

## The Coming Fiscal Crisis: Nephrology in the Line of Fire

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### Summary

**Nephrologists in the United States face a very uncertain economic future. The astronomical federal debt and unfunded liability burden of Medicare combined with the aging population will place unprecedented strain on the health care sector. To address these fundamental problems, it is conceivable that the federal government will ultimately institute rationing and other budget-cutting measures to rein in costs of ESRD care, which is generously funded relative to other chronic illnesses. Therefore, nephrologists should expect implementation of cost-cutting measures, such as age-based rationing, mandated delayed dialysis and home therapies, compensated organ donation, and a shift in research priorities from the dialysis to the predialysis patient population. Nephrologists also need to recognize that these changes, which are geared toward the population level, may make it more difficult to advocate effectively for the needs of individual patients.**

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*On questions of economic law it does not matter at all what the electors think or vote or say. The economic laws proceed.*

Winston Churchill, 1929

Nephrologists in the United States face a harsh economic future. The health care industry in this country consumes nearly one sixth of the gross domestic product (1) and is in serious financial straits. According to the federal government, the Medicare and Social Security programs are estimated to run a \$39 trillion deficit over the next 75 years (2). However, officials concede that even this astronomical sum is likely an underestimation of the true unfunded liability burden facing the public given that certain tools to constrain Medicare expenditures, such as severely reducing physician reimbursement, will be politically unpalatable (2). In fact, some outside experts estimate the real deficit to be closer to \$90 trillion (3). In addition, the federal government is estimated to have a debt of nearly \$22 trillion by 2022 (4), and this burden will likely grow over time through insufficient taxable income from its aging citizenry (3,5).

In 2010 the Patient Protection and Affordable Care Act (ACA) was enacted in part to remedy the health care economic crisis. The ACA's mandate for the formation of accountable care organizations (ACOs) has already begun to impress upon physicians the need for health care cost containment (6). An ACO is a network of physicians tasked with providing quality comprehensive care to a group of Medicare patients (6). If the ACO is able to do this in a cost-effective manner, it may be eligible to receive some of those cost savings from Medicare. However, if the ACO's costs exceed Medicare's expectations, the ACO will be responsible for

paying back to Medicare some of the excess costs (6). Because an ACO will serve at least 5000 Medicare beneficiaries (7), the rare patient with ESRD in a large ACO may find himself or herself receiving suboptimal care (6). To address this, earlier this year the Centers for Medicare & Medicaid Services (CMS) announced the ESRD Seamless Care Organization (ESCO) program (8). An ESCO is akin to an ACO in that dialysis units and nephrologists will be responsible for providing and coordinating good-quality, cost-effective care for patients with ESRD (8). If this occurs, some of those savings will be paid back to the ESCO. However, if costs exceed Medicare's expectations, the ESCO will be liable for paying back some of the costs (8).

Although ACOs and ESCOs may help reduce health care costs, they are complicated and rely on controlling physician remuneration. A simpler method to controlling costs—which may ultimately be integrated into ACOs/ESCOs in any case—would be to overtly ration patient care. The ACA contains a provision for a 15-member independent payment advisory board whose mandate is to present to Congress “proposals to reduce costs and improve quality for (Medicare) beneficiaries. When Medicare costs are projected to exceed certain targets, the Board's proposals will take effect unless Congress passes an alternative measure to achieve the same level of savings” (9). Although the ACA states that the independent payment advisory board cannot provide recommendations that lead to rationing (9), it does not clearly define rationing and the grim fiscal realities make health care rationing a distinct and realistic possibility. In fact, we believe it is only a matter of time before the federal government implements mandatory cost-cutting measures, and some policymakers are already advocating this (10). To this end, the ESRD program, which is primarily funded by Medicare, must be considered

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“low-hanging fruit.” In 2009, Medicare paid \$29 billion—nearly 6% of its total budget—for ESRD care (11). No other chronic disease is so generously funded as the ESRD program, a fact that has raised the eyebrows of some ethicists (12). Nephrologists who believe that ESRD care will remain unscathed in this era of cost consciousness need only hearken back to the not-too-distant past when overt rationing determined the fate of patients with CKD needing dialysis (13).

One strategy nephrologists can use to better understand how financial circumstances will influence future CKD care is to imagine themselves as high-level government bureaucrats whose job is to rein in government costs while maximizing health care efficiency. This paper will focus on the most attractive and feasible policies available to achieve the bureaucrats’ goals, including age-based rationing, mandated delayed dialysis and home therapies, compensated organ donation, and an increased emphasis on forestalling CKD progression.

### How Will the Government Measure the Value of Care?

The first step to achieving the bureaucrats’ goals is to be able to measure the value of care provided. In this vein, nephrologists may soon need to familiarize themselves with the concepts of quality-adjusted life-years (QALYs) and incremental cost-effectiveness ratios (ICERs), which are currently used by the United Kingdom’s National Health Service to determine how to best ration health care (14). A QALY measures the both the quantity and quality of life that would be obtained by pursuing a medical or surgical intervention (15). To calculate a QALY, one must determine a patient’s utility score (15). The utility score is a measurement, often from 0 (death) to 1 (perfect health), that quantifies through various methods the health preferences of a patient (15,16). After a utility score is ascertained, one multiplies the utility score by the amount of life a health care intervention is expected to give a patient (15). Thus, a health care intervention that adds 4 years of life to a patient with a 0.5 utility score provides 2 QALYs. To determine whether one intervention is economically preferable over another, one calculates an ICER by dividing the difference in costs between the two interventions by the difference in their QALYs (17). Traditionally, an intervention has been considered economically justified at  $\leq$ \$50,000/QALY (18). Investigators recently estimated the ICER of dialysis compared with that of palliative care to be \$110,814/QALY (19).

CMS is currently prevented by statute from considering cost when determining what is appropriate care for Medicare beneficiaries (20), and analyses show that a substantial number of Medicare-approved interventions are  $>$ \$100,000/QALY (21,22). To date, society has been willing to pay for dialysis despite its high ICER. However, as health care cost containment becomes paramount, we believe the federal government will change health care law to allow CMS to address cost per QALY when determining what medications, procedures, and surgeries it will pay for. Dialysis, an expensive procedure with a high mortality rate, will not be immune to these pressures.

### Restricting Access to Dialysis

Of all the strategies the federal government can use to ration care, the simplest would be to set age limits on who

is eligible for dialysis therapy. The literature would seem to support such a strategy from an economic standpoint, at least on a population level. Between 2000 and 2009, the incident and prevalent rates of dialysis patients 75 years or older increased by 12% and 37%, respectively (23), despite generally dismal outcomes. Kurella *et al.* noted a persistent 46% 1-year mortality for octogenarians and nonagenarians who initiated dialysis between 1996 and 2003, even though comorbid conditions such as anemia, heart failure, and malnutrition improved over the study period (24). A study by the same investigators of elderly nursing home patients starting dialysis revealed even worse results, with 87% of them dying or experiencing a functional decline in the first year after dialysis initiation (25). Not surprisingly, cost utility analyses reveal that elderly patients with ESRD have higher ICERs than younger patients (19,26).

Is it possible that despite its poor long-term outcomes dialysis at least extends the lives of elderly dialysis patients? Not necessarily, according to several studies from the United Kingdom. Murtagh *et al.* studied 129 patients with stage 5 CKD older than 75 years who elected to pursue dialysis or conservative care and controlled for lead-time bias (27). Although overall mortality at 2 years was lower in the patients choosing dialysis (24% versus 53%), it was no better in the subgroup with multiple comorbid conditions or heart disease. A more recent study of 844 patients with stage 5 CKD essentially confirmed these findings (28). In light of the exorbitant medical costs of caring for elderly hemodialysis (HD) patients—now  $>$ \$100,000 annually (29)—nephrologists should brace themselves for age-based rationing. Previous studies show that elderly patients with ESRD 80 years and older or 70 years and older with peripheral vascular disease are costlier to take care of than younger patients with ESRD without vascular disease (30), so age limits would most likely begin with these types of patients. Although no economic analyses are available to estimate the savings provided by restricting dialysis by age, we suspect it would be substantial, given that in 2010  $>$ 25% of incident dialysis patients were 75 years or older (31).

### Delaying Dialysis as a Financial Imperative

One must keep QALYs and ICERs in mind when considering the issue of dialysis initiation. Over the past 15 years, the estimated GFR (eGFR) of patients initiating dialysis has risen (32) without any discernible improvement in patient outcomes (33,34). The reasons nephrologists opted for earlier dialysis initiation most likely have their basis in older studies that touted the benefits of early dialysis initiation (35,36) and professional guidelines that provided justification for this strategy. Thirty-six years ago, Bonomini and colleagues argued that patients who started intermittent HD with creatinine clearance (CrCl)  $>$ 5 ml/min had less neuropathy and renal osteodystrophy and improved mortality compared with patients who initiated HD with lower CrCl (35). A follow-up study reported that early dialysis initiation, while confirming the mortality benefit, also improved lipid and BP control and lowered hospitalization rates (36). These early studies, along with National Kidney Foundation guidelines recommending that any patient with stage 5 CKD (eGFR  $<$ 15 ml/min

per 1.73 m<sup>2</sup>) be considered for dialysis (37), led to a significant increase in the number of patients initiating dialysis with an eGFR greater than 10 ml/min per 1.73 m<sup>2</sup> (32).

In contrast, recent studies report that early dialysis initiation is actually associated with increased mortality risk (33,34,38) and that delaying dialysis initiation is safe, as demonstrated by the Initiation of Dialysis Early or Late (IDEAL) trial that randomly assigned 828 patients with advanced CKD to an early (estimated CrCl of 10–14 ml/min per 1.73 m<sup>2</sup>) or late (estimated CrCl of 5–7 ml/min per 1.73 m<sup>2</sup>) start on dialysis (39). The median time difference to initiating dialysis was approximately 6 months. After 3.6 years of follow-up, the late starters experienced no increase in mortality or adverse events compared with the early starters.

To the government, mandating that initiation of dialysis be delayed offers highly attractive cost savings. Lee *et al.* performed a computer simulation using data from the U.S. Renal Data System (USRDS) and Kaiser Permanente to determine the cost-effectiveness of delaying dialysis initiation (19). In their current practice scenario, dialysis was started when the eGFR fell below 9 ml/min per 1.73 m<sup>2</sup>. Three delayed initiation scenarios were then used: slight delay, moderate delay, and significant delay. ICERs were calculated by comparing a dialysis strategy to its next least costly strategy (*e.g.*, by dividing the difference in cost between the current practice and slight delay scenarios by the difference in their QALYs). The ICERs favored delayed dialysis. The current practice scenario cost \$129,090/QALY, while the slight delay, moderate delay, and significant delay scenarios cost \$118,540/QALY, \$100,717/QALY, and \$40,446/QALY, respectively. On the basis of data from the IDEAL trial, direct dialysis costs were nearly \$10,800 more per patient in the early start group compared with the late start group, with the early start group's transportation costs being \$3600 more per patient (40).

### Mandating the Modality of Dialysis

The modality of dialysis provided strongly influences a patient's health care costs, making it a prime target for cost savings. In the United States in-center HD has been estimated as 20%–50% more expensive than peritoneal dialysis (PD) (41). Shih *et al.* noted that the adjusted annual cost in 2004 dollars for an incident PD patient was \$56,807 compared with \$68,254 for an incident HD patient (42). Significant cost savings over 3 years were also noted for incident PD patients who did not switch to HD or switched only after 2 or more years of PD therapy. Therefore, restricting access to HD would be financially advantageous. In fact, mandating PD as the treatment of choice is theoretically possible because most patients have no contraindications to PD (43). Even debilitated elderly patients not traditionally thought to be PD candidates can receive assisted PD through home nurses or family members (44). At least part of the cost savings involves the higher rate of employment (2.6 times higher) and productivity seen in PD versus in-center HD patients (45,46).

Despite the potential savings for Medicare, in 2009 only about 6% of patients with incident ESRD began renal replacement therapy on PD (23). If HD offered improved

survival compared with PD, its overwhelming use could be justified. However, no such benefit has been consistently identified (47–49). In addition, studies demonstrate either no difference in quality of life between HD and PD or greater patient satisfaction with the latter modality (50–52). Because there are no differences between HD and PD in terms of survival or quality of life, one can assume that the cost per QALY favors PD, something that has been confirmed in several studies of diverse populations. A Swedish study reported a cost of \$82,470/QALY for PD and \$98,530/QALY for HD (46); one in a Greek population concluded that HD cost approximately \$79,412/QALY while PD cost \$71,716/QALY in 2007 dollars (53). Thai investigators recently estimated the ICERs of HD and PD compared with palliative care to be \$63,000/QALY and \$52,000/QALY, respectively (26).

Although PD is the most common home dialysis modality, both short daily HD and home nocturnal HD are increasingly popular options (54). Not only may they offer additional health benefits, such as improved BP control and regression of left ventricular hypertrophy (55,56), they are also less expensive. The National Health Service estimated 10-year home HD costs to be far lower than those of both hospital-based and satellite-based HD (57). Compared with hospital-based and satellite-based HD, home HD saves \$30,758 and \$25,260 in 2010 dollars, respectively, while generating 0.38 more QALYs. A Canadian group compared 19 patients receiving thrice-weekly in-center HD to 24 receiving nocturnal HD at home; nocturnal patients had significantly higher utility scores than in-center patients (0.77 versus 0.53) while costing less (approximately \$48,103/QALY and \$84,733/QALY in 2000 U.S. dollars) (58).

One must note, however, that home dialysis modalities may be cheaper than in-center HD because home patients may be healthier than in-center patients (59). A randomized controlled trial would be helpful in determining whether clinically useful information, such as dialysis costs and mortality, favors home dialysis over in-center HD, although efforts to design such a trial have been unsuccessful to date (50). To reduce the influence of selection bias in observational studies, researchers use propensity score matching. Propensity score matching allows various underlying patient covariates to be reduced to a single score, enabling patients from each treatment group with similar scores to be matched (60). A recent propensity score analysis of privately insured dialysis patients revealed that the median yearly health care costs for each HD patient were \$43,510 more than for each PD patient, due mostly to significantly higher inpatient costs for the HD patient (61). The 2012 USRDS report showed similar results. After matching of PD patients to similar HD patients, yearly HD costs were at least 25% higher than PD costs (62).

### Compensating Kidney Donors

Kidney transplantation is the ideal treatment for ESRD, both medically and economically. Dialysis patients experience a 6.5- to 7.4-fold increase in all-cause mortality compared with the general population versus only a 0.1- to 0.6-fold higher rate for transplant patients (63). The comparative 5-year survival rates for HD, PD, and transplantation are 34%, 40%, and 73%, respectively (63). In 2009 the

Medicare per person per year costs for an HD patient, a PD patient, and a kidney transplant recipient were \$82,285, \$61,588, and \$29,983, respectively (11). Unfortunately, the demand for donated kidneys far outstrips available supply, and the median waiting list time is now approaching 4 years (64). In 2009, death while waiting for a transplant was the second most common cause of removal from the waiting list (64).

One strategy to help alleviate the lack of donor kidneys is kidney-paired donation (KPD) (65,66). With KPD, live donors who are not compatible with their intended recipients are matched with unknown, compatible recipients, and unknown donors are then matched to the intended recipients of the first live donors (66). Although society benefits through KPD, its overall effect on transplantation rates will probably be marginal, as it is a barter transaction (67), and financial disincentives still remain for potential donors to undergo medical evaluation for unknown recipients (68).

An option that is far more likely to reduce waiting list time involves financial compensation of kidney donors. Currently, concerns about exploitation of vulnerable populations have dampened enthusiasm for paid organ donation, as expressed in the 2008 Declaration of Istanbul on Organ Trafficking and Transplant Tourism (69). One nation that has practiced direct-paid organ donation for nearly 25 years is Iran (70). Kidney donors in that country receive health insurance and a government payment. However, critics note that Iranian donors, who are largely poor young men (71), receive only a year of free health care, a \$1200 government payment, and poorly regulated recipient payments (72).

Despite the limitations of the Iranian model, paid organ donation makes perfect economic sense. Kidney transplantation is subject to the same economic laws that govern other transactions. The 2012 Nobel Prize in Economics was awarded to Alvin E. Roth, whose work ultimately led to novel exchange markets, such as the physician residency matching program and incompatible kidney swaps. An article describing his work noted how “there is a more fundamental solution to the kidney shortage. Don’t ‘design’ a market; simply allow one. A ban on selling kidneys is essentially a price control of zero and, like other price controls, causes a shortage. There are thousands of ‘demanders.’ There are also thousands of potential suppliers who, at a price of zero, are not willing to give up a spare kidney” (67). The lifetime costs of a transplant patient are \$94,579 less expensive than those of a dialysis patient, and a living unrelated kidney donation provides the recipient 3.5 QALYs more than dialysis (73). Because altruistic incentives to get people to donate kidneys have been unsuccessful (74), paid donation may be the most viable option to increase transplantation rates. Despite concerns surrounding the exploitation of kidney donors, the adoption of payments for kidney donors offers such an enormous financial incentive to the government that it is highly likely over time such a policy will be adopted. Indeed, it appears that the public is already generally comfortable with the idea (75).

### An Emphasis on Forestalling the Progression of CKD

In recent decades, several multicenter, adequately powered, randomized controlled trials have failed to identify

treatment interventions that significantly improve outcomes in dialysis patients (76–80), providing a great deal of frustration for clinical nephrologists (81). We expect that this poor track record, coupled with the obvious financial benefits inherent in delaying the start of dialysis, will cause the government to shift its research funding to support attempts to delay CKD progression. This is no doubt a daunting task, as CKD is a highly complex, multifactorial disease that lacks suitable surrogate end points and biomarkers of disease progression (82). However, if these obstacles are overcome, it makes greater fiscal sense from the government’s perspective to invest in preventive strategies to slow progression of CKD.

### Conclusion

We strongly believe that the fiscal realities weighing heavily on the federal government will lead inevitably to health care rationing and other mandated strategies for patients with CKD. The untenable federal budget, the gargantuan unfunded liability burden of Medicare, and the aging population of the United States will all work to bring this eventuality sooner rather than later regardless of which political party holds the reins of power. Because government rationing programs are designed to maximize savings and benefits on a population rather than individual level, they will inevitably lead to a weakening of nephrologists’ capacity to advocate for their patients (83); that is, what is good economically speaking for society as a whole may not be beneficial for an individual patient. Nevertheless, by accepting reimbursement for the majority of their services from the government, nephrologists have become government employees of sorts, with all the restrictions that entails. The acceptance of government-mandated strategies will be variable. Although paid organ donation may be popular with the public (75), age-based rationing will certainly be controversial (84). How both the nephrology community and the general public ultimately deal with these and related issues remains to be seen. Regardless, nephrologists need to recognize that the days in which ESRD care revolved around large in-center HD units that catered to elderly patients with ESRD are likely to be numbered. Rationing, whether they like it or not, is coming.

### Disclosures

None.

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