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THE ETHICS OF MEDICARE POLICY: INCREASING TRANSPLANT ACCESS AND SURVIVAL

Elisa J. Gordon*

"'Tis not enough to help the feeble up, But to support him after."'1

Inspired by the Institute of Medicine (IOM) Reports—*Crossing the Quality Chasm*2 and *Leadership by Example*3—the American healthcare system is undergoing careful scrutiny of the quality of care that it provides. "Quality" refers to "the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge."4 Problems with quality of care occur when patients do not obtain beneficial health services (underuse), undergo treatments from which they do not benefit (overuse), and receive medical services but those services are provided poorly (misuse).5 Although the likelihood of attaining better health outcomes increases with better quality of care, other factors can intervene to undermine this relationship such that quality must be assessed by examining processes and outcomes of care.6 Policymakers, health professionals, and scholars are therefore paying greater attention to the outcomes of treatments and interven-

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1. WILLIAM SHAKESPEARE, TIMON OF ATHENS act 1, sc. 1, lines 107-08.
3. LEADERSHIP BY EXAMPLE: COORDINATING GOVERNMENT ROLES IN IMPROVING HEALTH CARE QUALITY (Janet M. Corrigan et al. eds., 2003).
5. Mark R. Chassin et al., The Urgent Need to Improve Health Care Quality, 280 JAMA 1000 (1998).
6. Id.
tions in an effort to reduce the burden of illness, injury, and disability, and to improve the health of the people of the United States.7

In the field of kidney transplantation, there is a relatively small but growing awareness of the need to focus on quality outcomes—specifically, long-term graft survival and quality of life. While short-term acute rejection has come under control, long-term graft survival remains inadequate.8 Short-term acute rejection occurs within one year of kidney receipt; concerns about long-term graft survival pertain to the period beyond one-year posttransplant. The number of kidneys lost is substantial and increases over time. As one transplant physician stated, “The complications of life-long immunosuppression now replace rejection as one of the major obstacles to long-term graft and patient survival.”9 Accordingly, economic concerns have shifted away from the transplant procedure to patient management and maintenance immunosuppression.10

But these efforts have paid little attention to the broader political, economic, and social contexts in which patients live and manage their kidney transplants in the long-term. Taking an ecological approach11 to assuring quality transplant outcomes requires that we consider such broader social factors. This Article focuses primarily on one such factor: the Medicare policy financing immunosuppression.

Over the last decade, the Medicare policies that finance kidney transplantation have undergone a series of modifications. Since 1972, when legislation funding renal replacement therapy for end-stage renal disease (ESRD) was enacted,12 entitlements have progressively expanded from covering solely the transplant operation and associated physician fees to now covering eighty percent of the costs of posttransplant immunosuppressant medications for three years.13 More

13. Medicare provided eighty percent of the cost of immunosuppressive medications for one year posttransplant in 1986; between 1993 and 1995, coverage was extended to three years. Robert S. Woodward et al., Effect of Extended Coverage of Immunosuppressive Medications by Medicare on the Survival of Cadaveric Renal Transplants, 1 Am. J. Transplantation 69, 69–73 (2001); see also Memorandum from Director-Office Program Operations Procedures, BPO, to
recently, the 109th Congress considered Bill S.173, the Comprehensive Immunosuppressive Drug Coverage for Transplant Patients Act of 2005, which is designed to expand coverage for Medicare beneficiaries for the life of the kidney. This trajectory of incrementally increasing Medicare coverage of immunosuppression for kidney transplant recipients is noteworthy because it reflects policymakers' recognition of the vital role of immunosuppression in the survival of kidney transplant grafts. It also signifies policymakers' efforts to assist kidney recipients facing financial hardship caused by the high costs of immunosuppressive medications. Medicare's increasing coverage of immunosuppression is certainly beneficial to kidney transplant recipients. The current health policy, however, still undermines efforts to improve long-term quality care.

In this Article I explain that the current Medicare policy is insufficient because it generates problems relating to quality in terms of barriers to access and cost. I argue that the current policy presents negative ramifications for kidney graft survival and patient quality of life (QOL). Specifically, kidney recipients' inability to afford medications after the three-year mark (not to mention the twenty percent of costs patients must pay out of pocket during the initial three years) places kidneys at risk of rejection. Kidney grafts lost accordingly return patients to dialysis, thereby creating an even greater demand for kidney transplants and further burdening society with greater costs. Ironically, it is the improvements in patient survival and QOL that make kidney transplantation the treatment of choice in the first place. Yet, the limitations of the Medicare policy undermine the very goals that transplantation has set out to achieve.

I propose a new framework for considering the goals of the kidney transplant endeavor. Instead of focusing on the receipt of the transplanted kidney, the policy should emphasize patient survival and quality of life over the first three years. This approach would ensure that patients are able to afford medications and retain their grafts, thereby improving long-term outcomes.

Associate Regional Administrators for Medicare (Dec. 7, 1994) (available at http://www.transweb.org/reference/articles/hrd.html). Policymakers and physicians recall that transplant recipients' entitlement to immunosuppressants was limited to three years because originally physicians thought that immunosuppression would not be required indefinitely but could be stopped after the patient became stable after six to twelve months. E-mail from John Sadler, President and CEO of IDF Parkview Dialysis Center, to Elisa Gordon, Assistant Professor of Bioethics and Health Policy, Loyola University of Chicago (Sept. 19, 2005, 15:54 CST) (on file with author). As the coverage of immunosuppressants expanded from one to three years, the decision was based on making coverage coincide with entitlement. E-mail from Paul Eggers, Program Director for Kidney and Urology Epidemiology, National Institutes of Diabetes and Digestive and Kidney Diseases, to Elisa Gordon, Assistant Professor of Bioethics and Health Policy, Loyola University of Chicago (Sept. 19, 2005) (on file with author).

14. See Andreas Laupacis et al., A Study of the Quality of Life and Cost-Utility of Renal Transplantation, 50 KIDNEY INT'L 235 (1996); Robert A. Wolfe et al., Comparison of Mortality in All Patients on Dialysis, Patients on Dialysis Awaiting Transplantation, and Recipients of a First Cadaveric Transplant, 341 NEW ENG. J. MED. 1725 (1999).
plant as the end goal (with increasing organ donation as the intermediate goal), we must extend our focus and goal to long-term transplant outcomes. I propose that we must accordingly revise Medicare policy by extending coverage to all kidney recipients for the life of the kidney. This extended coverage will promote long-term survival of kidney grafts and ensure that kidney transplantation remains cost-effective and worthwhile. This will help reduce costs to the public and will reduce the demand for kidney transplants by preventing premature rejection of kidneys due to limited access to immunosuppressive medications.

II. EPIDEMIOLOGICAL CONTEXT OF ESRD

In order to understand fully the magnitude of the impact and significance of the current Medicare policy on immunosuppressive medication coverage, it is important first to appreciate the epidemiological context of ESRD and the kidney transplant population. In 2002, there were over 431,000 patients with ESRD in the United States requiring some form of renal replacement therapy. In that same year, the ESRD incidence rate was 333 per million population (pmp) while the prevalence was about 1,435 patients pmp. The rate of increase of incidence has slowed since 2000 to 1.4% per year, while the prevalence rate increased by 2.5% from 2001 to 2002. The projected population growth over the next thirty years, especially among the elderly, minority, and diabetic populations, means that there will be increased demand for renal replacement therapy. By 2030, the number of patients with ESRD is estimated to be 2.24 million, a five-fold increase.

Presently, there are just over 65,903 candidates waiting for a kidney transplant. There was a 10.5% increase in the number of candidates waiting for a kidney transplant between 2002 and 2003, from 51,236 to 56,618. There was, however, only a 2.1% increase between 2002 and 2003 in the number of kidney transplants performed (from 15,707 to 16,043—a 3.7% increase for living donors and a 7.6% decrease for

16. Id. at 60, 64.
17. Id. at 60.
19. Id. at 55.
21. Id.
living donors). The fact that the growth in candidates continues to be higher than the rate of transplantation exacerbates the scarce condition of kidneys for transplantation.

As previously noted, long-term graft survival remains inadequate. Specifically, the rate of kidney graft survival diminishes over time.

To illustrate, the three-year, five-year, and ten-year survival rates are 81.6%, 69.5%, and 39.9%, respectively, among all kidney recipients in the United States. Thus, after three years, five years, and ten years, 5,624, 10,011, and 29,112 kidneys are lost, respectively. It is important to point out that the rate of kidney loss increases over time. Such high rates of graft loss and their cause warrant greater attention.

Table 1
Unadjusted Graft Survival at 1 Year, 3 Years, 5 Years, and 10 Years

<table>
<thead>
<tr>
<th>Survival at 1 Year (2000-2001)</th>
<th>Cadaveric</th>
<th>Living Related Donor</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>%</td>
<td>N</td>
<td>%</td>
</tr>
<tr>
<td>16,023</td>
<td>88.7%</td>
<td>11,423</td>
<td>94.3%</td>
</tr>
<tr>
<td># Kidneys Lost</td>
<td>2,041</td>
<td>11.3%</td>
<td>690</td>
</tr>
<tr>
<td>Survival at 3 Years (1998-1999)</td>
<td>15,799</td>
<td>78.4%</td>
<td>9,060</td>
</tr>
<tr>
<td># Kidneys Lost</td>
<td>4,353</td>
<td>21.6%</td>
<td>1,271</td>
</tr>
<tr>
<td>Survival at 5 Years (1996-1997)</td>
<td>15,224</td>
<td>65.7%</td>
<td>7,578</td>
</tr>
<tr>
<td># Kidneys Lost</td>
<td>7,948</td>
<td>34.3%</td>
<td>2,063</td>
</tr>
<tr>
<td>Survival at 10 Years (1991-1992)</td>
<td>14,372</td>
<td>36.4%</td>
<td>4,928</td>
</tr>
<tr>
<td># Kidneys Lost</td>
<td>25,112</td>
<td>63.6%</td>
<td>4,000</td>
</tr>
</tbody>
</table>

22. Id.
23. 2003 OPTN/SRTR Annual Report 1993-2002. The publication supplying the data from the table provides the following disclaimer: "The data and analysis reported in the 2003 Annual Report of the U.S. Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients have been supplied by UNOS and URREA under contract with HHS. The authors alone are responsible for reporting and interpreting these data." Id.
24. U.S. Organ Procurement and Transplantation Network and the Scientific Registry of Transplant Recipients, 2003 Annual Report (2003). The rate of kidney loss increases over time as follows: from one to three years (nine percent are lost), from three to five years (twelve percent are lost), and from five to ten years (thirty percent are lost). This reflects an increase in rate from three percent to eighteen percent. The first two transition points occur over a two-year period. Even though these survival rates are established every two years for the first two points in time, and the last point in time is taken after five years, a more accurate rate of graft loss would require a data from a seven-year point in time.
The main causes of graft loss after the first year posttransplant are patient death and chronic allograft nephropathy (CAN). CAN refers to the “progressive decline of renal function seen in some renal transplant recipients in association with alloantigen-dependent and alloantigen-independent factors.” Prevalence rates of CAN vary from eighty-one percent to eighty-six percent. Physicians have therefore proposed that attention be directed toward the prevention of CAN. To understand graft loss and CAN, it is imperative to appreciate the broader context of patients’ ability to obtain immunosuppression by turning our attention to issues of access and cost presented by Medicare’s entitlement policy.

III. ACCESS TO MEDICAL CARE

It is well established that access to medical care affects health outcomes. Gaining access to immunosuppressive medication is fundamentally important because kidney transplant recipients need it for their kidney graft to function. Access can be defined as “[t]hose dimensions which describe the potential and actual entry of a given population group to the health care delivery system.” Traditionally, research on access has examined factors influencing the (non)use of services, including the availability of insurance coverage, physical or geographic access to healthcare services, demographic characteristics of individuals potentially seeking healthcare services, and cultural factors that may explicitly or subtly affect use of healthcare services and communication with healthcare professionals. A more recent conceptualization of access, proposed by the IOM, has shifted focus onto the service itself and its effects—namely, the outcomes, effectiveness, and cost of using the services. The IOM’s approach is directly appli-

31. Id.
32. ACCESS TO HEALTH CARE IN AMERICA (Michael Millman ed., 1993).
cable to kidney transplantation because attaining immunosuppressive medications directly affects kidney graft survival, as discussed below. Since the IOM report, Marsha Gold has proposed another framework for access that encompasses factors pertaining to the impact of managed care on financing and delivering the healthcare systems and processes.33 Gold’s framework is relevant to the kidney transplant recipients who rely on private insurance (and thus managed care) in addition to Medicare. Her framework, however, does not apply to the majority of transplant recipients who rely on Medicare only, because ESRD patients are legally barred from enrolling in Medicare-managed-care plans which are designed to enhance quality care.34

Concerns about access raise questions about justice in terms of equity. Equity commonly refers to equal utilization of healthcare resources for equal need.35 Distributing services on the basis of people’s need for them36 constitutes a form of fairness based on egalitarian notions of social justice. Access to healthcare resources can also be said to be equitable when the distribution of health resources and individual background characteristics—health insurance, ethnicity, and income—have no effect on differences in utilization of healthcare resources.37 According to a 1983 report by a presidential commission studying inequality in healthcare, access is deemed ethical when “everyone has access to adequate care without being subject to excessive burdens.”38

When using the IOM framework of access to medical care, there are several goals related to equity of access. Only one goal, however, is pertinent to the current Medicare policy on immunosuppression coverage. Specifically, when the goal is to provide equality of opportunity, the criterion of equity becomes conceptualized as similar treatment based predominantly on need (either perceived or evaluated), as well as predisposing characteristics of the population (age, sex, race, education) and enabling factors (income, regular source, in-

36. Aday & Andersen, supra note 30, at 6.
37. ACCESS TO HEALTH CARE IN AMERICA, supra note 32.
The indicators of equitable access include regular source of care and insurance coverage.\textsuperscript{39}

The concept of "need" is a highly debated term for which there are different approaches to measurement.\textsuperscript{40} A traditional, clinical-oriented approach considers need as the state of pretreatment health.\textsuperscript{41} Accordingly, those with worse health have greater need for treatment. This approach does not apply to ESRD because dialysis is available as an alternative renal replacement therapy to transplantation. (As an exception, patients with poorly functioning circulatory systems have greater need for transplantation, which for them is lifesaving). Thus, "need" (at least for adults) does not factor into the point system in kidney allocation.

Alternatively, a health-economic approach construes need as an individual's capacity to benefit from healthcare.\textsuperscript{42} This approach considers the amount of healthcare resources necessary to address ill health. This approach is directly applicable to the case of kidney transplantation because all kidney transplant recipients need immunosuppressant medications for their transplanted kidney graft to function. As such, kidney graft survival depends upon recipients' attainment of immunosuppression. Yet, as discussed below, not everyone has the same capacity to obtain immunosuppressant medications. Because all ESRD patients are entitled to renal replacement therapy, and immunosuppression constitutes a part of transplantation as one type of renal replacement therapy, equity means that there should be parity in the regular attainment of immunosuppression and insurance coverage for it. Let us consider how the issue of equitable access to medications relates to kidney transplant recipients and their graft survival.

Access to health insurance is especially salient for kidney transplant recipients in their ability to obtain their immunosuppressant medications. Kidney transplant recipients must take immunosuppressive medications for as long as their kidney graft works so as to prevent kidney rejection. Based on Medicare policy, patients (who are not disabled or age sixty-five and older) are responsible for covering twenty percent of the costs of immunosuppressive medications for

\textsuperscript{39} Gold, \textit{supra} note 33.
\textsuperscript{40} Id.
\textsuperscript{42} Id.
\textsuperscript{43} Id.
three years and the full costs thereafter. Copayments for immunosuppression amount to approximately $167–$233 per month.44

Furthermore, kidney recipients commonly take multiple medications to manage a host of comorbidities such as hypertension, diabetes, and psychological problems.45 Affording both immunosuppressants and medications for underlying comorbidities may present an even greater financial challenge, especially for those lacking secondary insurance. The finding that hemodialysis patients who have a greater number of secondary insurance carriers are prescribed more medications for comorbidities46 could very well also apply to kidney transplant recipients. The inability to obtain sufficient medications would result in poorly managed comorbidities, which may then exacerbate patients’ chronic kidney disease, the condition of the transplanted kidney graft, or both. To date, no studies have documented this association.

IV. Disparities in Insurance Coverage

Insurance coverage among kidney recipients varies greatly and results in an unequal ability to gain access to medications, and thus raises concerns about graft survival equity. A review of data from the United Network on Organ Sharing (UNOS) on 9,398 cadaveric renal transplants revealed the following types of patient insurance coverage: sixty-eight percent Medicare, twenty-five percent private insurance, and five percent Medicaid.47 In addition, over twelve percent of the ESRD population are not eligible for Medicare and rely on Medicaid instead.48 Eligibility remains an issue for the Medicaid-only population.49 There are also sizable racial and ethnic differences in insurance coverage. For example, in one study, thirty-one percent of whites

44. Bertram L. Kasiske et al., Payment for Immunosuppression After Organ Transplantation, 283 JAMA 2445 (2000).
47. Yong Won Cho et al., New Variables Reported to the UNOS Registry and Their Impact on Cadaveric Renal Transplant Outcomes—A Preliminary Study (J.M. Cecka & Paul I. Terasaki eds., 1995). In an effort to contain costs to HCFA from the ESRD program, the Balanced Budget Act of 1997 mandated that private insurers cover the first thirty months of ESRD costs for their enrollees; Medicare will be the secondary insurance payor in these cases. Medicare Program, 64 Fed. Reg. 42,766 (Aug. 5, 1999).
49. Id. at 886.
compared to sixteen percent of blacks had private insurance.\textsuperscript{50} While this suggests inequity in access, it remains to be determined whether patients with private insurance have disproportionate access to immunosuppressant medications.

Immunosuppressive medications are expensive, even for patients with adequate health insurance.\textsuperscript{51} Without insurance, patients pay full cost for the drugs. Patients may also incur other costs in follow-up care.\textsuperscript{52} Most patients in one study perceived their health insurance to be inadequate because they were unable to afford the medications, the high copayment or deductible, and the cost of insurance.\textsuperscript{53}

Many kidney recipients face tremendous difficulty finding sufficiently paying jobs and employment with insurance benefits. Reports have found that up to eighty-three percent of kidney transplant recipients are unemployed.\textsuperscript{54} Various factors deterring patients from employment have been identified in the transplant literature, including the inability to find jobs with insurance coverage and having inadequate knowledge and skills necessary to obtain jobs, particularly those jobs that provide insurance coverage.\textsuperscript{55} ESRD patients tend to have lower levels of education, income, or both when compared to the general population.\textsuperscript{56} Additional barriers to employment that have been identified include employer discrimination based on health status and loss of disability income.\textsuperscript{57} But no studies have as yet conclusively confirmed these barriers.\textsuperscript{58}

\textsuperscript{50} Cho et al., supra note 47, at 406.
\textsuperscript{52} Id.
\textsuperscript{53} Mariana S. Markell et al., Unemployment in Inner-City Renal Transplant Recipients: Predictive and Sociodemographic Factors, 29 AM. J. KIDNEY DISEASES 881 (1997).
\textsuperscript{54} Id.; see also Diane L. Manninen et al., Work Disability, Functional Limitations, and the Health Status of Kidney Transplantation Recipients Post Transplant, 5 CLINICAL TRANSPLANTATION 193 (1991); Fax from United Network for Organ Sharing, to Elisa J. Gordon (May 26, 1998) (giving the employment status two years after a graft and basing such data on the OPTN/Scientific Registry data); Freda Wilkins et al., The Impact of Patient Education and Psychosocial Supports on Return to Normalcy 36 Months Post-Kidney Transplant, 17 CLINICAL TRANSPLANTATION 78 (2003); U.S. RENAL DATA SYSTEM, 1997 ANNUAL DATA REPORT (1997) [hereinafter 1997 ANNUAL DATA REPORT].
\textsuperscript{55} Joyce M. Carter et al., A Center-Based Approach to a Transplant Employment Program, 10 PROG. TRANSPLANTATION 204 (2000).
\textsuperscript{57} Carter et al., supra note 55; see also Markell et al., supra note 53.
\textsuperscript{58} Carter et al., supra note 55.
Health problems present yet another barrier to employment. In a follow-up survey study of kidney recipients' employment status after 2.5–3.5 years posttransplant (n=226), 42.5% were unable to work due to their health status.\(^{59}\) Having comorbidities can exacerbate the problem: diabetic kidney recipients were significantly less able to work than nondiabetic kidney recipients (74.4% vs. 34.7%).\(^{60}\) A major problem exists for those who are not physically well enough to work yet do not qualify for disability. Section 113 of the Beneficiary Improvement and Protection Act of 2000 extended immunosuppressive coverage for the life of the kidney, but only for patients who qualified for Medicare coverage because of age or disability. But there is a Catch-22: ESRD patients are typically no longer considered disabled following kidney transplantation because transplantation is considered rehabilitation, enabling patients to return to work. In addition, most kidney recipients do not have legally defined disabilities. Nevertheless, many kidney recipients experience a host of symptoms and physical limitations that restrict the kind and amount of work they can do—using eyes to read or inspect things, using fingers to grasp, and lifting or carrying weights.\(^{61}\) This disproportionate coverage (based on disability) calls into question the meaning of entitlement or equity in treatment regardless of financial capacity.\(^{62}\)

To compensate for limited financial support, kidney recipients may engage in unregulated, potentially harmful, or illegal strategies to obtain their immunosuppressants. These activities may either compromise or improve graft outcomes. For instance, anthropological research has found that kidney recipients may share medications with other patients or work “under the table” to increase income.\(^{63}\) In addition, when money is unavailable, patients have been reported to “stretch” their medications by taking less than needed to make them last longer,\(^{64}\) or simply not to purchase them. Still other patients have been reported to obtain unused, returned immunosuppressants (following dose changes) from transplant professionals.\(^{65}\) Patients may also admit themselves to the hospital emergency room for the purpose

\(^{59}\) Manninen et al., supra note 54, at 194.  
\(^{60}\) Id. at 200.  
\(^{61}\) Id. at 196–97.  
\(^{62}\) Rettig & Levinsky, supra note 7, at 330.  
\(^{63}\) See also Markell et al., supra note 53, at 885; Lesley A. Sharp, Organ Transplantation as a Transformative Experience: Anthropological Insights Into the Restructuring of the Self, 9 Med. Anthropology Q. 357 (1995).  
\(^{65}\) Gordon et al., supra note 64.
of receiving free immunosuppressants. While an emergency room visit is an effective way for individuals to obtain these medications, it is certainly not efficient as it increases healthcare costs to hospitals and society in general. These strategies are not unusual; other kinds of Medicare beneficiaries engage in them when Medicare does not cover the costs of prescribed medications.

Medicare coverage of immunosuppressants and patients’ financial wherewithal to purchase their medications can impact whether patients even receive a transplant. Transplant professionals at one academic hospital will perform the kidney transplant operation (as long as Medicare is obtained), regardless of whether kidney transplant candidates have established in advance a plan to pay for their antirejection medications. In contrast, when Medicare coverage for immunosuppressants lasted only one year, there were anecdotal reports that transplant surgeons would advise patients against transplantation if they could not pay for the medications needed thereafter. Similarly, in countries such as Mexico, transplant physicians will not perform the operation if no certain posttransplant financial coverage is available.

V. IMPACT OF INCOME AND INSURANCE COVERAGE ON KIDNEY GRAFT SURVIVAL

Financial constraints can adversely affect patients’ ability to afford immunosuppressant medications and thus to maintain kidney transplant survival and quality of life. For example, Medicaid patients have lower graft survival than patients with private insurance. In addition, low-income patients are more likely to experience allograft failure after one and five years of graft function than patients with an adequate income. While graft failure after five years is a policy issue, graft failure after one year is rather a matter of income and insurance coverage. Moreover, numerous studies have found that the high

66. Smith, supra note 64, at 222.
69. RETTIG & LEVINSKY, supra note 7, at 172.
71. CHO ET AL., supra note 47.
costs of immunosuppressive medications and limited insurance coverage result in noncompliance.\textsuperscript{73}

Adherence or compliance with immunosuppressant directives is essential for the survival of transplanted kidney grafts. Nonadherence is the third leading cause of renal graft loss after simple allograft rejection and systemic infection.\textsuperscript{74} Nonadherence with immunosuppressant directives has serious, adverse effects on transplant outcome, including graft loss, rejection episodes, and consequent resumption of dialysis.\textsuperscript{75} Similarly, studies of withdrawing or tapering of immunosuppressive agents due to financial strain have been shown to result in excessive rejection rates, graft loss, and patient death.\textsuperscript{76} Transplant nonadherence is common, ranging from five percent to more than forty-five percent.\textsuperscript{77}

Studies examining the sociodemographic and socioeconomic factors associated with nonadherence show that ethnicity, race, and socioeconomic status play a significant role, thereby indicating disparities in adherence rates. While myriad studies report that African Americans and Hispanic Americans are significantly more likely to be nonadherent than European Americans,\textsuperscript{78} other studies found no relationship

\textsuperscript{73} Marie A. Chisholm et al., Renal Transplant Patient Compliance With Free Immunosuppressive Medications, 70 TRANSPLANTATION 1240 (2000); Doreen Papajcik et al., A Tool to Identify Risk Factors for Noncompliance in the Adult Renal Transplant Recipient, 31 TRANSPLANTATION PROC. 845 (1999); Daniel A. Shoskes et al., Patient Death or Renal Graft Loss Within 3 yr of Transplantation in a County Hospital: Importance of Poor Initial Graft Function, 11 CLINICAL TRANSPLANTATION 618 (1997); Bonita R. Siegal & Stuart M. Greenstein, Differences Between Compliers and Partial Compliers: A Multicenter Study, 30 TRANSPLANTATION PROC. 1310 (1998).

\textsuperscript{74} Ralph H. Didlake et al., Patient Noncompliance: A Major Cause of Late Graft Failure in Cyclosporine-Treated Renal Transplants, 20 TRANSPLANTATION PROC. 63 (1988).

\textsuperscript{75} Bonita R. Siegal & Stuart M. Greenstein, Compliance and Noncompliance in Kidney Transplant Patients: Cues for Transplant Coordinators, 9 J. TRANSPLANTATION COORDINATION 104 (1999).

\textsuperscript{76} Vivekanand Jha et al., Impact of Cyclosporine Withdrawal on Living Related Renal Transplants, 37 AM. J. KIDNEY DISEASES 119 (2001); Kasiske et al., supra note 51; Charles E. Sanders et al., Tapering or Discontinuing Cyclosporine for Financial Reasons, 21 AM. J. KIDNEY DISEASES 9-15 (1993).

\textsuperscript{77} Several studies have found noncompliance rates between five and forty-five percent. Didlake et al., supra note 74; Patricia A. Frazier et al., Correlates of Noncompliance Among Renal Transplant Recipients, 8 CLINICAL TRANSPLANTATION 550, 553 (1994); Papajcik et al., supra note 73; Laurie A. Rudman et al., Mishandling the Gift of Life: Noncompliance in Renal Transplant Patients, 29 J. APPLIED SOC. PSYCHOL. 834 (1999); Robert T. Schweizer et al., Noncompliance in Organ Transplant Recipients, 49 TRANSPLANTATION 374 (1990); Shoskes et al., supra note 73, at 620; Siegal & Greenstein, supra note 75.

\textsuperscript{78} See, e.g., Donald E. Butkus et al., Racial Differences in the Survival of Cadaveric Renal Allografts: Overriding Effects of HLA Matching and Socioeconomic Factors, 327 NEW ENG. J. MED. 840 (1992); D.J. Kiley et al., A Study of Treatment Compliance Following Kidney Transplantation, 55 TRANSPLANTATION 51 (1993); Mary Rovelli et al., Noncompliance in Renal Transplant Recipients: Evaluation by Socioeconomic Groups, 21 TRANSPLANTATION PROC. 379 (1989); Siegal & Greenstein, supra note 75.
after controlling for socioeconomic status. Because minorities and lower income kidney recipients are more likely to be nonadherent, they are more likely to have disproportionately shorter graft survival rates than the majority population and higher income recipients.

The fact that African Americans were 1.7 times more likely than European Americans to suffer graft failure from a living related donation over nine years after controlling for immunologic factors (e.g., human leukocyte antigen matching, warm ischemic time) suggests that socioeconomic or behavioral factors may contribute to racial and ethnic disparities in outcomes. Therefore, not only can financial constraints directly lower graft survival, but they can also generate disparities in graft survival rates. This problem is made even more pressing considering that minority patients are already at a disadvantage with kidney transplant survival and gaining access to transplantation in the first place.

The current Medicare policy did not intend to generate disparities in medical outcomes by virtue of the insurance and income disparities experienced by kidney recipients. Having equal access to transplantation, as the entitlement policy promises, should mean that all kidney recipients would have sufficient Medicare or private insurance coverage to enable them to obtain the immunosuppressants that maintain kidney graft survival, and that this coverage continues for the duration of the life of the graft.

VI. IMPACT OF INSURANCE COVERAGE ON QUALITY OF LIFE

In addition to the survival of the kidney graft, it is also important to consider how the financial challenge of procuring enough funds to obtain immunosuppressants can demoralize kidney recipients and dramatically destabilize quality of life. Kidney transplantation has been touted as providing a better QOL over dialysis. But some meta-analyses question this proposition, given patients’ adverse health problems and difficulty in obtaining funds for medications.

Various empirical studies support the relationship between insurance coverage or financial support and QOL. Research shows that having pharmacy insurance coverage has a positive effect on life satis-

79. Didlake et al., supra note 74; Rovelli et al., supra note 78.
82. Donald Joralemon & Kim Mika Fujinaga, Studying the Quality of Life After Organ Transplantation: Research Problems and Solutions, 44 SOC. SCI. & MED. 1259 (1996).
faction, a component of QOL. Another study of posttransplant QOL also suggests that kidney recipients rate their QOL lower when they are disadvantaged economically. A QOL study examining the impact of financial changes on kidney recipients’ lives found that financial concerns presented the greatest stress compared to any other stressor after kidney transplantation. In a qualitative investigation of patients’ experiences living with kidney transplantation, one respondent reported the following devastating effects of transplant costs on his family’s life:

There are many days now when I wonder whether I should have gone through with this. We’ve spent all our life savings, money that was meant for our retirement and that we’ve saved to send my daughter to college. We’ve lost all we had—our house, my wife’s new car, all our assets—to pay for my operation. When I look back on it now I think it would be better if I was dead. Look what I’ve done to the people who love me.

Clearly, the financial strain that some kidney transplant recipients experience reduces their QOL and may very well negatively affect their graft survival. In sum, the current Medicare policy can be construed as a factor contributing to the decrease in kidney recipients’ QOL, even though it was designed to increase it. Basically, the Medicare policy’s limitations reinforce disparities in survival and QOL outcomes. This contention is borne out in economic analyses of the policy, described below.

VII. COST CONSIDERATIONS: EFFICIENCY

The financial expenditures for the ESRD program are increasing significantly as the ESRD patient population inexorably grows—especially among the elderly and those with many comorbidities who present greater healthcare needs—and survival increases. Accordingly, it is imperative to find ways to enhance cost efficiency for the ESRD system. Whereas ESRD patients represent half of one percent of the Medicare population, their care accounts for five percent of Medicare expenditures. In 1991, Medicare spending per beneficiary per year

83. Matas et al., supra note 45.
86. Sharp, supra note 63, at 374.
varied by age, ranging from $36,000 to $51,000.\textsuperscript{89} Kidney transplantation becomes more cost-effective than hemodialysis after 3.1 years.\textsuperscript{90} The cost of in-center hemodialysis is approximately $60,000 per member per year (pmpy), whereas the cost of kidney transplantation for functioning graft patients is approximately $15,357 pmpy in 2003.\textsuperscript{91}

Kidney transplantation can become even more cost-effective by improving graft survival. A study from 1994, conducted at the time when Medicare provided only one year of posttransplant immunosuppression coverage, estimated that the costs to Medicare during the three years posttransplant were three times higher for patients who experienced graft failure than for patients whose graft survived.\textsuperscript{92} The United States Renal Data System study also estimated that the cost of a return to dialysis due to kidney graft failure was approximately eight times the cost of immunosuppressant drugs. This study played a pivotal role in prompting the law to extend the duration of immunosuppressant coverage to three years.\textsuperscript{93} A more recent study found that the actual costs of posttransplant immunosuppression are lower than dialysis costs.\textsuperscript{94}

Compelling evidence that extending Medicare policy improves graft survival is found in one study that examined the extension of Medicare's immunosuppression coverage from one year in 1986 to three years in 1995.\textsuperscript{95} Using data from the USRDS and zip code median data from the census, Robert Woodward and colleagues compared the graft survival by income level of two cohorts of patients: those receiving transplants in 1992–1993 who had only one year of coverage (cohort 1) and those receiving transplants in 1995–1997 who had three years of coverage (cohort 2). At one year posttransplant for both co-

\textsuperscript{89} Id.

\textsuperscript{90} Kasiske et al., \textit{supra} note 44, at 2448. There has been a trend toward an earlier break-even point. Earlier studies reported a break-even point at four years, and more recent small-scale studies report 2.8 years. See Paul W. Eggers & Lawrence E. Kucken, \textit{Cost Issues in Transplantation}, 74 \textit{Surgical Clinics N. Am.} 1259 (1994); Laupacis et al., \textit{supra} note 14; Patricia R. Loubeau et al., \textit{The Economics of Kidney Transplantation Versus Hemodialysis}, 11 \textit{Progressive Transplantation}, 291 (2001).

\textsuperscript{91} U.S. Renal Data System, 2005 Annual Data Report: Medicare Costs of ESRD 680 tbl.K11 (2005). The transplant pmpy costs represent an average of the costs for new and ongoing kidney transplant recipients in 2003. The costs of the new patients are substantially higher given the operation and physician fees, but these are averaged out by the greater proportion of ongoing patients. The proportion of new to ongoing patients was not provided in the USRDS 2004 report.

\textsuperscript{92} 1997 Annual Data Report, \textit{supra} note 54.

\textsuperscript{93} Shih, \textit{supra} note 46.


\textsuperscript{95} Woodward et al., \textit{supra} note 13, at 69.
horts (the last point at which Medicare provided immunosuppression coverage), there was no difference in survival.\(^{96}\) At the second and third years posttransplant, however, low income was negatively associated with graft survival for cohort 1 (when Medicare was not providing coverage).\(^{97}\) For example, for cohort 1, at three years, the low-income group had a 3.9% lower three-year graft survival than the high-income group \((p = 0.004)\).\(^{98}\) In contrast, for cohort 2, the low-income group had a 0.8% lower three-year graft survival than the high-income group.\(^{99}\) Medicare’s extended immunosuppression coverage benefited low-income patients the most: those without extended coverage had a risk ratio of 1.40 \((p < 0.001)\), meaning that they had a forty percent higher risk of graft loss than high-income patients (controlling for other factors).\(^{100}\) The 4.5% of grafts lost at year three among low-income patients represents 354 grafts lost from cohort 1, and 555 grafts lost from cohort 2. The benefits of extended coverage were also experienced among the next to highest income group. This study shows that extending coverage offsets the existing survival differential between recipients’ socioeconomic backgrounds by affecting patients’ capacity to purchase immunosuppressant medications.

An even more recent study set out to estimate the expected economic and clinical effects of extending Medicare immunosuppression coverage from three years to the full life of the kidney graft (in 2000 dollars).\(^{101}\) The study found that lifetime immunosuppressant coverage would have both outcome benefits and cost benefits.

Regarding outcome benefits, lifetime immunosuppression coverage would reduce graft failure in the fourth year posttransplant from 4.4% to 3.2% annually.\(^{102}\) One patient in nine would have a functioning transplant graft for twenty years (which would have otherwise failed without extended coverage).\(^{103}\) The median projected patient survival would increase to 27.8 years, compared to 24.4 years without lifetime

\(97\) Id.
\(98\) Id.
\(99\) Id.
\(100\) Id.
\(101\) Eugene F. Yen et al., Cost-Effectiveness of Extending Medicare Coverage of Immunosuppressive Medications to the Life of a Kidney Transplant, 4 Am. J. Transplantation 1703 (2004). The estimates were based on a twenty-seven percent relative reduction in kidney graft loss in patients without alternative immunosuppression coverage as reported by Woodward. See Woodward et al., supra note 13, at 72.
\(102\) Id.
\(103\) Id.
In other words, one patient in thirteen, who would have otherwise died earlier, would be alive twenty years later.

Regarding costs, the annualized expected savings to society from lifetime coverage would be $136 million (based on current rates of transplantation). The expected discounted costs to Medicare after twenty years posttransplant would differ according to coverage level: $234,894 with existing coverage and $268,946 with extended coverage.

A comparative health policy perspective helps to illuminate how policy is affected by cultural factors, reveal other policy options available, and highlights the differential impact of policies on health. One comparative study of healthcare systems and kidney transplant outcomes found that industrialized nations differ in the percentage of patients with functioning renal transplants according to the kind of healthcare system: public or “Beveridge” Model (e.g., Canada, United Kingdom, Sweden); mixed or “Bismarck” Model (e.g., Germany, Italy, France); and private or “Private Insurance” Model (e.g., the United States, Japan). Public countries have the greatest percentage of patients with functioning renal transplants, ranging from forty-five percent to eighty-one percent; mixed countries range from twenty percent to forty-eight percent; and as a private country, the United States has twenty-six percent (Japan has a rate of 0.3% due to cultural and religious considerations). These data suggest that health policy plays a critical role in kidney transplant survival. More importantly, the United States should learn from these other policy models that in order to increase the proportion of functioning renal transplants, a greater level of financial support for such patients is imperative.

By these tokens, extending coverage of immunosuppression can help prevent premature kidney rejection (due to insufficient funds to purchase antirejection medications) and thereby limit the number of patients who would return to the waiting list for retransplantation. Improving transplantation survival is therefore imperative as a means of keeping Medicare costs down.

104. Id.
105. Id.
106. Id.
109. Id.
VIII. Conclusion

This Article makes three key points. First and foremost, expanding Medicare coverage for the life of the kidney is necessary. The current Medicare policy limiting immunosuppressive medication coverage to eighty percent for three years undermines the goals of increasing graft survival and enhancing the quality of life for kidney transplant recipients that the policy initially set out to address. This is particularly the case among the most financially needy patients. The policy is also more costly than providing longer-term coverage.

The second key point is that efforts to increase equity in the kidney transplant endeavor must encompass issues of equity in graft survival outcomes. Considerations of justice in terms of equity pervade the transplant effort, notably in efforts to foster equitable access to and allocation of kidney transplants. But attention to equity in kidney transplantation has been limited to the stages leading up to the receipt of the transplant, neglecting policies relating to posttransplant survival. As one commentator noted, "The ultimate test of the equity of a health policy is the extent to which disparities or inequities in health persist among subgroups of the population." Yet, as I have shown above, the current Medicare policy fosters social and economic disparities in transplant survival outcomes given limited Medicare coverage and disparities in insurance coverage. Therefore, to foster greater equity in outcomes, we must address questions of disparities in access to immunosuppression.

The third point has to do with revising our framework or vision for kidney transplantation and for addressing the first two points. The spectrum of our efforts in the kidney transplant endeavor has traditionally spanned from the stages of identifying patients in need of organs to the process of facilitating a safe transplant operation. As policymakers at the Centers for Medicare and Medicaid Services stated, "Increasing the supply of kidneys and other organs for transplantation is a priority initiative of the Secretary of the Department of Health and Human Services." I posit, however, that the spectrum of attention transplant professionals, scholars, and policymakers


Devote to transplant efforts should be extended beyond the point of receiving an organ transplant to the period of rehabilitation and maintenance of life with a transplant more than the current situation of three years. I also propose that we may have been placing disproportionate attention on one end of the spectrum (i.e., efforts to increase donation) to the neglect of the other end—transplant graft survival. These proposals together suggest that we must reconceptualize our end goal not just as transplantation, but also as long-term transplant survival. This framework is extremely important in order to make the transplant endeavor worthwhile for patients, donors, and society for improvement in health, quality of life, the availability of kidney grafts, and financial investment.

Accordingly, an expanded notion of "access to transplantation" is necessary given that attainment of a kidney transplant becomes moot if the social structural supports for maintaining a transplant are unavailable to patients. That is, in order for a kidney transplant to work in the first place, kidney recipients must have the resources to obtain immunosuppression for the life of the kidney. A broader notion of access to transplantation would therefore consider access to a surviving transplant through available immunosuppressants. Expanding the notion of access would foster greater parity in transplant survival and enable an ethical analysis of disparities in long-term transplant outcomes. Yet, even with these resources and complete access to immunosuppression, there may still be differences in survival by socioeconomic status. Such access, however, will narrow the gap considerably.

As some kidney transplant professionals acknowledge, a long-term approach to kidney transplant survival is necessary. Toward this end, transplant professionals have called for efforts to prevent and treat cardiovascular disease, infection, bone disease, neoplasia, and chronic allograft nephropathy. Other scholars have called for tailored therapies to individual patients; they recommend identifying patient segments that most clearly benefit from the most expensive immunosuppressive regimens to justify use. Still other scholars have argued for increased use of generics to enable patients to afford immunosuppressive medications. Pharmacoeconomic research is striving to ascertain the cost-effectiveness of various immunosuppres-

113. See, e.g., Magee & Pascual, supra note 8.
114. Gorman, supra note 10; Kal6, supra note 94.
sion regimens, thereby helping to reduce costs of medications to patients. These clinical approaches to improving long-term outcomes are necessary, but insufficient. Rather, it is imperative that we become cognizant of the broader political, economic, social, and cultural contexts in which patients live with and manage their kidney transplants in the long-term.

Medicare policy must shift in concert with the needs of the kidney recipient population and the advances in medical technology that enable long-term survival in the first place. Currently, the policy can present challenges to graft survival and quality of life because of the financial hardship it presents to patients without the economic support to obtain immunosuppression. Expanding Medicare coverage for the life of the kidney is necessary. Moreover, the proposed extension of Medicare coverage of immunosuppression is defensible in light of the increasing emphasis that ESRD policymakers are placing on quality improvement strategies to improve ESRD patients' functional status and outcomes.

Granted, a long-term approach is not exciting. Medicine has traditionally focused on acute care issues to the neglect of chronic care. Similarly, policymakers and researchers tend to focus on the short-term outcomes rather than long-term outcomes to receive the acclaim of definitive gains. These factors, however, do not preclude the proposed policy change. Expanding Medicare coverage would fall squarely within the trajectory of progressively increasing coverage provided by Medicare over time. As such, this proposal would not come out of place. Rather, this policy change would make the transplant endeavor all the more worthwhile.

This Article has presented the ethical grounds for the need to provide long-term healthcare coverage for immunosuppression. A corresponding argument on economic grounds requires a cost-benefit analysis of this proposal. To date, few analyses have been conducted. An effective argument for providing extended coverage should consider several variables, including: (1) the cost of QOL for patients with and without the financial wherewithal to purchase immunosuppressants, (2) the actual costs of extending coverage beyond three years versus the costs of dialysis, (3) graft survival statistics between adherent patients with immunosuppressants versus nonadherent patients


117. See Nissenson & Rettig, supra note 88.
due to financial strain after three years posttransplant,\textsuperscript{118} and (4) the number of patients waiting for second and third kidney transplants (due to graft loss from financial strain). In order to make a convincing policy argument, these economic analyses are needed.

Moreover, greater advocacy for policy change by transplant professionals, nephrologists, and pharmaceutical companies is needed, especially now that Congress is currently reviewing proposed legislation to extend Medicare coverage of immunosuppressants. It may be the case that health professionals are not necessarily focused on this issue given their distraction with ensuring appropriate reimbursement rates for patient care from Medicare.\textsuperscript{119} With ethical and economic analyses and advocacy, we can change health policy for the betterment and equity of kidney transplant outcomes.

\textsuperscript{118} See, e.g., Irina Cleemput et al., \textit{The Economic Implications of Non-Adherence After Renal Transplantation}, 22 \textit{Pharmacoeconomics} 1217 (2004). Because this study was conducted in Belgium and analyses performed one-year posttransplant, the impact of the U.S. Medicare policy on nonadherence due to the financial strain caused by Medicare coverage termination could not be assessed.

\textsuperscript{119} The Coalition of the Kidney Care Partners has been lobbying for increasing the composite rates of reimbursement. This is a longstanding, controversial issue. See Richard A. Rettig & Ellen L. Marks, \textit{Implementing the End-Stage Renal Disease Program of Medicare} (Rand Corp., Inst. For Civil Justice No. R-2505-HCFA/HEW, 1980).