

Increasing the Number of Kidney Transplants to Treat End Stage Renal Disease

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Executive Summary

Chronic Kidney Disease affects nearly 15 percent of the adult population in the United States and is the 9th leading cause of death. The most advanced form of Chronic Kidney Disease is End Stage Renal Disease (ESRD), in which the kidneys no longer function appropriately, thereby requiring the patient to undergo renal replacement therapy in order to live. Currently there are nearly 100,000 patients waiting for a kidney, and the number of transplants performed every year (20,000) is far less than the number of new ESRD cases every year (125,000). The market for transplantable organs is unique since ethical concerns effectively set their price at zero. As a result, there is a substantial excess demand and long queues for transplantable organs such as kidneys.

In July 2019, President Trump issued an Executive Order (EO) aimed at improving the care of patients with Chronic Kidney Disease. In 2020, the Department of Health and Human Services (HHS) published final rules that attempt to streamline the renal care system by removing regulatory barriers, increasing oversight of Organ Procurement Organizations (OPOs), and encouraging living donations.¹ HHS estimates that their changes to the OPO system alone could generate up to 4,500 additional kidney transplants per year by 2026² and HHS has set a goal of doubling the number of kidneys available for transplantation by 2030. CEA estimates that if the United States just matched Spain’s best in the world rate of deceased donor kidney transplants on a per million population (pmp) basis—an increase of roughly 7,300—and increased the number of living donors by 900, then these additional transplants would generate societal benefits with a net present value of \$16 billion per year.

¹Medicare Program, Specialty Care Models To Improve Quality of Care and Reduce Expenditures, 85 FR 61114 ; Removing Financial Disincentives to Living Organ Donation, 85 FR 59438; Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 FR 77898

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Introduction

Chronic kidney disease (CKD) - kidney damage or decreased function that persists for three months or more - affects 14.8 percent (USRDS 2018) of the adult population in the United States or about 37 million people (CDC 2019). It is the ninth leading cause of death in the United States and disproportionately affects the elderly and minorities (National Kidney Foundation 2020). Kidney failure or end stage renal disease (ESRD) is the most advanced form of CKD in which a patient needs renal replacement therapy to live. Renal replacement therapy can take the form of dialysis (either hemodialysis or peritoneal dialysis) or kidney transplantation. As of 2016, ESRD afflicts over 726,000 Americans and there are about 125,000 new cases annually (USRDS 2018; CDC 2019).

ESRD and CKD impose a tremendous burden in terms of health and health care spending. The Social Security Amendments of 1972 (P.L. 92-603) made it possible for qualified individuals with ESRD under age 65 to enroll in Medicare to pay for their dialysis or transplant and other medical care. Over time Medicare expenditures for ESRD and its antecedent condition, CKD, have grown to account for a large percentage of Medicare fee-for-service spending. While beneficiaries with ESRD comprised less than one percent of the Medicare population in 2016, they accounted for seven percent of total Medicare fee-for-service spending or \$35.4 billion. Fee-for-service Medicare spending for beneficiaries with CKD that had not progressed to ESRD accounted for another \$79 billion, which is roughly 23 percent of total Medicare fee-for-service spending. ESRD also impairs productivity, as individuals with ESRD have lower rates of employment than similarly aged peers.

People with ESRD require either renal replacement therapy or kidney transplants to live. Kidney transplantation is the preferred option, as it is associated with lower costs and better outcomes in the long-term. One source of transplantable kidneys come from deceased donors who medical professionals match with potential recipients. Another source of transplantable kidneys consists of donation from living persons, but ethical concerns set the price of kidneys to effectively zero, and Federal policies limit the degree to which living donors can be reimbursed for their expenses. These practices may disincentivize potential donors as higher income donors, typically, do not qualify for reimbursement and lower income donors may not receive enough reimbursement to cover all expenses associated with donation. Nearly 100,000 patients are currently waiting for a kidney, and the gap continues to widen between the number of transplants performed every year (20,000) and the number of new ESRD cases every year (125,000).

In July 2019, President Trump issued an Executive Order (EO) aimed at improving the care of patients with Chronic Kidney Disease. In 2020, the Department of Health and Human Services (HHS) published final rules that attempt to streamline the renal care system by removing regulatory barriers, increasing oversight of organ procurement organizations (OPOs), and encouraging living donations.³ HHS estimates that their changes to the OPO system alone could generate up to 4,500 additional kidney transplants per year by 2026. While HHS notes that there is uncertainty regarding the number of kidney

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transplants these rules will engender, HHS has set a goal of doubling the number of kidneys available for transplantation by 2030.

CEA estimates that even comparatively modest improvements to the United States renal care system could generate significant societal benefits. Specifically, CEA estimates that if the United States matched Spain's best in the world rate of deceased donor kidney transplants on a per million population (pmp) basis—an increase of roughly 7,300—and increased the number of living donors by 900, then these changes would produce societal benefits with a net present value of \$16 billion per year.

The Problem of Kidney Disease

Chronic Kidney Disease (CKD) is a major health problem in the United States. The prevalence of CKD – i.e., the total number of people with the condition - in the U. S. adult population is 14.8 percent (USRDS 2018) or about 37 million people (CDC 2019). Kidney disease is the 9th leading cause of death in the United States, causing more deaths than breast or prostate cancer (National Kidney Foundation 2019). CKD is more prevalent among the elderly than among younger adults – 38 percent of people 65 and older have CKD as compared with 13 percent in people aged 45-64 years and 7 percent in people aged 18-44 years (CDC 2019). It is more common in women (15 percent) than men (12 percent) and more common in Blacks/African Americans (16 percent) and Hispanics (14 percent) than non-Hispanic whites (13 percent) (CDC 2019).

CKD is classified along a continuum of disease severity ranging from Stage 1 (mild renal dysfunction) through Stage 5.⁴ Patients with Stage 5 whose disease is so severe that they would die without dialysis or kidney transplantation have End Stage Renal Disease (ESRD) (Agarwal 2016),⁵ defined as a substantial and irreversible failure of the kidneys' essential function—filtering the blood and removing waste products from the body while maintaining fluid and mineral balance (Wei et al. 2016).⁶ At the end of 2016, there were 726,331 prevalent cases of ESRD. The incidence for 2016 – the number of newly reported cases – was 124,675 (USRDS 2018). ESRD is more common among males than females and far more common among minorities. The probability over a lifetime or lifetime cumulative incidence of having ESRD in males ranged from a low of 3.43 percent in whites to a high of 8.09 percent Blacks/African Americans. Similarly, in women, the lifetime cumulative incidence of ESRD ranged from a low of 2.32 percent in whites to 6.83 percent in Blacks/African Americans (USRDS 2018).

⁴ The staging is based on the patients' level of glomerular filtration rate (GFR) which measure the kidneys' filtering capacity and the level of protein in the urine. In general, Stage 1 is a normal GFR greater than 90 ml/min but with protein in the urine. Stage 2 CKD has GFR of 60-89 ml/min.; Stage 3 has GFR 30-59 ml/min and are often anemic; Stage 4 has GFR of 15-29 ml/min; and Stage 5 is GFR less than 15 ml/min. Protein in the urine, indicating kidney damage, is present in all stages of CKD.

⁵ Also known as End Stage Kidney Disease or ESKD. Everyone with ESRD has Stage 5 CKD but not everyone with Stage 5 CKD has ESRD. ESRD is defined by the need for renal replacement therapy (dialysis or transplant). While CKD 5 has specific laboratory parameters, ESRD can be a bit subjective, i.e., when the nephrologist determines renal replacement therapy is necessary.

⁶ The kidneys also have an endocrine function producing the hormones erythropoietin (involved in red blood cell production) and renin (involved in blood pressure regulation). Kidneys also synthesize multiple substances important for bone development, remodeling and repair.

Treating End Stage Renal Disease

People with ESRD need renal replacement therapy - dialysis or transplantation of a functioning kidney – or they will die. There are two basic types of dialysis: hemodialysis uses a machine, usually at a dialysis center, much less frequently at home, to pass the blood through a filter called a dialyzer to remove waste products and regulate fluid and minerals. Treatment is usually 3-4 times per week with each session lasting 3-4 hours. Peritoneal dialysis uses the lining of the abdominal cavity – the peritoneum - as a filter. Sterile fluid containing Dextrose and other additives – the dialysate - is infused into the abdominal (peritoneal) cavity through a permanent, surgically placed catheter, left for several hours during which waste products and extra fluid are removed through filtration through the peritoneum, and then the fluid is drained off. Usually four or more exchanges per day are needed and they are typically performed manually by the patient or a caregiver, often a family member. This is sometimes called continuous ambulatory peritoneal dialysis. One type of peritoneal dialysis, automated peritoneal dialysis, uses a machine to do several of these fluid exchanges overnight while the patient is asleep.

Transplantation is the best form of renal replacement therapy. While a transplant recipient requires ongoing monitoring and medications, kidney transplantation both reduces medical spending on ESRD treatment and is associated with better long-term outcomes for the recipient. In 2018, for example, the life expectancy for ESRD patients who receive transplant is more than double the life expectancy on dialysis across all age groups (USRDS 2018). Healthy kidneys for transplantation can be obtained from deceased donors or from a living donor. All donor organs must be matched for blood type and immunological compatibility⁷ with the recipient or the recipient’s immune system will reject the organ.

Living donation is possible because humans have two kidneys and it is possible to live a healthy life after donating a kidney with the remaining kidney. Transplants from living donors generally have a higher success rate and higher long-term graft survival than kidneys from deceased donors, because the elective nature of living donation allows for better immunological matching between donors and recipients and the opportunity to maximize the health of the recipient and the donor organ (OPTN 2019e).⁸ Most living donors direct their donation to specific recipients. In 2018, 3,474 living donors were family members and another 1,678 living donors were directed to an unrelated recipient. Unfortunately, not every potential recipient has a compatible family member or friend to ask as a donor. A small number of living donors altruistically donate to strangers (338 in 2018).

Kidney transplantation is a major surgery with known complications for both living donors and recipients. Living donors must weigh future risks associated with kidney donation—including an increased likelihood of high blood pressure and potential increases in long-term kidney failure rates (Weill Cornell Medicine n.d.)—against their willingness to donate a kidney to those in need. All kidney transplant recipients must take immunosuppressive drugs, which have harmful side effects, to keep their immune systems from rejecting the foreign organ they have received. After transplantation, recipients must adopt a renal friendly health diets and lifestyles that are critical to maintaining the transplant. In addition, transplantation is not a permanent cure since transplanted kidneys do not

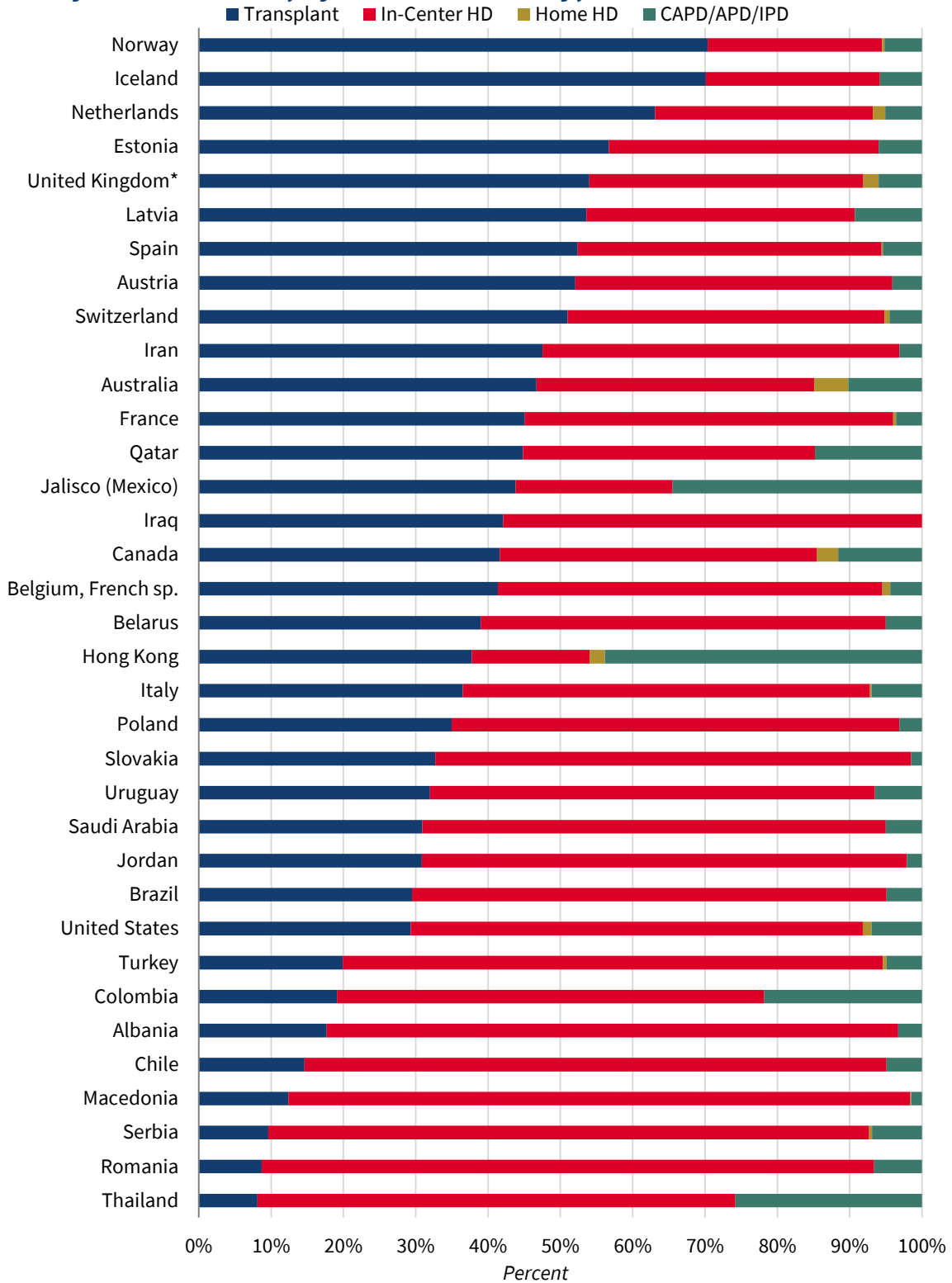
⁷ This entails matching the donor and recipient’s ABO blood types (A, B, AB, and O) and typing and cross-matching antigenic markers known as human leukocyte antigens (HLA).

⁸ We procured all OPTN data in this paper from the OPTN website on October 24, 2019.

always function for the lifetime of the recipient, with 21.4 percent of primary transplanted kidneys failing within 5 years. Despite these shortcomings, transplantation is the best treatment for ESRD.

Among new (incident) cases of ESRD in 2016, 87.3 percent were initially treated with hemodialysis, 9.7 percent with peritoneal dialysis, and 2.8 percent received a preemptive kidney transplant (USRDS 2018). Peritoneal dialysis and transplant were markedly more common among the small number of younger ESRD patients with 28.6 percent of new 0-21 year old ESRD patients on peritoneal dialysis and 19.9 percent receiving transplant. These percentages quickly declined with increasing patient age (USRDS 2018). At the end of 2016, among the 726,331 prevalent ESRD cases, 63.1 percent were receiving renal replacement therapy through hemodialysis, 7 percent with peritoneal dialysis, and 29.6 percent had a functioning kidney transplant (USRDS 2018). Compared to other countries, the United States has a lower percentage of ESRD patients treated by kidney transplantation and peritoneal dialysis as well as a higher percentage treated by hemodialysis (USRDS 2018; Scholten et al. 2019).

Figure 1. Distribution of Type of Renal Replacement Therapy Modality Used by ESRD Patients, by Selected Country, 2016



Source: United States Renal Data System.

Note: United Kingdom data includes England, Wales, and Northern Ireland.

The Cost of Treating End Stage Renal Disease

The Federal Government bears most of the cost of paying for ESRD care. In 1972, Medicare eligibility was extended to people with ESRD who needed either dialysis or a transplant. The Medicare ESRD benefits cover all Medicare-covered services for ESRD enrollees, not just those related to kidney failure (CMS 2013). Between 1972 and 2016, the number of covered persons grew from about 10,000 to 511,270. While we primarily discuss the ESRD spending incurred by the Medicare system, the Department of Veterans Affairs and Indian Health Service also cover ESRD treatment.

Medicare fee-for-service was the primary payer (including individuals dually eligible for Medicare and Medicaid) for 58 percent and secondary payer for 8 percent of ESRD patients in 2016 (USRDS 2018). While ESRD patients account for less than one percent of Medicare beneficiaries, they account for 7.2 percent of Medicare fee-for-service spending (USRDS 2018). Medicare Advantage covered 15 percent of ESRD patients. About 19 percent of people with ESRD had private, non-Medicare coverage (USRDS 2018).

Medicare fee-for-service spending (Parts A, B and D) for patients with ESRD totaled \$35.4 billion in 2016 (USRDS 2018). According to USRDS (2018), an additional \$79 billion was spent on CKD short of ESRD bringing total Medicare spending on CKD patients in 2016 to over \$114 billion or about 23 percent of Medicare fee-for-service spending).⁹ Medicare accounts for three quarters of annual United States medical spending to treat ESRD (Kirchhoff 2018). Under the 2016 Cures Act, all Medicare eligible ESRD patients will be able to enroll in Medicare Advantage programs starting in 2021.

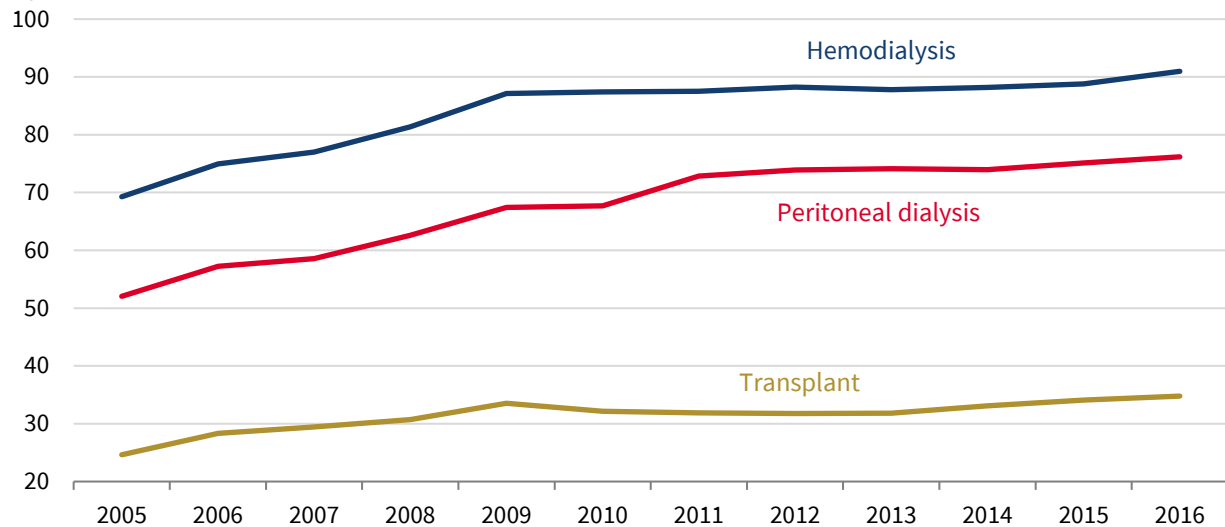
Comparative Costs and Benefits of Different Types of Renal Replacement Therapy

The three renal replacement therapy modalities differ in terms of cost, outcomes as measured by survival, quality of life and productivity as measured by employment. One of the starkest differences across the three modalities is cost. In 2016, Medicare ESRD spending per person per year was \$90,971 for hemodialysis, \$76,177 for peritoneal dialysis and \$34,780 for transplants—see Figure 2 (USRDS 2018)—though this cost differential may narrow when controlling for beneficiaries' health and location.

⁹ These figures appear to be all medical spending on CKD patients, not simply spending to treat renal disease. While these patients generally have multiple medical problems, the bulk of spending is on treating renal disease, especially in the more advanced stages.

Figure 2. Total Medicare ESRD Expenditures per Person per Year, by Modality, 2004–16

Expenditures (thousands of dollars)



Source: United States Renal Data System.

On an annual basis, hemodialysis is 16 percent more expensive than peritoneal dialysis, a finding that generally holds across most developed countries (Just et al. 2008). The primary ongoing costs of hemodialysis are facility space, dialysis machines, and staff. Hemodialysis machines cost about \$18,000 to \$30,000, last 5–10 years and can treat three to six patients per week. The cost of dialysates used in the machines range from \$1,000 to \$5,000 per year. Peritoneal dialysis avoids the facility and staff expenses, so the costs of dialysis solutions and sterile tubing are the main costs (Jindal 2009). The machines used in automated peritoneal dialysis add an additional cost of \$3,000 to \$10,000 for tubing (Jindal 2009). Annual costs for transplantation are less than the annual costs for either mode of dialysis. Most of the costs of transplantation are concentrated in the year of the transplantation and consist of the cost of procuring an organ, transplant surgery and post-operative care. Afterwards, the costs of transplantation include immunosuppressive medications and ongoing medical care, which are far lower than the ongoing costs of dialysis.

There is no significant difference in life expectancy between peritoneal dialysis and hemodialysis patients when matched for comorbidities (Shih et al. 2005; Mehrotra et al. 2011; Barone et al. 2014; Jaar et al. 2005; Chang et al. 2016). Mortality is similar between peritoneal dialysis and hemodialysis for elderly patients (Wright and Danziger 2009). Though some studies report that peritoneal dialysis patients have a higher quality of life than hemodialysis patients, many studies (Juergensen et al. 2006; Rubin et al. 2004; Wolcott and Nissenson 1988) find no significant difference between the two modalities for most quality of life measures (Kontodimopoulos and Niakas 2008; Kutner et al. 2005; Wu et al. 2004), particularly in the case of elderly patients (Wright and Danziger 2009). Peritoneal dialysis performed overnight as automated peritoneal dialysis may free up time for work, family and social activities as compared to the more commonly performed continuous ambulatory peritoneal dialysis. However, a review of randomized trials by the Cochrane Review, found no significant advantage for automated peritoneal dialysis in terms of clinically important outcomes like mortality, hospitalizations, abdominal infections and peritoneal dialysis catheter complications (Rabindranath et al. 2007).

Long-term survival is better for kidney transplant recipients than ESRD patients on dialysis, but in part this may reflect the fact that healthier patients are selected for placement on transplant lists (Wolfe et al. 1999). Nevertheless, when kidney recipients are compared with similar patients who are on the wait list but still on dialysis, there is still a survival advantage. While the risk of death is significantly higher in the post-operative period, reflecting the risk of surgery and the initiation of immunosuppressive therapy, it rapidly declines and the long-term survival of transplant recipients starts to exceed that of dialysis patients in a year or less post-transplant (Wolfe et al. 1999; Tonelli et al. 2011; Kaballo et al. 2018). The patient survival benefit of transplantation versus dialysis persists even when less than ideal (marginal) kidneys are used, although the benefits are smaller than when ideal kidneys are used (Ojo et al. 2001).

ESRD patients on dialysis have decreased participation in the workforce. Peritoneal dialysis appears to be associated with increased likelihood of being employed compared to hemodialysis but the effect is uncertain and likely small. A recent Swedish study found that peritoneal dialysis was associated with a four-percentage point higher probability of employment over hemodialysis and a six-percentage point lower probability of being on disability (Ghani et al. 2019). Yet, while cross-sectional studies have found that peritoneal dialysis patients are more likely to be employed than hemodialysis patients, it is difficult to determine the direction of causation. Given that it is more likely that healthier individuals with ESRD choose peritoneal dialysis, it may not be the treatment modality but rather the health of the patient that accounts for the differences in employment between peritoneal dialysis and hemodialysis.

Other studies utilizing different analyses suggest that treatment modality does not influence the ability to be employed but that there may be a small effect of employed patients preferentially choosing peritoneal dialysis (Just et al. 2008). Hence, a study that found that peritoneal dialysis patients who worked in the year before starting dialysis were 2.5 times more likely to continue employment in the four months after starting dialysis than hemodialysis patients. This study concluded that “it is likely that patient characteristics, rather than dialysis modality, function as the main determinants of employment status, but using a therapy such as peritoneal dialysis can make employment more feasible, and patients may select or be recommended for peritoneal dialysis to facilitate their employment” (Kutner et al. 2010, 2044). Similarly, Van Manen et al. (2001, 600) found that employment fell from 31% to 25% for hemodialysis patients and from 48% to 40% for peritoneal dialysis patients after one year of starting dialysis and concluded that the, “findings suggest treatment modality does not influence ability to maintain employment, but that employment may influence the choice of hemodialysis or peritoneal dialysis.”

Most studies report higher participation rates in life activities (physical function, travel, recreation, work) for kidney transplant patients than either peritoneal dialysis or hemodialysis (there was no difference between the two types of dialysis) (Purnell et al. 2013). A recent Swedish study reported that the probability of being employed one year after treatment was 21 percentage points higher for transplant recipients than dialysis patients. This effect increased to 38 percentage points after five years due to worsening outcomes and conditions on dialysis (Jarl et al. 2018).

In summary, kidney transplantation is superior to dialysis in terms of lower cost, longer life expectancy, better quality of life, and higher productivity. Other than lower annual cost, there is little difference

between the two types of dialysis. A 2013 review of the worldwide literature concluded that peritoneal dialysis and hemodialysis are “clinically equivalent modalities” with similar 1,2,3,4 and 5 year survivals and quality of life “...we will thus consider hemodialysis and peritoneal dialysis as perfect substitutes from an economic standpoint” (Karopadi et al. 2013, 2533).

Moving from Hemodialysis to Peritoneal Dialysis

There are multiple steps to place a patient on peritoneal dialysis with attrition at each step that limit the total number of ESRD patients who can undergo peritoneal dialysis. The first is patient selection. Not every ESRD patient can receive peritoneal dialysis. Contraindications include previous abdominal surgeries, large abdominal wall hernias, morbid obesity, intra-abdominal inflammatory and infectious conditions like diverticulitis, large abdominal aortic aneurysm, and a place of residence that does not permit peritoneal dialysis. Relative contraindications or barriers to peritoneal dialysis include physical barriers like impaired vision and dexterity and cognitive barriers like dementia, psychiatric illness and a history of non-adherence. Estimates of patients eligible to do peritoneal dialysis range between 40 and 80 percent (Blake et al. 2013). The number of eligible patients might be expanded for people whose age, co-morbidities and lack of family support are relative contraindications to peritoneal dialysis by providing trained staff to assist either automated or continuous ambulatory peritoneal dialysis at home as is done in some other countries. In the United States, healthcare worker assisted peritoneal dialysis is not covered by Medicare and utilizing it would likely eliminate some of the cost savings of home peritoneal dialysis versus in-center hemodialysis (Brown and Wilkie 2016).

The next step is patient choice. Not all people eligible for peritoneal dialysis will choose it when they are educated and given a choice of dialysis modalities to undertake. Studies suggest that about half of patients offered an informed dialysis modality choice will choose peritoneal dialysis (Blake et al. 2013; Brown and Wilkie 2016; Little et al. 2001). Interestingly, most medical professionals (physicians and nurses) treating renal disease say they would strongly prefer home peritoneal dialysis or home hemodialysis over center based hemodialysis for themselves (Schiller et al. 2010).

Following patient selection and consent to peritoneal dialysis, a catheter must be placed in the abdominal cavity. Surgeons or interventional radiologists who can place the catheters need to be available, a factor that often limits access to peritoneal dialysis when dialysis must be started urgently. Not every attempt placing a catheter is successful. Sometimes the placement cannot be completed or the catheter is placed but will not function adequately to allow peritoneal dialysis. Even after successful catheter placement, some patients or their family members are unable or unwilling to learn how to carry out peritoneal dialysis in a safe manner. About 15 percent of patients with attempted catheter placements will not succeed in performing home peritoneal dialysis (Blake et al. 2013).

Taking into account the attrition at each step of the process suggests that between 17 to 34 percent of ESRD patients could be receiving peritoneal dialysis. If we subtract out the ESRD patients who have received a transplant and apply this range to the population of ESRD patients currently on dialysis (509,014) there should be 86,532 to 173,065 patients who could be on peritoneal dialysis.¹⁰ Since about

¹⁰ These figures likely represent an upper bound since the 17-34 percent applies to all ESRD patients. Patients eligible for peritoneal dialysis are generally healthier than patients who end up on hemodialysis. But many of the

7 percent of ESRD disease patients (51,057 patients or about 10 percent of dialysis patients) are currently on peritoneal dialysis (USRDS 2018), an additional 35,475 to 122,008 patients could be moved from hemodialysis to peritoneal dialysis. These estimates of the numbers of patients who could be receiving peritoneal dialysis are in line with a recently reported study of an effort to move dialysis patients in an integrated healthcare delivery onto peritoneal dialysis (Pravoverov et al. 2019). Over an 11-year period utilization of peritoneal dialysis among new dialysis patients increased from 15.2 to 33.8 percent however, only 80 percent of these patients continued peritoneal dialysis one year after initiation (Pravoverov et al. 2019).

Potential Cost Savings from Peritoneal Dialysis: It is unlikely that large numbers of current hemodialysis patients would move to peritoneal dialysis because most of these patients are now comfortably receiving hemodialysis. Relative to new ESRD patients, many current hemodialysis patients would likely be unable or unwilling to move to a new treatment modality. A better estimate of the number of patients willing to switch would probably start by looking at the 124,675 new (incident) cases of ESRD each year. Currently, 9.7 percent of incident ESRD cases are initially treated with peritoneal dialysis. Moving this peritoneal dialysis percentage to 17-34 percent would add an additional 9,101 to 30,296 peritoneal dialysis patients each year. This would yield roughly \$135 to \$450 million in annual savings. However, these cost savings may narrow once beneficiary health and location are considered. Thus, the benefit from moving additional ESRD patients from hemodialysis to peritoneal dialysis may lead to smaller gains than estimated. Regardless of the potential cost savings, the needs of the ESRD patient ultimately dictate the type of treatment they should receive.

Comparative Moving to Kidney Transplantation

The Organ Procurement and Distribution System

The Organ Procurement and Transplantation Network (OPTN) is a non-profit entity that was established by Federal statute to run the nationwide organ procurement and distribution system (42 United States Code §274). The United Network for Organ Sharing (UNOS) is a private, non-profit organization that has run the OPTN under contract with the Federal Government since 1986. CMS has designated 58 Organ Procurement Organizations (OPOs) nationwide that manage the organ procurement, recovery, and allocation process within exclusive geographic areas designated as Donation Service Areas (DSA). Each OPO must join and abide by the rules of the OPTN (42 CFR §486.320). There is only one OPO per DSA granting them a monopoly on organ procurement within the service area. However, there may be many transplant centers and donor hospitals within a DSA. Transplants are performed at Transplant Centers (hospitals/medical centers) around the country. There are nearly 300 centers across the country although not every center transplants every kind of organ. Each center maintains its own transplant list and makes its own determinations as to who is accepted onto their list. Once a center accepts patients onto its list, the patients are registered in a national, computerized list maintained by UNOS. Transplant centers are required to join the OPTN.

healthiest patients who would otherwise go on peritoneal dialysis are the same healthy patients who receive transplants. Therefore, the range of dialysis patients remaining who could go on peritoneal dialysis could be less than 17-34 percent.

As of October 24, 2019, the OPTN (2019a) reported 94,850 candidates currently on the kidney transplant waiting list. 60,052 of these are active candidates, meaning they are eligible to be considered for a transplant. The remainder are temporarily classified as inactive by their transplant center because current medical problems make them unsuitable for transplantation at that time (OPTN 2019b). Inactive candidates can however stay on the list to accumulate waiting time until they are once again active. In the most recent full year, 2018, 38,796 transplant candidates were added to the list (OPTN 2019e).¹¹ During that same year, 36,478 were removed from the list: 14,714 received a deceased donor transplant, 6,430 received a living donor transplant, 3,959 died, another 4,394 became too sick to transplant, and 451 refused transplant (OPTN 2019d).

Barriers to Obtaining More Kidneys

In a typical market, imbalances between supply and demand are addressed via prices. When demand for a good exceeds supply, the price of the good increases thereby reducing demand for the good and inducing suppliers to produce more of the good, thereby eliminating the imbalance. The National Organ Transplant Act, potential buyers (i.e., waitlist patients) are forbidden from directly purchasing organs, and potential sellers (i.e., potential living donors) are prohibited from receiving financial compensation for donation, although they can be reimbursed in part for their expenses. Under these constraints, the overall number of transplants is determined by a supply of donated kidneys that is further reduced due to regulatory barriers.

For example, while living donors can be reimbursed for some expenses such as travel expenses, the reimbursement is incomplete because many expenses—such as lost wages and child/elder care expenses—are not currently reimbursed. Moreover, not all donors are reimbursed, as The National Living Donor Assistance Center—a main funder for reimbursement—only, until recently, made reimbursements to donors whose income is 300 percent of the FPL or less. Prior to HHS’s recent publication of Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, which addresses some of the following issues, there has been widespread concerns that OPOs are inefficient at obtaining potential deceased donor organs. Part of the problem lies in how the OPOs are evaluated.

Historically, OPOs have been evaluated based on two metrics: the donation rate ratio (actual organ donors/eligible deaths) and the organ yield rate (organs transplanted/actual donor). The former is problematic as OPOs self-report eligible deaths, raising issues regarding the fidelity of the reported donation rate ratio and inherent incentives to boost perceived performance. In addition, the eligible death definition excludes many known and potential donors: donors who meet the circulatory definition of death as opposed to brain death, as well as and donors older than 75 years old (SRTR 2019). The second measure, the organ yield rate, is the ratio of observed to expected number of organs transplanted. Since the number of kidneys transplanted per donor was approximately 1.5 in 2017 (Israni et al. 2019), some argue that the yield rate metric discourages OPOs from pursuing single-organ donors (often older donors) thereby leaving potential organs unutilized (Goldberg et al. 2017).

Poor utilization of recovered kidneys may also be a problem. The recovered kidney discard rate nearly quadrupled between the 1980s and 2009 as the donor pool expanded to include older people with more

¹¹ Potential transplant recipients can register on more than one waiting list. To get a better sense of the need for organs we utilize the number of new candidates, some of whom may have registered on multiple lists.

co-morbidities. The discard rate then leveled off as rise in donor age and co-morbidities came to a halt. The median donor age rose from 26 to 43 years and between 1994 and 2009 the median Kidney Donor Risk Index (KDRI) rose from 1.1 to 1.3. In addition, between 1999 and 2009, the number of kidneys biopsied to assess their suitability for transplant doubled from 23.1 to 48.9 percent leading to increased discards (Stewart et al. 2017). The increased discards resulting from changes in the donor pool and the increased biopsy rate were partially offset by an increase in the percentage of kidneys that were machine perfused – i.e. “pumped” – between 1999 and 2009 (8.7 to 30 percent) to keep the kidneys healthier and allow more logistical flexibility in scheduling surgery. Taken all together, changes in these factors over time explain most, but not all, of the increase in the discard rate between 1999 and 2009 (Stewart et al. 2017).

Though the utility of “Biopsy Findings” is debated, it is the most commonly reported reason for discard (38.2 percent), the fact that there is significant geographic variation in the odds of discard across the United States suggests that factors other than organ quality contribute to kidney discard (Mohan et al. 2018).¹² The percentage of discards reported as “*no recipient located—list exhausted* (indicating the OPO attempted but was unable to find a transplant center willing to accept the kidney)” rose from 10 to nearly 30 percent between 2008 and 2015 (Stewart et al. 2017). This suggests allocative inefficiency, but it also may indicate increased risk aversion by transplant centers. CMS established Medicare conditions for participation of transplant centers for the first time in 2007 (CMS 2007). Programs would be graded based on transplant graft and recipient survival rates, and programs with lower than expected survival rates would be judged out of compliance. This metric could discourage the acceptance and utilization of kidneys that are transplantable but less than perfect. While survival outcomes are risk adjusted, many feel that the process does not adequately reflect all risks, leading many centers to become risk averse and limit access to transplantation (Woodside and Sung 2016). Some low performing programs have responded by reducing their transplant volume (Schold et al. 2013) and becoming more selective in deciding which kidneys to accept (Schold et al. 2010). In 2016, eighteen percent of kidneys recovered from deceased donors were discarded (USRDS 2018).

Administration Policies to Increase the Supply of Kidneys for Transplantation

In 2020, HHS issued regulations¹³ that will hold OPOs accountable to objective performance standards. In particular, HHS focused on two new outcome measures—the donation rate and the organ transplant rate. Both would compare performance between OPOs as measured respectively by numbers of donors and organs transplanted to a more objective, CDC reported measure in the denominator—i.e., as a percentage of inpatient deaths in the donation service area, 75 years or younger with any cause of death that is not a contraindication organ donation. Moreover, these changes would hold OPOs accountable by requiring them to meet specified performance targets for these measures. OPOs that failed to do so could face possible decertification and replacement by higher-performing OPOs. HHS estimates that their changes to the OPO system alone could generate up to 4,500 additional kidney transplants per year by 2026. However, HHS notes that there is uncertainty regarding the number of kidney transplants their rules will engender.

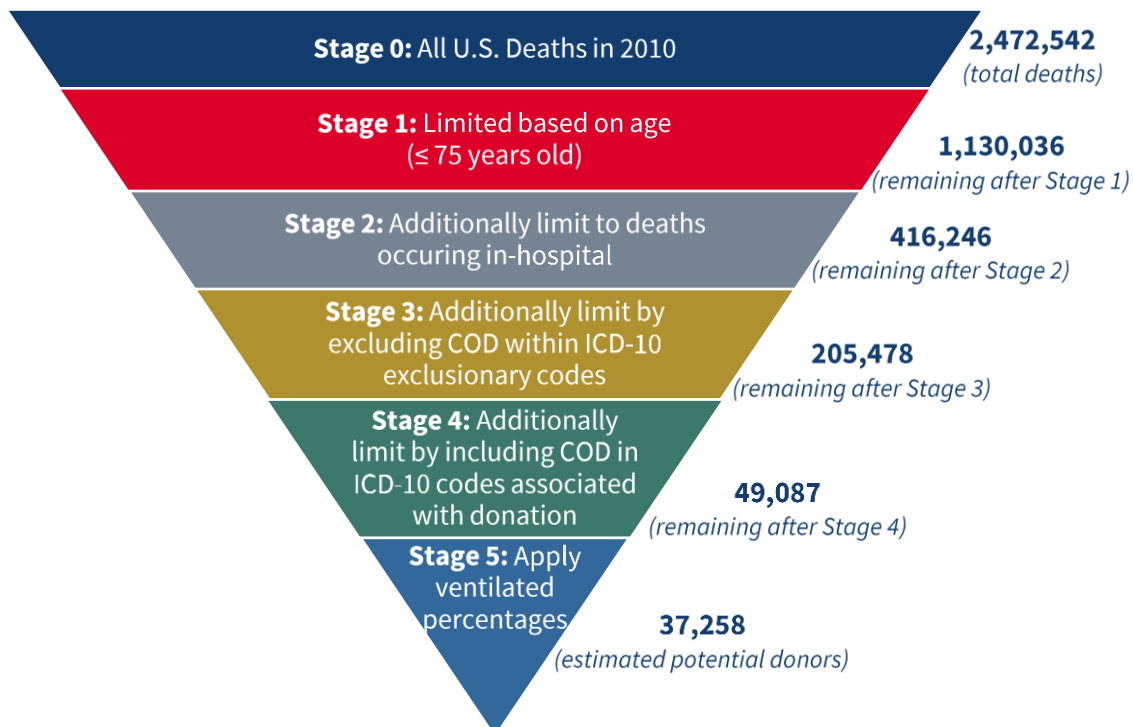
¹² Kidney quality though is an important factor - the median KDRI of discarded kidneys was 1.78 compared with 1.12 for transplanted kidneys. Mohan supra.

¹³ Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 FR 77898

How Many Additional Deceased Donor Kidneys Could be Obtained?

An important first step to estimate the number of additional deceased donor kidneys that could be obtained is considering the number of potential donors, which provides an upper bound on how many additional kidneys could be obtained. Starting with the total number of deaths each year, the number of potential donors decreases at each step of the organ recovery process (see figure 3) due to various exclusion criteria, including age and medical comorbidities, so that ultimately only a fraction of decedents can become deceased organ donors. Based on these criteria, the OPTN Deceased Donor Potential Study (Klassen et al. 2016) estimated that there were roughly 38,000 potential donors in 2010. When compared to the actual donors that year they estimated a “realization rate” (actual/estimated potential donors) of 19.2 percent overall (Klassen et al. 2016). The shortfall was particularly severe in the 50-64 (14.8 percent realization rate) and 65-75 (4.0 percent realization rate) donor age groups (Klassen et al. 2016). A more recent study estimated the “donation percentage” (actual/possible deceased donors) to be 31.1 percent across all age groups (Goldberg et al. 2017).

Figure 3. Kidney Recovery Process Attrition



Source: Klassen et al. (2016, Figure 1)

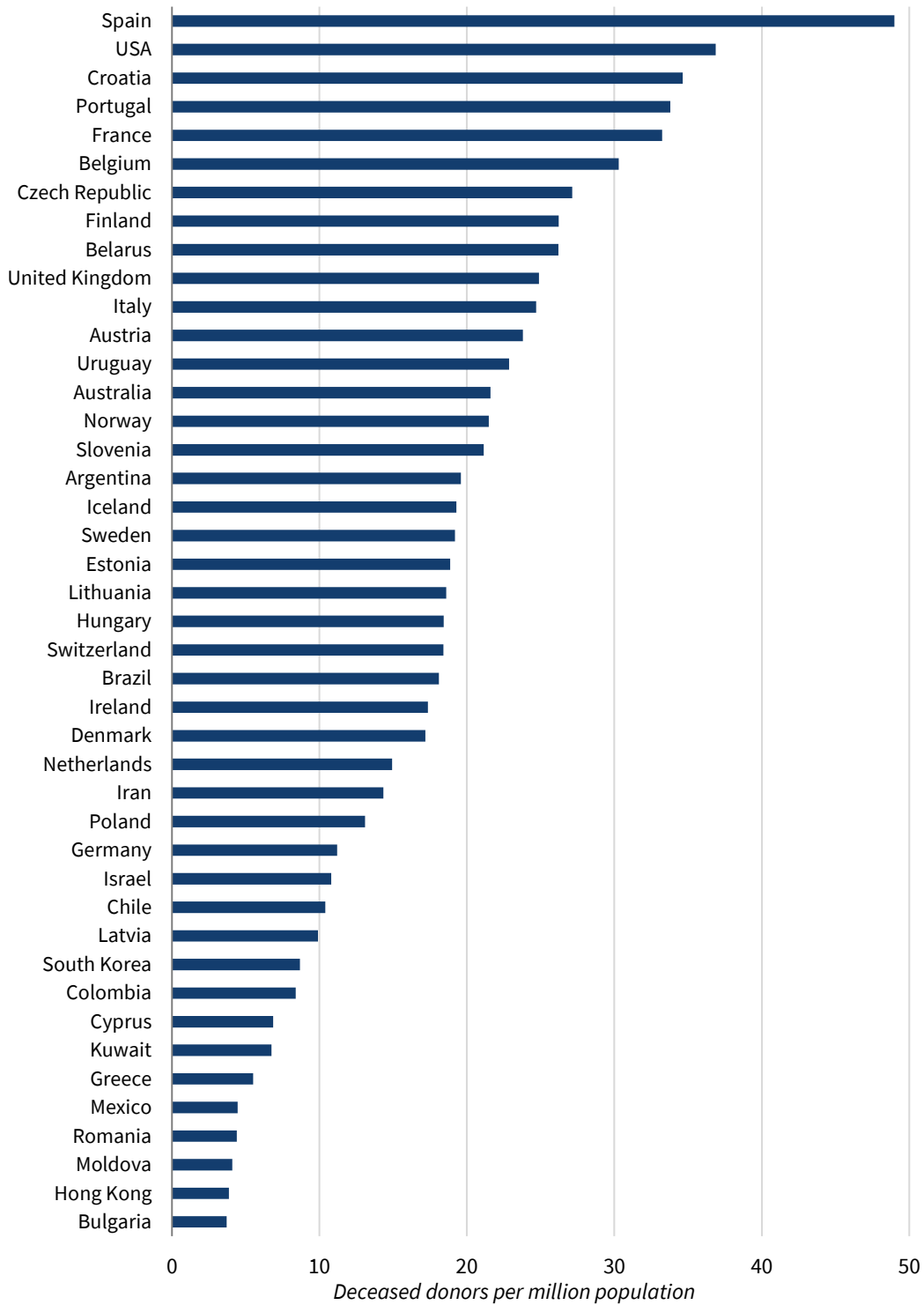
Building on these studies, the Bridgespan (2019) study estimated 17,000 additional kidneys could be obtained from deceased donors in the United States by more accurately identifying and utilizing potential deceased donors. However, this number is optimistic, as it assumes 100 percent consent to donate rates and 100 percent utilization of recovered organs (Bridgespan 2019), both of which are unrealistic because those rates are likely unachievable. As previously noted, 18 percent of donated kidneys are discarded. Moreover, not all potential donors consent, with current studies suggesting that roughly 50 percent of potential donors (or their families) consent to donation.

A more realistic assessment of the number of deceased donor kidney transplants that the United States could perform in the long-term may come from looking at Spain. Spain is widely acknowledged to have one of the best deceased-donor organ procurement systems in the world—see figure 4. In an effort to improve its performance and reach 40 deceased donors per million population (pmp) Spain studied, formulated, and implemented best practices for systematically identifying and referring potential donors, optimizing their care to preserve organ function and facilitating the use of organs from expanded criteria and nonstandard risk donors (Matesanz et al. 2017). As a result, in 2019 Spain had a world-leading 72.8 kidney transplants pmp from deceased donors while the United States was the third best country in the world at 50.59 pmp, 70 percent of Spain’s performance (IRODaT Database 2020).

Matching Spain’s performance would generate an additional 7,300 kidney transplants from deceased donors.¹⁴ While HHS estimated that their regulations could increase the number of deceased donor kidney transplants by roughly 4,500 a year by 2026, it is possible that other regulatory initiatives could further increase the number of transplants. For example, in the United States, the decision to donate organs is “opt-in,” so that a person can only become a donor by affirmatively stating this desire. By increasing the effort required to become a donor, the “opt-in” system provides disincentives for donation. Studies suggest that changing the system to an “opt-out” system, so that a person is assumed to be a donor unless they expressly state otherwise, could increase the number of donation by as much as one-third (Rithalia et al. 2009).

¹⁴ Spain’s rate of deceased donor kidney transplants was 72.8 per million population in 2019. Per million population, the United States had a rate of 50.59 deceased donor kidney transplants in 2019. If the United States’ rate of deceased donor kidney transplants pmp matched Spain’s rate, then the United States would perform roughly 7,300 additional deceased donor kidney transplants, which is equal to 328 million (United States population in 2019) times 22.2 (difference between US and Spain’s deceased donor kidney transplant rates in 2019) rounded to the nearest hundred.

Figure 4. Actual Deceased Organ Donors by Selected Country, 2019



Source: International Registry In Organ Donation And Transplantation.

How Many Additional Living Donor Kidneys Could be Obtained?

The literature is not clear on what types of strategies would increase living kidney donation (Barnieh et al. 2017), and it is not clear how effective the NLDAC type incentives are. A difference in difference model that exploited transplant centers' variation in applications for NLDAC donor assistance found that among participating transplant centers, NLDAC increased the number of living donor kidney transplants by about 14 percent (Schnier et al. 2018). While one paper reported that state laws that provide leave and/or tax benefits for living organ donors have not increased the number of living donors (Lacetera et al. 2014), another found that passage of tax incentive legislation increased living unrelated kidney donation rates by 52 percent in New York (Bilgel and Galle 2015).

The Administration's rules remove financial disincentives to living organ donation by adding reimbursements to living donors for lost wages and child or elder care expenses to current NLDAC incentives and increase the financial threshold for travel as well as subsistence reimbursement. If these new measures can increase the number of living kidney donors by the same 14 percent that was reported for earlier NLDAC incentives (Schnier et al. 2018), the number of living kidney transplants would increase by about 900, rising from 6,442 to 7,348. However, it is worth noting that several studies suggest that increases in the supply of deceased donor kidneys are associated with reductions in the supply of living kidney donations (Dickert-Conlin et al. 2019; Fernandez et al. 2013; Howard 2011).

The Economic Benefit of Increasing Kidney Transplantation

If United States OPOs matched Spain's deceased donor kidney transplants pmp rate and HHS's recent regulations generated another 900 transplants from living donors, the United States would perform an additional 8,200 additional kidney transplants each year. Each transplant would generate cost savings on an ongoing basis, as Medicare spending per person per year for transplant patients (\$34,780) is less than half the spending for the two types of dialysis, peritoneal dialysis (\$76,177) and hemodialysis (\$90,971). Though these savings must be weighed against (a) the initial upfront costs of transplantation and (b) the fact that transplanted patients live longer and so ultimately require medical care for more years of life than patients who do not receive a transplant. Matas and Schnitzler (2004) used a Markov model to estimate that, over a twenty-year period, the present value of medical costs associated with a living unrelated donor (LURD) kidney transplant were \$94,579 (USD 2002) lower than remaining on dialysis, while Held et al. (2016) estimated that kidney transplantation was associated with \$195,000 (USD 2015) in lifetime savings.

The second source of societal benefit is the value of the increased longevity associated with kidney transplantation, with previous studies estimating that kidney transplant is associated with a gain of 3.5 to 4.7 discounted quality-adjusted life years (QALYs). The Office of the Assistant Secretary for Planning and Evaluation (ASPE) at the Department of Health and Human Services estimates that the value of QALY is \$490,000 when using a value of statistical life of \$9.6 million (USD 2014) and a 3% discount rate (ASPE, 2016). If we inflate these estimates to 2018 dollars¹⁵ and use the lower range of the two previous

¹⁵ We inflated ASPE's value of statistical life/quality adjusted life year estimates using the Gross Domestic Product: Implicit Price Deflator. We inflated the value of medical cost savings using the chain-type price index for personal consumption expenditures on health care services.

estimates¹⁶, then the economic value of health gains from a kidney transplant is \$1.8 million. When added to nearly \$136,000 in medical cost savings this means that the total societal benefits of a kidney transplant is nearly \$2 million. Thus, an additional 8,200 kidney transplants per year would have an annual net present value of \$16 billion.

¹⁶ Though Matas and Schnitzler (2004) focuses on the benefits of living unrelated donor kidney transplants as opposed to deceased donors, which generally are inferior, we use their estimate as a lower bound. As discussed in Held et al. (2016) and observable in OPTN data, decades of medical improvements have increased outcomes of both living and deceased kidney transplants suggesting that using newer estimates—deceased or otherwise—would likely increase the societal benefits generated with each additional transplant.

Conclusion

Chronic kidney disease is an important disease for policymakers to confront for several reasons. First, it imposes a significant morbidity and mortality burden, as it affects hundreds of thousands of patients and is a leading cause of death in the United States. In addition, treatment is costly and—unique among chronic diseases—the vast majority of the costs are borne by the Federal Government. Moreover, as discussed in this paper, there is significant room for policies to improve the treatment of people with failed kidneys, particularly with respect to kidney transplantation. While HHS issued several regulations that aimed to improve the care of ESRD patients, with the overall goal of doubling the number of kidneys available for transplantation by 2030.¹⁷ CEA estimates that if the United States just matched Spain’s best in the world rate of deceased donor kidney transplants on a per million population (pmp) basis—an increase of roughly 7,300—and increased the number of living donors by 900, then the additional transplants would yield societal benefits with a net present value of \$16 billion per year.

¹⁷ Medicare Program, Specialty Care Models To Improve Quality of Care and Reduce Expenditures, 85 FR 61114 ; Removing Financial Disincentives to Living Organ Donation, 85 FR 59438; Medicare and Medicaid Programs; Organ Procurement Organizations Conditions for Coverage: Revisions to the Outcome Measure Requirements for Organ Procurement Organizations, 85 FR 77898

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