases.

Table S12-1: Statistical Model: Entime time to Entime for Moit List Dislusis and Transmust Patients						
Estimating Time to Failure for Walt-List Dialysis and Transplant Patients						
Accumption	Estimate Hair-lives for Patient and Graft Survival					
Assumption	Experience of the Median Patient is Representative of the Population					
Published	Hait-Lives	T		T	0	
Starting Point:	Patient	I ransplan	Iransplant Patient Iransplant Graft			
SRIR 2012;	vvait-list			LD		
	(2011)	(2005)	(2005)	(2010)	(2010)	
	10.5 yrs.	24.9 yrs.	15.0 yrs.	14.2 yrs.	9.9 yrs.	<u> </u>
I rend Prior				1 00/ /	1.00/ /	See Tables
5-Yrs	4.1% /yr.	0% /yr.	1.0% /yr.	1.0% /yr.	1.8% /yr.	<u>S12-4 & 5</u>
2015		24.9 yrs.	16.6 yrs.	14.9 yrs.	10.9 yrs.	Underline:
(Estimate based		Weighted*	*LD & DD	Weighted**	LD & DD	Input to
on Trend)	<u>12.3 yrs.</u>	<u>19.3</u>	<u>Yrs.</u>	<u>12.</u>	6yrs.	l able 2
Estimating Stead	v State (2020)) Based o	n Estimate	d 2015 Half-	Lives	
	Half-Life	<u>, </u>				
2015 to 2020	Patient	Transplar	nt Patient	Transplant	Graft	See Trend
Adjusted for	Wait-list					Rates
Trend Only	15.0 vrs	24 9 vrs	17.4 vrs	15.7 vrs	12.0 vrs	Above
Wolfe et al. (Ref	No		DD for "Wo	lfe Effects"	12.0 yrð.	
20) estimate	adjustment	No	21%	No	6%	
adverse effects		adjust-	increase	adjust-	increase	
of age and pre-		ment	ner 5-vr	ment	ner 5-vr	
transplant			decrease	mont	decrease	
dialysis on DD			In age:		in age.	
transplant			35%		in age,	
outcomes			increase		26%	
001001100.			ner		increase	
Under donor			-4 vrs no		ner -4vrs	
compensation			dialvsis		dialvsis	
age at			nre-trans		nre-	
transplant will			nlant	↓	transplant	
decrease and no		24 9 vrs	28.4 vrs	15.7 yrs	16 1 yrs	
dialysis pre-		24.9 yis. 20.4 yis. 15.7 yis. 10.1 yis.				
transplant will be		Tuncale			juai lo LD.	Underline
common	Bottom Line Estimates for Steady State					
Common	Patient Dottom Line Estimates for Steady State = Input to				Table?	
	Wait List					Tablez
	<u>15.0 yrs.</u>	24.9 yrs.	<u>24.9 yrs</u> .	<u>15.7 yrs</u> .	<u>15.7 yrs</u> .	
*Start year estimates: Sources: SRTR (Ref. 8) Table 5.3: Ref. (Kidney) Sect. 5: LISPDS (Ref.						
8) data behind Fig 6.7 ** Wtd average (0.32 LD: 0.68 DD) Estimates are unadjusted						

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Source: USRDS 2013, H Tables

Shown in Figure S12-2 are half-lives for kidney transplant <u>grafts</u> by donor type for the 1991-2011 period. These statistics are one of the few published statistics of half-lives for kidney transplant grafts and patients. In this case, it is for grafts only.

Shown in Table S12-2 are the estimated impact of two parameters that are likely to change under a successful program of donor compensation: (a) patients' age at the time of transplant, and (b) dialysis treatment pre-transplant. As a consequence, these two effects are likely to eliminate the half-life advantage that recipients of kidneys from living donors currently enjoy over recipients of kidneys from deceased donors. These effects, based on the excellent work of Wolfe, McCullough et al. (Ref. 19), are very large and favorable to the recipient.

For example, in the second row of Table S12-2, consider the years on dialysis for which the hazard ratio (an outcome of patient death per natural log of 10 years on dialysis) is 1.24. Consider a change of -4 years of dialysis (from +4 years pre-transplant to 0 years pre transplant or a minus the log of 4). 1.24 raised to the power (- log 4) is 0.74, which is the ratio of the hazard of death with 0 years of dialysis compared to the hazard of death with 4 years of dialysis. In other words, a patient with no dialysis pre-transplant has only 74 percent of the chance of death of a patient with 4 years of dialysis. Survival, in contrast to death, is 1/ 0.74 or 1.35. That is, a patient with 0 years of dialysis has a 35 percent increase in survival compared to a patient with <u>4 years</u> of dialysis pre-transplant. A similar calculation using a <u>5-year</u> difference in dialysis time yields a 41 percent improvement in survival, which is more likely with successful donor compensation than 4 years difference in dialysis time. But consistent with our conservative assumptions, our analysis assumed a 35 percent improvement in patient had no dialysis pre-transplant.



Table S12-2: The Expected Changes in Age and Time on Dialysis WillHave a Large Impact on Patient and Graft Survival of Patients Receiving aDeceased Donor Transplant

Hazard is Recipient Death					
Covariate: at Transplant	Anticipated Change Under the Proposed Compen- sation of	Estimated Hazard Ratio (from Published Research)*	Hypothe- sized Delta	Hazard Ratio Raised to the Delta Power	Implied Change In <u>Patient</u> <u>Survival</u> Due to Covariate
Patient's Age at Time of Transplant	Age At Transplant Will Fall 5 Years from 49 To 44	1.47 per 10 Years	-5/10 = -0.5	1.47 ^(-0.5) = 0.82	[(1/0.82) -1] X100% = 21% Increased Survival per 5-Yrs. Decrease in Age
Patient's Time on Dialysis	Time on dialysis pre- transplant will fall from 4 to 0 years	1.24 per log of years on dialysis	-log 4	1.24 ^(-log 4) = 0.74	[(1/0.74) -1] X 100% = 35 % Increased <u>Survival</u> Per 4-Yrs. Less Dialysis Time
 *Hazard Ratios (HR) are from Wolfe, McCullough et al. 2008 (Ref. 20). Patient death, long term models (4-15 years); Proportional hazards assumptions are supported. All HR: p < 0.05; Interaction terms were small and ignored. Log is natural logarithm. Implied change in <u>DD graft survival</u>: Patient age -5 years: HR 1.12; effect 6% increase); Dialysis, - 4 years: HR 1 18; effect 26% increase 					

These estimated effects on transplant outcomes may seem large. But they are consistent with other published literature and clinical experience. For example, Meier-Kriesche et al. (Ref. 30) reported "a waiting time of 6 to 12 months increased mortality 21%." And waiting over 48 months for a transplant "confer (s) a 72% increase in mortality risk after transplantation".

Figure S12-3 shows the actual graft survival for typical kidneys from deceased donors. The half-life is where the actual survival curve falls to the 50 percent survival level, i.e., the median patient. Also shown is the estimated half-life based on two alternative estimates of graft survival. The first is a half-life prediction based on a one-year survival rate projected out for the life of the graft -- a common practice, but highly erroneous. The error is caused by the high initial failure rate, which when projected out for the life of the patient or graft, provides a half-life estimate that is far too short. The second half-life prediction shown in Figure S12-3, based on 10-year survival, is much closer to the actual survival.

Most if not all half-lives used in the text of this paper are based on the 10-year survival function for recipient survival, which as indicated in Figure S12-3, is a close approximation of the actual survival curve, i.e., a good approximation of the half-life.

Figure S12-4 shows survival curves and half-life estimates for (a) transplant patients with kidneys from living donors, (b) transplant patients with kidneys from deceased donors, (c) dialysis patients 40-60 years of age, and (d) all dialysis patients. Clearly, transplant patients have the longest half-lives, with those receiving kidneys from living donors having the longest. These phenomena were reported earlier by Wolfe, McCullough et al. (Ref. 19). The purpose of including Figure S12-4 is to demonstrate the large patient half-lives calculated here. Neither the SRTR nor the USRDS publishes patient half-lives making our calculations necessary.







Figure S12-4: Patient Survival, 2011

7_17_15

Table S12-3 reports half-lives of kidney <u>grafts</u> estimated as part of this analysis, compared to the few published estimates from the SRTR. The agreement is very high. The half-life estimates used in the text of this paper are highly supported by the published literature.

Table S12-3: Comparing <u>Graft</u> Half-Lives Estimates: SRTR Published vs.						
Current Analysis (neid et al.) Based on To-real Mortality Rate						
Year	Living Donor G	Living Donor Graft Half-Life		Deceased Donor Graft Half-		
			Life			
	Published	Current	Published	Current		
	SRTR (2012)	Analysis	SRTR (2012)	Analysis		
		Using 10-year		Using 10-year		
		Failure Rates		Failure Rates		
2005	13.5 yrs.	14.9 yrs.	9.3 yrs.	9.8 yrs. (8.8		
		(13.4 yrs. with		yrs. with		
		correction)		correction)		
Source: SRTR 2012 Annual Report, (Ref. 8) Data Table, Kidney, and Figure						
6.7. Current analysis employed unadjusted data. Half-life estimate = log						
(0.5)/log(1 - mortality rate). Correction is 0.9 of original estimate, assuming a						
constant rate of failure. See Figure S12-3 above. Log is natural log.						

Table S12-4 provides rates of change in half-life estimates for both patients and grafts for both LD and DD transplants over the period 1997-2007. These estimates assume the rates of change in survival are applicable to half-lives as well. The mean estimates, line 3 of Table S12-4, are used for trend line adjustment in Table S12-1 Row 2, above although the statistics for DD grafts shown in Figure 12-2 are somewhat higher at 1.8 percent per year vs. 1.3 percent as the mean of the 4th column of Table S12-4.

Table S12-4: Rates of Change of Half-Lives of Kidney					
Transplant Recipients and Grafts, 1997-2007					
	Patient Survival %/yr.		Graft Survival %/yr.		
Based on	Living	Deceased	Living	Deceased	
	Donor	Donor**	Donor	Donor**	
5-yr					
1997-	0.5	0.7	0.8/ 1.2	1.2/ 1.2	
2002					
10-yr	0.0	0.8	1.3/ 0.9	1.8/ 1.4	
1997-					
2007					
Mean of					
5-yr &	0.0	1.0	1.0	1.8*	
10-yr					
Sources: Bold estimates are calculated from half-life					
estimates published by the SRTR (Ref. 8) (2012)					
Reference Tables (Kidney) Section 5; Non-bold					
estimates were derived from compound rates of change					
in reported 5-year and 10-year failure rates. ** Non-ECD					
indicates not an Extended Criteria Donor transplant.					
Weighted averages (0.32 LD; 0.68 DD). Estimates are					
unadjusted. * Estimated from the SRTR statistics shown					
in Figure S12-2 above.					

Table S12-5 provide estimates of half-lives (survival) for wait-list patients on dialysis by age and also changes over time in these metrics.

Table S12-5: Half-Lives: Kidney Wait List Patients (yrs.)					
Year	All Ages	Age 42	Age 57		
2011	10.5	17.6	9.9		
	Rate of				
	change				
2006-2011	4.1 %/yr.				
Source: SRTR (Ref. 8, 2012, Table 5.3) & USRDS (Ref. 7, 2013, Table H4) report modestly different values for annual mortality rates (AMR). The mean of the two are reported here. Estimates presented here are based on an assumption of a constant rate of failure (from 10 year survival) with a correction factor 0.9 X original. See Figure S12-3 above					

Figure 12-5 provides a graphic display of the current transplant outcomes (no donor compensation) measured in half-lives, distinguishing between both DD and LD grafts. All these statistics are derived in Table S12-1, including a weighted mean across DD and LD grafts to provide statistics on what we call total transplants.

Figure S12-6 provides a graphic display of the statistics from Table S12-1, reporting on what the steady state would look like which are envisioned for 2020 with a donor compensation program.



Figure S12-5: Median Patient (Half-lives) in Years* Wait-list Dialysis vs. Transplant, Current, No Donor Compensation*

July 13 2015 *17,671 total transplants; 67 % DD; 33 % LD, from the 2013 USRDS Report ,Table E.6. 2015 projected by trend from 2011.



• Depending on the mix of 2nd transplant and dialysis. Currently only 14 % receive 2nd transplant.

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