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POLICY FORUM

Implications of the Affordable Care Act for Kidney Transplantation

Christine S. Rizk, JD, and Sanjiv N. Singh, MD, JD

It has been argued that the kidney was the "heart" of antiquity. According to some medical historians, kidneys in the Old Testament symbolized the "core of the person" and thus "the area of greatest vulnerability" [1]. This metaphor of vulnerability is perhaps even more apt in the present day, where the failure of transplanted kidneys symbolizes the core defects of both the existing Medicare system and recent health reform implemented by the Obama administration. This article provides historical perspective on the evolution of coverage for kidney transplant patients and attempts to identify what initiatives would most effectively and efficiently improve their survival.

The Current State Of Access to Posttransplant Care

As of January 24, 2012, in the United States, there were 112,767 waitlist candidates on the various national transplant registries [2]. Of those candidates, 90,563 were waiting for kidneys, but in 2011 only 13,430 kidney transplants were performed [3]. The need for kidneys far outweighs the availability of suitable donor organs, and some postulate that the Patient Protection and Affordable Care Act of 2010 (ACA) may worsen the shortage by eliminating barriers to insurance coverage based on preexisting conditions, lifetime coverage caps, and required periods of pretransplant dialysis [4].

Even more critical from a clinical, economic, and moral perspective is the fact that the additional end-stage renal disease (ESRD) patients now expected to receive transplants by 2014 will be most vulnerable in the posttransplant phase of care. Coverage for pretransplant dialysis and maintenance drugs for ESRD, but not posttransplant care, receives strong support in Washington from large dialysis and pharmaceutical companies, which derive significant profits from dialysis, ESRD drugs, and dialysis-related services [5]. For ESRD patients, dialysis is covered by Medicare for life [6].

For posttransplant care, however, Medicare coverage is limited, providing only 80 percent of the cost of immunosuppressive medications for 36 months after transplantation (for those whose Medicare entitlement is based on ESRD) and no coverage thereafter. Despite the fact that effective and long-term immunosuppression is essential for survival of transplant patients [7], the vast majority are left to fund 20 percent of the cost for the first 3 years of immunosuppressive drugs ($13,000 to $15,000 total cost per year per patient) [8], and, for patients under 65 who are not disabled, all of the cost of immunosuppressive drugs thereafter [9].

Not surprisingly, this system leads to noncompliance. Many patients cope with the financial burden by "spreading out" their anti-rejection drugs, taking them less often or not at all [10, 11]. A recent meta-analysis reports that "about 22.6 of 100 adult transplant patients per year fail to take anti-rejection drugs" [12]. If allograft failure occurs due to nonadherence or a patient is considered unable to pay for posttransplant costs, with few exceptions, she is typically not relisted [13, 14]. According to a study focusing on medication nonadherence among transplant patients, nonadherence was more prevalent among kidney recipients than among recipients of other organs and more prevalent in the United States than in Europe [12].

Legislative History

Congress has continually struggled with the tension between supporting low-income patients and controlling the costs of government-funded health care. The legislative history of renal-transplant drug coverage highlights this struggle.

The Social Security Act Amendments of 1965, which created Medicare and Medicaid, initiated medical insurance for seniors, families with dependent children, the blind, and the disabled [15]. At the SSA's inception, Medicare provided for prescription drugs that were administered in the physician's office but did not provide coverage for outpatient prescription drugs [14].

In 1972, on the eve of President Richard Nixon's reelection, after much debate and political pressure to expand health care insurance, amendments were passed that provided increased coverage in specific areas. They specifically designated chronic kidney disease patients "disabled" for the purpose of receiving Medicare coverage but only after at least 3 months of dialysis and only for 12 months after transplantation [16].

Undoubtedly, these amendments were the original and now obviously outdated roots of the notion that posttransplant care benefits should be time-limited. At the time, such a notion was defensible. Dialysis was then a cost-effective and, more importantly, still superior way to extend lives, while kidney transplantation was a risky medical procedure on the frontier of available therapies. In the decades that would follow, however, renal transplantation outpaced dialysis in mortality reduction and overall clinical outcomes [17]. Meanwhile, the number of eligible patients who used dialysis far exceeded expectations, and the ESRD entitlement became quite costly [14].

In the last 3 decades, the dialysis entitlement has remained largely intact while posttransplant entitlements have waxed and waned in small stutters.

- As a response to the increased costs of dialysis, Congress passed an amendment in 1978 extending Medicare posttransplant coverage from 1 year to 3 years; however, this amendment did not cover the cost of outpatient immunosuppressive medications [14].

- In 1984, Congress passed the National Organ Transplant Act of 1984 to ban the sale of organs [18]; extended coverage for immunosuppressive drugs was considered but ultimately left out of the bill, mostly due to funding concerns and political bargaining [14].
- Posttransplant drug coverage gained some traction in the Omnibus Budget Reconciliation Act of 1987 which included Medicare coverage of 80 percent of a kidney transplant recipient's immunosuppressive drug costs (including outpatient immunosuppressive prescription drugs) for 1 year after transplant [14, 19]. This was eventually extended, in 1997, to cover 36 months of immunosuppressive drug costs [9].
- In 2000, Congress extended Medicare coverage of immunosuppressive drug costs to the life of the patient, but only for those who are disabled or over 65. This often leaves those patients most at risk for nonadherence and noncompliance—i.e., younger kidney recipients under 65—uninsured after 3 years [14].

Despite decades of legislative history and clinical data revealing the obvious gaps in posttransplant care entitlements, extending the duration of coverage for immunosuppressive-drug costs was not included in the ACA. In a provocative piece published in 2010 in the *Clinical Journal of the American Society of Nephrology*, Cohen and colleagues assert that "in response to pressure from the corporate dialysis community and their kidney coalition, several members of Congress acted to prevent the patient immunosuppressive provision from being included in the final health care reform package. Some of these opposing voices on Capitol Hill have been generously supported by the large dialysis providers for years" [5].

It is theoretically possible that the ACA's insurance exchanges will include lifetime coverage for immunosuppressive drugs. These exchanges will not be implemented until 2014, however. Moreover, it is not clear exactly what type of coverage will be offered and whether such lifetime coverage will be offered in the lower-priced options, where it is most needed [9].

Cost Savings for the Federal Government

Continuing the current limitations on coverage of posttransplant medications is actually costing the health care system more money in the long term. Studies have shown that it is less costly to continue covering the cost of immunosuppressive drugs for kidney transplant patients after 36 months than it is to cover the costs of resuming dialysis for the same population. For example, a University of Maryland study concluded that it was more cost-effective to continue covering immunosuppressive drugs than it was to pay for dialysis, finding that "the breakeven point was 2.7 years for all of the cases [it] analyzed and for 30 percent of all patients who did not need to be readmitted to the hospital during the year after their transplant, the breakeven point was only 1.7 years" [10]. A study conducted by the Institute of Medicine (IOM) also concluded that lifetime coverage of immunosuppressive drugs would lead to cost savings because it would reduce nonadherence and thereby improve kidney allograft survival, reducing long-term reliance on dialysis [12].

Current Legislation

The Comprehensive Immunosuppressive Drug Coverage for Kidney Transplants Patients Act of 2011, currently pending in committee in both the House and the Senate, would extend coverage of immunosuppressive drugs for kidney transplant patients for the lifetime of the kidney [20, 21]. The bill is bicameral, bipartisan, and supported by the transplant community [22]. As noted by Cohen et al, however, similar attempts have failed in the past, most recently with the proposed Durbin amendment to the ACA [5]. Similar attempts by Congress in 2003 and 2007 to extend lifetime immunosuppressive coverage also failed in the wake of funding concerns and political jockeying [14].

Conclusion

Extending immunosuppressive drug coverage for the lifetime of kidney patients is a cost-effective way for the federal government to increase the value of health care by improving clinical outcomes for those with ESRD while avoiding the costs of resuming dialysis and allograft failure. Low-income kidney transplant patients currently suffer heavy financial burdens and are denied access to transplant relisting because of their inability to pay for critical drugs. There is a clinical, economic, and moral imperative to, at long last, bridge this coverage gap—a gap that lies at the core of effective transplant care and detracts from the movement for comprehensive coverage begun by the Affordable Care Act.

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Christine S. Rizk, JD, handles disability law cases at Harvard University's WilmerHale Legal Services Center in Jamaica Plain, Massachusetts. Ms. Rizk received her JD from Harvard Law School and her BA from Northwestern University. Her research interests include access to public health care and the intersection of health care and insurance law.

Sanjiv N. Singh, MD, JD, is the founder and principal of SNS PLC, a boutique corporate and intellectual property law practice in San Francisco. He is also a physician with the Veterans Affairs Healthcare System in Palo Alto, California. He completed his residency and served as an attending physician at Stanford University Hospital and Clinics. His research interests include telemedicine and intellectual property.

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